HEALTH SERVICES AND DELIVERY RESEARCH

VOLUME 6 ISSUE 13 MARCH 2018
ISSN 2050-4349

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

Peter Kinderman, Sarah Butchard, Ashley J Bruen, Abbie Wall, Nia Goulden, Zoe Hoare, Carys Jones and Rhiannon Edwards

DOI 10.3310/hsdr06130

National Institute for Health Research

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

Peter Kinderman,[1] Sarah Butchard,[2]* Ashley J Bruen,[1] Abbie Wall,[1] Nia Goulden,[3] Zoe Hoare,[3] Carys Jones[4] and Rhiannon Edwards[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

*Corresponding author

Declared competing interests of authors: none

Published March 2018
DOI: 10.3310/hsdr06130

This report should be referenced as follows:

Kinderman P, Butchard S, Bruen AJ, Wall A, Goulden N, Hoare Z, *et al*. A randomised controlled trial to evaluate the impact of a human rights based approach to dementia care in inpatient ward and care home settings. *Health Serv Deliv Res* 2018;**6**(13).

Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: journals.library@nihr.ac.uk

The full HS&DR archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hsdr. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Services and Delivery Research* journal

Reports are published in *Health Services and Delivery Research* (HS&DR) if (1) they have resulted from work for the HS&DR programme or programmes which preceded the HS&DR programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

HS&DR programme

The Health Services and Delivery Research (HS&DR) programme, part of the National Institute for Health Research (NIHR), was established to fund a broad range of research. It combines the strengths and contributions of two previous NIHR research programmes: the Health Services Research (HSR) programme and the Service Delivery and Organisation (SDO) programme, which were merged in January 2012.

The HS&DR programme aims to produce rigorous and relevant evidence on the quality, access and organisation of health services including costs and outcomes, as well as research on implementation. The programme will enhance the strategic focus on research that matters to the NHS and is keen to support ambitious evaluative research to improve health services.

For more information about the HS&DR programme please visit the website: http://www.nets.nihr.ac.uk/programmes/hsdr

This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its preceding programmes as project number 12/209/53. The contractual start date was in May 2014. The final report began editorial review in October 2016 and was accepted for publication in August 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report 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 and Social Care. 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 and Social Care.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).

Health Services and Delivery Research Editor-in-Chief

Professor Jo Rycroft-Malone Professor of Health Services and Implementation Research, Bangor University, UK

NIHR Journals Library Editor-in-Chief

Professor Tom Walley Director, NIHR Evaluation, Trials and Studies and Director of the EME Programme, UK

NIHR Journals Library Editors

Professor Ken Stein Chair of HTA and EME Editorial Board and Professor of Public Health, University of Exeter Medical School, UK

Professor Andrée Le May Chair of NIHR Journals Library Editorial Group (HS&DR, PGfAR, PHR journals)

Dr Martin Ashton-Key Consultant in Public Health Medicine/Consultant Advisor, NETSCC, UK

Professor Matthias Beck Professor of Management, Cork University Business School, Department of Management and Marketing, University College Cork, Ireland

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

Dr Peter Davidson Director of the NIHR Dissemination Centre, University of Southampton, UK

Ms Tara Lamont Scientific Advisor, NETSCC, UK

Dr Catriona McDaid Senior Research Fellow, York Trials Unit, Department of Health Sciences, University of York, UK

Professor William McGuire Professor of Child Health, Hull York Medical School, University of York, UK

Professor Geoffrey Meads Professor of Wellbeing Research, University of Winchester, UK

Professor John Norrie Chair in Medical Statistics, University of Edinburgh, UK

Professor John Powell Consultant Clinical Adviser, National Institute for Health and Care Excellence (NICE), UK

Professor James Raftery Professor of Health Technology Assessment, Wessex Institute, Faculty of Medicine, University of Southampton, UK

Dr Rob Riemsma Reviews Manager, Kleijnen Systematic Reviews Ltd, UK

Professor Helen Roberts Professor of Child Health Research, UCL Great Ormond Street Institute of Child Health, UK

Professor Jonathan Ross Professor of Sexual Health and HIV, University Hospital Birmingham, UK

Professor Helen Snooks Professor of Health Services Research, Institute of Life Science, College of Medicine, Swansea University, UK

Professor Jim Thornton Professor of Obstetrics and Gynaecology, Faculty of Medicine and Health Sciences, University of Nottingham, UK

Professor Martin Underwood Director, Warwick Clinical Trials Unit, Warwick Medical School, University of Warwick, UK

Please visit the website for a list of members of the NIHR Journals Library Board:
www.journalslibrary.nihr.ac.uk/about/editors

Editorial contact: journals.library@nihr.ac.uk

Abstract

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

Peter Kinderman,[1] Sarah Butchard,[2]* Ashley J Bruen,[1] Abbie Wall,[1] Nia Goulden,[3] Zoe Hoare,[3] Carys Jones[4] and Rhiannon Edwards[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

*Corresponding author sarah.butchard@merseycare.nhs.uk

Background: Although it is widely recognised that adopting a person-centred approach is beneficial in the care of people living with dementia, a gap remains between the rhetoric and the reality of quality care. Some widely adopted care practices can result in the personhood of this group being threatened and their human rights being undermined.

Objectives: To evaluate the impact of applying a human rights based approach in dementia inpatient wards and care homes on the quality of care delivered and the well-being of the person living with dementia.

Design: A cluster randomised design was employed to compare the impact of implementing a human rights based approach intervention (i.e. training, applying the 'Getting It Right' assessment tool and receiving booster sessions) at 10 intervention sites with 10 control sites.

Setting: Eight NHS dementia inpatient wards and 12 care homes in the north-west of England.

Participants: People living with dementia who were residing on dementia inpatient wards or in care homes, and staff working at these sites. The aim was to recruit 280 people living with dementia.

Interventions: A sample of staff (an average of 8.9 per site) at each of the sites was trained in a human rights based approach to care, including the application of the 'Getting It Right' assessment tool. The tool was then introduced at the site and monthly booster sessions were delivered.

Main outcome measures: The primary outcome measure used in the research was the Quality of Life in Alzheimer's Disease scale to assess the subjective well-being of the person with dementia. Secondary outcome measures included measures of the quality of care provided (dementia care mapping) and direct measures of the effectiveness of the training in increasing knowledge of and attitudes towards human rights. The study also included an economic evaluation utilising the EuroQol-5 Dimensions, three-level version, and the Adult Social Care Outcomes Toolkit measure.

Results: The study recruited 439 people living with dementia: 213 to the intervention arm and 226 to the control arm. Primary outcome data were analysed using a linear mixed model. There were no significant differences found in the reported quality of life of residents between the control and intervention groups after the intervention [$F(1,16.51) = 3.63$; $p = 0.074$]. The mean difference between the groups was 1.48 (95% confidence interval –7.86 to 10.82).

Conclusions: Despite the fact that the training increased staff knowledge of and positive attitudes towards human rights, and although there were some changes in staff decision-making strategies in clinical situations, there was no change in the quality of care provided or in the reported well-being of people living with dementia in these settings. This led to questions about the efficacy of training in bringing about cultural change and improving care practices.

Limitations: There was limited uptake of the training and booster sessions that were integral to the intervention.

Future work: Future work could usefully focus on understanding the difficulty in translating change in attitude and knowledge into behaviour.

Trial registration: Current Controlled Trials ISRCTN94553028.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research programme and will be published in full in *Health Services and Delivery Research*; Vol. 6, No. 13. See the NIHR Journals Library website for further project information.

Contents

List of tables

List of figures

List of abbreviations

ADAS-Cog	Alzheimer's Disease Assessment Scale – Cognitive subscale
ASCOT	Adult Social Care Outcomes Toolkit
CPA	care programme approach
CQC	Care Quality Commission
DCM	dementia care mapping
DEEP	Dementia Engagement and Empowerment Project
DMEC	Data Monitoring and Ethics Committee
EQ-5D-3L	EuroQol-5 Dimensions, three-level version
FREDA	Fairness, Respect, Equality, Dignity and Autonomy
GP	general practitioner
ICC	intraclass correlation coefficient
IDEA	Identity, Dignity, Equality and Autonomy
ISRCTN	International Standard Randomised Controlled Trial Number
ME	mood and engagement
MMSE	Mini Mental State Examination
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NWORTH	North Wales Organisation for Randomised Trials in Health
PANEL	participation, accountability, non-discriminatory, empowerment and legality
PPI	patient and public involvement
QOL-AD	Quality of Life in Alzheimer's Disease
RCT	randomised controlled trial
SD	standard deviation
TSC	Trial Steering Committee
WEMWBS	Warwick–Edinburgh Mental Well-Being Scale
ZBI	Zarit Burden Interview

Plain English summary

This study aimed to explore whether or not training staff to use a new assessment tool called 'Getting It Right' could improve the quality of care provided in dementia-specific NHS wards and care homes. The assessment tool was based on human rights principles and explicitly linked person-centred care to the human rights FREDA (Fairness, Respect, Equality, Dignity and Autonomy) principles. The assessment tool and training were designed by and piloted at Mersey Care NHS Foundation Trust. Staff members completed the assessment tool with residents on their unit and were offered booster consultation sessions to help them with any problems they encountered completing it.

Twenty sites were recruited to the study across the north-west of England (eight NHS wards and 12 care homes). These sites either received the intervention package described above (training, applying the 'Getting It Right' assessment tool and receiving booster sessions) or continued with care as usual. The measures were completed before the study began and after 4 months to see whether or not there were any differences in the well-being of people living with dementia and the quality of care provided. Staff members were also interviewed to look at whether or not the way that they made decisions had changed.

It was found that, although there were improvements in staff knowledge about human rights following the training, and staff expressed more positive attitudes towards human rights, there were no improvements in the care provided or in the well-being of people living with dementia. Staff also reported different decision-making strategies following the intervention.

Although staff generally reported that the approach was simple and easy to use, there was evidence that it had not been used routinely. Interviews showed that management support was an important factor in whether or not the approach was applied. Future research could focus on different ways of ensuring that people apply new initiatives.

Scientific summary

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.

Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research.

Chapter 1 Introduction

Scientific background

Dementia in society

There are currently > 850,000 people living with a diagnosis of dementia in the UK.[1] As well as the biological changes associated with a dementia process, which can lead to a range of cognitive difficulties, dementia is associated with numerous psychological and social consequences. Sixty-one per cent of people living with dementia have reported feeling anxious or depressed, 40% have reported feeling lonely and just over one-third do not feel part of their community.[1] This poses a major threat to the quality of life of a large number of people in our society and is in direct conflict with the National Dementia Strategy, the aim of which is to help people with dementia to 'live well with dementia'.[2] The cost of dementia to the UK each year is estimated to be £26B.[3] We live in an ageing population and the issues associated with dementia will continue to increase. The status quo is unsustainable. Providing good-quality care to people with dementia will continue to be a concern over the coming years.

In 2007, the Alzheimer's Society published *Dementia UK*.[4] This report stated that:

> *Dementia must be made a publicly stated national health and social care priority. This must be reflected in plans for service development and public spending.*
>
> *Dementia UK.*[4] *© Alzheimer's Society 2007*

In 2009, *Living Well With Dementia: A National Dementia Strategy*[2] was published, outlining the government's plan for providing quality services in dementia care. Dementia has been highlighted as a government priority. In 2015, the prime minister launched a programme of work[5] that aims to deliver major improvements in dementia care and research by 2020. The focus of this is improving the services provided for people with dementia, with the view that England could become the best country in the world for dementia care and support, for people with dementia, their carers and families to live, and for undertaking research into dementia.

Dementia is widely feared in society[6] and, traditionally, people with dementia have been among the most devalued, experiencing the double stigma of old age and cognitive impairment. Kitwood[7] suggested that personhood (i.e. the state of being a person) is bestowed on us by the treatment of others. The stigma and misperceptions surrounding dementia and the resulting reactions of people towards those living with dementia have led to care practices that can undermine the humanity and personhood of an individual with dementia.[7] The literature highlights issues such as removing all choice and personal autonomy from people with dementia,[8] restraint, and restrictions on 'wandering'. It is clear that there are occasions when human rights for people with dementia are unnecessarily limited and their application is not routinely considered in clinical decision-making.[9] It is essential that approaches are adopted that maintain the humanity of an individual and challenge the stigma associated with dementia that people often report feeling.

Human rights

Human rights are brought into UK law through the Human Rights Act.[10] They represent the fundamental ways in which a person can expect to be treated simply by virtue of being human. Although human rights are based on values held for centuries, they became formalised following the atrocities of the second world war, in particular the Holocaust. It was acknowledged that human beings can inflict dreadful suffering on each other and that explicit statements on our rights as human citizens were required. The articles of the Human Rights Act are broad-ranging, covering physical, psychological and social issues, and they represent the minimum standard of treatment that we should expect. *Table 1* outlines the articles of the Human Rights Act.

TABLE 1 The articles of the Human Rights Act

Part I	The convention rights and freedoms
Article 2	The right to life
Article 3	The right not to be tortured or treated in an inhuman or degrading way
Article 4	The right to be free from slavery or forced labour
Article 5	The right to liberty and security
Article 6	The right to a fair trial
Article 7	The right to no punishment without law
Article 8	The right to respect for private and family life, home and correspondence
Article 9	The right to freedom of thought, conscience and religion
Article 10	The right to freedom of expression
Article 11	The right to freedom of assembly and association
Article 12	The right to marry and found a family
Article 14	The right not to be discriminated against in relation to any of the rights contained in the European Convention
Protocol 1: Article 1	The right to peaceful enjoyment of possessions
Protocol 1: Article 2	The right to education
Protocol 1: Article 3	The right to free elections
Protocol 13: Article 1	Abolition of the death penalty

The United Nations adopted the Universal Declaration of Human Rights in 1948.[11] The European Convention on Human Rights,[12] created in 1950 by the Council of Europe, was the first post-war attempt to unify Europe and institutionalise the shared values of democracy, human rights and the rule of law. The UK was among the first states to ratify the Convention and British jurists were highly influential in its design. The Human Rights Act[10] incorporates most of the Convention rights into UK law. It came into force across the UK in October 2000.

Human rights law, including the rights composing the Human Rights Act, can be understood through the FREDA (Fairness, Respect, Equality, Dignity and Autonomy) principles.[13] The FREDA principles are not law in and of themselves. They are the values that run through the rights protected by the Human Rights Act and are at the heart of high-quality health and social care.

Human rights in health care

> *Where, after all, do human rights begin? In small places, close to home – so close and so small that they cannot be seen on any map of the world. Yet they are the world of the individual person . . .*
>
> *Eleanor Roosevelt, 1958*[14]

Human rights are diagnosis neutral and compel us to treat everyone as human beings regardless of the difficulties they may be experiencing. They also recognise, however, that, in certain complex cases, a balance may need to be struck in order to meet competing rights of different individuals or to protect an individual from unwarranted risk, and rights may need to be limited. A human rights based approach describes the process of using the articles of the Human Rights Act in a very practical way to influence daily life.[15] A human rights based approach to care both allows for that balance to be considered and provides a lens through which such difficult decisions can be made. Failure to take the human rights of the service user into account can also lead to legal suits that impose an additional financial burden and undermine public confidence in services.[16,17] The *NHS Constitution for England* states that the NHS:

> *. . . has a duty to each and every individual that it serves and must respect their human rights.*
>
> *Department of Health.[18] © Crown copyright. Contains public sector information licensed under the Open Government Licence v3.0*

Not only is it unlawful for NHS organisations to work in a way that is incompatible with human rights, but the application of a human rights based approach establishes minimum standards of care that help to safeguard individuals, particularly those who are vulnerable. They also remind us that individuals require a great deal more than safeguarding in order to maintain their self-respect and sense of dignity. The culture of organisations has led, on occasion, to staff delivering task-orientated, risk-averse care that fails to consider the human rights of an individual.[16] Human rights, in this context, can therefore be viewed as codifications of how relationships can be understood and the social obligations we hold as human beings.[19]

The Human Rights Act[10] is law; however, in health-care settings, it needs to be translated into a clear set of principles that guide everyday practice, bridging the gap between the legal system and good-quality health care.[20] *Human Rights in Healthcare*[21] achieves this translation by outlining the key ingredients of a human rights based approach. An alternative but similar construction is found within the PANEL principles.[8] The PANEL principles are participation, accountability, non-discriminatory, empowerment and legality, and these are defined more fully in *Table 2*. They represent the guiding principles for organisations to follow to maximise the chances of the services they deliver aligning with a human rights based approach.

Making the link between law and ethical practice is not the only step required. There is also a need to translate the concepts of a human rights based approach into practical strategies that can facilitate the everyday decision-making of staff; in other words, there is a need to make 'choices guided by values'[22] and by the more practical elements of a human rights based approach, such as proportionality (i.e. responding to situations in a way that is appropriate in magnitude and degree), the fit with other legal frameworks such as the Mental Health Act[23] and Mental Capacity Act,[24] proactive strategies (predicting responses to events through knowledge of the person and responding before a negative event occurs) and balancing rights and risks to make sensible decisions.

The disability model of dementia

Discussions around dementia and the difficulties it causes to individuals have historically been dominated by a medicalised notion of dementia, in which there is no cure and nothing can be done other than watch the person decline.[25] More recent social movements to recognise dementia as a disability[26] have opened up opportunities to frame dementia within a rights based approach. The United Nations' *Convention on the Rights of Persons with Disabilities*[27] aims to ensure that, ultimately, people living with a disability do not experience discrimination and that their rights are maintained and promoted. The UK has ratified the Convention, which means that all UK laws and policies should be compliant with it.[28] As a result, people living with dementia should be able to utilise the Convention to protect and promote their rights.

TABLE 2 Explanation of the PANEL principles in health-care settings

PANEL principle	Description
Participation	To ensure that all stakeholders are meaningfully engaged in the service
Accountability	To ensure that there is clear accountability and transparency to services being provided
Non-discriminatory	To ensure that particular attention is paid to vulnerable groups
Empowerment	To ensure the empowerment of all stakeholder groups
Legality	Looking at things through a human rights lens and ensuring that all actions taken are legal

Human rights and dementia

Although there is still limited empirical work being carried out specifically in the area of dementia and human rights, the last few years have seen an expansion of this topic as an area of focus. Several charters of human rights have been produced[29,30] that aim to influence policy related to dementia. Literature also exists considering some of the major issues that may threaten an individual's human rights. Laird[31] has provided examples of how fundamental human rights can be violated in health-care settings:

> *[S]ituations cited by British Institute of Human Rights include failure to change soiled bed sheets, neglect leading to pressure ulcer development, not helping people to eat when they are too frail to eat themselves, excessive force used to restrain people and washing or dressing people without regard to dignity.*
>
> *Laird,[31] p. 6*

It is notable, however, that the majority of publications are focused at a policy level[32] or are discussion papers reviewing a concept[33] as opposed to attempts to apply a human rights based approach in practice and evaluate its effectiveness. In 2016, Dementia Alliance International launched *The Human Rights of People Living with Dementia: From Rhetoric to Reality*.[34] Although this was a move to ensure that people living with dementia are aware of their rights, it stopped short of outlining the specific applications of a human rights based approach. In addition, the Dementia Engagement and Empowerment Project (DEEP) has worked alongside people with dementia to produce *Our Dementia, Our Rights*.[35] Although this was a real attempt to raise the issue of rights in the collective minds of society, and to produce a document in an accessible format, it did not evaluate the impact that the practical application of human rights law could have on the day-to-day lives of people living with dementia.

Since the work of Tom Kitwood,[7] it has been widely accepted that person-centred principles are important in the provision of high-quality dementia care. These principles have, however, been criticised for being vague and difficult to research and enforce.[36] There are high levels of congruence between the fundamental principles of person-centred care and a human rights based approach, such as empowerment and inclusion.[37] A human rights based approach gives backbone and a legal framework to person-centred principles,[37] potentially making them clearer to operationalise and more accessible to rigorous research.

Human rights training

Although there are various models of training to promote human rights awareness,[38] there is limited evidence of their efficacy in terms of behavioural change.[39] These models include:

- values and awareness model – this focuses on transmitting basic knowledge of human rights
- accountability model – this assumes that participants will already be involved in the protection of individual and group rights and focuses on professional responsibility in relation to this
- transformational model – this is geared towards empowering individuals who have previously experienced human rights abuses to both recognise human rights abuses and commit to their prevention.

The suggested common themes in these models are fostering and enhancing leadership, coalition and alliance development and personal empowerment.[38]

Attitudinal change for staff through human rights awareness training may be more effective when there is emphasis on staff's emotional responses and defences and the impact of organisational culture.[39] Reflections on rights awareness training in both dementia and intellectual disabilities services suggests that change might be achieved through placing ethical decision-making centrally. This has been termed 'dilemma-based learning'.[37]

Human rights evaluation

The need to evaluate human rights initiatives is often overlooked and there is no real consensus about *how* to evaluate them.[40] It has been argued that the evaluation of human rights based approaches is problematic for a number of reasons, including a belief that legal concepts should be monitored rather than evaluated, a fear that evaluation will lead to legal ramifications and a distaste for quantifying the extent of human misery and abuse when rights are not being upheld.[37]

Donald[40] provides a clear framework for evaluating human rights based approaches in health-care services. This framework encourages the exploration of human rights knowledge and understanding; skills in applying human rights based approaches; attitudes, perspectives and values; and, ultimately, the outcome and impact of applying the approach for the realisation of human rights. There is an argument that this is more palatable, as it allows researchers to directly assess the process and impact of the human rights based approaches rather than attempting to quantify abuses.

Rationale for research

Cultures of care

It may be comforting to assume that the human rights of the most vulnerable people in our society are routinely upheld and promoted by those tasked with caring for them. Unfortunately, the sad truth is that this is not always the case. The Francis report,[41] arising from the lack of care provided at Mid-Staffordshire NHS Foundation Trust, highlighted the importance of creating the:

> *. . . right culture of care . . .*
>
> *Francis.[41] © Crown copyright. Contains public sector information licensed under the Open Government Licence v3.0*

to ensure that people are treated in ways that promote dignity and respect.

The Care Quality Commission (CQC) routinely uncovers practices that threaten the human rights of people living with dementia. For example, in one care home, inspectors noted that many residents stayed in bed all day for no apparent reason. When the inspectors questioned staff about this practice, they were told, 'One side [of the house] we get up Monday, Wednesday and Friday. The other side we get up Tuesday, Thursday, Saturday'.[42] This is obviously unacceptable and in direct conflict with the principles of the Human Rights Act.[10]

When considering the moral imperative we all hold to protect the vulnerable, it has been highlighted that 'compassion is the basis for all morality'.[43] If we want to develop cultures of care in which person-centred care is a reality, then it has been suggested that 'the NHS must be a fertile soil for meaningful caring relationships'.[44] The work of Buber and Smith[45] encouraged viewing relationships as 'I-Thou', thereby engaging on a human-to-human level with the people we provide care and support for, as opposed to 'I-It', which adopts a detached task-orientated approach whereby people are viewed as jobs to be done and tasks to be completed. It has been suggested that, in many care settings, 'the gap between the rhetoric and the reality remains uncomfortably wide'[46] when we are considering models of person-centred care. There is no obligation to carry out person-centred care other than knowing that it is the right thing to do. With their statutory weight, human rights approaches can strengthen person-centred approaches[47] and maximise the chances that they will be adopted.

Training and care

The training currently given to care providers does not automatically feel congruent with the aim of producing compassionate, person-centred cultures of care. It is recognised that there are major failings in the training of staff who provide care, particularly those who work in the care home sector. The CQC found that, of those care homes told to improve after a visit, 71% had significant training gaps, with dementia care, safeguarding and the Mental Capacity Act faring worst.[48] This is particularly worrying given that > 70% of people who are residents of care homes are living with dementia,[1] and that the very fact that a person resides in a care home increases the chances that there will be queries about their capacity.

