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Human rights in dementia care

Submission date	Recruitment status	[ ] Prospectively registered
18/03/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/03/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date
01/03/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Planned Sample Size: 280; UK Sample Size: 280; Description: The above figure for 'total sample size' refers to the estimated number of participants with a diagnosis of dementia,based on 10 clusters with 14 individuals per group in both the intervention and control arms of the trial

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
England

United Kingdom

Study participating centre
Mersey Care NHS Trust
Community Services Dept
Mossley Hill Hospital
Liverpool
United Kingdom
L18 8BU

Sponsor information

Organisation
University of Liverpool

Sponsor details
Department of Clinical Psychology
Thompson Yates Building
Quadrangle Brownlow Hill
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England

United Kingdom
L69 3GB

Sponsor type
Hospital/treatment centre

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

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