

# Human rights in dementia care

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
18/03/2015	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
20/03/2015	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
17/12/2020	Mental and Behavioural Disorders	

## 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/1117; 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?
<a href="#">Results article</a>	results	01/03/2018	17/12/2020	Yes	No
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes