A randomised controlled trial to evaluate the impact of a human rights based approach to dementia care in inpatient ward and care home settings

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Scientific summary

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Background

Traditionally, people with dementia have been among 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 that help to safeguard individuals, particularly those who are vulnerable. It has many overlaps with a person-centred approach but has the backbone afforded by the fact that it is a legal requirement to uphold the human rights of those in care. The overall aim for this study was to establish whether or not 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 1-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 or not 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 or not 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 or not 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 or not 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, the 'Getting It Right' assessment tool and booster sessions) at 10 intervention sites with 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 if 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 that examined their decision-making strategies in complex clinical situations.

Inclusion/exclusion criteria

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

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 facility's core business and they had enough residents with dementia at the time to fulfil the requirements of the study.

Individuals within clusters

The main inclusion criterion for individuals within the cluster was having a diagnosis of dementia. Although issues such as age, severity of dementia and length of time at the setting were recorded, they were not inclusion/exclusion criteria. The main exclusion criterion for an individual was not having the capacity to consent and having no proxy available to support them in this.

Sample size

The sample size was based on the primary outcome measure, the Quality of Life in Alzheimer's Disease (QOL-AD) scale, and was based on conservative figures on several parameters: effect size (0.5) and intraclass correlation coefficient (ICC) (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 two-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 because they did not have 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 were collected at baseline and then at 4 months post intervention. Every effort was made to encourage participants living with dementia to complete the self-report measures, but when this was not possible a proxy was sought. Initially, a family carer was approached, and in instances when that person was not available a staff member was permitted to act in this capacity. 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 QOL-AD to assess the subjective well-being of the person with dementia.

The secondary outcome measures comprised:

- dementia care mapping (DCM) to explore the 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 that their human rights were being upheld
- staff interviews involving vignettes to explore decision-making strategies
- the completion of economic evaluation measures – EuroQol-5 Dimensions, three-level version, the Adult Social Care Outcomes Toolkit and the Client Service Receipt Inventory – to explore the economic impact of the evaluation and the cost of the intervention
- the completion of baseline and follow-up human rights knowledge and attitudes questionnaires on the day of training with the intervention group but only at the baseline data collection point with the control group.

In addition, an independent research assistant and a member of the dementia patient and public involvement group interviewed staff members at the intervention sites about their experiences of being involved in the study.

Statistical analysis

Given that it 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 the QOL-AD was limited, an additional term (self-report vs. proxy) was added to the model to assess the importance of this difference.

The qualitative elements of the study (the staff decision-making interviews and follow-up interviews) were analysed using a thematic analysis.

Results

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

Primary outcome measure

As it was found that proxy reports rated quality of life significantly lower than did self-reports, the data from these two sources were analysed separately. There were no significant differences found in the reported quality of life of residents between the control and the 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 [$t(30) = -7.02$; $p < 0.001$] and the human rights attitudes [$t(55) = -53.87$; $p < 0.001$] questionnaires, with an increase in the scores of both immediately following training.

No improvements were seen in care as measured by DCM. Care plan audits showed that care plans were significantly better in both the control and the intervention group at follow-up [$F(1,220.19) = 22.093$; $p < 0.001$].

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

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

Conclusions

The findings of this study did not support the hypothesis that increasing staff knowledge and attitudes towards human rights leads to improvements in the care and well-being 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 in the 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 are 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 they were not routinely considered during the provision of 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. To provide quality care that is person centred and respectful of the rights of people with dementia, it is essential that the cultures in which care is delivered 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
- monitoring of progress in relation to human rights based targets.

These factors link well with the PANEL (participation, accountability, non-discriminatory, empowerment and legality) principles, which form the basis of a human rights based approach to care. They encourage the active participation of all stakeholders, including managers, staff and service users. They highlight the importance of staff at all levels 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 that practices are non-discriminatory. They seek to empower all staff, regardless of grade; empower service users to take control of their own services; and provide a clear framework, through adherence to human rights principles, 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. Although this method of training may be more time-consuming, and initially more expensive, it may avoid the dangers of training and retraining with no notable difference seen in service delivery.

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

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 improves the quality of services provided.

Future research implications

A major concern arising from 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 well-being.

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 because human rights are fundamental principles that apply simply because we are human beings. However, public engagement during the study highlighted that the understanding of rights may be subtly different when dementia is involved. 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 that could warrant further research to investigate their role in quality of life and well-being of people living with dementia.

Patient and 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 has 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 series of short films based on the practical application of a human rights based approach to dementia care.

Trial registration

This trial is registered as ISRCTN94553028.

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