

Human rights in dementia care

Submission date 18/03/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/03/2015	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/12/2020	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

Contact name
Dr Sarah Butchard

Contact details
Mersey Care NHS Trust
Community Services Dept
Mossley Hill Hospital
Liverpool
United Kingdom
L18 8BU

Additional identifiers

Protocol serial number
18379

Study information

Scientific Title
Embedding a human rights based approach to dementia care

Study objectives
The study will employ a randomised controlled trial (RCT) design to explore the research question: Does the application of a Human Rights based approach lead to improvements in the care and well-being of people with dementia who are in an inpatient/care home setting?

Specifically, the study will evaluate whether the delivery of targeted Human Rights training to staff and the subsequent introduction of a Human Rights Based Care Assessment Tool - "Getting it Right" - impacts positively on the ongoing care and well-being of individuals with dementia. It will evaluate this via a range of accepted objective outcome measures and self-reports by people living with dementia, their family carers and staff supporting them

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NW/11117; First MREC approval date 15/08/2014

Study design

Randomised; Interventional and Observational; Design type: Process of Care, Qualitative

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Dementias and neurodegeneration; Subtopic: Dementia; Disease: Dementia

Interventions

1. **Booster sessions:** Following the one day training event there will be three once monthly booster sessions at the unit to embed the Human Rights Based Approach and ensure compliance with applying the assessment tool.
2. **Getting it Right Assessment:** The Getting it Right Assessment tool (based on the principles of a Human Rights Based Approach and Person Centred care) will be completed by trained staff with people with dementia on their unit.
3. **Training package:** There is a one day training package based on a Human Rights Based Approach to dementia care which will be delivered to all staff in the intervention arm of the study.

Intervention Type

Other

Primary outcome(s)

QoL-AD; Timepoint(s): Pre and post intervention

Key secondary outcome(s)

1. ASCOT measure; Timepoint(s): Pre and post intervention
2. Care plan audit; Timepoint(s): Pre and post intervention
3. CSRI; Timepoint(s): Pre and post intervention
4. Dementia Care Mapping; Timepoint(s): Pre and post intervention
5. EQ5D; Timepoint(s): Pre and post intervention
6. FREDA questionnaire; Timepoint(s): Pre and post intervention
7. Human Rights attitudes questionnaire; Timepoint(s): Pre and post training
8. Human Rights knowledge questionnaire; Timepoint(s): Pre and post training
9. Staff interviews; Timepoint(s): Pre and post intervention

10. WEMWBS; Timepoint(s): Pre and post intervention

11. Zarit Carer Burden Index; Timepoint(s): Pre and post intervention

Completion date

31/08/2015

Eligibility

Key inclusion criteria

Inclusion criteria will be broad:

1. Clusters: All NHS sites involved in the study will be dementia-specific wards. Care homes may be included if caring for people with dementia is part of the facilities core business and they have enough residents with dementia to fulfil the needs of the study.
2. Individuals within clusters: the main inclusion criteria for individuals is a diagnosis of dementia. Issues such as age, severity of dementia, length of time at the setting will be recorded but are not regarded as inclusion/ exclusion criteria in themselves
3. Male & female
4. At least 18 years old

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

439

Key exclusion criteria

Individuals who do not have capacity to consent and have no Personal Consultee available to support them in this. There are no other formal Exclusion Criteria, although all participants (people with dementia, carers, staff) will be informed they can withdraw from the study at any stage: requests to withdraw will not be questioned and will be scrupulously honoured.

Date of first enrolment

01/03/2015

Date of final enrolment

31/08/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Mersey Care NHS Trust

Community Services Dept

Mossley Hill Hospital

Liverpool

United Kingdom

L18 8BU

Sponsor information**Organisation**

University of Liverpool

ROR

<https://ror.org/04xs57h96>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research

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

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	01/03/2018	17/12/2020	Yes	No
HRA research summary			26/07/2023	No	No