ISRCTN38001825 https://doi.org/10.1186/ISRCTN38001825

Safewards

Submission date	Recruitment status
29/08/2012	No longer recruiting
Registration date	**Overall study status**
29/08/2012	Completed
Last Edited	**Condition category**
20/11/2017	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] 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
11269

Study information

Scientific Title
Safewards: a trial of an intervention to reduce conflict and containment in acute inpatient psychiatry

Acronym
Safewards

Study objectives
When people are very mentally ill and on an acute psychiatric ward, they can sometimes behave in disturbed and unpredictable ways, doing things that they would not usually do. Some of those behaviours are unsafe or even seriously risky, either to patients or those around them, for example being angry and aggressive to others, or trying to harm themselves. We call all these things together conflict. In attempting to cope with or prevent such events, staff may use containment methods, such as restraint, or extra medication.

Our research team has been investigating the ways staff can act so as to produce an environment which will reduce the frequency of these events, and make wards safer places. We have two ideas about how to do this.

The first is about generating physical wellbeing amongst the staff. A healthy and energetic staff group will be more able to devote time and effort to good patient care. Promoting physical health amongst the staff will enable them to do more effectively what they already know how to do: look after the patients to the best of their ability. Good quality care from the staff will reduce conflict with patients and the need for containment. The second idea is to establish structure, change the words and language staff use, improve mutual regard and build alliances between patients and staff. This trial is about testing these interventions, to see which one works best.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 11/LO/0798

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)
Quality of life

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
Severe Mental illness

Interventions
Organisational. Optimising structure, thinking carefully about the words and language nurses use, and enhancing mutual regard between staff and patients. Staff wellbeing. Promoting physical health will enable staff to look after patients to the best of their ability.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Rates of conflict and containment measured at 6 months

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/12/2011

Completion date
31/07/2013

Eligibility

Key inclusion criteria
1. Acute psychiatric wards defined as those that primarily serve acutely mentally disordered adults, taking admissions mainly directly from the community
2. Specifically to include admission wards, assessment wards, triage wards, treatment wards, pre-discharge wards, extra or intensive care; in so far as these wards provide whole or part of the acute care pathway for those temporarily admitted directly from the community
3. Wards to be included regardless of the gender of patients to which they provide a service, whether male, female or mixed, and regardless of the ward's door locking policy
4. Male and female participants
5. Aged 18 - 65 years

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Wards with other specialist functions (e.g. forensic, long term care, older people, child and adolescent)
2. Wards with major planned changes during the trial (e.g. reconfiguration of catchment areas or patient populations, refurbishment, managerial restructuring)
3. Wards where two or more of the following apply:
3.1. An acting ward manager, no ward manager in post, or cover from ward manager primarily responsible for another ward; unless the local organisational structure is that of one ward manager having responsibility for two wards
3.2. A locum consultant psychiatrist, where that post is the identified sole consultant responsible for inpatient care
3.3. Nursing vacancy rates above 30% (9.5% of acute wards in 2005)

Date of first enrolment
05/12/2011

Date of final enrolment
31/07/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE5 8AF

Sponsor information

Organisation
King's College London (UK)

Sponsor details
16 De Crespigny Park
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Sponsor type
University/education

Website
http://www.kcl.ac.uk/

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research [NIHR] ref: RP-PG-0707-10081

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
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?
Results article	results	01/09/2015		Yes	No
Other publications	quality of intervention delivery	17/11/2017		Yes	No