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# Improving physical health and reducing substance use in psychosis

**Submission date**
23/04/2010

**Recruitment status**
No longer recruiting

**Registration date**
23/04/2010

**Overall study status**
Completed

**Last Edited**
21/06/2018

**Condition category**
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

## Plain English summary of protocol

Background and study aims
The physical health of people with severe mental illness (SMI) is very poor, resulting in a markedly increased mortality (death) rate. While risk factors such as age, family traits and ethnicity may increase the risk of physical illness, people with SMI are more likely to lead unhealthy lifestyles, such as eating an unhealthy diet, smoking and not exercising, which increases the risk of preventable physical diseases such as diabetes and heart disease. About 50% of patients with SMI have a substance use disorder; the most common substances used are alcohol and cannabis. Despite being at increased risk, people with SMI are less likely to receive appropriate health checks and adequate treatment due to barriers when accessing services. In light of this the Department of Health have emphasised the importance of good health screening in people with SMI and has led to endorsement of programmes addressing physical health in people with SMI. Despite this, none of these physical health programmes have been adequately tested in the UK. Thus, the development of an integrated approach, which is person centred and simultaneously targets physical health, mental health and substance use, is long overdue in the UK. The aim of this study is to find out whether an intensive health promotion intervention improves the lifestyle and physical health people with SMI, reducing their risk of developing health problems such as heart disease, cancer and diabetes.

Who can participate?
Patients aged 18 - 65 with SMI

What does the study involve?
Participants' care coordinators are randomly allocated to either receive training to give the intervention or to continue giving usual NHS care. In the intervention group the care coordinators ask their patients to attend some 1:1 sessions and if they wish to, group sessions on specific topics of their choice (e.g. smoking, diet etc) which are given alongside the usual care normally received from the care coordinator. In the usual care group participants continue with regular NHS treatment. Participants in both groups are asked various questions about their symptoms, mood, levels of anxiety, diet, exercise, use of NHS services, views on their health risks, and any side effects caused by medication. Their physical health is monitored, including weight, waist, hip and blood pressure measurements. A trained researcher takes a small sample of blood (the equivalent of a few tablespoons) to check blood sugar, cholesterol and fat levels

and assess their risk for diabetes, heart disease and other related health problems. Urine and saliva samples are also taken to check for drug use. This information is kept strictly confidential within the research team. At 12 and 15 months the assessments are repeated to investigate changes over time.

What are the possible benefits and risks of participating?
It is hoped that participants will benefit by reducing their risk of developing health problems such as heart disease, cancer and diabetes. The risks involved are those of ordinary blood tests such as a slight scratch and occasionally a small bruise from where the sample is taken. Although similar forms of treatment have been used to address the issues outlined above, this treatment has not previously been offered to people with mental health problems. Although no side effects are anticipated, the technique may be found to be ineffective.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
February 2010 to July 2013

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Ms Poonam Gardner Sood

### Study website
http://www.iop.kcl.ac.uk/projects/?id=10249

# Contact information

### Type(s)
Scientific

### Contact name
Ms Poonam Gardner Sood

### Contact details
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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
4399

# Study information

### Scientific Title
Improving physical health and reducing substance use in psychosis: a multicentre, cluster randomised controlled trial (IMPaCT RCT)

### Acronym
IMPaCT RCT

### Study objectives
1. The addition of a 12 month intensive health promotion intervention to usual mental health care delivered by care coordinators will be more effective than usual mental health care in improving metabolic outcomes and substance use on completion of intervention at 12 months and 24 months follow up (from baseline) in people with severe mental illness (defined as schizophrenia, schizoaffective disorder or bipolar affective disorder)
2. The addition of an intensive health promotion intervention to usual mental health care delivered by care coordinators will be more cost-effective than usual mental health care in improving metabolic outcomes and substance use in people with severe mental illness on completion of intervention at 12 months and then 24 months later from baseline

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The Joint South London and Maudsley and The Institute of Psychiatry NHS Research Ethics Committee, 27/07/2009, ref: 09/H0807/41

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Cluster randomised trial

### Study setting(s)
Hospital

### Study type(s)
Prevention

### Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Secondary complications; Disease: Severe Mental illness

## Interventions
Pre-randomisation:
Within each of the CMHTs in SLAM, Oxleas and Sussex team leaders who agree to participate in the trial will be asked to present a list of their current care coordinators. These care-coordinators will be offered a basic training delivered in a half day session on physical health awareness. The purpose of this training is to ensure that all care-coordinators, irrespective of which treatment arm they are allocated to, have the same baseline level of understanding of physical health issues. Care-coordinators will then be invited to consent to participate in the trial. Those who consent will be randomly allocated to either treatment arm (HPI or TAU). The care-coordinators allocated to the HPI will undergo specific training to deliver the HPI.