In providing training we are assuming that we are equipping people to make complex clinical decisions on a day-to-day basis. In reality we are often training people to become task orientated and driven. Models of training that include real-life situations tend to produce better outcomes with more emotional attachment to them.[37]

Care planning

The availability of a good-quality person-centred care plan does not automatically ensure that good-quality person-centred care is provided, but it does provide a template by which the standard of care can be judged. In 2017, NHS England stated that:

> *. . . care planning is a crucial element in delivering improved care for people living with dementia.*
>
> *Reproduced from NHS England.[49] Contains public sector information licensed under the Open Government Licence v3.0*

The National Institute for Health and Care Excellence (NICE)'s[50] quality standard statement 4 for dementia requires that each person has a personalised care plan. There are models of good-quality care planning, such as enhanced care planning, but these are often not adopted. Traditional care planning approaches adopted in NHS services, such as the care programme approach (CPA), do not always lend themselves to the full involvement of people living with dementia because of the somewhat restrictive nature of their content and a focus on risk assessment.[51] It has been suggested that the CPA maintains:

> *. . . a system which too often defines people by their diagnosis and medication . . .*
>
> *© The National Survivor User Network[52]*

and

> *. . . finds it difficult to recognise the whole person and the unique individual . . .*
>
> *© The National Survivor User Network[52]*

Any model of quality dementia care recognises the centrality and importance of an in-depth knowledge of the person, their wishes and their preferences in providing support that is person centred and, therefore, is more likely to uphold their human rights.[53] It follows, therefore, that a good-quality care plan should be a vehicle for collating this detailed knowledge about a person and their care.

Decision-making in care settings

It is recognised that 'making decisions that concern people's health and quality of life creates complex ethical dilemmas, and one has to choose among alternatives'.[54] This can lead to decisions that have an impact on an individual's human rights. For example, Robinson *et al.*[9] explored the area of balancing risks and rights in relation to wandering. They highlighted that staff often act in particular ways, such as having a locked-door policy, because they are worried about being viewed as negligent. The implementation of a human rights based approach may provide staff with a more comprehensive and robust framework in which decisions can be made, drawing on human rights principles, particularly proportionality, least restrictive practice and proactive strategies, rather than relying on the most risk-adverse approach.[37]

Rationale

We are existing in systems where the care provided to some of the most vulnerable people in society is failing to meet their complex needs. Additionally, we are not equipping our workforces to meet these needs because of woeful lack of investment in their development.

This project will build on the existing literature exploring how the human rights of people living with dementia can be undermined and unnecessarily restricted within traditional models of care but expand the focus to look at an operationalised model of providing care that embeds a human rights based approach. The proposed intervention aimed to put human rights at the heart of care planning and service delivery. A human rights based approach was chosen as the appropriate focus for this project because not only does the NHS have a legal requirement to uphold the human rights of service users, but it is recognised that quality care is both person centred and respectful of an individual's human rights.[55]

Embedding a human rights based approach through the application of the 'Getting It Right' assessment tool[56] and training package aimed to maximise quality of life and well-being for people with dementia and provide a framework for staff to make decisions about care within a human rights based approach, using the principles of proportionality, proactive strategies, positive risk-taking and use of least restrictive practices.

Conceptual framework

The underlying conceptual framework for the study was that the introduction of a human rights based approach to health care would lead to improvements in the well-being of people with dementia and the care they receive. This is summarised in *Figure 1*, which highlights how the outcome measures used allowed the exploration of these areas and the links between them. Specifically, the Quality of Life in Alzheimer's Disease (QOL-AD)[57] allowed a measurement of changes in subjective well-being but did not explain why these changes had taken place. The care plan audit measured the documented standard of care that a person should be receiving and also tapped into increases in human rights based language, etc., which would suggest that the human rights based nature of the intervention had an effect over and above simply providing generic training. However, care plans do not capture the actual care that is delivered and how it affects well-being. Dementia care mapping (DCM) was used to explore whether or not care provided on a unit changed and the effect that this had on the well-being of service users on the unit.

The completion of human rights knowledge and attitude questionnaires measured changes in these areas pre and post training but did not look at the impact that these had on staff in their everyday working lives and how they affected service user well-being. Staff interviews were conducted to explore whether or not the introduction of a human rights based approach led to differences in decision-making processes when considering care issues. Similarly, the FREDA-based questionnaire was included to allow the team to explore whether or not service users felt that their human rights were respected more after the intervention.

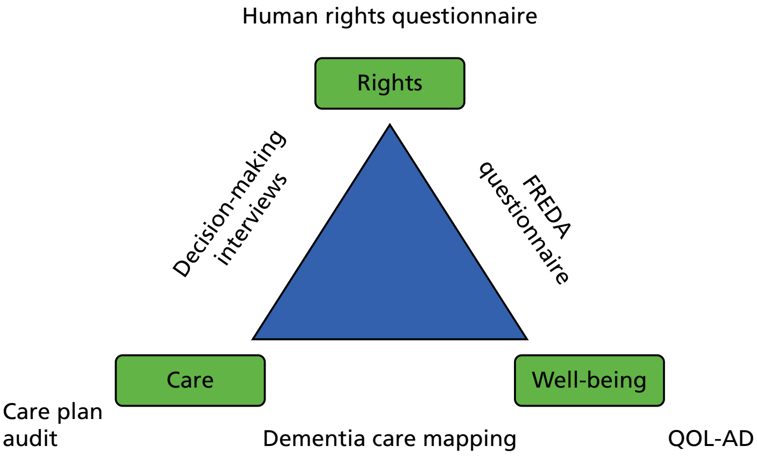


FIGURE 1 Conceptual framework for the study. QOL-AD, Quality of Life in Alzheimer's Disease.

Aims and objectives

Aim

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.

Specific 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, as measured by scores on the QOL-AD scale.[57]
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, as measured by vignette-based interviews with staff.
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,[56] as opposed to the standard care planning procedure, leads to identifiable improvements in the person-centred quality of service users' care plans, as measured by care plan audits.
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, as measured by the Warwick–Edinburgh Mental Well-Being Scale (WEMWBS)[58] and the Zarit Burden Interview (ZBI).[59]
5. To validate a novel human rights and well-being questionnaire for dementia inpatient care.
6. To explore the costs and consequences of human rights training for staff looking after people with dementia in hospital and care home settings in terms of patient-reported well-being, care plan development, staff stress, family member well-being and overall quality of care, compared with usual patient management.

Chapter 2 Trial design and methods

Study design

The study was designed to evaluate whether or not the application of a novel human rights based intervention could improve the standard of care delivered in dementia inpatient wards and care home settings as opposed to treatment as usual.

The research employed a cluster randomised design to compare the impact of implementing the intervention (i.e. the training package, the 'Getting It Right' assessment tool[56] and booster sessions) at 10 intervention sites with 10 control sites. The control sites continued with treatment as usual. No active placebo was indicated. It was acknowledged that there may have been significant variation in what constituted treatment as usual across the sites involved in the study.

Data collection points were at baseline (see randomisation) and at 4 months post intervention. Training was delivered at the intervention sites and booster sessions were given over a 3-month period post training.

Intervention package

The intervention package being applied was a novel human rights based intervention package that had previously been piloted within the host trust (Mersey Care NHS Foundation Trust). It consisted of three linked elements.

1. A one-day training package delivered to staff from the intervention unit at a time and place that was convenient to the site. The training was delivered by co-applicant Sarah Butchard, who jointly developed the intervention package and is an experienced clinical psychologist and senior clinical teacher. It was based on dilemma-based learning, utilising clinical scenarios that commonly occur in dementia services. It incorporated both direct learning about a human rights based approach and its utility in dementia and the practical application of the human rights based assessment tool ('Getting It Right'[56]).
2. The completion of 'Getting It Right'[56] (see *Appendix 1*), which was based on person-centred principles and on the learning from enhanced care planning.[53] The aim of using the tool was to build up a person-centred care plan that was explicitly linked to the FREDA principles. Each unit was given multiple copies of the assessment tool following the training and requested to complete the assessment with both new and existing residents on the unit. There was no stipulation made as to how many assessments needed to be competed at each unit. It was emphasised that any member of staff, not just those who were qualified, could complete the assessment with residents, and that it was more important that it was completed by someone who had a good relationship with that resident.
3. Monthly booster sessions were delivered by Sarah Butchard to address issues arising from the application of the assessment tool. Three booster sessions were offered, one per month, following the training. These adopted a consultation model and allowed staff to reflect on any difficulties they had in applying the assessment tool.

Ethics approval and research governance

A protocol was submitted for ethics consideration to the National Research Ethics Service committee North West – Haydock (reference number 14/NW/1117) in June 2014 and it was approved in August 2014. No requests for alterations were made before approval was granted. For participating NHS sites, approval was also sought from the relevant NHS trust research and development department.

The trial was registered with the International Standard Randomised Controlled Trial Register Number (ISRCTN) Registry under the reference number ISRCTN94553028 (www.isrctn.com/ISRCTN94553028).

Patient and public involvement

Ensuring that people living with dementia were meaningfully involved in all aspects of the study was seen as essential because of the congruence of this with the key aims of the project: to ensure dignity and respect while remembering that the individuality of human needs does not diminish with the passage of time or diagnosis.

People living with dementia and their carers were included in all stages of the study; they were fully involved in the development of both the assessment tool and the FREDA-based questionnaire [IDEA (Identity, Dignity, Equality and Autonomy)] through a series of focus groups and consultation exercises.

Two people living with dementia and a carer were key members of the Trial Steering Committee (TSC) and contributed fully to these meetings throughout the study, advising on its smooth and ethical running.

Alongside this, a patient and public involvement (PPI) reference group was set up that included service users, carers and other interested stakeholders. This group worked on the wider issues having an impact on, and evolving from, the research, such as the perception of human rights among people living with dementia.

People living with dementia and carers also co-facilitated the post-study interviews with staff who had completed training to examine views on acceptability.

The group was consulted about the results of the study and their comments have been incorporated into the discussion.

Participants

The populations to be investigated during this study were people living with dementia, their carers and the staff of NHS inpatient dementia wards and care homes. All of the people living with dementia were either an existing resident of or a new admission to the ward or care home. 'Carers' in this context referred to family members, or significant others, of the people living with dementia. People living with dementia did not need to have a carer in order to be involved in the study.

Inclusion/exclusion criteria

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

Clusters

All inpatient ward sites were NHS dementia specific. Care homes were included if caring for people with dementia was a part of the facility's core business and if they currently had enough residents with dementia 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.

Setting

The research was conducted in dementia inpatient wards within NHS trusts and in care homes. *Table 3* shows the sites that participated in the study and their basic characteristics.

Although the initial aim was to recruit 10 NHS wards and 10 care homes, practicalities resulted in eight NHS wards and 12 care homes being recruited. In reality, however, far more people living with dementia are care home residents than are admitted to specialist dementia wards. It is estimated that one-third of people with dementia live in care homes.[60] It is harder to obtain specific figures on those accessing specialist dementia wards, but figures for the local regions where the study was carried out suggest that only 1.5% of people living with dementia will need support on a specialist dementia inpatient ward.[61] It is, therefore, reasonable that more care homes than wards were included if the figures are to represent the population of people living with dementia.

Sample size

The sample size was based on the primary outcome measure, the QOL-AD scale,[57] and on conservative figures on several parameters.

TABLE 3 Characteristics of the sites involved in the study

Site	NHS trust or care home	Intervention or control	Number of beds	Total number of staff	Number of day staff	Average number of staff on shift
Dale Park	Care home	Intervention	44	38	38	7
Redholme Memory Care	Care home	Control	55	47	35	9
Abbotsbury	Care home	Intervention	20	23	19	5
Finch Manor	Care home	Intervention	89	85	51	18
Avalon	Care home	Control	20	31	19	5
Acacia Court	Care home	Control	26	16	16	5
Irwell Ward	NHS trust	Control	17	43	33	6
Meadowbank Ward	NHS trust	Intervention	13	45	23	9
Tudorbank	Care home	Control	46	34	24	7
Greenacres	Care home	Intervention	41	38	20	5
Cherry Ward	NHS trust	Intervention	11	37	23	8
Whiston & Halton Wards	NHS trust	Control	20	50	35	6
Leigh Ward	NHS trust	Control	23	36	24	6
Hollins Park	NHS trust	Intervention	18	32	21	6
Larkhill Hall	Care home	Intervention	66	63	37	11
Cressington Court	Care home	Control	56	59	32	9
Macclesfield	NHS trust	Intervention	15	47	43	7
The Harbour	NHS trust	Control	36	91	73	10
Thomas Leigh	Care home	Control	19	40	13	4
St Luke's	Care home	Intervention	56	78	51	22

Effect size

The literature indicated that previous similar research yielded effect sizes of 0.6.[62] It is necessary to be more conservative given practical experience, and hence an effect size of 0.5 was used when calculating the sample size.

Intraclass correlation coefficient

Other trials utilising the QOL-AD scale have applied an intraclass correlation coefficient (ICC) of 0.02 based on pilot work.[63] As this was a different intervention and the difference between groups/clusters was the important aspect, we chose to apply a more conservative ICC of 0.05.

Sample size

The sample size was calculated based on detecting an effect size of 0.5 in the QOL-AD scale[57] using a two-sided *t*-test. To achieve 80% power with a significance level of 0.05, and an ICC of 0.05, a sample size of 10 clusters with 11 individuals per group was required. Based on prior research, a retention rate of 77%[64] was accounted for, which required a sample size of 10 clusters with 14 individuals per group. This resulted in a total sample of 280 participants.

Family carer well-being was explored via the WEMWBS.[58] The study had aimed to recruit a family caregiver for each participant but it was acknowledged that, in reality, this would not be possible. The sample size for this group was therefore dictated by the number of participants who had a family carer willing to take part in the trial. Vignette-based staff interviews were developed to explore the decision-making strategies employed. The aim was to recruit 50% of staff at each site. Similarly, as the care plan audit was designed specifically for this trial, a more pragmatic approach to sample size was taken. A sample was taken of 50% of all care plans at a particular site.

Recruitment procedure

Initial expressions of interest to be involved in the study were invited from local NHS trusts and care homes via existing networks and contacts. A decision was made to recruit initially within the north-west of England owing to logistical and financial constraints.

The research team also worked closely with the National Institute for Health Research (NIHR) ENRICH (Enabling Research in Care Homes) programme to identify care homes that identified themselves as willing to participate in research and to support care homes in being involved in the study. Initially all care homes in the north-west area that had been identified as research ready were approached and invited to take part in the study.

Characteristics of sites

The sites recruited varied in terms of their size, current levels of occupation and proportion of residents living with dementia. *Table 4* outlines these characteristics at both baseline and follow-up. It is evident from these figures that even if a care home was not branded as exclusively for people living with dementia, a high proportion of residents were living with this condition.

Informed consent

Obtaining informed consent is always an ethical dilemma when working in dementia care, and particularly when working with people in the later stages of dementia. The very fact that people are living in care homes or on a dementia ward means that they are likely to be in the later stages. The team acknowledged that people in the later stages, and particularly those without carers, are vulnerable to potential abuses of rights, and, therefore, it was important that they were included in the study. Every attempt was made to obtain informed consent from every potential participant, in line with the Mental Capacity Act.[24] Experienced clinical staff assessed the capacity of each potential participant, in line with best practice in research governance and the recommendations of the Mental Capacity Act,[24] and individuals gave (or withheld) consent if they were able to do this themselves. If a person was not able to give informed consent, they were not asked to complete the self-report measures. Although the QOL-AD scale[57] was

TABLE 4 Characteristics of participating sites at baseline and follow-up

		Number of		
Site	**Time point**	**Beds**	**Service users**	**Service users with dementia**
Redholme Memory Care	Baseline	55	48	48
	Follow-up	55	50	50
Irwell Ward	Baseline	17	13	12
	Follow-up	17	12	11
Dale Park	Baseline	44	42	41
	Follow-up	44	42	41
Acacia Court	Baseline	26	23	23
	Follow-up	26	24	24
Abbotsbury	Baseline	20	18	13
	Follow-up	20	18	15
Avalon	Baseline	20	18	18
	Follow-up	20	19	18
Tudor Bank	Baseline	46	37	16
	Follow-up	46	40	20
Greenacres	Baseline	41	39	13
	Follow-up	41	32	8
Meadowbank Ward	Baseline	13	12	12
	Follow-up	13	13	13
Cherry Ward	Baseline	11	11	11
	Follow-up	11	11	11
Hollins Park	Baseline	18	11	11
	Follow-up	18	14	13
Leigh Ward	Baseline	23	19	16
	Follow-up	23	19	11
Larkhill Hall	Baseline	66	60	44
	Follow-up	66	66	46
Cressington Court	Baseline	56	44	32
	Follow-up	56	40	31
Whiston & Halton Wards	Baseline	20	18	18
	Follow-up	20	18	13
Macclesfield	Baseline	15	11	11
	Follow-up	15	11	11
Finch Manor	Baseline	89	72	55
	Follow-up	89	71	55
Thomas Leigh	Baseline	20	18	18
	Follow-up	19	18	18
St Luke's	Baseline	56	54	54
	Follow-up	56	50	50
The Harbour	Baseline	36	28	28
	Follow-up	36	29	28

chosen specifically because it is claimed to be suitable for people in the later stages of dementia, it was felt reasonable to assume that if a person was unable to give informed consent, then completion of the measure would be too cognitively complex for them. There was no reason for people without a family caregiver to be excluded from the study if they were able to give informed consent to participate.

When possible, when a person was unable to give consent, and therefore unable to complete the self-report measures, someone (either a family carer or a staff member) was invited to complete a proxy QOL-AD scale.

If a person was unable to give informed consent, and so they were not included in the self-report element of the study, they could still be included in DCM in cases when a nominated consultee could be identified. When it was not possible to identify a nominated consultee, or if the consultee advised against including the individual in the study, the person was not included in any aspect of the research. Informed consent was sought at both baseline and follow-up. *Figure 2* presents a flow chart outlining these issues.

Ethics arrangements

Both research assistants had regular contact with other members of the research team and were encouraged to share any concerns that they encountered during data collection. In addition, a TSC and a Data Monitoring and Ethics Committee (DMEC) were established, and these met regularly. Any serious concerns and issues that may have reached the threshold of a serious adverse event were taken to the TSC and/or

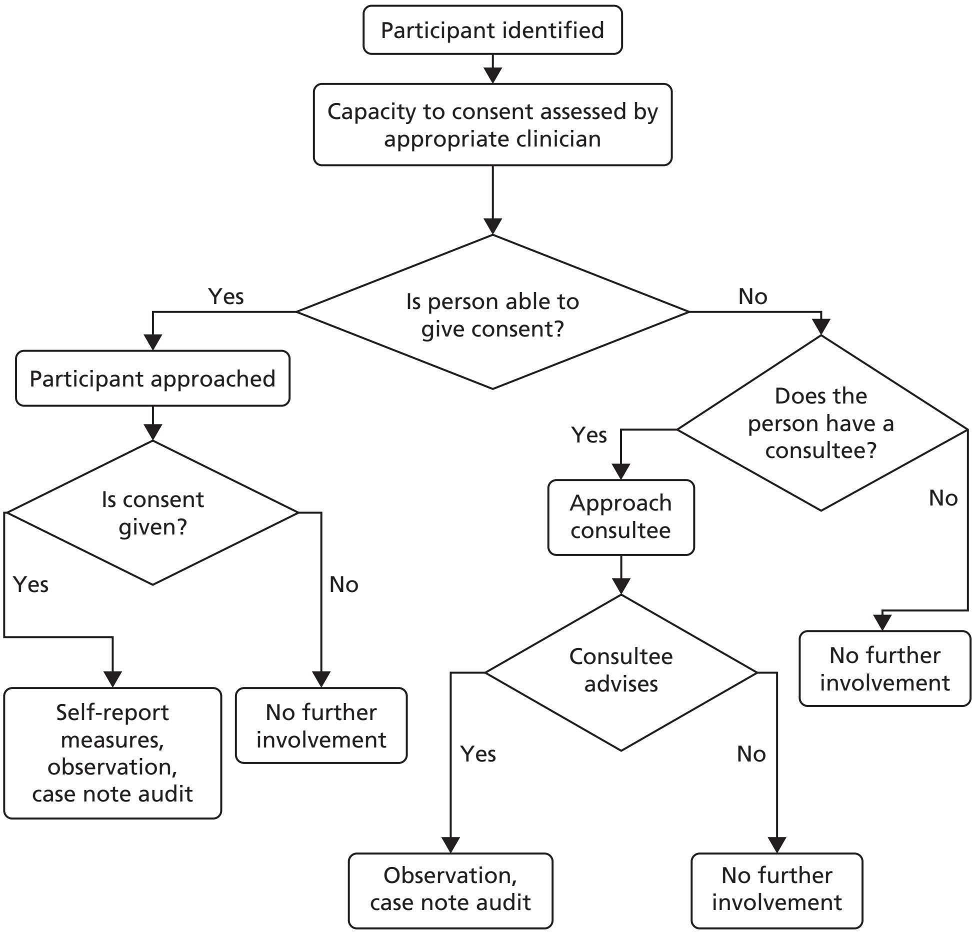


FIGURE 2 Flow chart to illustrate the process of consent and participation.

the DMEC, as appropriate, and discussed thoroughly. Minutes of these meeting were kept and shared with NIHR. No reportable serious adverse events were identified during the study. Issues that were discussed with the committees as potential difficulties included changes to the protocol (which are outlined later in this report) and concerns about quality of care.

Randomisation

The randomisation of clusters was achieved by secure web access to the remote randomisation system at North Wales Organisation for Randomised Trials in Health (NWORTH) (https://nworth.bangor.ac.uk/randomisation/), Bangor University, using a dynamic adaptive randomisation algorithm.[65] The randomisation was performed by dynamic allocation to protect against subversion while ensuring that the trial maintained good balance to the allocation ratio of 1 : 1 across the trial. The complete list randomisation system was used and, therefore, there was an exact allocation of the sites to groups. No stratification variables were used for randomisation.

It is recognised that randomisation would usually take place after baseline measures were completed to avoid any bias generated by participants knowing which group they were in. In this study, however, it was not possible to do this. Site staff needed to know in advance when their training would take place so that practical arrangements could be made for staff to attend the training (e.g. ensuring that the site had adequate staff cover). Similarly, if baseline measures were completed too far in advance of the training, then there was a risk that factors other than the intervention would influence any changes identified. For this reason, sites were randomised before the baseline measures were collected. To minimise the effects of allocation to group before baseline measures were taken, the information given about the exact nature of the training provided, particularly its focus on human rights, was revealed only to those staff who needed to know it for planning (e.g. ward managers).

Allocation concealment

A web-based system was used to cluster randomise each recruited site. A complete-list randomisation was used, meaning that an even number of sites were entered into the system and allocated, at random, half to the usual-care group and half to the training group. The result was not seen until the allocation process was complete, and it was seen only by those who had access to the system. It was also possible to provide a blinded allocation report for the people who needed to be blinded to group allocations; groups were named group 1 and group 2 rather than control and intervention.

Implementation

Following recruitment, the web-based system generated the random allocation sequence. Sites were enrolled by the trial team, specifically the trial manager, Sarah Butchard, after which the web-based system completed the assignment of sites to the control or intervention group. If a service user was willing and able to consent to participate in the study, then they were included. Consent was obtained directly from the service user if possible; if this was not possible, then a proxy, usually a member of staff, was asked to provide consent on the service user's behalf.

Blinding

Service users, research assistants who were collecting the data and the trial statistician were blinded. Service users received daily care and did not know whether or not staff had received the training. Staff members were obviously unblinded at follow-up as they knew whether or not the unit had received the training. Research assistants attended the sites to complete assessments and did not know to which group a site had been assigned. The trial statistician was able to see the data labelled as group 1 and group 2. The unblinding of the trial results occurred at a results meeting attended by members of the independent monitoring committees.

Data collection and management

The primary and secondary outcome measures were completed at baseline and then at 4 months after baseline. *Figure 3* outlines the data collected at each time point. All measures were completed by two research assistants, who spent a week at each unit completing measures at each time point.

Dementia care mapping was completed first at each site to reduce the chances of the research assistants becoming unblinded at follow-up, as it was less likely that they would come across the assessment tools during this process. *Table 5* shows the breakdown of tasks at each site.

All of the research data were collected on paper at the sites, and these were considered to be the source data. The data were then stored at the University of Liverpool for entry into the electronic system. These source data relevant to the participants' outcome measures were managed through MACRO, an electronic data-capture system provided by NWORTH. MACRO 4.2 (Elsevier, London, UK; www.elsevier.com/solutions/macro) was used from 18 April 2015 to 15 December 2015, and MACRO 4.4 was used from 15 December 2015 onwards. MACRO meets regulatory compliance for the designing of electronic case report forms, data entry, data monitoring and data exporting, as well as good practice guidelines. MACRO has built-in systems for an audit trail and quality assurance.

A step-by-step cleaning process was implemented for the trial data, which was outlined in the data management plan written for the study. A random sample of 5% of the case report forms at each time point was selected for source data verification. This essentially involved cross-checking the data held in MACRO with the paper source data. If the percentage error rate for each site was > 2%, further checking was initiated based on this finding. A further 10% of randomly chosen case report forms could be checked, or if a systematic error was found with a particular item, then detailed checking of that item would be completed.

Further screening of the data was completed at all time points to identify outliers of potential errors.

Development of the intervention

The intervention for this trial was the introduction of a novel human rights based assessment tool, 'Getting It Right',[56] into dementia wards and care homes. This tool was rooted in the principles of person-centred care and was specifically developed by Mersey Care NHS Foundation Trust to improve the person-centred nature of care plans and to ensure that the human rights of the service user were considered. Following human rights training by the British Institute of Human Rights, the assessment tool[56] was developed by a project team at Mersey Care NHS Foundation Trust, which consisted of service user representatives, carers, researchers and staff from disciplines including nursing, clinical psychology, occupational therapy and psychiatry.

The tool was designed to be completed by a staff member and the service user collaboratively and, thus, encouraged both parties to consider the human rights that should be recognised during the service user's stay in care. More specifically, the tool maps these human rights onto a wide range of areas of care, including preferences of food and drink, preferred name and access of visitors. The function of the tool was to generate a person-centred care plan that would maximise the person's quality of life while they were on the unit and help to ensure that their human rights were acknowledged and upheld. The staff member was supported by a complementary manual and the end product was a care plan that could be kept by the service user as well as serving as the basis for the subsequent care that the person would receive. The tool was designed to be user friendly, with bold print, pictorial representations and clear, colour-coded sections.

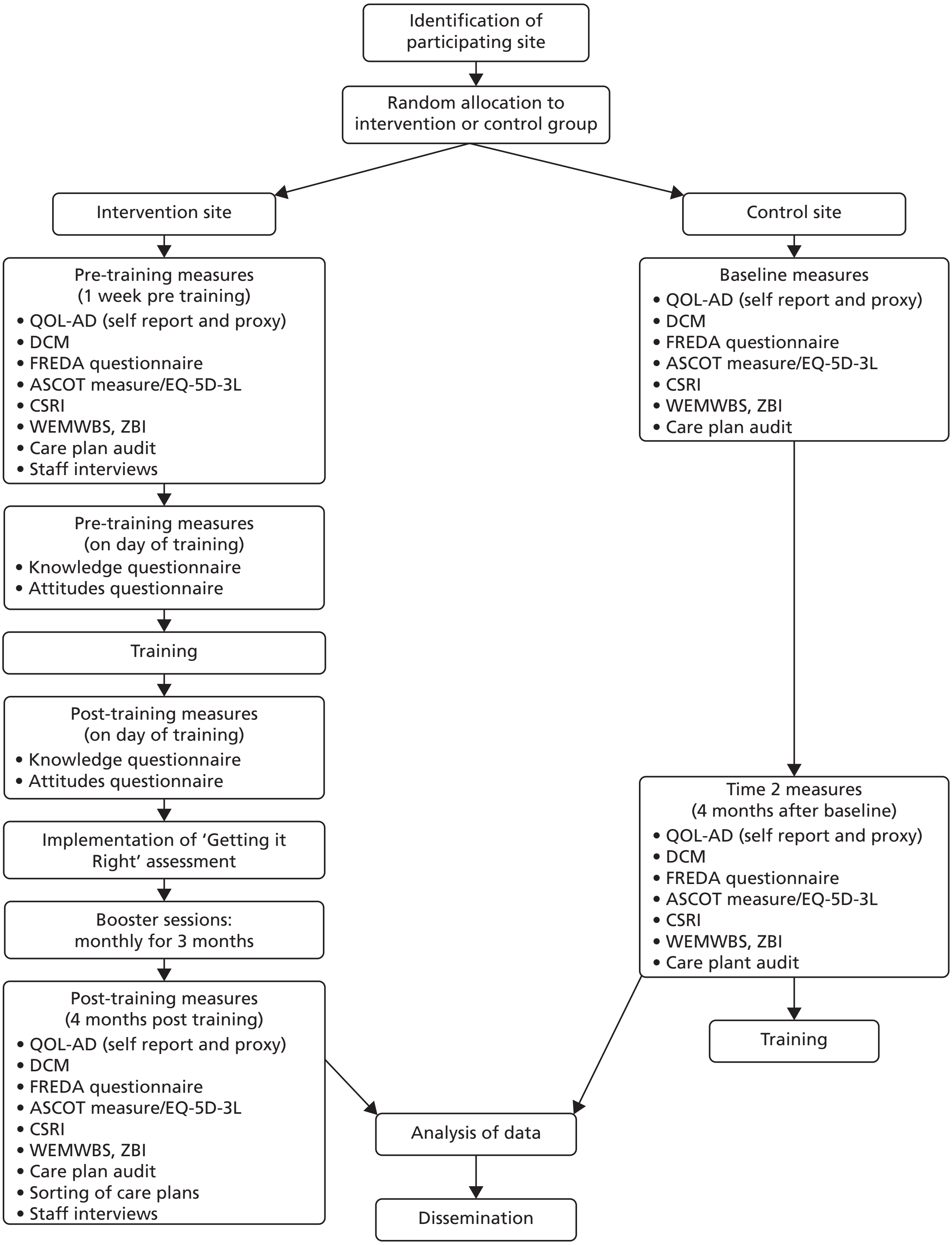


FIGURE 3 Flow chart to illustrate the process of data collection. ASCOT, Adult Social Care Outcomes Toolkit; EQ-5D, EuroQol-5 Dimensions.

TABLE 5 Breakdown of tasks at each site

Day	Planned activities
1	DCM
2	Care plan audits
3	Self-report/proxy measures Staff interviews
4	Self-report/proxy measures Staff interviews
5	Self-report/proxy measures Staff interviews

To aid the implementation of the assessment tool, a staff training package was also developed. This took the form of one-day training, split between providing a general introduction to human rights and their relation to health care, and providing advice and instructions on how to correctly administer the tool. The training package utilised ‘dilemma-based learning’[37] and included a specially designed and commissioned DVD (digital versatile disc) containing dramatised care-based scenarios that encourage interactive learning of human rights based approaches when making clinical decisions. During the training, participants were prompted to engage in discussions about how they would respond to clinical situations using a human rights-focused approach. As such, the training was framed as adopting the values and awareness model of human rights training.[38]

The training was designed to be delivered to all grades and professions of care unit staff. This was the model used in the pilot phase when staff attending training encompassed a range of both (e.g. ward manager, registered nurses, support workers, domestic staff, occupational therapists and physiotherapists). The key issue was that training was provided to the team as a whole, in line with evidence that this increases discussion of the issues and allows staff to support each other in embedding the training into practice.

Following the initial training, each site was also offered three monthly booster sessions to help build their confidence in embedding the approach.

The ‘Getting It Right’ tool[56] and associated training package were piloted within Mersey Care NHS Foundation Trust, and underwent an evaluation using a number of outcome measures: a specifically designed audit tool, vignette-based semistructured interviews, and human rights knowledge and attitude questionnaires.

Outcome measures

Primary outcome measure

Service user well-being

The primary outcome measure used in the research was the QOL-AD[57] scale to assess the subjective well-being of the person with dementia. The European consensus on outcome measures for psychosocial intervention research in dementia care[66] states that the QOL-AD scale is the measure of choice when looking at quality of life, as it is brief, has demonstrated sensitivity to psychosocial intervention, correlates with health-utility measures and can be used by people with Mini Mental State Examination (MMSE) scores of as low as 3.

The QOL-AD proxy version was also used with both staff and family caregivers to elicit the views of those supporting the person living with dementia.

Secondary outcome measures

Family carer well-being

It is recognised that caring for someone with dementia can be stressful.[67] Family carer well-being was therefore also assessed to explore whether or not it was improved by the application of a human rights based approach on a unit. This was assessed using the WEMWBS,[58] and the ZBI[59] explored carers' perceptions of caring responsibilities.

Standard of care

A care plan audit was conducted at each site to provide a measure of the documented plan of care for each service user. An audit tool was specifically designed for the study, which was based on the gold standards of person-centred care in dementia care settings as outlined in the enriched care planning for people with dementia model[53] and with a human rights based focus. The aim was to establish whether or not human rights based training is an explanatory variable for any changes in care and well-being observed over and above a standard training package, as the tool allowed the presence of human rights based language and concepts in care plans to be directly assessed.

The standard of care provided at the site and its link to well-being was assessed via DCM,[68] an observational assessment yielding quantitative measures of well-being and ill-being for an individual with dementia.

Staff decision-making

Decision-making was explored through vignette-based interviews at the participating sites with staff of various grades. It was felt that this qualitative element of the study served several purposes. It provided an outcome in its own right, in that it explored how staff make decisions in difficult complex situations. The interviews also aimed to provide more information on the mediators of any effect observed, as questions were asked directly about decision-making and what assists with this. If the intervention was successful, then more human rights based language and a clearer framework for decision-making would be seen in the post-intervention interviews.

Knowledge of human rights

To assess knowledge acquisition during the training, pre- and post-training measures of human rights knowledge were collected via a human rights knowledge questionnaire, as recommended by *A Guide to Evaluating Human Rights Based Interventions in Health and Social Care*.[40] These data were collected on the day of the training. A human rights attitudes questionnaire was also used to look at changes in attitudes both pre and post training. Again, data from this were collected on the day of training.

Health economics

The trial also conducted a cost–consequences analysis, in which the consequences included patient-reported health-related quality of life [EuroQol-5 Dimensions, three-level version (EQ-5D-3L)], patient-reported well-being (QOL-AD[57]), family member well-being (WEMWBS[58] and ZBI[59]) and overall quality of care [Adult Social Care Outcomes Toolkit (ASCOT[69]) and CSRI].

Development of outcome measures specific to the study

Care plan audit tool

A care plan audit tool was developed specifically for the study as there was no existing measure available that would capture the information required, namely the person-centred nature of the care plan and specific references to human rights language. The audit tool was based on the gold standards of person-centred dementia care as laid out in *Enriched Care Planning for People with Dementia: A Good Practice Guide to Delivering Person-centred Care*,[53] a document derived from Kitwood's principles of person-centred care.[7]

The audit tool employed a 'tick-box' format, which meant that data could be expressed as a percentage as well as a raw number for both baseline and follow-up, and then compared formally. There is, however, also the capability to capture more qualitative data, which would allow for reflection on the person-centred nature of care plans and the inclusion of human rights based language in these. If the intervention was successful, it would be expected that care plans post training would be more person centred and include more human rights based language.

Vignette-based interviews

Interview schedules were developed by combining the areas of enhanced care planning from Kitwood's model of dementia care[7] and the human rights considered most relevant to health care. Ten vignettes were constructed that, between them, covered all relevant areas using examples from clinical practice. Using hypothetical examples such as these avoided asking directly about care provision, which may not lead to responses that reflect true practice owing to demand characteristics and staff concerns about the perceived potential repercussions of their responses.

Knowledge and attitudes questionnaires

The human rights knowledge and attitudes questionnaires were adapted from the original learning disabilities questionnaires outlined in *A Guide to Evaluating Human Rights Based Interventions in Health and Social Care*.[40]

Issues of specificity

It is important that the outcome measures utilised allowed exploration of the specificity of the intervention in improving care and well-being over and above the application of general training. This has been addressed in a number of ways.

- The care plan audit measured the documented standard of care that a person should be receiving but also tapped into increases in human rights based language and concepts that would suggest that the human rights based nature of the intervention had an effect over and above simply providing generic training.
- The completion of human rights knowledge and attitude questionnaires measured changes in these areas pre and post training but did not look at the impact that this had on staff in their everyday working lives and how it affected service user well-being.
- Staff interviews were conducted to explore whether or not the introduction of a human rights based approach leads to differences in their decision-making processes when considering care issues. Again, this would be evaluated through the identification of key phrases and concepts in the transcripts that would specifically indicate that a human rights based approach had a direct influence on daily decision-making.
- The FREDA-based questionnaire enabled the team to explore whether or not service users felt that their human rights were respected and upheld more after the intervention.

Taken together, these elements allowed an evaluation of the proposal that the human rights based approach outlined had benefits that would not be seen by generic training.

Development of the FREDA assessment tool

Although there is recognition that violations of human rights can occur in health-care settings, little has been done to attempt to quantify the extent to which this occurs. To this end, work was undertaken to develop and begin validating a questionnaire measure based on the FREDA principles in order to assess how well individuals subjectively experience their human rights as being upheld.

The FREDA principles have been used elsewhere in health care to aid individuals' understanding of their human rights.[70] However, the validity of these constructs has not been empirically tested. Therefore, the initial stage of this tool development was to consult with service users and their carers.

Items for the FREDA questionnaire were first generated from focus groups with people living with dementia and their carers. Participants came to one of two focus groups to discuss the care that they had received in relation to their human rights. The main aim of the focus groups was to investigate whether or not the FREDA principles adequately covered areas relevant to dementia care, along with eliciting examples of when such principles were valued or disregarded. All participants consented to the data generated by the focus groups being used in relation to the development of the human rights agenda.

People in the later stages of dementia are often excluded from consultation because of the increased communication and comprehension difficulties that can arise as the condition progresses. Given that this measure would be exploring the potential violations of an individual's rights, it felt important that this group of people who may be vulnerable to having their human rights undermined were included in the consultation. A method developed by Kate Allen[71] was utilised, which involves showing the person living with dementia a picture of an unknown person and asking them to reflect on how that person would feel in a particular situation and what advice they would give them. It is suggested that this elicits more information than asking direct questions about the treatment that they have received. This method was used on a dementia inpatient ward within Mersey Care NHS Foundation Trust and the information elicited was incorporated into the data collected from the focus groups.

Following the focus groups and ward interviews, the information was themed and statements were developed that reflected these themes. Grouping these statements together revealed four overarching themes: identity, dignity, empowerment and autonomy. The developing questionnaire was, therefore, named the IDEA questionnaire.

This resulting questionnaire was piloted with a group of people living with dementia in the community. As a result of this piloting phase, some changes were made to the structure and phrasing of items on the measure (e.g. removing any double negatives from the questions).

Changes to protocol

Despite the suggestion that the QOL-AD scale is suitable for people whose MMSE scores would imply that they have severe symptoms of dementia, in practice it became evident very quickly that there were limited numbers of people living with dementia on the inpatient wards and care homes who were able to complete the self-report version of the measure. Although every effort was made to identify and recruit all service users at each site who could complete this, it was also necessary to utilise proxy reports for those people who could not complete the questionnaire themselves. In these cases, a family caregiver was first sought, and, if none was identified, then a member of staff was asked to complete the proxy version. In total, 357 proxy measures were completed and, of these, 345 were completed by staff members.

Although the initial aim was to recruit 50% of staff from each site for an interview, it soon became apparent that this would not be practical. At each site a percentage of staff worked only night shifts and there were also many staff who were not available during the data collection week owing to annual leave, rota patterns, and so on. Therefore, a more pragmatic approach was taken and eight staff members per site were recruited to take part in the decision-making interviews.

Although it had been envisaged initially that booster sessions would last 2 hours, this was not practical when visiting the sites. In general, managers were not happy to release staff for this length of additional time and chose to speak directly to the team members themselves rather than involving other members of staff. Many of the booster sessions were refused.

It was proposed that the Alzheimer's Disease Assessment Scale – Cognitive subscale (ADAS-Cog) be used to compare the cognitive abilities of people living in care homes with those of people on NHS wards. In practice, the majority of people living with dementia were unable to complete the assessment and, in addition, a large number of people refused to complete it. Given the small numbers collected, it was not possible to make a comparison between the groups. For this reason, no attempts were made to complete the scale at follow-up.

Fewer carers than expected were recruited to the study. The research assistants were surprised that many of the care home residents did not have visitors, and often when visitors were present they did not want to complete questionnaires as they felt that this would interrupt their time with the resident. As a result, the numbers of questionnaires completed were not large enough to allow meaningful comparisons to be made.

Statistical analysis

Missing data

There are two types of missing data possible in this data set: missing items within questionnaires at a time point and missing measures at a time point.

In the case of items missing within a questionnaire, the following approach was taken. If a missing value rule existed for a questionnaire, then this was utilised. Over and above this, if $\leq 25\%$ of the items in a questionnaire were missing, then these were replaced with a pro-rated individual item score.

It was expected that there would be participants missing at follow-up who were present at baseline and vice versa and so the analysis model was influenced by this. The data were assessed for differences between those present at both baseline and follow-up and those present only at baseline for possible predictors to be included in the sensitivity models.

Baseline characteristics

Participant demographics, including age and gender, were reported, and split by allocated group, for baseline and follow-up. The type of dementia patients were living with was also included, when appropriate. There was no statistical comparison of the data for the two groups.

Interim analyses

No interim analyses were planned or scheduled to be completed. During the trial, no additional analyses were identified or requested by the DMEC.

Primary effectiveness analyses

The original model of analysis was planned to be a multilevel analysis of covariance model. Owing to the very nature of the wards and care homes, it was understandable that, for a number of reasons, participants present at baseline might not be present at follow-up. Therefore, a linear mixed model was used to assess the effect of time (baseline or follow-up) and group (control or intervention) and interaction of time and allocated group. The model also included site as a random effect. The main effect of interest was the group effect.

As it became evident that the ability to collect self-report data on the primary outcome measure was limited, proxy data were collected in the absence of self-report data. An additional term (self-report vs. proxy) was added to the model to assess the importance of this difference. If it was found that this term was significant, then separate analyses of self-report and proxy data were completed. This understandably affects the number of data available for the analysis and would have implications for the power of the study. The alternative was to include a self-report versus proxy and condition (group) interaction. This assesses whether or not there is a consistent difference between self-report and proxy data in both groups. The former model of analysis was chosen to allow simpler, more intuitive understanding of the data. Either way, the power of the models that could be applied would have been affected by the implications of using a mixture of proxy and self-report data.

Secondary effectiveness analyses

A linear mixed model was applied for all secondary outcome measures when appropriate. For the knowledge and attitudes questionnaire, data were collected pre and post training for the intervention group and only at baseline for the control group. This precluded the use of the linear mixed model to establish a group effect, and therefore a paired sample *t*-test was used to establish whether or not there was a difference in score before and after training.

Additional analyses

As indicated the significance of covariates, age, gender, DCM score, dementia type and whether or not the person had a carer were investigated by adding these to the linear mixed model.

It was also noted that one site had a different follow-up time from the other sites, with only 11 weeks in follow-up rather than the established 16 weeks. This nuance was investigated by allowing the time variable to vary for this site.

Economic analyses

Based on the Medical Research Council's guidelines for the evaluation of complex interventions,[72] our standard operating procedure for economic evaluation alongside pragmatic randomised controlled trials (RCTs) and experience in the conduct of economic evaluation alongside trials of psychosocial interventions in dementia care,[63,73] we, from a public sector, multiagency perspective:[74–79]

- fully costed the human rights staff training programme, distinguishing between set-up/training costs and running costs, with the former amortised over 3 years
- collected service use data using an adapted Client Service Receipt Inventory, which recorded participants' frequency of contacts with hospital services and selected community-based services at baseline and follow-up; participants' medication usage was also recorded and service use was costed using national unit costs for the price year 2014–15[80,81]
- conducted a cost–consequences analysis in which the consequences included patient-reported well-being (QOL-AD[57]), family member well-being (WEMWBS[58] and ZBI[59]) and overall quality of care (ASCOT).

The EQ-5D-3L was included for participants with mild to moderate dementia to allow comparison with other published studies, and with previous trials, but a cost–consequences approach rather than cost–utility analysis was undertaken because of the range of relevant outcomes spanning the person with dementia, their family members, hospital and care home staff and objective measures of care quality.

Dementia care mapping

Dementia care mapping is an observational tool. A trained observer (mapper) records the behaviours of several participants for a specified amount of time (in this case 6 hours) to gain an insight into participants' day-to-day experience. Owing to ethical reasons, observations can take place only in communal areas. After a 5-minute period, the mapper records a Behaviour Category Code that indicates what the individual was doing. Alongside this, a mood and engagement (ME) value is recorded, indicating how engaged the individual was and if their mood was positive or negative. *Table 6* summarises the definitions of each score for ME.

Dementia care mapping is an established approach that looks at person-centred care in practice. This measure was completed for all sites at both baseline and follow-up. The study focused on one aspect of DCM that records the ME levels of up to eight participants living with dementia within a 6-hour time frame. The ME score for each unit at both baseline and follow-up were recorded and compared to look for changes in the quality of care provided.

TABLE 6 Summary of ME values[82]

Mood	ME value	Engagement
Very happy, cheerful. Very high positive mood	+5	Very absorbed, deeply engrossed/engaged
Content, happy, relaxed. Considerable positive mood	+3	Concentrating but distractible. Considerable engagement
Neutral. Absence of overt signs of positive or negative mood	+1	Alert and focused on surroundings. Brief or intermittent engagement
Small signs of negative mood	–1	Withdrawn and out of contact
Considerable signs of negative mood	–3	
Very distressed. Very great signs of negative mood	–5	

Reproduced with permission of the School of Dementia Studies, University of Bradford.[82]

Qualitative analysis

There were two sets of data in the study that were analysed qualitatively. These were the staff decision-making interviews and the post-study interviews with intervention sites. Both sets of data were analysed using thematic analysis as outlined by Braun and Clarke.[83] Thematic analysis is a method for identifying, analysing and reporting patterns (themes) within data. At its most basic, it organises and describes the data set in rich detail. In reality, however, it frequently goes further and interprets various aspects of the research topic.[84] *Table 7* outlines the stages of thematic analysis proposed by Braun and Clarke.[83]

Staff interviews

Data from the staff decision-making interviews were initially analysed as one data set using thematic analysis, as outlined by Braun and Clarke.[83] An inductive, or 'bottom-up', approach[85] to data analysis was taken. An inductive approach assumes that the themes are derived directly from the data[86] as opposed to imposing the data onto a pre-existing model.

From this analysis, themes were identified related to staff decision-making strategies. Themes were not combined as fully as they would usually be in thematic analysis, as it was felt important to identify specific, rather than general, decision-making strategies in this context. The interviews were then reanalysed to identify the frequency with which these strategies were discussed in each group (i.e. intervention baseline, intervention follow-up, control baseline and control follow-up).

