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Southern Health NHS
NHS Foundation Trust

Research Bulletin

Welcome to the Southern Health NHS Foundation Trust research bulletin. Over the following pages, you can read about the research that is currently running in our Trust. If you would like to get involved in any of the studies, or hear more about them, the Research and Outcomes team would be happy to discuss the study with you.

The Research and Outcomes Team

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Open clinical studies

ACTIONS

Can the antidepressant citalopram improve the negative symptoms of schizophrenia?

Negative symptoms such as lack of interest, emotional flatness, not being able to concentrate, wanting to avoid people or feeling the need to be protected may not improve with antipsychotic medication. Research has shown that these left over negative symptoms can limit long term recovery.

ACTIONS is a randomised controlled trial which aims to understand if citalopram reduces negative symptoms and improves quality of life for service users. Participants will receive either placebo or citalopram alongside their usual antipsychotic medication for 12 months under supervision of their psychiatrist. The study is funded by the National Institute of Health Research and sponsored by Imperial College London.

Who can take part?

- Service users with a diagnosis of schizophrenia, schizophreniform, schizoaffective disorder or psychosis
- Having prominent negative symptoms
- Age 18-65, inclusive
- Clinically stable for the last 3 months with a consistent antipsychotic treatment
- Competent and willing to provide written, informed consent

People who can not take part in this study:

- Have been advised that you are unable to take SSRI class anti-depressant
- Pregnant or planning to become pregnant
- Had ECT in the last 8 weeks
- Have substantial cognitive or language difficulties
- Have major depressive disorder
- Are dependent on substance/alcohol use in the past 3 months
- Currently taking any antidepressant
- Your clinician is intending to treat you with an antidepressant

For more information: Professor David Baldwin, the Principal Investigator is leading this study within Southern Health. If you are considering taking part and would like more information please ring Research and Outcomes Department on 02380 475258.

PARADES

What is the experience of advance planning for severe episodes of mental illness for people Bipolar Disorder?

This study will explore whether enough people with bipolar disorder are aware of the options available to them under the Mental Capacity Act and whether being provided with information on the subject would have any impact on their attitude towards this.

The University of Nottingham is conducting research into whether people with bipolar disorder use the Mental Capacity Act to make plans in advance about important aspects of their welfare, such as medical treatment and finance related decisions. This is important because it allows people to make decisions for a time in the future when they may not be in a position to decide things for themselves due to their illness.

Who can take part?

- Adults aged 18 or over who have been diagnosed with bipolar disorder by a doctor
- General Adult and Old Age Psychiatrists practising in England at either Senior House Officer, Specialist Registrar or Consultant level

What is involved?

Two online surveys aimed at persons with bipolar disorder or psychiatrists can be found at *http://www.nottingham.ac.uk/chs/research/projects/parades/index.aspx* This takes approximately 30 minutes of your time.

For more information

Please email Dr Sarika Kakwani :*Sarika.Kakwani@southernhealth.nhs.uk* who is leading this study within Southern Health or contact the Research and Outcomes Department on 02380 475258.

DPIM

DNA Polymorphism in Mental Illness

This is a National Portfolio study running in the Trust, in conjunction with University College London (UCL).

The study aims to find out differences in DNA in patients with Bipolar Affective Disorder or Schizophrenia, to ascertain specific genes that may influence treatment response as well as prognosis. Southern Health is taking part in the schizophrenia arm of this study.

Who can take part?

- Service users with a diagnosis of Schizophrenia
- Aged 18 and above
- Be of White Caucasian origin
- English, Irish, Scottish or Welsh ancestry (with the exception of 1 European grandparent)

What is involved?

Service users who are keen to take part and have been consented into the study will be asked to:

- provide a small blood sample for the purpose of genetic testing
- complete a short interview based on their experiences of mental illness.

The objective of this study is to obtain fine mapping of disease genes causing susceptibility to psychiatric illness and to pave the way for new treatments and preventative strategies associated with fewer or absent side effects.

For more information

Dr Stefan Gleeson is leading the study within Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

Molecular Genetic Investigation into Bipolar Disorder

Molecular Genetic Investigation of Bipolar and other Mood Related Disorders

This study aims to identify susceptibility genes for Bipolar and related mood disorders. It is hoped this will lead to developments of more effective treatments with fewer side effects, and an improved quality of life for those affected. Support from the Wellcome Trust and the Bipolar Research Disorder Research Network has attracted high profile participants such as Stephen Fry and Kerry Katona.

Who can take part?

- Service users who experienced at least one episode of hypomania/mania (lasting at least 4 days) or have been diagnosed with bipolar disorder
- Aged 18 and above
- Be of White Caucasian origin
- Not be using (non-prescribed) intravenous drugs.

What is involved?

