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Patient involvement - inpatient care (WP3)

Submission date 29/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/04/2010	**Overall study status** Completed	
Last Edited 20/12/2019	**Condition category** Other	

Plain English summary of protocol

Background and study aims
The Francis report focussed attention on the quality of inpatient care. Staff report that they feel under-skilled and have too little time to provide therapeutic activities, and service users report that wards were boring places and provided little therapy. The aim of this study is to find out whether the quality of inpatient care can be improved by providing staff training.

Who can participate?
Adult inpatients from relevant boroughs (Southwark, Lambeth, Croydon, Lewisham) during a fixed time period

What does the study involve?
Participating wards are randomly allocated to either receive increased skills training to increase group activities, or to be put on a waiting list. Staff and inpatients' perceptions of the ward are measured using questionnaires.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. South London and Maudsley NHS Foundation Trust NHS Foundation Trust (UK)
2. Oxleas NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2008 to March 2012

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

Who is the main contact?
Prof. Til Wykes

Study website

http://www.perceive.iop.kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Til Wykes

ORCID ID
http://orcid.org/0000-0002-5881-8003

Contact details
Institute of Psychiatry
PO Box 77
16 De Crespigny Park
London
United Kingdom
SE5 8AF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4237

Study information

Scientific Title
Patient involvement in improving the evidence base on inpatient care - increasing the therapeutic activities on wards (WP3)

Study objectives
This is a randomised wait list control study with frequent assessments of the effects and acceptability of increasing activities on inpatient wards.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bromley Research Ethics Committee, 27/11/2007, ref: 07/H0809/49

Study design
Randomised interventional process of care and treatment trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network, Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics), Service Delivery; Disease: Not Applicable

Interventions
Wards will be randomly assigned to receive increased psychologically based group activities or wait list control and will be followed every 6 months. Individual patients will enter the study once. This work package will also test the feasibility of new measures generated in linked work packages 1 and 2. WP3 includes increased skills training for in-patient staff so as to directly increase the availability of therapeutic interventions. The participatory theme continues from the initial work packages through to the interventions by including service user researchers to lead research as well as collecting data.

Follow-up length: 0 months
Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Staff and service user perceptions of the ward, measured every 6 months, at four time points (at times, 0, 1, 2 and 3)

Secondary outcome measures
Measured every 6 months, at four time points (at times, 0, 1, 2 and 3):
1. Length of hospital stay
2. Readmissions

Overall study start date
01/04/2008

Completion date

01/03/2012

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/04/2017:
1. All in-patient admissions from South London and Maudsley NHS Foundation Trust and Oxleas NHS Foundation Trust during a fixed time period
2. Adults of either sex

Previous inclusion criteria:
1. All in-patient admissions from relevant boroughs (Southwark, Lambeth, Croydon, Lewisham) during a fixed time period
2. Adults of either sex

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned sample size: 800; UK sample size: 800

Total final enrolment
120

Key exclusion criteria
Patients will only be excluded if they have been entered into the study on an earlier admission

Date of first enrolment
01/11/2008

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

South London and Maudsley NHS Foundation Trust
United Kingdom
SE5 8AZ

Study participating centre
Oxleas NHS Foundation Trust
United Kingdom
DA2 7WG

Sponsor information

Organisation
South London and Maudsley NHS Trust (UK)

Sponsor details
Clinical Treatment Centre
1st Floor, Maudsley Hospital
Denmark Hill
London
England
United Kingdom
SE5 8AZ

Sponsor type
Hospital/treatment centre

Website
http://www.slam.nhs.uk/

ROR
https://ror.org/015803449

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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
Planned publication in high impact journals in two papers. One will summarise the service user outcome data as this follows the stepped wedge design. The other paper is more complex as it reports staff data which has some repeated measures in the stepped wedge design.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Til Wykes

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2018		Yes	No
Results article	results	01/12/2018		Yes	No
Results article	results	01/01/2019		Yes	No
Results article	results	18/12/2019	20/12/2019	Yes	No