TABLE 7 Phases of thematic analysis

Phase	Description of the process
1. Familiarising yourself with your data	Transcribing data (if necessary), reading and re-reading the data, noting down initial ideas
2. Generating initial codes	Coding interesting features of the data in a systematic fashion across the entire data set, collating data relevant to each code
3. Searching for themes	Collating codes into potential themes, gathering all data relevant to each potential theme
4. Reviewing themes	Checking if the themes work in relation to the coded extracts (level 1) and the entire data set (level 2), generating a thematic 'map' of the analysis
5. Defining and naming themes	Ongoing analysis to refine the specifics of each theme, and the overall story the analysis tells, generating clear definitions and names for each theme
6. Producing the report	The final opportunity for analysis. Selection of vivid, compelling extract examples, final analysis of selected extracts, relating back of the analysis to the research question and literature, producing a scholarly report of the analysis

Post-training interviews

Semistructured interviews were conducted with staff at intervention sites on an opportunistic basis. This included managerial staff, members of staff who attended training and those who did not attend training. The interviews were completed by a research assistant and a member of the PPI reference group. Interviews were recorded, transcribed and inductively, then subsequently deductively, analysed using thematic analysis. Each site was individually analysed to identify the main themes from each site. The main theme of management style was then deductively analysed using Bass and Avolio[87] characteristics of active/transformational and passive/transactional management styles to identify descriptions of these characteristics within each site and how these affect descriptions of the relationships that service users and family members have with staff. Some sites were unable to accommodate the interviews owing to changes in management and lack of staffing.

Chapter 3 Trial results

Flow of participants in the trial

Sites

In total, 50 sites were contacted and offered the opportunity to be involved in the study (care homes, $n = 34$; NHS wards, $n = 16$). Twenty-eight sites declined to participate, and so 22 were randomised to either the intervention or the control arm. Between randomisation and data collection, two sites opted out of the study as they no longer wanted to be involved. These sites had previously been randomised and they withdrew because of a change of management. Of these sites, one had been randomised to the control arm and one had been randomised to the intervention arm. During data collection, two of the intervention sites did not complete training; therefore, they were classed as intent to treat (their data were still included in the intervention group's analysis). The reason given for not completing the training at both sites was that there was not enough time or resources to release staff to attend the training. One of these sites accepted a 'booster' session and wanted to use the 'Getting It Right' assessment tool.[56] The recruitment of sites to the study is outlined in *Figure 4*.

Overall recruitment

In total, the study recruited 439 people living with dementia, with 213 in the intervention arm and 226 in the control arm. These people may have completed self-report measures, had proxy measures completed, been observed in DCM or been involved in the care plan audit. They may have completed one, or more than one, element of the study. *Table 8* summarises the number of aspects of the study that participants were involved in.

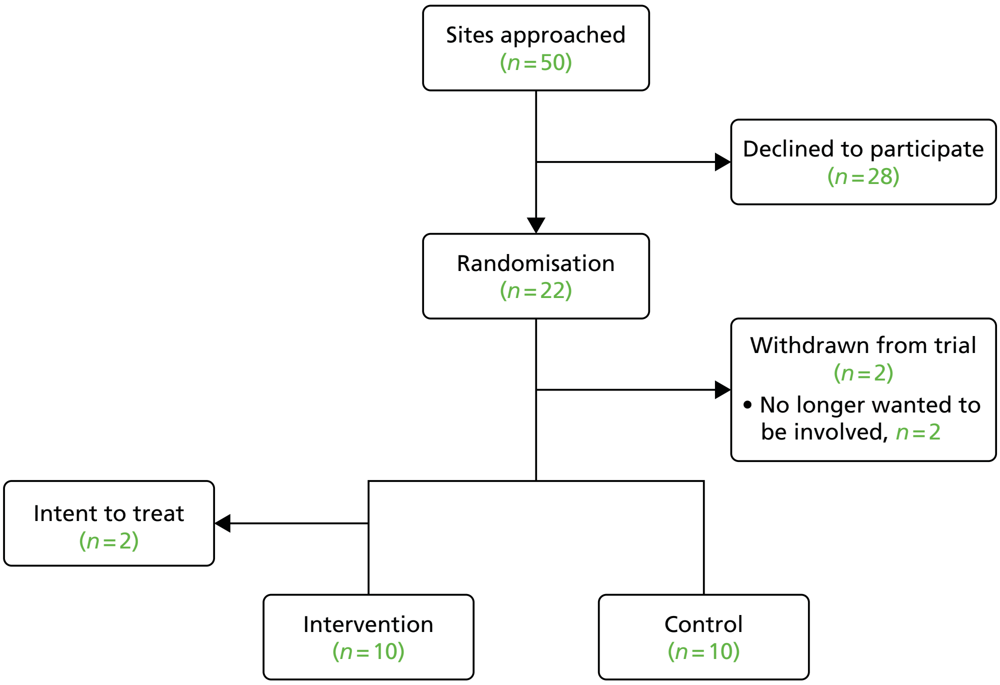


FIGURE 4 Number of sites approached to take part in and recruited to the study.

TABLE 8 Number of aspects in which service users recruited to the study were involved (self-report/proxy measures, DCM and care plan audits)

Aspects (*n*)					
Baseline			Follow-up		
1	2	3	1	2	3
93	124	115	80	122	120

New participants were able to be recruited at follow-up. Sites rather than participants were randomised to receive control or intervention, and participants did not receive control or intervention. This was an expected feature of recruitment, as it is was possible that participants would not be at the same site from baseline to follow-up. Recruitment from each site, for baseline and follow-up, was based on the individuals present at the time of the visits. In addition, 245 staff members were recruited to the study.

Staff completing the training

The aim was to recruit as many staff as possible from each intervention site to the training day. In practice, this was extremely difficult, and site managers reported this to be the case even when multiple training days were offered. *Table 9* summarises the number of staff trained at each intervention site and the number of booster sessions that each site accepted during the intervention (i.e. the 3 months following the training).

If the two sites that did not engage with the training are excluded, then an average of 8.88 staff per unit were trained, which equates to 28.7% of staff being trained. There was a large range in the proportion of staff trained at a particular site (11.6–52.4%).

It was initially envisaged that the booster sessions would take place every month and last 1–2 hours, and that staff who had either attended the training or who had not been able to attend the training but were completing the assessment tool could share their experiences, and that any difficulties or concerns could be addressed. This was to be similar to a consultation-style session and to be supportive in nature. In reality, only two sites accepted all three booster sessions offered. Booster sessions were most often rejected because of lack of time. They were also often not utilised in the way that was initially expected. In the majority of the sessions, the team member met with the manager of the unit alone, and the manager reflected on the assessment tool. This did not meet the aims of allowing the staff to explore difficulties that were arising and to cement the learning from the training session.

TABLE 9 Staff attending the training day and number of booster sessions accepted at each site

Site	Day staff at site (*n*)	Staff trained (*n*)	Proportion of staff trained (%)	Booster sessions (*n*)
A	38	8	21.1	3
B	51	22	43.1	2
C	23	6	26.1	2
D	20	6	30.0	2
E	23	6	26.1	3
F	21	11	52.4	2
G	37	7	18.9	2
H	43	5	11.6	1
I	19	0	0	1
J	51	0	0	0

Service users completing the primary outcome measure

One hundred and forty-nine service users were able to self-complete the primary outcome (QOL-AD[57]) and a further 256 proxies were recruited to complete it. *Figure 5* outlines the flow of participants completing the QOL-AD at each time point.

The most common reasons for not completing the follow-up visit after completing the baseline visit were death and being discharged from the care home or hospital ward. Differences in demographics and outcome results were tested for between the groups who died and those who did not die, and between the groups who were discharged and those who were not discharged.

The mean age of the participants who died (87.0 years, standard deviation (SD) 7.4 years] was significantly higher than the age of participants who did not die [81.4 years, SD 7.6 years; $t(320) = -2.867$; $p = 0.004$]. The QOL-AD score of participants who died (28.93, SD 5.35) was significantly lower than the QOL-AD score of the participants who did not die [32.85, SD 7.21; $t(242) = 2.002$; $p = 0.046$].

The mean age of the participants who were discharged (78.4 years, SD 7.7 years) was significantly lower than the age of those who were not discharged [82.5 years, SD 7.4 years; $t(320) = 3.840$; $p < 0.001$]. There was a significant difference in the proportion of men and women in the not-discharged and discharged groups [$\chi(1) = 9.219$; $p = 0.002$]. The reason for this is that the group who were not discharged had a higher proportion of women (63.0%) than men (37.0%), whereas the discharged group had a higher proportion of men (58.1%) than women (41.9%).

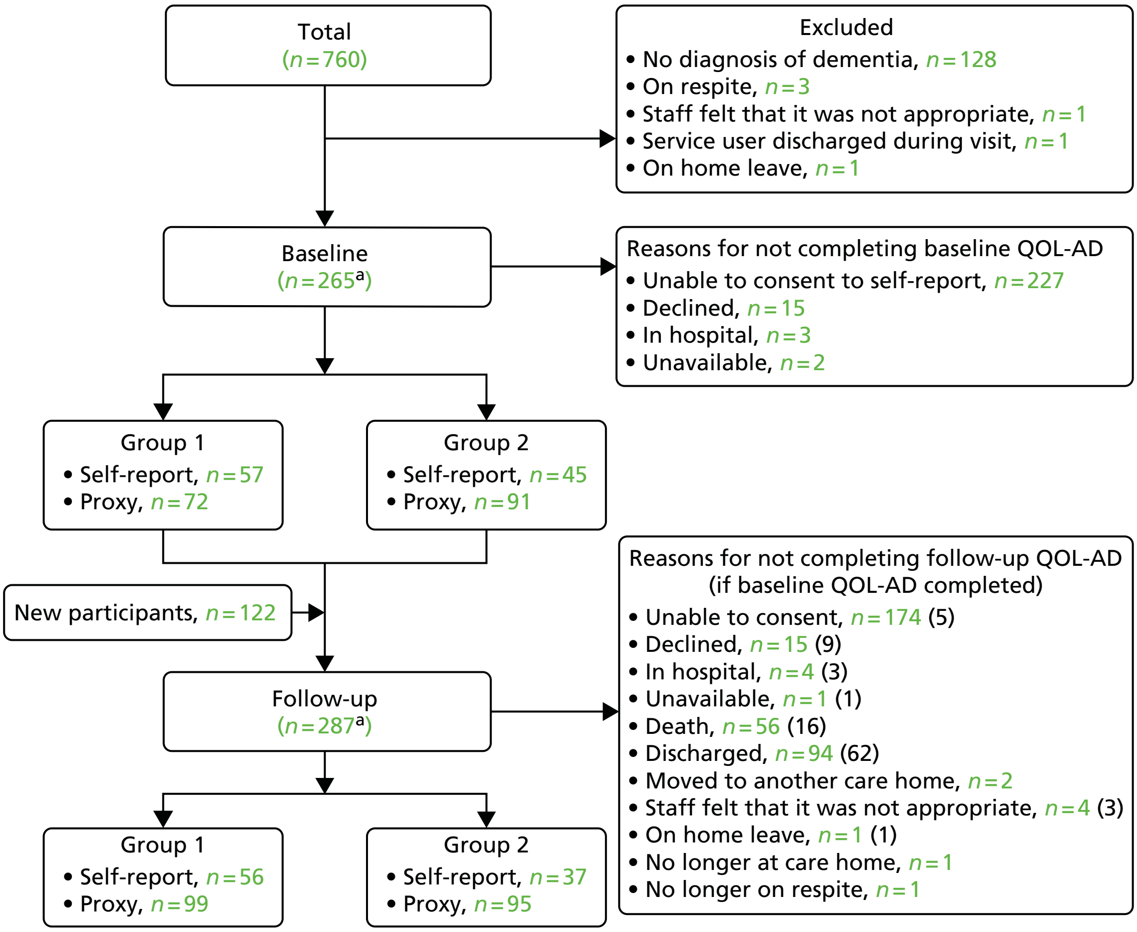


FIGURE 5 Time points and number of service users/proxies completing the QOL-AD. a, Some participants completed only the baseline QOL-AD, some participants completed only the follow-up QOL-AD and some completed both the baseline and follow-up QOL-AD.

Staff interviews

A total of 245 staff members were interviewed during the study: 101 members of staff completed an interview at baseline only, 88 members of staff completed an interview at follow-up only and 56 members of staff completed interviews at both time points. This yielded a total of 301 interviews. *Table 10* summarises the number of interviews completed by staff at both baseline and follow-up in the control and intervention groups.

Care plan audits

At each site, 50% of eligible service users were randomly selected to participate in the care plan audit aspect of the study. *Figure 6* outlines the number of service users involved in the care plan audits at each time point, while *Table 11* summarises the reasons that care plans were not selected for audit.

Dementia care mapping

At each site, eight service users were randomly selected to participate in DCM. *Figure 7* shows the number of potential participants and those involved at each time point.

Maintenance of 'blind' assessments

Although the intention was that the attending researchers would not be aware of a site's allocation while they were completing the assessments, in some cases this was unavoidable. Unblinding occurred three times at baseline and four times at follow-up, so in total seven sites were not blinded to the researchers by completion of the assessments. *Table 12* summarises the reasons why researchers became unblinded to group allocation and when this unblinding process took place.

TABLE 10 Number of interviews completed at each time point in control and intervention groups

	Time point (*n*)		
Group	**Baseline**	**Follow-up**	**Total (*n*)**
Control	77	70	147
Intervention	79	75	154
Total	156	145	301

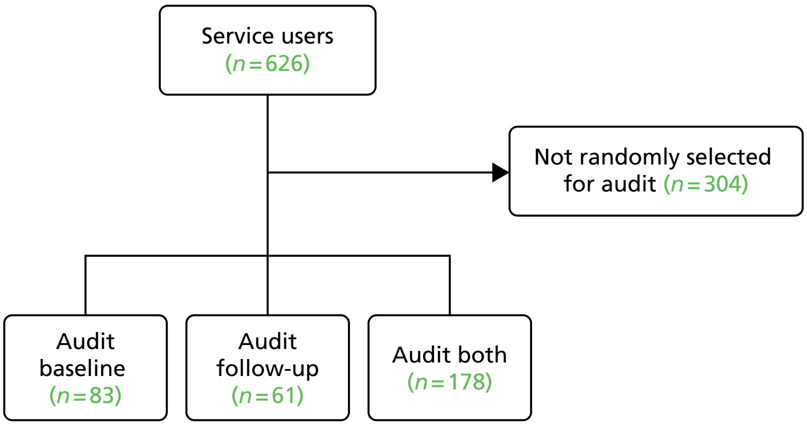


FIGURE 6 Time points and number of service users involved in care plan audits.

TABLE 11 Reasons why care plans were not audited

Reason	Total (*n*)
At baseline	
Not randomised for selection	242
New service user at follow-up	125
Declined	1
In hospital	1
Not available	1
At follow-up	
Not randomised for selection	236
Declined	12
In hospital	3
Not available	1
Service user died	48
Service user discharged	93
Not appropriate	4

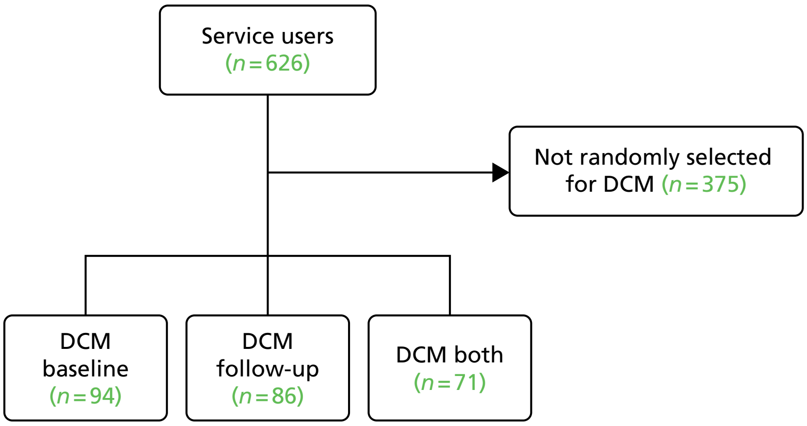


FIGURE 7 Time points and number of service users completing DCM.

TABLE 12 Reasons why researchers became unblinded

Reasons	Total (*n*)	Time point at baseline or follow-up	Intervention or control
Baseline			
Manager spoke about training	1	Day 5	Intervention
Human rights training was scheduled on staff rota	1	Day 5	Intervention
Informed by research team	1	Before collecting any data	Control
Follow-up			
Manager asked when they would receive training	1	Before collecting any data	Control
'Getting It Right' toolkit[56] was present in care plans	2	Day 1	Both intervention
Informed by staff during interviews	1	Day 5	Intervention

Characteristics of the samples at each time point

Tables 13 and *14* give the baseline and follow-up characteristics (age, gender and type of dementia), respectively, for each of the allocated groups.

Combining the diagnostic categories of 'Alzheimer's disease' and 'other' would yield figures (baseline, 57.8%; follow-up, 59.8%) that are more in keeping with national prevalence figures for Alzheimer's disease, which suggest that 62% of people living with dementia are living with Alzheimer's disease-type dementia.[1]

TABLE 13 Baseline characteristics

	Group, *n* (%)		
Characteristic	**Control**	**Intervention**	**Total, *N* (%)**
Age (years)			
Mean (SD)	81.2 (8.0)	82.2 (7.3)	81.7 (7.7)
Gender			
Female	93 (57.1)	103 (60.9)	196 (59.0)
Male	70 (42.9)	66 (39.1)	136 (41.0)
Type of dementia			
Alzheimer's disease	55 (33.7)	67 (39.6)	122 (36.7)
Vascular dementia	46 (28.2)	45 (26.6)	91 (27.4)
Dementia with Lewy bodies	7 (4.3)	2 (1.2)	9 (2.7)
Mixed	19 (11.7)	14 (8.3)	33 (9.9)
Frontotemporal dementia	2 (1.2)	0 (0.0)	2 (0.6)
Other	29 (17.8)	41 (24.3)	70 (21.1)
Missing	5 (3.1)	0 (0.0)	5 (1.5)

TABLE 14 Follow-up characteristics

	Group, *n* (%)		
Characteristic	**Control**	**Intervention**	**Total, *N* (%)**
Age (years)			
Mean (SD)	81.1 (8.0)	82.0 (7.6)	81.5 (7.8)
Gender			
Female	120 (53.8)	127 (59.6)	247 (56.7)
Male	103 (46.2)	86 (40.4)	189 (43.3)
Type of dementia			
Alzheimer's disease	77 (34.5)	85 (39.9)	162 (37.2)
Vascular dementia	61 (27.4)	50 (23.5)	111 (25.5)
Dementia with Lewy bodies	8 (3.6)	4 (1.9)	12 (2.8)
Mixed	30 (13.5)	15 (7.0)	45 (10.3)
Frontotemporal dementia	3 (1.3)	0 (0.0)	3 (0.7)
Other	38 (17.0)	59 (27.7)	97 (22.6)
Missing	6 (2.7)	0 (0.0)	6 (1.4)

Table 15 gives the characteristics of the staff recruited to the study in both the control and the intervention groups. The groups appeared to be similar in their characteristics, and the key features are that the majority of the staff members involved were white British and female. There were far more unqualified than qualified staff recruited to the study.

See *Appendix 2* for a full list of roles of the staff interviewed for the study.

Primary analysis of outcomes

The primary intention-to-treat analysis did not demonstrate any evidence of a difference between the treatment groups. The primary model fitted was as described, with the model fitted using self-report/proxy, time point, allocated group and the interaction of time and allocated group as fixed effects and site as a random effect. *Table 16* shows the mean values for the control and intervention group scores on the QOL-AD[57] (both self-report and proxy) at both baseline and follow-up.

There are higher numbers of proxy measures completed at follow-up than at baseline because proxy measures were not introduced until several sites had been completed at baseline. *Table 17* summarises the QOL-AD scores for carer proxy (in this context referring to those measures completed by carers about the person living with dementia as opposed to the proxy measures reported in *Table 16*, which were on behalf of the person living with dementia).

As previously mentioned, it was harder than expected to recruit carers to the study. Of the measures completed, seven were completed by family carers and 61 were completed by professional carers.

TABLE 15 Characteristics of staff recruited to the study

	Group, *n* (%)		
Characteristic	**Control**	**Intervention**	**Total, *N* (%)**
Age (years)			
Mean (SD)	39.3 (12.3)	39.5 (12.0)	39.1 (12.6)
Gender			
Female	94 (76.4)	100 (80.6)	194 (78.5)
Male	29 (23.6)	24 (19.4)	53 (21.5)
Ethnicity			
White/white British	104 (83.9)	113 (91.1)	217 (87.5)
Black/black British	5 (4.0)	0 (0.0)	5 (2.0)
Asian/Asian British	6 (4.8)	1 (0.8)	7 (2.8)
Mixed	3 (2.4)	1 (0.8)	4 (1.6)
Other	4 (3.2)	4 (3.2)	8 (3.2)
Missing	2 (1.6)	5 (4.0)	7 (2.8)
Qualified member of staff?			
Yes	21 (16.9)	19 (15.3)	40 (16.1)
No	102 (82.3)	103 (83.1)	205 (82.7)
Missing	3 (0.8)	2 (1.6)	3 (1.2)

TABLE 16 Unadjusted mean values for the two treatment groups at the two assessment points for QOL-AD

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	117	14.08	51.00	32.12 (6.96)
Follow-up	146	13.00	46.09	31.98 (6.69)
Baseline self-report	58	26.00	51.00	35.79 (5.70)
Follow-up self-report	55	22.75	44.91	35.14 (5.67)
Baseline proxy	59	14.08	41.17	28.51 (6.19)
Follow-up proxy	91	13.00	46.09	30.07 (6.56)
Intervention				
Baseline	127	15.00	48.75	33.09 (7.34)
Follow-up	127	16.55	45.00	32.99 (6.38)
Baseline self-report	45	26.00	48.75	37.56 (5.03)
Follow-up self-report	38	23.83	45.00	35.61 (5.49)
Baseline proxy	82	15.00	47.67	30.63 (7.27)
Follow-up proxy	89	16.55	42.55	31.87 (6.43)
Total				
Baseline	244	14.08	51.00	32.62 (7.16)
Follow-up	273	13.00	46.09	32.45 (6.56)
Did not complete				
Baseline	67	N/A	N/A	N/A
Follow-up	148	N/A	N/A	N/A

N/A, not applicable.

TABLE 17 Unadjusted mean values for the two treatment groups at the two assessment points for QOL-AD carer proxy

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	27	14.18	46.58	35.60 (7.46)
Follow-up	31	21.00	45.50	35.33 (6.98)
Intervention				
Baseline	19	17.73	42.55	32.33 (6.41)
Follow-up	13	17.00	39.00	33.01 (5.76)
Total				
Baseline	46	14.18	46.58	34.25 (7.16)
Follow-up	44	17.00	45.50	34.65 (6.67)
Did not complete				
Baseline	276	N/A	N/A	N/A
Follow-up	379	N/A	N/A	N/A

N/A, not applicable.

Table 18 shows the mean IDEA questionnaire scores for both the control and the intervention groups. It can be seen from the figures that only small numbers of these questionnaires were completed as they appeared to be too cognitively complex for most of the participants. All proxy measures of the IDEA questionnaire were completed by family carers as it was not felt appropriate to ask staff to comment on whether or not they were upholding a resident's human rights. The range of possible scores on the IDEA questionnaire was 29–87. A higher score on the IDEA questionnaire reflects less satisfaction with human rights. The IDEA questionnaire is included in *Appendix 3*.

Table 19 shows the mean scores on the care plan audit for both the control and the intervention groups at both baseline and follow-up. The minimum possible score on the care plan audit was 0 and the maximum was 86. A higher score implies a more detailed, person-centred care plan. The care plan audit tool is included in *Appendix 3*.

Table 20 summarises the mean values on the knowledge questionnaire for both the control and the intervention groups at both baseline and follow-up. The maximum possible score on the knowledge questionnaire was 13 and the minimum was 0. Follow-up measures were not completed with the control group. A copy of the knowledge questionnaire is included in *Appendix 3*.

Table 21 shows the mean scores for each group on the attitudes questionnaire. The minimum possible score on the attitude questionnaire was 12 and the maximum was 60. Follow-up measures were not completed in the control group. A copy of the attitude questionnaire is included in *Appendix 3*.

TABLE 18 **Unadjusted mean values for the two treatment groups at the two assessment points for the IDEA questionnaire**

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	42	29.00	63.37	36.81 (6.41)
Follow-up	25	29.00	56.79	39.13 (7.02)
Baseline self-report	40	29.00	63.37	36.90 (6.42)
Follow-up self-report	21	29.00	56.79	38.88 (6.89)
Baseline proxy	2	29.00	41.00	35.00 (8.49)
Follow-up proxy	4	33.14	53.00	40.48 (8.66)
Intervention				
Baseline	28	29.00	53.17	35.33 (6.01)
Follow-up	17	29.00	54.22	36.41 (7.01)
Baseline self-report	27	29.00	53.17	35.37 (6.12)
Follow-up self-report	15	29.00	54.22	35.91 (6.92)
Baseline proxy	1	34.37	34.37	34.37 (N/A)
Follow-up proxy	2	33.64	46.65	40.15 (9.20)
Total				
Baseline	70	29.00	37.00	36.22 (6.25)
Follow-up	42	29.00	56.79	38.03 (7.06)
Did not complete				
Baseline	260	N/A	N/A	N/A
Follow-up	391	N/A	N/A	N/A

N/A, not applicable.

TABLE 19 Unadjusted mean values for the two treatment groups at the two assessment points for the care plan audit

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	107	24.00	60.00	41.69 (7.24)
Follow-up	136	21.00	63.00	44.38 (8.01)
Intervention				
Baseline	112	24.00	59.00	43.82 (6.58)
Follow-up	127	27.00	61.00	47.20 (6.43)
Total				
Baseline	243	21.00	63.00	43.19 (7.78)
Follow-up	239	24.00	61.00	45.62 (6.70)

TABLE 20 Unadjusted mean values for the two treatment groups at the two assessment points for the human rights knowledge questionnaire

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	32	6.00	11.00	9.00 (1.34)
Follow-up	N/A	N/A	N/A	N/A
Intervention				
Baseline	36	5.00	12.00	9.31 (1.41)
Follow-up	43	6.00	13.00	11.40 (1.58)
Total				
Baseline	68	5.00	12.00	9.16 (1.38)
Follow-up	43	6.00	13.00	11.40 (1.58)

N/A, not applicable.

TABLE 21 Unadjusted mean values for the two treatment groups at the two assessment points for the human rights attitude questionnaire

Time point	*n*	Minimum	Maximum	Mean (SD)
Control				
Baseline	41	40.00	60.00	51.24 (5.18)
Follow-up	N/A	N/A	N/A	N/A
Intervention				
Baseline	58	40.00	60.00	49.78 (4.32)
Follow-up	57	44.00	60.00	53.02 (4.11)
Total				
Baseline	99	40.00	60.00	50.38 (4.73)
Follow-up	57	44.00	60.00	53.02 (4.11)

N/A, not applicable.

When the full data set was examined for the QOL-AD,[57] the additional covariate included for self-report/proxy was statistically significant, indicating that there was a difference between the data collected by self-report and those collected by proxy. Therefore, as per the analysis plan, the data have also been split to investigate the models on the self-report and proxy data separately.

There was no indication that the interaction between time and allocated group was significant.

All outcomes were assessed for normality within the model fitting; the data for the proxy QOL-AD exhibited some trends towards non-normality and a cubic transformation was applied. *Tables 22* and *23* summarise these data.

TABLE 22 Degrees of freedom, *F* and *p*-values for the fixed factors of the fitted models for the primary outcome QOL-AD and subsequently split for self-report and proxy

Source	Numerator df	Denominator df	*F*	*p*-value
Complete data set				
Intercept	1	16.22	7136.13	< 0.001
Status QOL-AD	1	295.29	77.20	< 0.001
Time	1	274.35	0.09	0.761
Group	1	16.51	3.63	0.074
Time × Group	1	266.73	0.001	0.980
Self-report data				
Intercept	1	14.67	3692.15	< 0.001
Time	1	73.02	1.10	0.297
Group	1	14.88	0.23	0.641
Time × Group	1	74.90	0.04	0.836
Proxy data				
Intercept	1	13.04	4596.29	< 0.001
Time	1	177.18	1.90	0.170
Group	1	13.53	4.35	0.056
Time × Group	1	181.67	0.02	0.886

df, degrees of freedom.

TABLE 23 Degrees of freedom, *F* and *p*-values for the fixed factors of the fitted models for the primary outcome

Source	Mean difference	df	SE	95% CI	Effect size
Complete data set					
Group	1.48	16.505	0.655	–0.28 to 3.24	0.03
Self-report data					
Group	0.449	14.879	0.664	–2.15 to 3.05	0.10
Proxy data					
Group	1.785	17.678	0.548	–0.33 to 3.90	0.14

CI, confidence interval; df, degrees of freedom; SE, standard error.

Secondary outcome measures

There was no evidence of a significant difference for the allocated group for either of these outcomes. The IDEA questionnaire scores demonstrated trends towards non-normality, and a square root transformation was applied to rectify this. There was no indication that time and allocated group were significant; this is displayed in *Table 24*.

For the care plan audit there was a significant effect of time [$F(1,220.19) = 22.093$; $p < 0.001$].

Owing to the limited number of family carers present providing data for the IDEA proxy questionnaire, the WEMWBS[58] and the ZBI,[59] it was not possible to analyse these with any stability using a linear mixed model. Descriptive statistics have been included in *Appendix 2*.

There was a statistically significant difference in both the knowledge [$t(30) = –7.02$; $p < 0.001$] and the attitudes questionnaires [$t(55) = –53.87$; $p < 0.001$] demonstrating an increase in both immediately post training. These figures are summarised in *Table 25*. The difference between the intervention and control group at baseline was also assessed and no statistically significant difference was seen [knowledge, $t(66) = –0.914$, $p = 0.364$; attitude, $t(97) = 1.532$; $p = 0.129$]. Given the short time span and no control data over the same period, these results must be interpreted carefully, but there is some evidence of an improvement in these domains post training.

TABLE 24 Degrees of freedom, *F* and *p*-values for the fixed factors of the fitted models for the secondary outcomes, IDEA and CPA

Measure	Mean difference	df	*F*	*p*-value	SE	95% CI	Effect size
Carer QOL-AD							
Group	11.576	6.440	1.850	0.219		31.587 to 38.814	0.04
IDEA questionnaire							
Group	–0.002	9.758	1.130	0.313		34.492 to 39.288	–0.08
Care plan audit							
Group	1.960	18.138	1.149	0.298	1.041	42.580 to 46.930	0.12

CI, confidence interval; df, degrees of freedom; SE, standard error.

TABLE 25 The paired sample *t*-test results for the knowledge and attitudes questionnaires completed pre and post training

	Paired differences					
Measure	Mean (SD)	Standard error of the mean	95% CI of the difference	*t*	df	Significance (two-tailed)
Human rights attitude questionnaire baseline – human rights attitude questionnaire follow-up	–3.00 (3.82)	0.51	–4.02 to –1.98	–5.87	55	< 0.001
Human rights knowledge questionnaire baseline – human rights knowledge questionnaire follow-up	–2.13 (1.69)	0.30	–2.75 to –1.51	–7.02	30	< 0.001

CI, confidence interval; df, degrees of freedom.

Additional analyses

Additional covariates

The additional covariates included in the linear mixed models were age, gender, DCM, dementia type and whether or not a person had a carer (Carer _ YN).

For the QOL-AD measure,[57] none of these covariates was statistically significant. For the IDEA questionnaire, there was an indication that gender was statistically significant [$F(1,70.43) = 5.96$; $p = 0.02$]. The results of all these models are given in *Appendix 2*.

For the CPA, the additional covariate added into the model was the completion of the QOL-AD[57] (self-reported, not completed and proxy completed). This was statistically significant, indicating that there were differences in the CPA scores.

Variation of follow up

One of the sites had only an 11-week follow-up period rather than the 16-week period stipulated. Allowing the time difference to feature in the linear mixed model by adjusting the time variables to have three levels (baseline, 11-week follow-up and 16-week follow-up) did not change any of the statistical interpretation of the models. Therefore, it was deemed that there was no impact of this difference in follow-up time on the outcomes observed.

Intraclass correlation coefficient

The ICC was calculated for the QOL-AD. The difference between pre and post results was calculated first. Then the variance component was calculated with site as a random effect. Using this method, the ICC was found to be 0.09.

Dementia care mapping

At each site, the ME scores for participants were grouped together to give an overall score at baseline and follow-up. The scores were then separated into intervention and control, and an overall average of the ME scores was calculated. The results of the mapping exercise are displayed in *Table 26*.

TABLE 26 Average ME scores for intervention and control at baseline and follow-up

		Time point (%)	
Group	**ME score**	**Baseline**	**Follow-up**
Intervention	+5	0.8	0
	+3	39.3	29.3
	+1	57.8	69.5
	–1	1.8	1.1
	–3	0.3	0.1
	–5	0	0
Control	+5	1.4	0.1
	+3	34.1	28
	+1	62	69
	–1	2	2.5
	–3	0.5	0.4
	–5	0	0

In accordance with one of the study objectives, it was hypothesised that an increase in ME scores would be seen at sites where training had been delivered. However, *Table 26* highlights that, regardless of whether sites were intervention or control, there was no improvement in ME scores. In addition, for the majority of sites there was a decrease from baseline to follow-up.

Health economics

Outcome measures

Descriptive statistics for the outcome measures are shown in *Table 27* for baseline and *Table 28* for follow-up. As can be seen, completion rates of the carer measures (ZBI[59] and WEMWBS[58]) were low, precluding any further analysis.

The mean EQ-5D-3L self-report score at baseline was 0.74 (SD 0.267), which is similar to the mean UK population score of 0.78 (SD 0.26) for the age group of 65–74 years. We note that proxy scoring of the EQ-5D-3L was much lower (mean 0.35, SD 0.337), which is a similar finding to other studies involving proxy reporting for people with dementia.[63] The lower proxy scores of the EQ-5D-3L were driven by lower ratings in the self-care item.

Service use

Most health and social care contacts at both baseline and follow-up were home visits. The mean number of contacts was highest for general practitioners (GPs) and community nurses. A more detailed breakdown of the community- and hospital-based services used during a 4-month period is available in *Appendix 2*.

TABLE 27 Outcome measures at baseline (all available participants split by group)

Measure	*n*	Minimum	Maximum	Mean (SD)
Control				
ASCOT total	45	0.22	1.00	0.8396 (0.16536)
ASCOT proxy total	60	0.46	1.00	0.7848 (0.15177)
EQ-VAS	40	50.0	100.0	75.350 (15.8802)
EQ-5D-3L total	56	–0.016	1.000	0.72641 (0.265127)
EQ-VAS proxy	93	10.0	100.0	61.452 (22.4768)
EQ-5D-3L proxy total	95	–0.349	1.000	0.35873 (0.329315)
WEMWBS total	3	41.0	47.0	44.000 (3.0000)
ZBI total	3	28.000	37.000	33.03333 (4.593836)
Intervention				
ASCOT total	40	0.74	1.00	0.8870 (0.09504)
ASCOT proxy total	87	0.16	1.00	0.8182 (0.18658)
EQ-VAS	31	50.0	100.0	81.935 (17.4010)
EQ-5D-3L total	45	–0.043	1.000	0.76378 (0.271051)
EQ-VAS proxy	109	5.0	100.0	63.789 (17.6363)
EQ-5D-3L proxy total	107	–0.371	1.000	0.34907 (0.345178)
WEMWBS total	3	48.0	52.0	50.333 (2.0817)
ZBI total	3	8.381	34.000	19.71429 (13.062209)

VAS, visual analogue scale.

TABLE 28 Outcome measures at follow-up (all available participants split by group)

Measure	n	Minimum	Maximum	Mean (SD)
Control				
ASCOT total	43	0.24	1.00	0.8451 (0.1712)
ASCOT proxy total	88	0.2	1.0	0.793 (0.170)
EQ-VAS	38	20.0	100.0	74.868 (21.701)
EQ-5D-3L total	53	–0.016	1.000	0.74428 (0.25537)
EQ-VAS proxy	128	10.0	100.0	59.414 (21.136)
EQ-5D-3L proxy total	128	–0.536	1.000	0.34233 (0.34451)
WEMWBS total	0			
ZBI total	0			
Intervention				
ASCOT total	27	0.09	1.00	0.8522 (0.1990)
ASCOT proxy total	88	0.4	1.0	0.824 (0.161)
EQ-VAS	24	0.0	100.0	73.125 (28.239)
EQ-5D-3L total	33	–0.077	1.000	0.66467 (0.32191)
EQ-VAS proxy	108	10.0	100.0	61.861 (17.540)
EQ-5D-3L proxy total	105	–0.429	1.000	0.42918 (0.32765)
WEMWBS total	2	38.0	48.0	43.000 (7.071)
ZBI total	2	10.000	30.381	20.19048 (14.41151)

VAS, visual analogue scale.

Medication

At baseline, medication records were collected for 254 participants. Medications were categorised by British National Formulary therapeutic class, obtained from Prescription Cost Analysis[88] data, and are shown in *Table 29*. The most frequently prescribed category of medication was for the central nervous system, which includes dementia medication, analgesics, antidepressants and hypnotics and anxiolytics. A total of 101 out of the 254 participants for whom information was available were prescribed a dementia drug. Eight of these people were prescribed more than one dementia drug.

A more detailed breakdown of the medications prescribed is available in *Appendix 2*.

Cost of the intervention

There were no intervention design costs as the intervention was developed before this study took place. Nine training sessions were delivered on site to staff. Staff who received training at hospital sites ranged from NHS band 3 support workers to NHS band 7 ward managers. Staff who received training at care home sites ranged from care home managers to care home assistants. Each training session lasted 5 hours and was delivered by a NHS band 8a trainer. Sites were given two copies of the training manual and 12 copies of response booklets. In total, 71 members of staff were trained at a cost of £7157, or £101 per staff member. The intervention costs are summarised in *Table 30*.

TABLE 29 Numbers of prescriptions by category for 254 participants at baseline

Category of medication	Prescriptions (*n*)	
	Baseline	Follow-up
Anaesthesia	5	1
Cardiovascular system	377	337
Central nervous system	722	651
Ear, nose and oropharynx	3	1
Endocrine system	105	102
Eye	29	17
Gastrointestinal system	297	266
Infections	29	25
Malignant disease and immunosuppression	1	5
Musculoskeletal and joint diseases	19	13
Nutrition and blood	211	156
Obstetrics, gynaecology and urinary tract disorders	16	10
Respiratory system	57	31
Skin	32	8
No medication	7	6
Sterile water	1	0
Total	1911	1602

TABLE 30 Cost of the intervention

Site	Type of cost (£)					Number of staff trained	Cost per staff member trained (£)
	Staff time	Trainer's travel	Training materials	Administration	Total		
901	473.35	44.58	43.46	29.83	591.22	8	73.90
904	880.10	19.81	43.46	29.83	973.20	11	88.47
904 (second visit)	880.10	19.81	43.46	29.72	973.09	11	88.46
910	591.25	24.77	43.46	44.58	704.06	6	117.34
912	564.00	14.86	43.46	14.92	637.24	6	106.21
913	684.85	44.58	43.46	44.58	817.47	6	136.25
916	1040.25	29.72	43.46	29.72	1143.15	11	103.92
917	507.45	19.81	43.46	14.92	585.64	7	83.66
919	584.90	59.44	43.46	44.58	732.38	5	146.48
Total	6206.25	277.39	391.14	282.67	7157.45	71	100.81

Qualitative results

Staff decision-making interviews

The thematic analysis identified 21 themes from the combined data set (301 interviews). The interviews were then reanalysed to identify the frequency of each decision-making strategy within the data and for each group (i.e. control baseline, control follow-up, intervention baseline and intervention follow-up). This information is shown in *Table 31*.

There were similar total numbers of decision-making strategies in each group. *Table 31* shows that the most common theme in all groups, with the exception of the control group at follow-up, in relation to decision-making strategies was working as a team or consulting with other staff. The most common strategy described in the control group was hierarchical decision-making, whereby responsibility for making a decision was passed to another member of staff who was considered to be in a higher position and therefore more able to decide. It can be noted, however, that there was a drop in the reliance on hierarchical decision-making in the intervention group (although it remained the second most popular strategy in this group).

TABLE 31 The frequency of decision-making strategies utilised by each group

	Group (*n*)			
	Control		Intervention	
Theme	Baseline	Follow-up	Baseline	Follow-up
Teamwork/talking to other staff	228	185	225	241
Hierarchical decision-making	191	222	192	147
Previous experience	87	83	66	45
Speak to the family	84	95	104	124
Knowledge of the person	69	65	86	89
Using pre-existing documents	68	75	98	84
'It's in their best interests'	67	60	57	61
Using legislation (e.g. DOLS, Mental Capacity Act)	65	49	42	52
Observe/monitor	64	44	44	57
Common sense	58	81	65	27
Training	58	47	29	28
Share information	28	33	20	33
Speak to the person	24	69	40	48
Empathy	21	21	14	22
Human rights	25	17	20	49
Policy and procedure	19	26	28	18
It's not my job	19	22	20	12
Fear	16	19	10	1
Person-centred care	15	19	15	43
Follow the rules	9	10	15	4
Total	1223	1245	1190	1183

DOLS, Deprivation of Liberty Safeguards.

Although there are some variations in decision-making strategies across the groups, and it is acknowledged that any conclusions drawn would need to be cautious, it does appear that there are some differences in the intervention group at follow-up. Staff in this group were less likely to cite common sense as a strategy that they would employ to help them make decisions, whereas this strategy actually increased in the control group. The intervention group was also less likely to cite fear, the need to follow rules and 'it's not my job' as methods by which they made a decision. The intervention group was also more likely to explicitly mention human rights (such as dignity, respect and positive risk-taking) and person-centred care. It is perhaps not surprising that the intervention group was more likely to mention specific human rights based approaches, given the training that they had undertaken and their knowledge by this time that the site was involved in a human rights study. Given that it has been suggested that person-centred principles are closely linked to the key elements of a human rights based approach,[37] it is interesting to note that there was also more discussion of person-centred principles in the intervention group at follow-up, despite the principles not having been explicitly taught in the training.

Follow-up interviews

Follow-up interviews were offered to all intervention sites that completed the training. Some sites were unable to accommodate the interviews because of changes in management and lack of staffing. In total, six of the eight sites that completed training completed interviews designed to look at acceptability and effectiveness of the intervention. Interviews were conducted on an opportunistic basis and included staff who had attended the training, staff who had not attended the training and, when possible, the unit manager. The interviews were completed by a research assistant (not the same research assistant who had visited the site to collect data) and a member of the PPI reference group, who was either a person living with dementia or a carer.

On average, four staff per site were interviewed. Of the eight sites that had completed the intervention, four had a new manager by the time of these interviews. *Table 32* shows the staff who were interviewed at each site and the percentage of staff trained who remained at the site at this point (approximately 6–10 months after the intervention). Sites here are listed as 1, 2, 3, etc., so that they are not identifiable. Given that the information gathered at individual sites is later linked to management styles, it was felt important to preserve the sites' anonymity.

Three themes were derived from the data on the use and acceptability of the intervention. It is fully acknowledged that the questions posed to staff guided them to discuss the acceptability and effectiveness of the intervention and that the themes generated are therefore not surprising. The overarching themes and subthemes related to acceptability and effectiveness are summarised in *Table 33* and described in more detail below.

TABLE 32 Sites that completed follow-up interviews

Site (*n*)	Staff interviewed	Attended training	Did not attend training	Manager interviewed	Staff trained still at site (%)	Manager still in post
1	4	4	0	No	Unknown	Yes
2	4	4	0	Yes	86	Yes
3	4	1	3	Yes	67	No
4	3	1	2	No	Unknown	No
5	6	3	3	Yes	100	Yes
6	3	1	2	No	Unknown	No

TABLE 33 Themes from the follow-up interviews at intervention sites

Theme	Subtheme
Accessibility of the intervention	Simple
	Time-consuming
	Similar to current practice
	Management support
Benefits to the residents	Increased knowledge about residents
	Improved care plans
	Increased trust between service users and staff
Benefits to staff	Access to training
	Increased knowledge about residents
	Feeling like they were behaving in a less institutionalised way
	Changed thinking

Accessibility of the intervention

In general, staff found the training and the assessment tool extremely simple and understandable:

> *The tutor lady was fab. Simple.*
>
> *The information that was given. The way it was laid out as well. It was explained simply in layman's terms. The way we understand it. When someone comes in and talks to you the likes of solicitors they talk and I go listen just tell me as it is and that is what was good about the kit. It was in our terms. There was no complex words. Nothing that we didn't understand.*

It was noted that the 'Getting It Right' assessment tool[56] could be time-consuming to complete, and this had implications for its completion:

> *. . . it is such a busy unit. It is hectic to try and fit the extra stuff in.*

However, there was also a sense that completing the tool was worth the effort:

> *It does take quite a bit of time to gather all the information from the individual. Learning about the individual and what they like especially if they can't always tell you. And meeting family members and being able to have those conversations because sometimes they just want to off load what they have been going through. So it is quite timely but that is fine because it is so worthwhile because it allows you to collect so much data basically off the patient about what is important and how we are going to make their stay better that it is worth while taking the time over it.*

Some sites reported that they felt that the intervention was similar to their current practice, particularly in terms of life story work, which was routinely carried out:

> *We were partly doing it anyway and this was just a slight improvement on what we were already doing.*

Both positive and negative comments were made about the level of management support for the intervention and the impact that this had on its application:

> *But I am the one who gave the staff the support and said how are you getting on, have you been through it? We supported each other.*
>
> *No, they just got put in the office and we never got around to it.*

Benefits to the residents

There were several potential benefits to residents identified in the interviews. It was recognised that the completion of the 'Getting It Right' assessment tool[56] ensured that more information was readily available about each resident and that this had an impact on residents' care and treatment. Interviewees also emphasised the positive involvement of the family in gathering this information:

> *Because you are asking the family as well they are surprised at oh how do you know that about me. So they're I feel that they are more involved. Rather than just plodding along everyday it is making them feel involved as well. You are all working collectively then. All singing under the same umbrella. If you talk about something individual to them. It makes them think more as well. It makes them feel more important knowing their background.*

Similarly, staff highlighted that the completion of the assessment tool improved care plans and that this translated into more individualised care:

> *I went through the care plan in great depth and found out bits and pieces and I spoke to the family to find out more and got bits. We got books and music because we found out things this lady used to do. I do find some people do sit and do not talk as such where I am happy to just sit and talk and eventually she will talk back.*

This continued even when the staff members were no longer directly using the assessment tool:

> *. . . when the staff are formulating care plans the information is there. We got given your care plans but we don't have that paperwork here but now the content of the care plans reflect that information. There is a lot more information. A lot more making sure we have background information. They get more involved with family and friends to get as much information about that individual.*

There was also a sense that completing the assessment tool and gathering the information increased trust between residents and staff:

> *The main things is that the service users trust you. Because they are frightened. Dementia is a frightening thing. So they have got to have trust and if people can come along and say this is Jack he likes this he likes that without having to explain to 24 different staff. I think it helps build trust and it helps build that professionalism that they feel they can trust you. That they are not every 5 minutes having to explain who they are. Makes them feel understood and cared for.*

In turn, this facilitated a more empathic approach to care:

> *The books that we filled in we have used them on a daily basis. Use them to support people. I feel like I can empathise more. We have one lady who has bad dementia and we understand what she needs and what she wants. She folds tissues up and she thinks that is money. [We] understand why they do something that might seem strange to us. She just folds them up and she has them in her handbag she gives them to you. And you take them off her and she feels 1000 times better.*

Benefits to staff

It could be seen as concerning that staff felt that this training, which was not designed to be core training in dementia care, was filling a need for training for members of staff, particularly those who were unqualified:

> *The support workers do not often get training and they feel that they have benefitted from the training. It has made them think about things.*

This resulted in many staff being extremely positive about the training they received:

> *I just remember it all being really exciting. I was buzzing.*

And the impact it had on them and their ability to do their job:

> *And it did make a massive difference to our job. A massive difference.*

Staff highlighted that getting to know residents better, and having a greater understanding of their past, helped them become closer to the residents and, in turn, improved their working lives:

> *Like one guy who absolutely loves chatting and he will chat to you all day long. The minute you mention [name] his eyes just light up. Because that is all he knows and remembers. So we have got history on the computer, so we have looked up things that involve him. You know reading into things like that so you can talk to him properly and his eyes light up, it is amazing. Going back like more like information more than anything else, getting more background on them and their interests. It has had a big impact on myself.*
>
> *One lady we have got different pictures in her room now, because I found out a lot more about her . . . That made me feel so happy though because I felt so much closer to her.*

Staff commented that the training in particular had changed the way that they thought about situations and encouraged them to think of things through a human rights lens, considering each person as a human being with rights:

> *I just think that people think they know the Human Rights Act but it is in terms of their own situation, rather than how it translates to everyone else because I have never [experienced it] . . . it is always a given the right to have a choice and all those things but it is not necessarily so. And I think that institutions and care staff tend to think that they are the rules and if you live in a particular place meal times have always got to be on time and if you don't want what is on the menu you don't eat and it still goes on. If you don't eat it you won't have anything else. Well that is not right. It certainly shouldn't be like that today. So with this training it makes staff realise we are only part of a bigger world and everyone has got a right.*

This also led to a more compassionate approach among staff, and recognition of potential 'mistakes' they may make, by helping them to understand the reasons behind behaviour:

> *I think people's attitudes changed during the training. People should only be vilified if they know what they are doing is wrong. Sometimes people come working in a place like this and they have got no experience and they do just see tasks. They do just see 18 baths or 18 toilets. That is all they see. They focus on that and it is easy to forget the person. I just think that with this it – makes you think what have I done? I have done that in the past. Would I do it again? No. Because I have seen it from a different perspective.*

This resulted in staff feeling like they were behaving in a less institutionalised way and responding more to the needs of the person living with dementia. In this way, the training and adoption of the approach provided freedom to act in way that the staff fundamentally felt was right but that had previously been criticised:

> *In a way it has taken pressure off. In as much that nobody expects everybody to be in their clothes by 10 o'clock. If they are not in their clothes by 10 a.m. there is a blooming good reason for it. And people go along with that. You know it is less of an institutionalised way. Because it is about what fits in with the service user, not what fits in with the programme on the ward. There is more awareness and like I say it has created a bit more freedom for us.*

Suggestions for improvements

During the interviews, staff were also asked to suggest improvements to the approach. The following suggestions were made:

1. training more staff from each unit so that knowledge could be shared and the whole team could appreciate the approach
2. providing more booster sessions to cement learning
3. digitalising the 'Getting It Right' assessment tool[56] to make it easier to use.