Service users who consent will be asked to meet a member of the Cardiff research team. The team will then interview the person. This interview takes approximately 1½ hour and take a 30ml blood sample, at a time and place that is convenient for you.

For more information
Dr Alain Gregoire who is leading the study within Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

OASIS

Observational Assessment of Safety in Seroquel™

Seroquel™ XL is a new formulation of the antipsychotic medication Seroquel™ (quetiapine). The study aims to evaluate the short term safety when used by patients with schizophrenia and mania associated with bipolar disorder and compares this to the older preparation of quetiapine immediate release. This is a national study covering the whole of England and supported by the Drug Safety Research Unit and the Medicines Health Regulatory Authority.

Who can take part?

- Any person started by their psychiatric care team on either Seroquel™ XL or quetiapine IR in the study period will be eligible to take part.
- Aged 18 and above

What is involved?
If you have recently been prescribed Seroquel™ XL or quetiapine IR ask your clinician if you can take part in this study.

For more information
Dr Carmen Parr is leading the study within Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

AdEPT

Understanding and Preventing the Adverse Effects of Psychological Therapies (AdEPT)

Many people with mental health difficulties are helped by psychological therapies (“talking treatments”), but there is some evidence from research studies and individual clients that people can occasionally feel worse after therapy. We do not know how often this is because of the treatment as people could have become more distressed anyway, for example, after stressful life events. The AdEPT study, sponsored by Sheffield University, is aimed at understanding and preventing these adverse effects (feeling worse) following psychological therapy.

Who can take part?

- Service users have experienced therapy they felt made them worse or ‘went wrong’.
- Aged 18 and above
- You have a good understanding of English in verbal or written form.

What is involved?

If you are a service user or a therapist you complete a questionnaire in either paper or e-mail form, or on the internet (*http://www.shef.ac.uk/scharr/sections/hsr/mh/mhresearch/adept*). After this, you maybe asked to take part in an interview or focus group; although there is no obligation to do so.

For more information
Dr Claire Corbridge is leading the study within Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

Mindfulness for Voices (M4V)

Mindfulness-based therapy groups for people distressed by hearing voices: a pragmatic randomised controlled trial

Most people who hear voices say that voices sound like someone talking to them in the same room or over the telephone. The majority of people with schizophrenia hear voices and some people find hearing voices distressing. The study aims to test whether using CBT with mindfulness meditation reduces voice distress, improves psychological well-being and increases the control participants feel they have over the voices.

Who can take part?
- Service users with a diagnosis of schizophrenia or schizoaffective disorder
- Aged 18 and above

People who can not take part in this study:
- Those who have drug or alcohol induced psychosis, or a primary diagnosis of substance misuse

What is involved?
You will be allocated at random to either attending a 12 session Mindfulness for Voices group or to continuing with their usual mental health care. Outcomes will be compared between these two groups.

For more information
If you are interested in this study please contact Dr Laura Dannahy *lauradannahy@nhs.net* who is leading the study within Southern Health or contact Lizzie Clark 07920210209.

New Ways of Working Mental Health

Assessing and informing the emergence of Peer Worker roles in mental health service delivery

Peer workers are increasingly playing an important role in service delivery, alongside mental health professionals and other mental health workers. A number of factors can impact the successful widespread adoption of new roles from being a service user to becoming a Peer Worker. This study aims to explore facilitators and barriers to the successful introduction of Peer Worker roles in UK mental health service settings with a view to providing guidance to organisations on recruiting, training and supporting Peer Workers in their role.

Who can take part?
- Aged 18 and above
- Users of mental health services that employ Peer Workers

- Peer Workers
- Other team members working alongside Peer Workers
- Managers

What is involved?
You will be interviewed by a member of the research team from St George's University of London which should last about 50 minutes. The first part of the interview will be structured which means you will be asked a set of questions about Peer Workers and the second part of the interview will be more in depth. You will also be asked to attend a 'feedback workshop' a few weeks after the interview along with other people connected to the organisation you receive service from.

For more information
Sarah Richmond WRAP coordinator is leading the study within Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

WIT

Worry Intervention Trial for Persecutory Delusions

In partnership with Southampton and Oxford Universities, an exciting clinical research trial is beginning within the Southern Health Trust funded by the Medical Research Council, looking to target worry as a form of treatment for paranoid psychosis.

Research has previously shown that worry is an important contributing factor in the occurrence of paranoid thinking. This research trial aims to deliver and assess the outcome of a newly developed 6 week CBT based worry intervention on individuals with persecutory delusions. Previous pilot data has shown this to be very successful in reducing both worry and persecutory delusions within this population.

Who can take part?
- Aged 18 and above
- Service users with current persecutory delusions that has persisted for at least 3 months
- Service users with a diagnosis of Schizophrenia, Schizoaffective disorder or Delusional disorder
- A significant level of worry (which most people with paranoia have)
- Stable psychotropic medication

What is involved?
You will be allocated at random to receive either additional six sessions of cognitive behavioural therapy for worry reduction on top of your normal care, or your usual current care.

For more information
Professor David Kingdon is leading this study within Southern Health. Please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

PD Rehab

Randomised Controlled trial to assess the clinical and cost effectiveness of physiotherapy and occupational therapy in Parkinson's Disease

Occupational Therapy and Physiotherapy are traditionally used when patients with Parkinson's Disease develop some impairment of activities of daily living. Occupational therapy mainly aims to improve physical function and independence. This involves a qualified therapist assessing a patient's problems with their disease, often at home, then devising practical ways to help them such as providing aids and adaptions (e.g. walking aids, hand rails, raised seating etc). Physiotherapy focuses on working with the patient, carer and family to improve their understanding of the condition, maintain general fitness and independence in mobility, both inside and outside the home.

This study aims to answer the question: do patients with Parkinson's disease benefit from therapy and does the benefit persist after they have finished their occupational therapy and physiotherapy? The study is a National Study happening in about 40 centres across the UK.

Who can take part?

- People with Parkinson's Disease who feel they experience restriction in their activities of daily living
- Aged 18 and above
- Able to provide informed consent

People who can not take part in this study:

- Those who have dementia
- Those who are already receiving occupational therapy and physiotherapy

What is involved?
A qualified therapist will check that you are able to enter the trial and take consent. A set of baseline assessments will be performed at the start of the study and you will be randomly allocated to receive occupational therapy and physiotherapy immediately or to have the therapies deferred until the end of the study after 15 months. You will have a 50:50 chance of getting therapy immediately.

For more information
Dr Helen Roberts is leading this study within Southern Health. Please contact the Research and Outcomes Department on 02380 475258 if you are interested in taking part in this study.

Studies in set-up

AMICUS (starting in May)

Amisulpride Augmentation in Clozapine-Unresponsive Schizophrenia

In around a third of people with schizophrenia, the illness shows a poor response to standard treatment with antipsychotic medication. Clozapine is the only antipsychotic with convincing evidence for the successful improvement of strictly-defined treatment-resistant schizophrenia but even clozapine at times can have limited efficacy. A common therapeutic approach of augmentation but a robust evidence base is lack to justify the choice for a second antipsychotic. This multi-centre, randomised, double-blind, placebo controlled study aims to test the benefits, costs, and risks of augmenting clozapine with amisulpride.

For more information
Dr Amanda Taylor is leading this study for Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in this study.

REFRAMED (starting in September)

REFRActory depression - Mechanisms and Evaluation of Dialectical Behaviour Therapy

Most depression is treatable. However, some patients with major depression respond poorly to currently available treatments, and endure severely disrupted family, social and working life. Many chronically and treatment-resistant depressed patients suffer from a personality disorder or problems such as being perfectionist, rigid or avoiding risks. Personality disorders are difficult to treat and patients with both depression and a personality disorder respond poorly to drug therapies and psychological treatments such as cognitive behavioural therapy.

Dialectic Behaviour Therapy (DBT) has proven efficacy in treating personality disorders, and has also shown early promise for patients with difficult to treat depression. This study shall test a new DBT protocol for participants with treatment resistant depression in a large randomised controlled trial.

For more information
Professor David Kingdon is leading this study for Southern Health; please contact the Research and Outcomes Department on 02380 475258 if you are interested in this study.

Viewpoint (starting in June)

Viewpoint survey of experiences of stigma and discrimination

The Rethink and Institute of Psychiatry stigma partnership focuses on projects to develop an evidence base for ‘what works’ to reduce stigma and discrimination in mental health. The Viewpoint Survey will conduct a cross-sectional assessment of experiences of stigma and discrimination among 1000 representative individuals receiving mental health treatment in 5 regions of England. This will establish a baseline for future surveys to track whether or not service user experiences of stigma and discrimination in England improve in the future.

For more information
Dr Carmen Parr is leading the study within Southern Health: please contact the Research and Outcomes Department on 02380 475258 if you are interested in this study.

MARC

Memory Assessment and Research Centre

MARC is the Memory Assessment and Research Centre. Based at Moorgreen in Southampton, we run trials for people with Alzheimer’s disease.

If you or someone you know has Alzheimer’s disease and are interested in getting involved in research, this bulletin will help you find out about what it entails and the latest trials taking place at MARC.

MARC is one of the leading centres in Europe for dementia research: Dr David Wilkinson and Professor Clive Holmes are internationally renowned for their expertise in this area.

Our long-term commitment to research means we have one eye on the future but are just as concerned with helping you live day-to-day. We understand as a carer or relative, the condition affects you too. MARC is here to provide access to support and advice as we know what a huge impact this illness can have.

