

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

Submission date 04/03/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 04/03/2011	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 27/09/2019	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

PCS SF-36v2; Timepoint(s): 1 year follow-up

Key secondary outcome(s)

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

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 teams across 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 health 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

United Kingdom

England

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)

ROR

<https://ror.org/03400ft78>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

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?
Results article	results	01/10/2014		Yes	No
Results article	results	01/05/2018	27/09/2019	Yes	No
Protocol article	protocol	04/07/2011		Yes	No