Management style

As management support was such a key feature in many of the interviews, the data gathered were subsequently analysed using a deductive approach and mapped on to the characteristics from Bass and Avolio's[87] management style. It is acknowledged that the information gathered in this way was not specifically about management style and any conclusions made are tentative.

Bass and Avolio[87,89] describe transactional leadership as a relationship in which both the leader and follower are working to meet their own self-interests. In this type of leadership, the leader gives clear direction as to what the follower must do in order to be rewarded. Whereas transformational leadership is described as moving beyond pure self-interest. In this style of leadership, the leader works to enhance motivation towards a shared vision. The model breaks down each leadership style into different characteristics. Transformational leadership comprises intellectual stimulation, individualised consideration, charisma and inspiration. By comparison, transactional leadership comprises leadership styles such as passive management by exception (i.e. waiting for problems to arise before taking corrective action), active management by exception (i.e. monitoring performance and taking corrective action if the follower fails to meet standards), laissez-faire and contingent reward. *Table 34* outlines the characteristics associated with both transformational and transactional leadership styles.

It has been suggested that a transformational management style can enhance commitment, involvement, loyalty and performance and help individuals deal with stress.[90] In contrast, a transactional management style is likely to induce stress in staff.

TABLE 34 Characteristics of transformational and transactional leadership styles

Leadership style	Characteristics
Transformational leadership	Intellectual stimulation
	Individualised consideration
	Charisma and inspiration
Transactional leadership	Passive management by exception
	Active management by exception
	Laissez-faire
	Contingent reward

When the data from the interviews were deductively analysed in line with the management styles outlined above, certain patterns were noted. At sites 2 and 5, more codes were identified that related to a transformational management style, and to two characteristics in particular: intellectual stimulation and individual consideration.

Intellectual stimulation refers to a managerial style whereby the manager encourages their staff to behave in creative ways, generating novel solutions for old problems. It is suggested that this leads to a working environment that values people questioning their own assumptions and those of the organisation and tolerates differences in views and opinions.[89] Four codes appearing to relate to intellectual stimulation were identified in the interviews.

1. Managers actively seeking ways in which the team can improve:

   > *We heard about the study from another care home that is actually a dementia care home and we sort of asked could we join. We were desperate to be involved.*

2. Managers being open to criticism:

   > *If I have got problems in my home can you tell me. If you can do something better that is great. It affects everybody.*

3. Managers showing evidence of problem-solving and adapting the human rights based approach and the 'Getting It Right' toolkits:

   > *They still use the books, but the pages have been printed and put on the walls in the bedroom. This makes them much easier to use for staff and patients.*

4. Managers actively disseminating information about a human rights based approach:

   > *Well basically we just got an e-mail saying listen, we are going to start trying this, see if it works, see if it is helpful and they brought in the paperwork and went through it with us and we just started implementing it on the ward.*

Individual consideration is characterised as helping others to develop, letting others know how they are doing and giving personal attention to those who seem rejected. Two codes were identified that related to this aspect of transformational style.

1. Managers being active in motivating staff to attend training and to utilise the assessment toolkits:

   > *But I am the one who gave the staff the support and said 'how are you getting on? Have you been through it?' We supported each other. Do you understand it? I think at first they said we just have to concentrate on the red things and that was it, you can leave the others. And I said it is not that you can leave them it is just that initially when they come into the building, they are the things you need to give them, safe care but everything is important. And they were like OK we will carry on doing it. But we worked together with that one. I was integral. I am really lucky with my staff.*

2. 'Understanding staff' and their motivations:

   > *For them to have volunteered for it, nobody ever volunteers for training. They would be reluctant at first. If I hadn't driven it, would they have done it, probably not? I do that with any of the training because if you didn't they would say if you can't be bothered they can't be bothered. Put it that way. I do think someone has to give them that drive. If you explain it to them they are like OK.*

At sites 1 and 3, there were more codes relating to a transactional management style. These mainly fit into the laissez-fare style of management, although one code fits into the passive management by exception category.

Laissez-faire describes a manager who is content to continue functioning in the way the organisation has worked: someone who does not encourage staff to develop, embraces the status quo and asks no more of staff than what is essential. Four codes relating to a laissez-faire style of management were identified in the interviews.

1. Lack of management support and encouragement:

> *I think it covered every aspect but I don't think we have enough support and staffing levels. A lot of staff on the floors.*

2. Failure in communication between past and present management. The following quotation was from a new manager who had not been in position when the study took place at their unit:

> *I only heard about the study from this evaluation.*

3. Failure to communicate to staff:

> *No they just got put in the office and we never got round to it. I don't know where they are because our manager has left.*

4. Using a lack of resources as a reason not to make changes:

> *Always resources stop me from doing these things. You always want more than what you have got. I don't feel as though profit and care are good bedfellows really. When certain things are counted and continent aids are counted that does not lead to respect or rights. That is a major issue.*

Passive management by exception is described as dealing with an issue only if it arises. It describes a manager who is happy if staff are meeting agreed standards as long as things are working and as long as individuals know the standards. One code was identified that related to this style of management.

1. Passive support:

> *We didn't use it but I can't see what would prevent us. I was wanting to have a word with the manager about it rather than just go ahead off my own back. I would rather ask, check with the manager to check that it is OK.*

At sites where there were more descriptions of managers being active or transformational in adopting a human rights based approach, staff described utilising the 'Getting It Right' toolkits and they felt generally more supported and understood and experienced the worth of prioritising them to provide person-centred care. Staff provided examples of service users' improved well-being, and of engagement and increased trust with services users and their families.

At sites that had more themes related to transactional management, there was a smaller degree of uptake of the approach. Although staff reported that they were excited about the approach ('I just remember it all being really exciting. I was buzzing'), a lack of management support meant that the approach was not applied: 'No they just got put in the office and we never got round to it'.

Chapter 4 Discussion and conclusions

Summary of findings

The findings of the study are very clear. There was no evidence that introducing this human rights based approach improved the well-being of people with dementia or the quality of care in dementia inpatient wards or care homes. The delivery of the training had the desired effect in that it significantly increased both knowledge about human rights and positive attitudes towards human rights. Similarly, there was a shift in decision-making strategies in the intervention group at follow-up, with this group relying less on 'common sense' to make decisions and talking more explicitly about using human rights concepts, such as dignity, respect, least restrictive practice, positive risk-taking, and person-centred care, to influence choices. However, neither of these factors translated into an increase in quality of care or in the reported well-being of people living with dementia.

There was an improvement in the quality of care plans at follow-up, but group was not a factor (i.e. there were improvements in both the control and the intervention group). This suggests that it was the process of care plans being monitored, rather than the intervention, that had an impact on the quality of care plans. Similarly, as there was no difference in care provided or reported well-being as a result of improved care plans, it could be inferred that what people are getting better at is writing person-centred care plans as opposed to delivering person-centred care. People who completed the QOL-AD[57] had significantly better care plans than people who did not. This was most apparent when the QOL-AD had been completed by a proxy. Those who did not have a QOL-AD completed had the lowest-quality care plans. Although research has previously been carried out into how a good-quality care plan can improve the care people receive,[91] there is limited work on what influences the development of a good-quality plan. In this situation, it may be that the process of completing a QOL-AD about an individual prompted the staff member to update that person's care plan with the relevant information. If so, it would highlight the importance of staff feeling responsible for getting to know specific residents in order to enable them to develop good-quality care plans. At some sites there has been a move away from people having a key worker to acknowledging that all staff need to be able to interact with all residents, but this may be diluting feelings of responsibility for care planning.

Men reported significantly higher numbers of human rights violations on the IDEA questionnaire. Given the numbers collected and the fact that there appeared to be a floor effect on the questionnaire (with most participants reporting no or extremely limited human rights violations), it may be that this is not really a clinically significant finding. However, it could reflect several of the characteristics of care settings that were identified in this study. During the interviews, staff were asked to identify issues that they found challenging in their daily work, and the most common theme related to aggression and challenging behaviour. Although aggression and challenging behaviour do not apply only to men, these issues were identified as particular to male service users. Trying to manage this difficult situation, which many staff report feeling unequipped to deal with, may result in practices that could undermine an individual's human rights, such as restraint, seclusion and an over-reliance on medication.[92] Similarly, it was clear from the demographics that the majority of staff providing care were female (67.4%). This may have had an impact on issues of privacy and dignity in relation to issues such as personal care.

Comparison with pilot

The approach was initially piloted on Acorn ward in Mersey Care NHS Foundation Trust. It was adopted well and has been used by that site since 2012. During a recent visit,[93] the CQC praised the approach, stating that:

> *we saw that this had an impact on the frontline, with the implementation of a Human Rights Based Approach. This involved the development of a person centred assessment tool, which incorporated the values of Human Rights law.*
>
> *Care Quality Commission,[93] © Care Quality Commission. Contains public sector information licensed under the Open Government Licence v3.0*

and it was highlighted as an area of good practice (p. 15). During data collection, the 'Getting It Right' assessment tool[56] was observed to be used in control care homes because it had been implemented on the pilot inpatient wards and then shared with these care homes when the people were discharged.

Reflection was therefore needed as to why uptake and adoption was so positive at the pilot site and yet was more difficult at intervention sites. It seems that there are several factors that may have contributed to this difference. Staff members from the pilot ward were involved in the study from its outset, including the design of the assessment tool and training package. As a result, they may have felt more ownership for the approach and engaged with it more fully. All staff on the ward were trained in the approach together as there was trust investment to support this and backfill was provided while the training took place. Staff in the current study suggested that it would have been better if more staff from each unit were trained as it would have increased support and understanding. There was more support available during the pilot from a number of sources: the ward manager was fully supportive of the approach, advocated for it and allowed staff the time to complete the assessment tools; the trust board was keen to see a human rights approach adopted and provided support in thinking about how this approach may replace other documentation; the ward identified a lead person to ensure that the assessment tools were completed and this person oversaw its application; and the trainers were readily available to address any questions or queries as they were at the same base. All of these factors may have contributed to better adoption at the pilot site.

Generalisability

The baseline comparability of the two groups was good and the characteristics reflected national statistics for people living with dementia. As such, it is likely that a representative sample of the population of people living with dementia was recruited to the study. This would allow some degree of generalisability. There are, however, a number of factors that could affect this.

Although units were recruited from across the north-west of England, which is a relatively diverse area in relation to cultural and socioeconomic variables, the participants involved in the study were less diverse, particularly in terms of ethnicity. Although there are no definitive figures on the ethnicity of the unit residents, the research assistants felt that they were overwhelmingly white British or white Irish. Similarly, the vast majority of the staff (87.5%) were white British. This is unlikely to represent the general care home and inpatient population across the country.

It was acknowledged that sites varied considerably in what they would consider 'treatment as usual'. Differences were observed in the extent to which sites adopted the human rights based approach and applied it to their work. There appeared to be some common themes that accounted for differences in uptake, such as management style, but there are also likely to be idiosyncratic reasons. As such, it could be concluded that it may be more useful to consider each site individually and to tailor training and support to a site's particular requirements, as happened initially at the pilot site. This, of course, would have implications for the cost-effectiveness of interventions.

Appropriateness of outcome measures

Well-being measures

As in previous studies,[94] QOL-AD scores were lower when the measure was completed by a proxy than when it was completed by the person living with dementia. Previous studies have shown that agreement between proxy and self-report on the QOL-AD is higher when examining observable functions such as physical health and disability and relatively poorer for more subjective measures. It has also been shown that disagreement between proxy report and self-report increases as the severity of dementia increases.[95] This is interesting in the context of this study, as many of the people involved will have been living with severe dementia. Similarly, previous work has found that whereas care home residents'-reported QOL-AD scores correlate highly with levels of depression, carer-completed reports on the same measure correlate highly with levels of dependence and behavioural issues.[96] Therefore, as dementia progresses and people living with it become more dependent, proxies would see those living with dementia as having a lower quality of life, whereas there is evidence that levels of depression decrease as severe dementia progresses[97] and so these same people living with dementia may rate their subjective quality of life higher.

In this study, self-reported quality of life, as measured by the EQ-5D-3L, was just as high as the reported norms of people of a similar age without dementia. This again challenges the assumption that living with dementia has a negative impact on self-reported quality of life. It is often assumed that the reason for a difference between self-report and proxy report measures is that people with dementia lack the required insight into the impact of their condition to be able to accurately report on their quality of life, but it is of course possible that proxies are unable to imagine what it is like to live with dementia, particularly in the later stages, and as such may assume that the quality of life will be poor. This may not be the reality for the person living with dementia. As such, it is possible that the self-report and proxy report versions of the same measure are actually measuring different concepts. Pickard and Knight[98] identify two distinct proxy perspectives. The 'proxy-patient' perspective requires proxies to project themselves into the patient's internal state, whereas the 'proxy-proxy' perspective is based on the proxy's judgement. The authors found that there tends to be less discrepancy between self-report and proxy report when a proxy is explicitly asked to adopt a proxy-patient perspective. There is also evidence that a proxy's own quality of life has an impact on their judgement.[99] It could, therefore, be questioned whether or not it is appropriate to use proxy measures to capture the subjective well-being of people living with severe dementia.

Although it has been suggested that the QOL-AD[57] can be usefully completed with some people with a MMSE score of as low as 3[100] (although it was originally suggested to be valid for use with people with MMSE scores of > 10[57]), it quickly became obvious that the majority of people living with dementia in the care homes and wards visited were unable to complete the measure, even with assistance from skilled clinicians. Of course, this does not mean that information about quality of life cannot be elicited from people with more severe dementia[101] or that the team did not think that this was important. Indeed, processes undertaken to elicit information from people in the later stages of dementia were described earlier in this report (see *Development of the FREDA assessment tool*).[71] Rather, the use of the QOL-AD and the heavy reliance on proxy measures would raise the question of whether or not it was an appropriate measure to use in this context. It may have been more useful to interview residents about their experiences of quality of life to elicit their views in a more naturalistic way.

Figure 8 summarises the domains of well-being covered by the QOL-AD.[57] Given the items included in the measure, it is worth considering why an intervention would be expected to bring about change in these domains. The current intervention under investigation, even if successful, is not likely to change a person's financial issues, their ability to do things around the house (although a person-centred approach may encourage people to do more) or their marriage.

It may be more useful to look at other concepts that have been shown to have links to subjective well-being in dementia. Studies have indicated that care home residents with greater perceived control (e.g. regarding decisions about food, social activities, daily routines, privacy and sense of self) experienced significantly

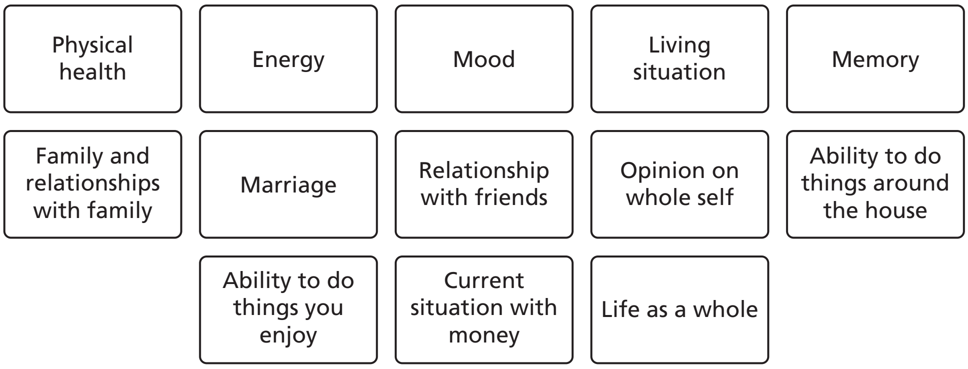


FIGURE 8 The constructs included in the QOL-AD.

greater psychological well-being.[102] Similarly, a study of care home residents in Singapore identified five predictors of quality of life in this population:[103] comfort, dignity, food enjoyment, autonomy and security. Taken together, this evidence would suggest that a more innovative measure, designed to tap into concepts that actually matter to people living with dementia, is needed if we are to accurately capture the subjective quality of life of people living with dementia, particularly those with more severe dementia.

Dementia care mapping

Dementia care mapping was utilised to observe the care provided at each unit. In particular, the ME scores from each unit were compared at baseline and at follow-up to uncover any differences in care following the intervention. However, it is important to be cautious about how much can be extrapolated from the overall ME scores. Although DCM was originally created as a clinical tool to help improve the quality of care in clinical settings, it has been used effectively in a number of research studies to gain a more objective measure of service user well-being.[104] There are potentially a number of factors, over and above the hypothesis of no change to care, that could have accounted for no change or a decrease in ME scores.

It was apparent that at baseline the majority of staff were not aware that the research was being carried out; therefore, at this time several staff initially believed that they were being observed and were uncertain about the motives of the research assistants. As a result, levels of engagement with service users may have been influenced and potentially increased, particularly given that there was a clear finding within the study that care plans improved when people felt that they were being monitored. Generally, at sites at follow-up, staff appeared to be more relaxed and it was felt that the behaviours observed were potentially a more accurate representation of the day-to-day care being provided. Given this finding, it could have been useful to complete a pre-baseline set of measures to allow the staff to become accustomed to being observed. This would, of course, have had financial and time implications for the completion of the research.

Between baseline and follow-up, there were a large number of service users who had been discharged or had died, which, at times, resulted in a different service user being observed at follow-up. According to the Bradford Dementia Group,[105] it is difficult to see change at separate time points when observing different people, and therefore any changes that were hypothesised to occur at intervention sites may not be reflected in the overall ME scores.

Throughout the study, it was noted that there was a large turnover of staff at sites from baseline to follow-up. For a number of sites, there was a larger proportion of agency staff being employed at follow-up than at baseline. Although the use of agency staff is beneficial for meeting the desired staffing levels, it does not necessarily result in continuity of care for service users. A lack of consistent staff could potentially be unsettling for some service users,[106] and this could be a reason why ME scores decreased at particular sites at follow-up. In addition, at some sites agency staff were not being used and hence staffing levels were extremely low. This is highly likely to have had an impact on ME scores, as staff members were able to meet only the basic care needs of service users.

In some sites in particular, the environment could have had an adverse impact on ME scores. More specifically, the layout of the communal areas where mapping took place was not ideal. At times, individuals could not be observed, which meant that they were given a behaviour category code of Q (quit: individual was not in mapping area) for a number of time frames. At these particular sites, there may have been several observations that could not be reported, and, owing to this, the overall ME scores for these sites may not be a true representation as behaviours and levels of engagement could have been missed. This was, of course, true at both time points.

A general observation made during DCM was that, at follow-up, some service users' cognitive abilities had declined, and in some instances their physical health had deteriorated. This could result in individuals not being able to participate or have difficulty participating in behaviours that generate higher ME scores. This may account for no change or a decrease in the overall ME scores obtained. However, given the client group involved this would not be unexpected after a 4-month follow-up.

During DCM, the team observed a number of representatives from external organisations facilitating various activities with service users. At one site in particular it was noted that, at baseline, activities took place throughout the day, but at follow-up this did not occur. As activities can potentially have a positive influence on an individual's ME score, this may account for the decrease in ME scores at this site.

For these reasons, it is important to think about the scores obtained during DCM in context rather than in isolation.

Strengths

Recruitment

The study recruited more participants than had been originally planned. Although initially it was feared that the recruitment rate of people living with dementia might be low because many might not be able to complete the self-report measures, the introduction of proxy report measures ensured that a high proportion of people at each site could be included in the study. Research assistants strove to recruit as many people as possible at each site and the only reasons that they did not recruit everyone at each site were lack of consent, the person not being available during the data collection period, the person not having a dementia diagnosis and time pressures on staff to complete proxy measures (see *Figure 5*). It was considered important that as many people as possible at each site were given the opportunity to be involved in the study. Similarly, as it could not be known until analysis whether or not there were significant differences between proxy and self-report scores on the QOL-AD;[57] therefore, it was important to obtain as many of each category of questionnaire as possible. It was felt that the development of good working relationships at each site between the research assistants and the staff at the unit contributed considerably to the high recruitment figures. Reflection by the TSC and in research team meetings focused on how important it was that the research assistants had previous experience working in dementia care settings, as this allowed the development of a trusting working relationship with staff at the care homes that was built on mutual respect and understanding.

