A randomised controlled trial to evaluate the impact of a Human Rights Based Approach to dementia care in inpatient ward and care home settings

Kinderman, P[1].; Butchard, S.E.[2]; Bruen, A.J.[1]; Wall, A.[1]; Goulden, N.[3] ; Hoare, Z.[3]; Jones, C.[4] & Edwards, R.T.[4]

1. Institute of Psychology, Health and Society, University of Liverpool, Liverpool, UK
2. Mersey Care NHS Foundation Trust, Liverpool, UK
3. North Wales Organisation for Randomised Trials in Health (NWORTH), School of Healthcare Sciences, Bangor University, Bangor, UK
4. Centre for Health Economics and Medicines Evaluation, Institute of Medical and Social Care Research, Bangor University, Bangor, UK

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The research reported in this ‘first look’ scientific summary was funded by the HS&DR programme or one of its predecessor programmes (NIHR Service Delivery and Organisation programme, or Health Services Research programme) as project number 12/209/53. For more information visit https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1220953/#/

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors have tried to ensure the accuracy of the authors’ work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this scientific summary.

This ‘first look’ scientific summary presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health.

FIRST LOOK DRAFT

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Scientific Summary

Background

Traditionally, people with dementia have been amongst the most devalued in our society. This has led to care practices that undermine the humanity and personhood of individuals with dementia. A Human Rights Based Approach to care establishes minimum standards of care which help to safeguard individuals, particularly those who are vulnerable. It has many overlaps with a person-centred approach but has the backbone afforded by it being a legal requirement to uphold the Human Rights of those in care. The overall aim for this study was to establish whether the application of a Human Rights Based Approach to Health Care leads to significant improvements in the care and well-being of people with dementia in hospital inpatient and care home settings. The approach chosen was an intervention developed and piloted in Mersey Care NHS Foundation Trust and involved a one day training package for staff, the implementation of the 'Getting it Right' assessment tool and booster sessions to support the implementation. The 'Getting it Right' assessment tool was a person-centred care planning tool that explicitly linked the FREDA (Fairness, Respect, Equality, Dignity and Autonomy) principles to areas contributing to person-centred care.

Objectives

1. To investigate whether the application of a Human Rights Based Approach to Health Care, as opposed to treatment as usual, leads to significant improvements in the quality of life of people with dementia in hospital inpatient and care home settings.
2. To explore whether training on the application of a Human Rights Based Approach to Health Care leads to identifiable improvements in the quality of staff decision making.
3. To explore whether training in the application of a Human Rights Based Approach to Health Care, and the use of the Getting it Right Assessment tool, as opposed to the standard care planning procedure, leads to identifiable improvements in the person centred quality of service users' care plans.

4. To explore whether the application of a Human Rights Based Approach to Health Care leads to changes in the well-being of family carers of people with dementia who are in hospital inpatient and care home settings.
5. To validate a novel Human Rights and well-being questionnaire for dementia inpatient care based on the FREDA principles.
6. To explore the costs and consequences of embedding a Human Rights Based Approach.

Methods

A cluster randomised design was employed to compare the impact of implementing the intervention, i.e. the training package, ‘Getting it Right’ Assessment Tool, and booster sessions at 10 intervention sites as compared to treatment as usual at 10 control sites. Eight NHS wards and 12 care homes were recruited across the North West of England. From these sites people living with dementia were recruited to complete self-report measures whenever they could give informed consent. When people were unable to give informed consent a proxy was sought. Staff members were also recruited to complete interviews which examined their decision making strategies in complex clinical situations.

Inclusion/Exclusion Criteria

Inclusion criteria were broad and are outlined below in relation to both sites (clusters) and individual participants at these sites.

a) *Clusters* – All inpatient ward sites were NHS dementia specific wards. Care homes were included if caring for people with dementia was a part of the facilities core business and they currently had enough residents with dementia to fulfil the requirements of the study.
b) *Individuals within clusters* – The main inclusion criteria for individuals within the cluster was a diagnosis of dementia. Issues such as age, severity of dementia, length of time at the setting were recorded but were not inclusion/ exclusion criteria in themselves. The main exclusion criterion was that an individual did not have capacity to consent and had no proxy available to support them in this.