Studies currently recruiting in MARC

DeNDRON 066 Genetch/Quintiles Monclonal AD

Investigation into a new medicinal product MABT5102SA in the treatment of mild to moderate Alzheimer's disease

Etanercept is widely used in over 8000 people per year in the UK to suppress inflammation in Rheumatoid Arthritis. In Alzheimer's disease the brain becomes inflamed and it is hoped that participants with Alzheimer's taking etanercept will experience reduced brain inflammation and therefore experience a decrease in symptoms.

For more information
Dr David Wilkinson is leading this study within Southern Health: please contact Memory Assessment and Research Centre 02380475206 if you are interested in this study.

STEADI-09

Safety and Tolerability of Ethanercept in Alzheimer's Disease

This is a single-centre, double-blind, placebo-controlled trial of etanercept for patients diagnosed with Alzheimer's disease. Etanercept is a widely used treatment for chronic inflammatory conditions such as rheumatoid arthritis. The study will test if etanercept reduces brain inflammation and will also examine the safety of etanercept in people with Alzheimer's disease.

The Trust needs help to recruit 40 patients over the next 12 months.

Who can take part?

- People with mild to moderate Alzheimer's disease
- Aged 55 and over
- Able to give informed consent
- Willing to have a weekly subcutaneous injection at home
- A carer who spends at least 24 hours per week with the patient and willing to participate in the study

People who can not take part in this study:

- People with any previous history of tuberculosis (TB)
- People with active rheumatoid arthritis, psoriasis or ankylosing spondylitis
- People with chronic leg ulcers
- People with an indwelling urinary catheter

What is involved?
You will be screened to see if you can take part in this study and given written informed consent. A doctor and nurse would perform baseline assessments and then you would be randomly allocated to

receive etanercept or placebo. You will be seen in their own home for a once weekly subcutaneous injection of etanercept or placebo, over a 24 week period. You will also be seen for check-up visits at the Memory Assessment and Research Centre (MARC) at Moorgreen Hospital, Southampton.

For more information
Dr Joe Butchart is leading this study within Southern Health: please contact Memory Assessment and Research Centre 02380475206 if you are interested in this study.

Scarlet Road

Study to test the effect of gantenerumab in people who may be in the early stages of Alzheimer's disease

This two year study evaluates the effect of a subcutaneous injection of gantenerumab a new experimental drug from Roche, on the symptoms of early (prodromal) Alzheimer's disease. This is a national study hoping to recruit 360 people with early Alzheimer's disease

Who can take part?

- Aged 50-85 years
- Able to give written and informed consent
- People with very early (prodromal) Alzheimer's Disease who are not receiving memantine or cholinesterase inhibitors
- People who have a partner and the partner is willing to provide information about your memory skills.
- Your study partner has noticed a recent gradual decrease in your memory (e.g. over the last 12 months), which you were not aware of.

People who can not take part in this study:

- Other prior or current neurologic medical disorder
- A history of stroke
- A documented history of transient ischaemic attach within the last 12 months.
- History of schizophrenia, schizoaffective or bipolar disorder
- Currently meets criteria for major depression
- Within the last 2 years, unstable or clinical significant cardiovascular disease

What is involved?
You will come to the Memory Assessment Research Centre to check if you are eligible to enter the trial and give informed written consent. After this you will come to the Memory and Assessment Research Centre to have an injection every 4 weeks. Not everyone will get the study drug. People are randomised to get either 105mg of gantenerumab or 225mg gantenerumab or a placebo. You will have a two in three chance of receiving gantenerumab.

For more information
Dr David Wilkinson is leading this study within Southern Health: please contact Memory Assessment and Research Centre 02380475206 if you are interested in this study.

Studies in set-up

ICoS (starting in May)

Inflammation Cognition and Stress; the effect on Mild Cognitive Impairment

This observational study will compare the cognitive decline to the degree of life stress in 140 participants with Mild Cognitive Impairment (MCI). Does life stress contribute to the worsening cognitive decline and is the damage caused due to the production of pro-inflammatory cytokines? This 18 month study aims to answer these questions and considers factors such as personality traits, coping style and social support to see how they influence the physiological stress response.

For more information
Professor Clive Holmes is leading this study within Southern Health: please contact Memory Assessment and Research Centre 02380475206 if you are interested in this study.

PAD11 (starting in May)

Peridontal Inflammation and Alzheimer's disease

Does the chronic inflammatory condition periodontitis effect the progression of Alzheimer's disease? This is a 6 month observational study comparing the cognitive decline to the degree of periodontal disease in 65 people with mild to moderate Alzheimer's disease. People will visit the Memory Assessment and Research Centre four times, two of which will assess for the presence of periodontal disease.

For more information
Professor Clive Holmes is leading this study within Southern Health: please contact Memory Assessment and Research Centre 02380475206 if you are interested in this study.

Contact information

The Research and Outcomes Department:

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Or by post, to: **Research and Outcomes Department**
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