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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

Contact name
Ms Jacqueline White

Contact details
Faculty of Health and Social Care,
University of Hull,
Cottingham Road
Hull
United Kingdom
HU6 7RX
-
Jacqueline.white@hull.ac.uk

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 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

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 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
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

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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes