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Rehabilitation Effectiveness for Activities for Life

Submission date	Recruitment status	[_] Prospectively registered
23/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2015	Mental and Behavioural Disorders	

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
5664

Study information

Scientific Title
A multicentre study of rehabilitation services and the efficacy of promoting activities for people with severe mental health problems

Acronym
REAL

Study objectives
The details for the cluster randomised controlled trial phase of the project are listed here. This is one phase of a larger programme of research that runs for 5 years. The aims and objectives of this study overall are:
1. To investigate current provision and quality of mental health rehabilitation services in England
2. To investigate the clinical and cost effectiveness of an enhanced rehabilitation intervention for poorer quality services
3. To identify the characteristics of mental health rehabilitation services and their service users that are associated with better outcomes

The first phase of the study involves a comprehensive survey of all inpatient rehabilitation units in England to assess the quality of each using a specialised, standardised toolkit that has been developed in another study (the Quality Indicator for Rehabilitative Care [QuIRC]). We will describe current service provision, factors associated with service quality and whether provision is appropriate to local psychiatric morbidity. Services that score below the median on the quality assessment toolkit will be invited to participate in a cluster randomised controlled trial that will test the efficacy of an enhanced rehabilitation intervention (a staff training programme) to facilitate service users' activity (Phase 3). This intervention (the "GetREAL" intervention) will be developed as part of the research programme (Phase 2). At the same time as Phase 3 is being carried out, the other services (that scored above the median on the quality assessment toolkit) will be invited to take part in a cohort study to investigate service and service user characteristics that predict better outcomes such as successful community discharge (Phase 4).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Research Ethics Committee, 16/06/2009, ref: 07/Q0603/26

Study design
Randomised interventional process of care trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Can be found at http://www.ucl.ac.uk/REAL-Study/StudyPopulationAndEligibilty.html

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: All Diagnoses, Schizophrenia; Disease: Schizophrenia

Interventions
Intervention arm:
Services will receive the GetREAL intervention as developed in Phase 2. One of two GetREAL teams will spend five weeks with each service randomly allocated to receive the GetREAL intervention (i.e. each GetREAL team will work with 8 or 9 services). The GetREAL team comprises an OT, an activity worker and a service user. The GetREAL intervention will include a full training day for all front line staff and a further 4 weeks of hands on work.

Control arm:
Units in the comparison arm will continue to deliver usual care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of time service users spend engaged in any activity

Secondary outcome measures
Service users' social functioning as rated using the Life Skills Profile

Overall study start date
28/07/2009

Completion date
30/06/2013

Eligibility

Key inclusion criteria
All rehabilitation services and service users in England

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 900; UK Sample Size: 900

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
28/07/2009

Date of final enrolment
30/06/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
London
United Kingdom
NW3 2PF

Sponsor information

Organisation
University College London (UK)

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Sponsor type
University/education

Website
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ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Programme Grant for Applied Research (PGfAR)

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	28/08/2013		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	02/09/2015		Yes	No