Sample size

The sample size was based on the primary outcome measure; the QOL-AD and was based on conservative figures on several parameters; effect size (0.5) and intraclass correlation coefficient (0.05). A sample size of 10 clusters with 11 individuals per group achieves 80% power to detect an effect size of 0.5 using QOL-AD when the ICC is 0.05 using a 2 sided t-test with a significance level of 0.05. Taking a retention rate of 77% into account requires 14 participants to be recruited per cluster. This resulted in a total sample size of 280 participants. Attempts were made to recruit an informal carer for each participant living with dementia but no participants were excluded due to not having a carer. Eight members of staff from each site were interviewed about their decision making strategies in relation to complex clinical decisions.

Data Collection

Data from each site was collected at baseline then at 4 months post intervention. Every effort was made to encourage participants living with dementia to complete self-report measures but when this was no possible a proxy was sought. Initially a family carer would be approached, when one was not available a staff members could act as a proxy. In total 357 proxy measures were completed and of these 345 were completed by staff members.

Outcome Measures

The primary outcome measure used in the research was the Quality of Life in Alzheimer's disease (QOL-AD) to assess the subjective well-being of the person with dementia.

Secondary outcome measures included:

- Dementia Care Mapping (DCM) to explore quality of care provided
- A Care Plan Audit to look at the quality of care plans
- A novel FREDA based questionnaire to investigate the extent to which participants felt their Human Rights are upheld
- Staff interviews involving vignettes to explore decision making strategies

- Economic evaluation measures; ED5Q-3L, ASCOT and CSRI were completed to explore the economic impact of the evaluation and the cost of the intervention
- Human Rights knowledge and attitudes questionnaires were completed on the day of training with the intervention group and only at baseline in the control group.

In addition staff members at intervention sites were interviewed by an independent research assistant and member of the dementia PPI group about their experience of being involved in the study.

Statistical Analysis

Given that is was reasonable to assume that many participants who were involved at baseline would not be available at follow up a linear mixed model was used to assess the effect of time (baseline or follow up), group (control or intervention) and interaction of time and allocated group. Once it became evident that the ability to collect self-report data on QOL-AD was limited an additional term (self-report vs proxy) was added to the model to assess the importance of this difference.

Qualitative elements of the study; the staff decision making interviews and follow up interviews were analysed using thematic analysis.

Results

The study recruited 439 people living with dementia with 213 in the intervention arm of the study and 226 in the control arm. Additionally 245 staff members were recruited to the study. There was good comparison between the groups at baseline.

Primary outcome measure

As it was found that proxy reports rated quality of life significantly lower than self-report the data from these two sources were analysed separately. There were no significant differences found between the reported quality of life of residents in the control and intervention groups after the intervention ($F_{1,16.51}$=3.63, p=0.074).

Secondary outcome measures

There was a significant difference in both the Human Rights knowledge questionnaire (t(30)=-7.02, p<0.001) and the Human Rights attitudes quiz (t(55)=-53.87, p<0.001) demonstrating an increase in both immediately following training.

No improvements were seen in care as measured by Dementia Care Mapping (DCM). Care plan audits showed that care plans were significantly better in both control and intervention groups at follow up ($F_{1,220.19}$=22.093, p<0.001).

There were some changes in staff reported decision making strategies in the intervention group at follow up. In this group there was less reliance on 'common sense' as a way of making clinical decisions and more explicit references to Human Rights strategies and person centred care as ways of guiding decision making.

Interviews with intervention sites following the completion study highlighted that staff found the approach to be simple and of use but did not always apply it. It was found that a major factor in whether the approach was adopted or not was management support.

