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# Cluster Randomised Controlled Trial of the Serious Mental Illness Health Improvement Profile [HIP]

| Submission date | Recruitment status |
| --- | --- |
| 04/03/2011 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 04/03/2011 | Completed |
| **Last Edited** | **Condition category** |
| 27/09/2019 | Mental and Behavioural Disorders |

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

8505

# Study information

### Scientific Title
Cluster Randomised Controlled Trial of the Serious Mental Illness Health Improvement Profile [HIP]

### Acronym
HIP Cluster RCT

### Study objectives
Patients with serious mental illness who have had a health check by a nurse trained in the HIP Programme will have better physical health related quality of life at 12 months than patients who receive treatment as usual

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Cambridge 4 Research Ethics Committee on 04/11/2010 (ref:10/H0305/733)

### Study design
Randomised interventional treatment

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

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

### Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Bipolar affective disorder, Schizophrenia; Disease: Schizophrenia, Bipolar affective disorder, Schizoaffective disorder

### Interventions
The HIP Programme - The Serious Mental Illness Physical Health Improvement Profile (HIP) and HIP training package for nurses; Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
PCS SF-36v2; Timepoint(s): 1 year follow-up

### Secondary outcome measures
1. MCS SF-36v2
2. EQ-5D
3. Levels of health care resource use
4. PHASe (adapted)
5. QRISK®2
6. HIP Audit Form
7. Patient Semi-structured Interview Schedule, Nurse Focus Group Interview
8. Schedule and Psychiatrist/GP Telephone Interview Schedule

### Overall study start date
04/04/2011

### Completion date
07/04/2014

## Eligibility

### Key inclusion criteria
1.Registered mental health nurse (MHN) working in a community mental health setting
2. Registered with the Nursing and Midwifery Council [NMC] for at least 6 months
3. Employed at Agenda for Change band 5-7
4. Working in one of the community mental health teamsacross the study sites
5. Has at least 5 patients on their caseload with a primary diagnosis of serious mental illness (SMI) (as confirmed by the Team Leader)

Patients:
1. Aged over 18
2. On the caseload of the MHN participant at the start of the project
3. Has a primary diagnosis of SMI (as confirmed by the last recorded diagnosis in the patient record either being schizophrenia, schizoaffective or bipolar disorder as confirmed by the Team Leader).; Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size 50 Nurses, 250 patients; UK sample size 50 Nurses, 250 patients

### Key exclusion criteria
Following screening by the Research Assistant, MHNs will not be included if they:

1. Are still in preceptorship following recent Nursing and Midwifery Council [NMC] registration as a MHN
2. Are about to go on maternity leave
3. Are pregnant or up to 6 months post partum

Following screening by the Trial Coordinator and the Team Leader patients with SMI will not be included if they:

1. Currently lack the capacity to consent to treatment as documented by a heath professional on Form 4 in their case notes (NWMHFT, 2005) as they would also be considered unable to consent to participation in research.
2. Have a serious or unstable medical condition (e.g. advanced/incurable cancer; severe co-morbidity such as people on renal haemodialysis, end-stage Chronic obstructive pulmonary disease (COPD) and New York Heart Association (NYHA) classification grade 3 or 4 heart failure; severe unpredictable pain)
3. Where the Team Leader considers participation in the trial will put the patient, nurse or research assistant at increased risk or increased cost to the service to manage risk

### Date of first enrolment
04/04/2011

### Date of final enrolment
07/04/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Faculty of Health and Social Care,**
Hull
United Kingdom
HU6 7RX

## Sponsor information

### Organisation
Norfolk and Waveney Mental Health NHS Foundation Trust (UK)

### Sponsor details
Hellesdon Hospital, Drayton High Road
Norwich
England
United Kingdom
NR6 5BE

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/03400ft78

## Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research (NIHR) (UK)- Research for Patient Benefit (RfPB) (ref: Grant Codes: PB-PG-1208-18122)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 04/07/2011 | | Yes | No |
| Results article | results | 01/10/2014 | | Yes | No |

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|---|---|---|---|---|---|
| Results article | results | 01/05/2018 | 27/09/2019 | Yes | No |