Study design

The study involved a rigorous investigation of the intervention that allowed clear claims about its effectiveness and utility to be made. Without a rigorous framework for evaluation and a clear conceptual framework (outlined in *Figure 1*), claims about effectiveness could have been made without giving consideration to the impact on well-being of the people living with dementia. It would have been possible to say that training improved knowledge and attitudes, changed decision-making strategies and, without considering a control group, improved care plans. Without looking at the elements of care and well-being, it could have been concluded that the intervention was a success. The translation to improvements in care and well-being is not always considered in such approaches.[107]

Patient and public involvement

There were high levels of engagement with people living with dementia and carers in all aspects of the study through the PPI work, and their contributions both guided the study and influenced its direction. In total, 79 people living with dementia or carers gave input into some element of the study design, delivery or the subsequent public engagement work. The involvement of people living with dementia and those who support them was felt to be paramount in this study because of its congruence with the underlying principles of a human rights based approach to care. PPI is concerned with a shift to carrying out research and development with or by members of the public and service users rather than on or for them simply as participants.[108] This helps to uphold and promote the rights of each person to have 'a right to voice', with suppression or denial of that voice being a potential violation of rights.[109] Similarly, the nature of this study and the fact that it was funded by NIHR makes this even more important,[110,111] as it could be considered a core democratic principle that:

> *. . . people who are affected by research have a right to have a say in what and how publicly funded research is undertaken.*
>
> *Copyright INVOLVE February 2012.[110] This publication is the copyright of INVOLVE. We are happy for our materials to be downloaded, printed out, copied, used and distributed free of charge for non-commercial purposes. Where our materials are copied, used or distributed, the source of the material must be identied and the copyright status acknowledged. No alteration or adaptation of any of the materials may be made without obtaining the permission of INVOLVE. Reproduction or distribution of materials either in whole or in part for a commercial purpose is prohibited without the prior written permission of INVOLVE*

Alzheimer Europe recently issued a position paper[112] regarding involving people with dementia in research through PPI. In this paper the authors recommend that people living with dementia be involved in all aspects of research, including the initial generation of research ideas. An important output from this study is the development of a PPI reference group comprising people living with dementia and carers who have developed an interest in promoting the area of human rights in dementia. Although the group's initial role was to support the current study, the members felt that it was of utmost importance that the output would be accessible information that increased public awareness about the human rights of people living with dementia and how easily these can be undermined in society. This PPI reference group will continue to exist after this study ends and will form the basis for the development of further research in the area.

Innovative methods

Innovative methods were used throughout the study to try to ensure that information was elicited in ways that would be as ecologically valid as possible. It has previously been discussed in this report (see *Development of the FREDA assessment tool*) that every effort was made to include people living with later stages of dementia in the development of the assessment tool.[71]

A key element of the study was the exploration of staff decision-making strategies. To assess this, staff were provided with clinical vignettes that were designed specifically for this study and that combined potential human rights violations with person-centred principles. Vignettes have long been used to investigate a number of phenomena in the social, behavioural and health sciences.[113] In this study, staff were read a number of clinical vignettes and asked what they would do in each particular situation. On each occasion they were asked supplementary questions of 'how would you come to that decision?' and 'what would help you in coming to that decision?' It was felt that asking staff to reflect directly on their own experiences and how they make decisions may feel threatening to many. Similarly, it is often unethical or impossible to assess clinical decision-making experimentally with real clinicians and service users in health-care settings. Therefore, although vignette designs may be an alternative method for investigating how health clinicians make decisions that affect service user care, it has been questioned whether or not a written stimulus, and a participant's responses to it, can accurately represent certain aspects of what happens in the real world. It has been suggested that three conceptually distinct, but functionally inter-related, factors contribute to validity.[114]

1. Vignettes must simulate aspects of real-world scenarios and bear some resemblance to situations encountered by the participant (construct validity).
2. Vignettes, and the differences between vignettes, elicit some kind of effect that is hypothesised to exist independently in the real world (internal validity: the degree to which changes in the dependent variable can be accurately attributed to changes in the independent variable).
3. Vignette studies should produce results that generalise to real-world situations encountered by the participants and others like them (external validity).

It is important to note that vignettes are not intended to recreate real-world situations.[113,115,116] Rather, they are designed to 'approximate, isolate, manipulate, and measure key aspects of the decision-making processes that individuals use in real world situations'.[116] Similarly, participants' behaviour in a vignette study is not intended to be interpreted as representative of their behaviour in the real world, but rather viewed as strong predictors or proxies for such behaviour.[115,116] It is, therefore, more useful to think about whether or not the mental and behavioural processes used in responding to the vignettes are activated in a way similar to the manner in which these processes are used in real life.

In considering these factors, the vignettes used in this study were developed collaboratively with staff working in dementia care settings so that they accurately reflected clinical situations that may be encountered on a regular basis. The vignettes were refined during the pilot phase of the study and they elicited a wide range of distinct responses that reflected a variety of decision-making strategies. It cannot be claimed, however, that the responses reflected proxies to behaviour, as little, or no, behavioural change was noted as a result of the intervention despite changes in decision-making strategies.

National dementia initiatives

The approach was also congruent with a number of national initiatives related to dementia. There is a clear commitment to reducing the prescription of antipsychotic medication to people with dementia.[92] The principles of a human rights based approach, particularly proportionality, least restrictive practice and proactive strategies together with a detailed understanding of the person with dementia, through a person-centred care plan, are key in finding alternatives to antipsychotic prescribing in challenging behaviour. A key to managing challenging behaviour is the understanding of the need being expressed through this behaviour.[117] An in-depth knowledge of the person is obviously essential in helping formulate this. It was proposed that the application of this approach would lead to more detailed person-centred care plans that allow a more detailed knowledge of the person.

The National Institute for Health and Care Excellence (NICE),[50] in its quality standard for dementia, states that:

> *People with dementia have an assessment and an ongoing personalised care plan, agreed across health and social care that identifies a named care coordinator and addresses their individual needs.*
>
> *NICE.*[50] *© NICE 2010* Dementia Support in Health and Social Care. *Available from www.nice.org.uk/guidance/QS1. All rights reserved. Subject to Notice of rights. NICE guidance is prepared for the National Health Service in England. All NICE guidance is subject to regular review and may be updated or withdrawn. NICE accepts no responsibility for the use of its content in this product/publication*

The proposed intervention, if applied, would clearly address this issue.

Many of the concepts covered in the 'Getting It Right' assessment tool[56] map directly onto the standards of the Quality Network for Older Adults Mental Health Services[118] and allow wards to meet the required standards more readily. It was hoped, therefore, that the approach may be acceptable to sites as it would help them to meet other requirements.

Limitations

Effectiveness and acceptability of the intervention

Despite staff and managers stating that they found the approach useful and simple to use – 'It was explained simply in layman's terms' – there was limited uptake of the approach in practice. It was hard to get staff to attend the booster sessions and releasing staff for training seemed extremely difficult. Although NHS wards were harder to recruit, once recruited they had clear mechanisms in place to enable staff to attend the training day. In contrast, care homes were relatively easier to recruit but were often unable to protect the time required for staff to attend the training. There were multiple occasions when the trainer would visit a care home to find that no staff had been given dedicated time to attend the training and so staff were taken off active duty to attend, resulting in additional pressure on the other staff who had to cover their work. The fact that 2 out of 10 intervention sites were unable to undertake the training in the required time frame, despite having prior knowledge of the requirements, demonstrates the difficulties or level of willingness sites had in releasing staff for training and development. Similarly, several staff from care homes reported attending the training on their days off as they were interested in the topic but had not been given the time to attend during working hours. Although this shows a positive commitment from these staff, it calls into question the commitment of those care homes to the approach.

Although it was initially envisaged that as many staff as possible would be trained at each site, in reality only 8.88 members of staff (28.7%) at each site were recruited to the training. The proportion of staff trained at each site ranged widely, between 11.6% and 52.4%. Similarly, the protocol suggested that three 'booster sessions', which were designed to support the implementation of a human rights based approach, should be delivered to each site. In reality, this was not possible. There is obviously a major difference between training the majority of staff at each site and facilitating booster sessions to embed the approach (the expectation), and training an average of 28.7% of the staff with minimal follow-up (the reality). However, staff who had attended training were positive about it, and felt that it was tailored to their needs and had an impact on their ability to complete their job successfully: 'The tutor lady was fab. Simple'. Given the reluctance of sites to engage with the training and booster sessions, it is interesting that a theme from interviews with staff in the intervention sites was that they would have liked more training, training for more staff and more booster sessions.

There was also evidence that the 'Getting It Right' assessment tool[56] was not routinely completed at participating sites. When it was used, however, it was considered to be helpful ('the training and the handouts and the paperwork that they gave us has definitely helped') and it had a positive impact on the work people were carrying out. Unfortunately, there was no mechanism within the study to specify the number of assessments that needed to be completed at each unit, and in hindsight this may have improved the completion rate.

These somewhat mixed findings about the acceptability and effectiveness of the intervention seem to reflect the finding that uptake varied across sites and that a number of factors influenced uptake. However, it was clear that the majority of staff enjoyed the training and felt that it was targeted at a level appropriate to their skills and knowledge. They also valued the 'Getting It Right' assessment tool,[56] but a variety of factors meant that they were not always able to use it in their setting.

Ultimately, despite positive reports from staff about the approach, there was also evidence of difficulty engaging teams with the training, problems getting staff to attend follow-up sessions, limited use of the assessment tool and the approach having no impact on the care and well-being of people living with dementia. Therefore, the intervention could not be concluded to be effective. This will be considered when offering training to the control sites (in line with the original protocol) and different models will be considered.

A further limitation of the study related to the intervention was the lack of any fidelity assessment. No attempts were made to assess whether or not residents found the application of the 'Getting It Right' assessment tool[56] useful. The study may have been improved by adding this to the evaluation framework.

On reflection, the evaluation mechanism used to assess the effectiveness of the intervention was completed with a population once removed from the direct intervention. Although staff received the human rights training, completed the assessment tool and attended the booster sessions, the primary outcome measure (QOL-AD[57]) was completed with the residents at each unit. The team still maintain that it was of utmost importance that the well-being of people living with dementia, who were of course the recipients of the care from staff who had received the intervention, was assessed. Without improvements to the care and well-being of people living with dementia, there is little use in applying the intervention. However, as discussed in *Appropriateness of outcome measures*, *Well-being measures*, it may have been more useful to consider other ways of measuring the impact of the intervention on people living with dementia.

Treatment as usual

There was considerable variation in the baseline treatment and care at each individual site. Different sites adopted different models of care and completed different documentation that formed the basis of the care plan. There was no way to standardise the baseline care provided across the sites. In addition, and as previously discussed, on occasion, external events may have had an impact on the recorded standard of care at different time points. For example, at one site an orchestra was visiting during baseline data collection, which could have increased the well-being scores of residents and, therefore, skewed the baseline results.

Although the RCT is widely considered the gold standard for evaluating new interventions, some questions have been raised about its efficacy in dementia studies. It is recognised that promoting change in people living with dementia is very difficult and, as a result, many interventions targeting behavioural or psychological change are found to be ineffective in RCTs,[119] even when qualitative evidence related to the same intervention is overwhelmingly positive.[63] If we add high levels of variation of treatment as usual to the picture, then these issues will be compounded further. There is perhaps a need to seek alternative ways of effectively and rigorously evaluating the impact of interventions targeting the well-being of people living with dementia.

Measurement of cognitive abilities

There were difficulties with the completion of the ADAS-Cog,[120] which resulted in fewer people than expected being able to complete the measure. As a result, there was no conclusive way to ensure that the severity of dementia was comparable between hospital wards and care homes.

The ADAS-Cog is generally recommended as a useful tool to assess cognitive functioning in dementia trials[66] and it is especially useful for determining the extent of cognitive decline, which can help to evaluate which stage of Alzheimer's disease a person is experiencing. Similarly, the ADAS-Cog is often used in clinical trials because it can determine incremental improvements or declines in cognitive functioning. Despite this, it is a time-consuming assessment to complete (up to 45 minutes per person) and in reality the majority of participants refused to complete it. On reflection, the use of a briefer screening assessment, such as the MMSE or Addenbrooks Cognitive Examination, might have yielded more useful results. Although these measures are less detailed than the ADAS-Cog, there is a greater chance that people would have engaged with them and, therefore, that some level of comparison could have been made.

Blinding

Despite the intention that the research assistants collecting the data would have remained blinded, this did not occur at 7 out of the 20 sites. It is acknowledged that this could have biased the data collection but, given the results, which suggest that there was no difference in care and well-being, it perhaps becomes less important. It is also important to note that as staff acted as proxies for service users when no care was available (i.e. the majority of cases), staff who had attended the training were also unblinded and this may have influenced their responses to the follow-up questionnaires.

High staff turnover

There were high levels of staff and management turnaround at several of the intervention sites, as illustrated in *Table 35*. Additionally, at follow-up, four of the eight intervention sites that had completed training had new managers. *Table 35* also shows that at a number of sites staff had not been replaced, meaning that the remaining staff members were under additional pressure. Conversely, at some sites there were additional new staff at follow-up, meaning that the staff team was larger than at baseline. Obviously, none of these staff would have been trained in a human rights based approach and would therefore have reduced the proportion of staff trained in the approach at these sites. These factors are likely to have had implications for the continuation of the intervention at each site. Given that, on average, < 30% of staff at each site were trained, high staff turnover will make it even less likely that a critical mass of staff will be present to implement the intervention.

It is estimated that > 40% of care home staff leave their job within a year of taking up post and 60% leave within 2 years.[121] Crucially for those in care, the level of staff turnover can be a matter of life or death.[122] The CQC has noted a statistical link between those care homes with increased rates of staff turnover and notifications of death and has suggested that:

> *too many changes in staff may result in gaps in care.*
>
> *Care Quality Commission.[123] © Care Quality Commission. Contains public sector information licensed under the Open Government Licence v3.0*

It has been proposed that high levels of staff turnover make it impossible to adhere to the principles of continuity of care that NICE highlights as being of utmost importance.[122]

TABLE 35 Staff turnover

	Total staff (*n*)	
Site	**Left before follow-up**	**New at follow-up**
A	7	7
B	8	3
C	8	2
D	0	2
E	4	2
F	2	2
G	5	8
H	4	2
I	5	8
J	2	2
K	4	7
L	1	3
M	3	2
N	2	0
O	9	8
P	7	5
Q	0	2
R	0	4
S	2	1
T	3	3

Recruiting carers

There were major problems with the recruitment of informal carers to the study. It was initially expected that, when possible, a carer would be recruited for each participant. This goal was not achieved by a long way. The research assistants reported that many residents had no visitors at all, and, of those who did, their visitors were reluctant to complete measures. It has been estimated that 85% of care home residents have no visitors.[124] Although this figure may be an overestimation in reality,[124] it does suggest that there is a shift in the relationship of carer and person receiving care when the recipient enters a care setting. The term 'couplehood' is used to refer to the shared identity and experiences that a couple have that help to reinforce their sense of themselves as a couple.[125] It could be hypothesised that the transition from living together at home to living apart, with one half of the couple in a care setting, may have an impact on couplehood as there may be reduced opportunities for new shared experiences. This could usefully be explored in further research.

Given that difficulty recruiting carers is commonly reported in dementia studies, this raises questions about the most appropriate way to engage them in research.

Use of proxy measures

Because participants with dementia found it difficult to complete the self-report version of the QOL-AD,[57] it was necessary to also seek proxy completion of the measure. As in previous studies, significantly lower scores were found from proxy report than from self-report. As a result, it was necessary to analyse the data from the proxy and self-report measures separately, which resulted in smaller numbers for each group than would have been possible had the group been able to be analysed as a whole. The issues related to the use of proxy measures are described in detail in *Appropriateness of outcome measures*, *Well-being measures*.

The issue of proxy completion was compounded by a lack of visitors, which required staff to complete proxy measures for residents.

Interpretation

Theory of planned behaviour

A major finding of the study is that although the intervention has changed the knowledge staff have about human rights, the attitudes that they hold and their reasoning about decision-making in relation to clinical care, it has not altered their behaviour when delivering care. The theory of planned behaviour[126] (*Figure 9*) may provide some insights into this finding. This theory proposes that the chances of an individual behaving in a particular way is influenced by their attitude towards the topic, their perceptions of other people's (their peers') attitudes to the issue and their perceived level of control over the situation.

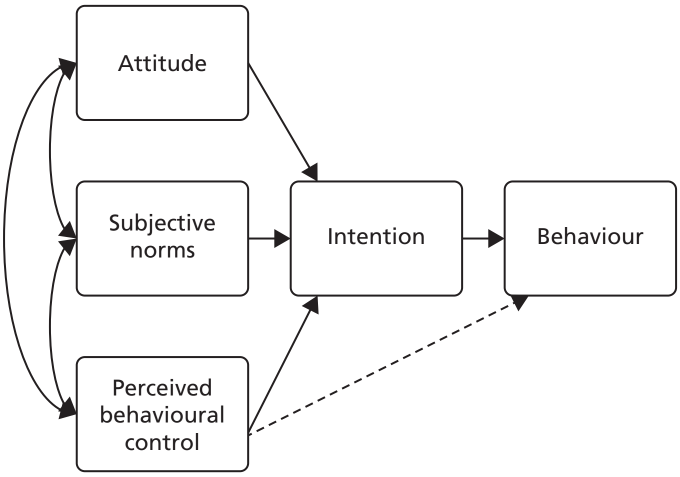


FIGURE 9 Theory of planned behaviour.

Although the current intervention may change an individual's attitude to human rights (as demonstrated by significant changes in the attitudes questionnaire scores) and their intention to behave in a way more congruent with a human rights based approach (as evidenced by improvements in care plans and different decision-making strategies), the actual behaviour, as measured by DCM, remains unchanged. The theory of planned behaviour would suggest that this discrepancy between actual and intended behaviour may be accounted for by considering staff's perceived level of control and perception of others' views about human rights. Although the current study did not directly collect information on these areas, some tentative conclusions could be drawn from the available data.

Although the initial intention was to train as many staff as possible in a human rights based approach, practicalities meant that an average of < 30% of staff at each site were trained. Similarly, there was limited uptake of the booster sessions that would have provided staff, both trained and untrained in the approach, with the opportunity to discuss the application of a human rights based approach to care. As a result, there may have been fewer opportunities for staff members to assess their peers' attitudes to and understanding of such an approach. This is further backed up by information from the follow-up interviews at intervention sites, in which staff suggested that having more opportunities to discuss the approach with other staff at the unit may have been helpful in applying it.

It has been hypothesised that perceived control relies on two elements: locus of control and self-efficacy. Whereas locus of control refers to a person's beliefs around whether people in general can achieve positive outcomes and avoid bad outcomes through their own actions or whether external factors control these outcomes, self-efficacy refers to the perception that a person themselves has the skills and abilities to enact effective responses. A common theme across all groups, derived from the staff decision-making interviews, was the use of hierarchical decision-making. This implied that staff felt a lack of control in making autonomous clinical decisions and instead relied on seeking consent to act in a particular way from others, which may, in turn, have led to staff feeling that they lacked the self-efficacy to bring about change. Similarly, the follow-up interviews at intervention sites highlighted that staff applied the model more effectively at units where managers encouraged them to be independent thinkers and adopted a more transformational approach to leadership.

Given that a key finding of many care home studies is a lack of uptake of new interventions, future research could explicitly use the theory of planned behaviour to investigate human rights based approaches and their application.

Management style

The results of the follow-up interviews demonstrated the importance of management style in maximising the chances of this intervention being adopted at any particular site. Although there is insufficient evidence to make wide-ranging claims about this element of the study, initial findings showed that sites with a more transformational manager were more likely to adopt the approach and think of ways to adapt it, whereas sites with a more transactional manager were less likely to adopt the approach and more likely to dismiss its relevance.[90] It is perhaps not completely surprising that management style has such an impact on uptake given that hierarchical decision-making was one of the most popular decision-making strategies. If managers are not supportive and other staff look to them to make decisions, then the approach will not be adopted.

An issue highlighted in the study was that there was a high level of turnover of managers at the units. By the time of the follow-up interviews, half of the sites at which the intervention was delivered had new managers, and there was evidence of poor communication between past and current management: 'I only heard about the study from this evaluation'. There is recognition that care homes that provide person-centred, high-quality care tend to have managers who focus on leadership rather than just management[127] and that emotional intelligence is the key to good-quality care.[128] A Joseph Rowntree Foundation report[129] exploring ways of improving the quality of care in care homes highlighted management as a key driver in developing and implementing improvements. The report proposed that a change culture must start with managers who are willing to embrace change (in this study the transformational managers) and that these managers must empower staff to participate in decision-making about both clinical care and the more organisational aspects of the unit. This fits well with the finding that staff felt reluctant to make decisions independently and instead sought advice from more senior colleagues. Linking to the theory of planned behaviour, it would appear that managers are key in enabling staff to feel that they have behavioural control over any initiatives and facilitating staff ability to implement these independently. This maximises the chances that initiatives will actually be implemented.

Given these findings, it would seem vital that managers with the correct skills and the ability to develop effective teams are recruited to these important positions. There has been a move within the NHS and other services to utilise values-based recruitment.[130] Values-based recruitment aims to select candidates for roles based on their individual values and behaviours and how closely these align with those of the organisation. It may be that selecting managers based on their values, particularly those related to an ethos of person-centred care, may improve the care provided at a unit.

Cultures of care

Culture has been defined as 'the basic assumptions, values and norms shared by and influencing how members of an organisation behave and interact'.[131] Too often, substandard care is accepted and unquestioned. It is expected that quality of life will be low in care homes and that little else is aimed for. This can lead to care that is task orientated and driven by goals and objectives rather than by resident-orientated factors.[129] It is notoriously difficult to change cultures of care and, although many initiatives are introduced, a culture of care continues to exist that falls short of the optimal standards.

It is unacceptable that the culture of care in care homes remains substandard and unable to meet the basic needs of the people to whom it applies. A recent UNISON report[132] found that < 20% of care home staff who responded to their questionnaire felt that they had enough time to provide care that upheld the dignity and individuality of residents. This led to residents not receiving treatment such as assistance to go to the toilet, efficient monitoring of their condition and meeting of personal care needs, and 88% of workers reported that they did not have time for a conversation with their residents.

A large-scale study looking at what constitutes an excellent culture in care homes (Care Home Organisations Implementing Cultures for Excellence – CHOICE)[133] identified seven factors that contribute to a positive culture in care homes:

1. shared purpose in providing the best person-centred care
2. a sense of community between all involved in the care home
3. managers ensure that external pressures do not have a negative impact on service delivery
4. staff are empowered to take responsibility for residents' well-being by active management processes
5. openness to change for the benefit of residents
6. using the care home environment to the benefit of residents
7. person-centred activity and engagement is integral to care work.

Again, these factors mirror those of this report in that they highlight the importance of cementing person-centred practice in care, not just talking about it; the centrality of management in ensuring that staff are empowered to take responsibility for their own practice and are protected from external pressures that may have an adverse impact on their ability to provide the best-quality care; and the necessity of cohesion among staff and managers in developing a positive culture at the unit.

This study aimed to utilise a human rights based approach to bring about cultural change. Previous work by the Equality and Human Rights Commission found that public authorities continued to lack a culture of respect for human rights, despite some examples of good practice.[134] They identified a number of barriers that they suggested could contribute to this finding. These included 'initiative overload', [135] with staff feeling that there is always something new to implement; a lack of autonomy among staff; the hierarchical and target-driven nature of health-care settings;[136] and a low awareness of human rights among staff, service users and members of the public. It has been suggested that the use of human rights language in conversations with organisations, staff and members of the public is ineffective because of this lack of awareness.[137] In contrast to this belief, the current study has demonstrated that training could raise awareness of human rights, improve attitudes towards human rights and, in the context of decision-making, change staff's use of language about human rights.

The CQC has integrated the FREDA principles into the inspection framework. When rights are fully integrated into policy and practice within services, the impact has been anecdotally described as:

> *. . . a magnet pulling services in the direction that best supports the dignity, respect, equality and autonomy of those that use them.*
>
> *Equality and Human Rights Commission.[134] © Equality and Human Rights Commission 2009. The copyright in the document this publication has been adapted from, and all other intellectual property rights in that material are owned by, or licensed to, the Commission for Equality and Human Rights, known as the Equality and Human Rights Commission ('the EHRC')*

This study does not endorse this finding. Instead, it suggests that although a human rights based intervention can change knowledge, attitudes and decision-making, it does not influence care delivery.