Conclusions

The findings of this study did not support the hypothesis that increasing staff knowledge and attitudes towards Human Rights led to improvements in the care and wellbeing of people living with dementia. It does not of course imply that the issues of Human Rights are not important for this group of people. People at later stages of dementia remain some of the most vulnerable in our society and unfortunately reports of Human Rights abuses continue. There remains a need to find a way to ensure that the Human Rights of people with dementia and both respected and promoted.

The study highlighted some of the difficulties that exist within health and social care systems. The care and support that people received was inconsistent and failed to meet the standards we might expect for some of the most vulnerable in our society. Person-centred care was not routine and there were many examples of institutionalised behaviours. Human Rights were concepts that were alien to staff and were not routinely considered when providing care. Staff did not feel empowered to act independently to support the people at their units and the management support that was provided was variable. In order to provide quality care that is person centred and respectful of the Rights of people with dementia it is essential that the cultures care is delivered in are suitable. The results of this study taken together give some indications of factors that may influence the development of these cultures of care. These include:

- Managers who lead and are willing to adopt an innovative approach to change
- All staff feeling empowered to make decisions and to act in ways that they see as appropriate.
- A shift away from training that has awareness raising as its only aim
- A tolerance of risk
- Full involvement of service users in service development and delivery
- Entire sites adopting new cultures
- Monitor progress in relation to Human Rights based targets

These factors link well with the PANEL principles which form the basis for a Human Rights Based Approach to care. They encourage active participation of all stakeholders including managers, staff and service users. They highlight the importance of all levels of staff being accountable for their own actions as opposed to always deferring to more senior colleagues. They actively promote the voices of vulnerable groups, in this case people living with dementia, in ensuring practices are non-discriminatory. They seek to empower all staff regardless of grade and to empower service users to take control of their own services and they provide a clear framework through adherence to Human Rights principle to ensure that all decisions taken are legal.

Implications for Health Care

The study highlights a number of implications for health care both in the way that it is currently provided and in relation to future planning. The study highlights that training alone in a traditional format is potentially not a good medium for bringing about cultural change. Instead training must embrace models that allow learners to understand the material, apply it to their own work and feel that this is making a difference to the wider organisation. Whilst this method of training may be more time consuming and initially more expensive it may limit the dangers of training and retraining with no notable difference to service delivery.

The findings also suggested that the management of services is of vital importance when implementing a new initiative. For this reason managers should be chosen who have values congruent with that of the direction the organisation wishes to move in.

It was noted that care plans improved in both groups at follow up implying that monitoring improved their quality. It may be that monitoring services against explicitly Human Rights based standards may improve the quality of services provided.

Future Research Implications

A major concern raised by the study was the effectiveness of current outcome measures in capturing meaningful change in dementia. A research priority should be the development of more appropriate and dementia sensitive tools to measure outcomes related to quality of life and wellbeing.

At the outset this study worked from the premise that the Human Rights of people living with dementia would be the same as everyone else due to the nature of Human Rights being fundamental principles which apply simply because we are human beings. Public engagement throughout the course of the study however highlighted that the understanding of Rights when dementia is involved may be subtly different. One area that consistently arose was the centrality of identity in preserving and promoting the rights of people living with dementia. Similarly, there were numerous fascinating debates in the sessions related to the changing nature of autonomy and the relative importance, or not of individual autonomy as a concept. These are both areas which could warrant further research to investigate their role in quality of life and well-being of people living with dementia.

Patient & Public Involvement

In line with the ethos of the study, i.e. maintaining and promoting the Human Rights of those with dementia, people living with dementia and people supporting them were involved in all aspects of the study including; the design of the Getting it Right assessment tool and FREDA questionnaire, as members of the Trial Steering Committee, through work of the wider reference group and as interviewers post intervention.

The reference group have been working on ways to ensure that the Rights of people living with dementia are promoted more widely. To this end they are producing a short film based on the practical application of a Human Rights Based Approach to dementia care.

Trial registration

The trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under the reference number ISRCTN94553028

Funding

The project was funded by the NIHR through the HS&DR programme.