After randomisation:
1. The treatment as usual group (TAU) will consist of continuing usual CMHT care: To control for the attention received in the intervention group a single psycho-education session in which health promotion leaflets on healthy dietary routines and physical exercise together with general and community support for a healthy lifestyle will be provided to care-coordinators.
2. Health Promotion Intervention (HPI): The main philosophy of the health promotion intervention is to teach care co-ordinators relevant motivational interviewing skills that allow them to empower their client, using a directional, client-centered motivational approach to promote intrinsic motivation, better knowledge, coping strategies and new skills to ensure a positive impact on physical well being. In this intervention, consenting care coordinators of the CMHTs that have been randomised to deliver the HPI will be given specific training based on motivational interviewing techniques to deliver health promotion. The intervention aims to target one or more health behaviours from a pre-defined list that includes substance use, exercise, diet, diabetes control, that have been identified as problematic and increased risk for worse medical outcomes by the participant and the care coordinator. The training has already been described and given ethics approval (Physical Health and Substance Use Measures in Psychosis-Manual; ref number 09/H0807/5). The training is manualised and modularised so that the care coordinator can individualise the health promotion intervention to the specific needs of the participant. There will also be a module using Cognitive Behavioural Therapy (CBT) to address psychotic symptoms which are impeding the clients? engagement in the HPI. People may start the community-based HPI as soon as they are well enough to attend, even if they are inpatients, to mirror clinical practice.

Follow up length: 24 months
Study Entry: Registration only

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure

1. Quality of life (QLS)
2. Metabolic syndrome components:
2.1. Waist circumference
2.2. Resting blood pressure
2.3. Fasting plasma glucose level, HbA1c, HOMA-IR
2.4. Triglyceride levels
2.5. HDL Cholesterol
3. Cost and cost-effectiveness of the HPI
4. Use of substances
5. PANSS score

Measured at baseline, 3 months, 12 months and 24 months.

### Secondary outcome measures
Specific measures related to each module will be carried out at the end of each module, such as:
1. Diabetes module (glycated haemoglobin and fasting glucose)
2. Substance use module (Time Line Follow Back), Nicotine Dependence Questionnaire
3. Exercise (IPAQ)
4. Diet (waist circumference, weight)

Measured at baseline, 3 months, 12 months and 24 months.

### Overall study start date
01/02/2010

### Completion date
01/03/2014

## Eligibility

### Key inclusion criteria
All patients within consenting CMHTs who meet the following criteria will be recruited to the study:
1. Aged between 18 - 65 years old, either sex
2. Have a diagnosis of psychotic disorder including International Classification of Diseases, version 10 (ICD-10) diagnosis F20-29, F31.2, F32.3, F33.3 but excluding first episode psychotic illness as these patients are participating in another study
3. Are registered on the enhanced level of the Care Approach Programme (CPA)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
84 care coordinators; 504 patients

### Key exclusion criteria
1. Patients with primary diagnosis of learning disability
2. Physical health problem that will independently impact on metabolic measures and substance use
3. Pregnancy as a health promotion intervention may interfere with the necessary care
4. Life threatening or terminal medical conditions in which intensive care is already provided

### Date of first enrolment
01/03/2010

### Date of final enrolment
01/07/2013

## Locations

### Countries of recruitment
United Kingdom

### Study participating centre
**South London and Maudsley NHS Foundation Trust**
United Kingdom
-

### Study participating centre
**Oxleas NHS Foundation Trust**
United Kingdom
-

### Study participating centre
**Sussex NHS Foundation Trust**
United Kingdom
-

### Study participating centre
**Shropshire NHS Foundation Trust**
United Kingdom
-

**Study participating centre**
**Somerset NHS Foundation Trust**
United Kingdom
-

# Sponsor information

**Organisation**
National Institute for Health Research (NIHR) (UK)

**Sponsor details**
Room 132, Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.nihr.ac.uk/Pages/default.aspx

**ROR**
https://ror.org/0187kwz08

# Funder(s)

**Funder type**
Government

**Funder Name**
National Institute for Health Research (NIHR) (UK) (ref: 1049)

**Alternative Name(s)**
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
The main trial findings will be published in 2016/2017. Subsequently, several other papers will be published to address other important research questions.

### Intention to publish date

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are available from Dr Fiona Gaughran (please contact via Dr Poonam Gardner Sood - poonam.gardner-sood@kcl.ac.uk) and Prof Sir Robin Murray (please contact vie Averil Baxter - Averil.baxter@kcl.ac.uk) on reasonable request.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 16/10/2013 | | Yes | No |
| Results article | results | 01/03/2015 | | Yes | No |
| Results article | results | 22/03/2016 | | Yes | No |
| Results article | cost-effectiveness results | 22/12/2017 | | Yes | No |
| Results article | results | 28/12/2017 | | Yes | No |