Training

The findings of this study call into question the efficacy of training as a medium for improving care and changing culture. Although the training appears to significantly increase knowledge about human rights and positive attitudes towards human rights immediately following the training, it does not translate into improvements to care practices and in the reported well-being of people living with dementia.

There is a current government mandate through Health Education England to provide effective, relevant dementia education and training for the entire workforce.[138] However, it is recognised that there is limited evidence about what effective dementia training and education for this diverse workforce looks like.[139]

It seems important to consider what any training programme is aiming to achieve. Kirkpatrick's model for the evaluation of learning[140] identifies four levels for evaluating the efficacy of training.

- Level 1: reaction – learners' reaction to and satisfaction with the programme.
- Level 2: learning – the extent to which learning has occurred included increasing knowledge, skills, confidence and attitude change.
- Level 3: behaviour – the extent to which staff behaviour or practice have changed and whether or not participants are applying their learning in practice.
- Level 4: results – examines what results have occurred because of the training, in this case the impact on people living with dementia.

The remit of this study was to train staff in a human rights based approach, with the aim of assisting staff to make decisions in complex clinical situations. It also trained staff in a new way of care planning and provided them with a tool to complete more person-centred assessments. What it did not do explicitly was teach people the skills to *behave* in a more person-centred way. Given that there are low levels of knowledge of more basic issues related to dementia observed, could we have expected people to make this transition independently? There was low uptake of the booster sessions, but, even if the uptake had been higher, the sessions would not have been detailed enough to fulfil this role. To start meeting these goals, we would be looking at a far more intensive model of coaching and consultation; there are examples of this such as the Newcastle model of challenging behaviour,[141] but they are far more time and labour intensive and, therefore, are likely to also have financial consequences.

Preliminary results from *What Works in Dementia Training and Education? A Critical Interpretive Synthesis of the Evidence*[139] suggest that there are a number of elements that contribute to training to bring about changes to people living with dementia. These are that the training:

- uses face-to-face delivery, discussion and activities that support the application of learning to practice
- is delivered by an experienced trainer
- is > 1 hour in duration
- is designed for a specific service setting
- provides training on a structured tool or delivery manual that assists the application of learning in practice.

This study utilised all aspects of this framework but failed to embed the approach into care. Given the results from this study it would be useful to add that management support is also required both to attend the training and, more importantly, to apply the approach to clinical situations.

Patient and public involvement

A key element of the study has been the involvement of people living with dementia and those who support them. Not only was this congruent with the theoretical underpinning of the study by promoting participation and accountability, it was also essential in gaining a meaningful understanding of what human rights means to this group of people in the context of living with dementia. Much work has been undertaken over recent years to build rights based approaches into policy[26,29,30,32,34,35] but this work has focused less on the practical application of these approaches to the everyday lives of people living with dementia. Without this focus, there is a danger that human rights based approaches will suffer the same fate as person-centred care, whereby ‘the gap between the rhetoric and the reality remains uncomfortably wide’.[46]

From the outset, the PPI reference group felt that it was essential to engage with the realities of applying a human rights based approach to dementia care. A series of focus groups involving both people living with dementia and carers were held during the study, with the aim of eliciting information about the relevance of human rights to people living with dementia. In total, 79 people attended these groups; some continued as part of the PPI reference group, while others attended just one or more focus groups. Some focus groups were linked to other existing networks, such as the local memory group and service user forum, to hear from a wider range of voices than might otherwise have been accessed. No existing human rights models were presented to the groups; instead, they were asked to reflect on, and explore, elements of their experiences that had had a positive and negative impact on their sense of well-being as individuals living with dementia.

This information was collated and a thematic analysis[83] was undertaken to identify themes within the wide data set. These themes were then shared with the PPI reference group and translated into statements, directly relevant to dementia care, that reflected the rights of people living with dementia. These statements are presented in *Table 36*. Subsequently, human rights informed models were considered and the group felt that the statements fitted most comfortably into the FREDA framework. A notable exception, raised in all of the focus groups, was the importance of preserving identity in dementia. This theme highlighted the importance of preserving elements of identity in the face of changing abilities. It is recognised that although dementia can pose a threat to an individual’s sense of identity, there is clear evidence of the persistence of self-identity throughout the course of the condition.[142] A social constructionalist model of self-identity[143] would posit that the interactions between the person living with dementia and other individuals are key in upholding the self-identity of the person living with dementia. If we view human rights as concepts that are universal to us purely because we are human, then an argument could be made for actively promoting identity in dementia as a fundamental right. To this end, we included identity in the FREDA framework when considering dementia.

TABLE 36 Mapping of dementia care onto FREDA principles

FREDA principle	Statement
Fairness	Do not make assumptions about me
	Give me time and space
	Do not exclude me because of my dementia
Respect	Listen to me
	Find out who's important to me
	Make a positive effort to get to know me
	Speak to me
	Look at me when you speak to me
Identity	Respect my intelligence
	Recognise my skills and talents
	Respect my choices about how I want to live my life
	Let me live my life
Equality	Give me input into the care I receive
	Respect my culture, race and religion
	I have the right to intimate relationships
	I have the right to vote
Dignity	Do not embarrass me
	Ask my opinion
	Do not patronise me
	If you are helping me, explain what you are doing to me
Autonomy	Allow me to express my views
	Respect my personal freedom
	Give me the freedom to do what I want, which may include taking risks
	Provide assistance to make decisions for myself
	Take my significant others into account
	Give me advice but do not try to control me

It was felt that these statements, linked to an already well-recognised and respected human rights framework, made a good start in defining what human rights mean, on a day-to-day basis, to people living with dementia. The FREDA principles have usefully been applied in other health-care settings, including with people living with an intellectual disability.[144] Defining the issues related to the systematic and subtle ways in which human rights can be threatened in dementia care is, of course, a useful endeavour, but if this information is not shared in a way that is accessible to many people it will not influence the treatment that people receive. The PPI group is currently working with filmmakers to produce a series of short films that will represent these principles and their interpretation in an engaging way.

Language

It was considered important that all language used in this report was in line with the underlying principles of the study, namely upholding the human rights of people living with dementia. To this end, every effort was made to adhere to the language guidance provided by DEEP, which was compiled by people living with dementia.[145]

Implications for health care

The findings of this study have a number of implications for both the current provision of health care and future developments.

There is a tendency within health and social care for training to be used as a primary mechanism for bringing about sustained change in care settings. Current initiatives, such as the requirement for all staff working in health care to have a basic level of dementia awareness,[138] are, in theory, clearly beneficial to the population and aim to promote 'positive outcomes for people living with dementia, their families and carers'.[138] In practice, however, these training initiatives are often delivered online, with little opportunity given for discussion or debate of the issues raised, and the extent to which these actually have an impact on the lives of service users and carers is unclear. Health Education England states that it:

> *exists for one reason only: to support the delivery of excellent healthcare and health improvement to the patients and public of England by ensuring that the workforce of today and tomorrow has the right numbers, skills, values and behaviours, at the right time and in the right place.*
>
> *Health Education England.[146] © Crown copyright 2017. Contains public sector information licensed under the Open Government Licence v3.0*

Training is one vehicle for such changes, but the findings of this study imply that although training may increase knowledge and attitudes about a topic, and may even change the way people discuss the topic and intend to act, it results in little change to actual behaviours.

Many models of learning suggest that simply imparting information is not enough to bring about cultural and organisational change. Bloom's taxonomy[147] outlines the stages of learning that culminate in all stakeholders creating a better culture together. This requires more than direct learning and learners instead need to be active participants in the process: first remembering the information, and then understanding it and critically analysing it, before being supported to apply it and then synthesising it with their current knowledge and practice to create new cultures within organisations. This process is obviously more complex, time-consuming and costly than providing an online or 1-day training package and expecting staff to utilise it.

One finding from this study was that although staff members found the approach to be useful and simple, they did not independently apply it. The theory of planned behaviour, when applied in this situation, would suggest that further opportunities to discuss the topic and enabling staff to feeling empowered to make independent decisions may improve the chances that this initiative will be adopted. These findings could be useful beyond the confines of this study, as they suggest that, if training is to be embedded in practice, there need to be opportunities for staff to consult on and debate the issues involved, as well as a freedom for them to act independently in ways that are congruent with the approach. Obviously this would require a shift in both the methods through which training is delivered and the follow-up support required.

The King's Fund suggests that a major reform of the health and social care system is required to make it fit for purpose for the future.[148] They identify three challenges to innovative change in NHS systems: system inertia, whereby systems are stuck doing things in ways that they have always done them; the complexity of NHS systems where interactions cannot always be predicted; and risk adversity within the NHS. All three barriers were encountered in the current study and have been discussed. The King's Fund claims that, as in social enterprises, the answer comes in part from engaging with staff at all levels to empower them to make changes to their organisation. Related to this is seeking to build a social movement for change in which innovation occurs by harnessing the creativity, energy and commitment of the workforce. These suggestions are in line with a human rights based approach to care that recognises the participation of, and aims to empower, all stakeholders.

A human rights based approach would also include people living with dementia and their carers as important stakeholders in this process. The inclusion in this study of a wider reference group of people living with dementia and carers has highlighted the importance of their involvement in all aspects of service delivery. There can be multiple benefits of services engaging with service users and carers. DEEP has produced *Making an Impact Together,*[149] which encourages people with dementia to work together to ensure that they receive quality services, but also outlines the benefits to the services. Service user groups often have a lot more freedom to highlight areas in which change is needed and to push for this change to happen.

One clear finding was that, in both the intervention and the control groups, care plans had improved by the follow-up data collection point. One interpretation of this could be that it is the process of being monitored that leads to improvements. There has long been a tension related to human rights between clinicians who feel that the most effective way to encourage staff to engage with human rights is through supporting them to apply them, and human rights advocacy bodies (e.g. the British Institute of Human Rights) that propose human rights to be a legal framework against which people should be monitored.[37] This finding would seem to suggest that the latter is more effective in this case and imply that the most effective way to bring about change may be to set clear standards for services related to human rights against which those services are then monitored.

To bring about innovative change within systems, however, effective management and leadership is vital. In this study it was observed that when managers were more open to change and willing to let their staff act more independently, there was greater uptake of the approach. The issue of values-based recruitment for ensuring that managers who are willing to foster cultures where change can take place are recruited has been discussed in *Management style*. The findings would suggest that any new approaches should target management in the first instance to help ascertain what would work in their unit. This is the approach that will be adopted in the control sites that are still to receive training.

Although this study concluded that *this* human rights based intervention was not effective in bringing about behavioural changes that resulted in the improved care and well-being of people living with dementia, this does not of course imply that the human rights of people living with dementia are not important. As outlined above, barriers to the adoption of human rights approaches have been noted, including a lack of awareness of human rights and a reluctance to engage with the concept. This study has clearly demonstrated that staff will engage with the concepts of human rights and identify them as useful in the work they do. Addressing the cultural issues described above may pave the way for a more explicitly human rights based approach to be adopted.

A final point relates to the current systems of measurement and data capture in health services. Although it is acknowledged that outcome measures are essential in ensuring that high-quality services are being delivered, the current study and previous high-profile studies[63] call into question the effectiveness of the current measures in capturing a true reflection of well-being and quality of life for those living with dementia. Services may want to spend more time focusing on the elements of a person's life on which they feel the specific interventions will actually have an impact and then finding ways to capture those data effectively.

Future research implications

Some areas for future research and investigation have arisen from this study.

As discussed in detail above, there were concerns about the suitability of the outcome measures used in this study. The utility of the QOL-AD as an appropriate measure of change following the implementation of this intervention was questioned, and a review of the concepts contained in the measure suggested that many interventions currently delivered would not be likely to make a change. Given that there is a clear, and welcomed, mandate to further develop research that explores the most effective ways to promote well-being and deliver high-quality care, it is vital that effective measurement tools are available that will accurately capture change. This study would suggest that this should be a research priority. Without appropriate measures, a lack of clarity will continue over the most appropriate ways to support people living with dementia, particularly those living with the later stages. Related to this issue, however, there appears to be a lack of research focused on fully understanding what contributes to quality of life in the later stages of dementia, and many assumptions are made about this. To develop meaningful evaluation tools, it will first be vital to fully understand the factors that contribute to quality of life in the later stages of dementia.

It was clear from this study that engaging carers in research is extremely difficult. More work must be carried out to ensure that carers are given every opportunity to engage with research and to have their voices heard. The PPI reference group suggested that the most effective way to help informal carers see the benefits of research for both themselves and those they care for would be to have the research promoted by people living with dementia and other informal carers who have been involved in the research process previously. Members of the PPI group were keen to take on these roles in the future.

A fuller understanding is needed of why interventions are not routinely applied when they are reported qualitatively as being effective and acceptable to services. Two further research focuses can be drawn from this:

1. explicitly applying the theory of planned behaviour to human rights based approaches to look at whether or not altering a person's perceived control over the situation improves the uptake of the intervention
2. working directly with managers to understand the impact management style has on the application of a human rights based approach (and other novel approaches to care).

At the outset, this study worked from the premise that the human rights of people living with dementia would be the same as those of everyone else because human rights are fundamental principles that apply simply because we are human beings. However, public engagement throughout 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 about the changing nature of autonomy and the relative importance, or not, of individual autonomy as a concept. Both of these areas could warrant further research to investigate their role in the quality of life and well-being of people living with dementia.

The IDEA questionnaire was developed as a way of trying to capture the extent to which people living with dementia felt that their human rights were being upheld. It was developed collaboratively with people living with dementia, staff and carers, but all of the people living with dementia who took part were at earlier stages of the condition. Within the study, the IDEA questionnaire was not found to be an effective tool as it tended towards a floor effect, with the majority of people stating that they had experienced no violations of their rights. The questionnaire was also too complex for people in the later stages of dementia to complete effectively. More work is needed to ascertain whether or not this tool would be effective for use with people in the earlier stages of dementia. It is also essential that work is undertaken to find ways to capture the extent to which people in the later stages of dementia feel that their human rights are upheld.

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 was a concept that was alien to staff and it was not routinely considered during the provision of care. Staff did not feel empowered to act independently to support people in their units and the management support that was provided was variable. To provide quality care that is person centred and respects 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 indication of the 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 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 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 that 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*.

Overall, the study was hopeful in identifying that the majority of staff caring for people living with dementia were keen to explore how a human rights based approach to care could improve the lives of people living with dementia. In reality, however, these same individuals worked in cultures and organisations that did not explicitly promote person-centred care and the promotion of human rights. It is the challenge of those in positions of relative power to ensure that meaningful change is made that will allow the enthusiasm of care staff to translate into more effective and compassionate caring relationships with those they support.

Acknowledgements

We would like to thank the external members of the TSC for their advice and support during the project: Professor Dawn Brooker (University of Worcester), Mr Thomas Dunne (service user), Ms Gina Shaw (service user), Mr Graham Garvin (carer), Mrs Anna Gaughan (Life Story Network Community Interest Company), Mr Toby Williamson (Mental Health Foundation) and Dr Matthew Tedford (Royal Liverpool and Broadgreen University Hospitals NHS Trust). Our thanks also go to the DMEC comprising Dr Jane Simpson (Lancaster University), Dr Rebecca Walwyn (Research Design Service, Yorkshire and the Humber), Dr Steven Lane (Research Design Service North West) and Ms Julie Morton (University of Salford). The team would also like to thank Ella Perry (Mersey Care NHS Foundation Trust), who completed the interviews at sites following the end of the study and worked on the interpretation and reporting of these results.

We are grateful to the participants, wards and care homes that supported this study and gave their time so generously. We would also like to offer our appreciation to the members of the Service User Reference Forum, who supported the study and acted as an external reference group for service user and carer issues.

Particular thanks are given to Jill Pendleton (Mersey Care NHS Foundation Trust), who was a driving force in the initial development of applying a human rights based approach to dementia care, co-authored the 'Getting It Right' assessment tool with Sarah Butchard and provided advice and support throughout the process.

Contributions of authors

Peter Kinderman (Professor of Clinical Psychology) acted as principal investigator on the study, and led the team in study design, grant application and management, and recruitment. He shared responsibilities with Sarah Butchard for the supervision of research assistants, and with other members of the team in data collection, the interpretation of findings and the drafting of the final report.

Sarah Butchard (Clinical Psychologist) conceived, planned and designed the study. She acted as the trial manager and co-ordinated the running of the study, delivered the intervention, interpreted the qualitative elements of the study and led on the writing of the final report.

Ashley J Bruen (Research Assistant) completed data collection and interpretation of the DCM findings and drafted elements of the final report.

Abbie Wall (Research Assistant) completed data collection and interpretation of the DCM findings and drafted elements of the final report.

Nia Goulden (Trial Statistician) developed the statistical analysis plan, undertook the statistical analysis, aided interpretation of the results and drafted sections of the final report.

Zoe Hoare (Principal Statistician) gave input into the design and methodology of the study, designed the randomisation system, oversaw the development of the statistical analysis plan and subsequent analysis, and had input into the interpretation of the results and the presentation of the final report.

Carys Jones (Research Officer, Health Economics) was involved in design, analysis, the interpretation of findings, and the writing and review of the report.

Rhiannon Edwards (Professor of Health Economics) was involved in design, the interpretation of findings, and the writing and review of the report.

Data sharing statement

All available data can be obtained from the corresponding author once they have been fully anonymised and checked.

This statement confirms that the report contains no defamatory material or brand names. The identity of all individuals has been protected throughout the report.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data are used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation.

References

1. Alzheimer's Society. *Dementia 2014: Opportunity for Change*. London: Alzheimer's Society; 2014.
2. Department of Health and Social Care. *Living Well With Dementia: A National Dementia Strategy*. London: Department of Health and Social Care; 2009.
3. Prince M, Knapp M, Guerchet M, McCrone P, Prina M, Comas-Herrera A, *et al. Dementia UK: Update*. London: Alzheimer's Society; 2014.
4. Alzheimer's Society. *Dementia UK*. London: Alzheimer's Society; 2007.
5. Department of Health and Social Care. *Prime Minister's Challenge on Dementia 2020*. London: Department of Health and Social Care; 2015.
6. Alzheimer's Society, Saga Home Care. *Are You Worried About Dementia?* YouGov; 2012. URL: https://yougov.co.uk/news/2012/05/22/are-you-worried-about-dementia/ (accessed 8 August 2017).
7. Kitwood T. *On Being a Person. Dementia Reconsidered: The Person Comes First*. London: Open University Press; 1997.
8. Scottish Human Rights Commission. *Human Rights in a Health Care Setting: Making it Work – An Evaluation of a Human Rights-based Approach at The State Hospital*. Glasgow: Scottish Human Rights Commission; 2009. URL: http://hub.careinspectorate.com/media/108573/shrc-human-rights-in-a-healthcare-setting.pdf (accessed 8 August 2017).
9. Robinson L, Hutchings D, Corner L, Finch T, Hughes J, Brittain K, *et al.* Balancing rights and risks: conflicting perspectives in the management of wandering in dementia. *Health Risk Soc* 2007;**9**(Suppl. 4):389–406. https://doi.org/10.1080/13698570701612774
10. Great Britain. *Human Rights Act 1998*. London: The Stationery Office; 1998. URL: www.legislation.gov.uk/ukpga/1998/42/contents (accessed 8 August 2017).
11. UN General Assembly. *Universal Declaration of Human Rights*. 1948. URL: www.refworld.org/docid/3ae6b3712c.html (accessed 8 August 2017).
12. Council of Europe. *European Convention on Human Rights*. Strasbourg: Council of Europe; 2010. URL: www.echr.coe.int/Documents/Convention_ENG.pdf (accessed 15 August 2017).
13. Curtice MJ, Exworthy T. FREDA: a human rights-based approach to healthcare. *BJPsych Bull* 2010;**34**(Suppl. 4):150–6. https://doi.org/10.1192/pb.bp.108.024083
14. Eleanor Roosevelt. *'The Great Question': Remarks Delivered at the United Nations in New York, March 27 1958*. New York, NY: United Nations; 1958.
15. Nyamu-Musembi C, Cornwall A. *What is the 'Rights Based Approach' All About? Perspectives from International Development Agencies*. Brighton: Institute of Development Studies; 2004.
16. Equality and Human Rights Commission. *Close to Home: An Inquiry into Older People and Human Rights in Home Care*. 2011. URL: www.equalityhumanrights.com/sites/default/files/close_to_home.pdf (accessed 15 August 2017).
17. Department of Health and Social Care. *Transforming Care: A National Response to Winterbourne View Hospital*. London: The Stationery Office; 2012. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/213215/final-report.pdf (accessed 15 August 2017).
18. Department of Health and Social Care. *The NHS Constitution for England*. London: Department of Health and Social Care; 2012.

19. Kinderman P. *A Human Rights Commission Structure, Functions and Powers (Consultation; Joint House of Commons House of Lords Committee on Human Rights*). Leicester: British Psychological Society; 2004.
20. Roberts A, Townsend S, Morris J, Rushbrooke E, Greenhill B, Whitehead R, *et al.* Treat me right, treat me equal: using national policy and legislation to create positive changes in local health services for people with intellectual disabilities. *J Appl Res Intellect* 2013;**26**:14–25. https://doi.org/10.1111/jar.12009
21. Department of Health and Social Care. *Human Rights in Healthcare*. London: The Stationery Office; 2008. URL: www.humanrightsinhealthcare.nhs.uk/ (accessed 15 August 2017).
22. Casali GL, Day GE. Treating an unhealthy organisational culture: the implications of the Bundaberg Hospital Inquiry for managerial ethical decision making. *Aust Health Rev* 2010;**34**:73–9. https://doi.org/10.1071/AH09543
23. Great Britain. *Mental Health Act*. London: The Stationery Office; 1983.
24. Great Britain. *Mental Capacity Act*. London: The Stationery Office; 2005. URL: www.legislation.gov.uk/ukpga/2005/9/contents (accessed 15 August 2017).
25. Guleria R, Curtice M. *Dementia, Rights, and the Social Model of Disability*. London: Royal College of Psychiatrists; 2016. URL: www.rcpsych.ac.uk/workinpsychiatry/faculties/oldage/aboutthefaculty/newsletters/enewsletterjanuary2016/dementiaandrights.aspx (accessed 15 August 2017).
26. Mental Health Foundation. *Dementia, Rights, and the Social Model of Disability*. London: Mental Health Foundation; 2015. URL: www.mentalhealth.org.uk/publications/dementia-rights-and-social-model-disability (accessed 15 August 2017).
27. United Nations. *Convention on the Rights of Persons with Disabilities*. United Nations; 2006. URL: www.un.org/disabilities/documents/convention/convoptprot-e.pdf (accessed 15 August 2017).
28. Office for Disability Issues. *UN Convention on the Rights of Persons with Disabilities: Initial Report on How the UK is Implementing it*. London: Office for Disability Issues; 2011. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/345120/uk-initial-report.pdf (accessed 15 August 2017).
29. The Alzheimer Society of Ireland. *A Charter of Rights for People with Dementia*. Dublin: The Alzheimer Society of Ireland; 2016. URL: www.alzheimer.ie/getattachment/About-Us/Policy/Human-Rights/A-Charter-of-Rights-for-People-with-Dementia/Charter-of-Rights-for-People-with-Dementia.pdf.aspx (accessed 15 August 2017).
30. Alzheimer Scotland. *Charter of Rights for People with Dementia and their Carers in Scotland*. Edinburgh: Alzheimer Scotland; 2009. URL: www.alzscot.org/assets/0000/2678/Charter_of_Rights.pdf (accessed 15 August 2017).
31. Laird S. Projects put human rights at the heart of good practice: service providers adopting a rights-based approach to care are seeing a change in culture. *Nursing Older People* 2010;**22**(Suppl. 3):6–7. https://doi.org/10.7748/nop.22.3.6.s10
32. World Health Organization. *Ensuring a Human Rights Based Approach for People Living with Dementia*. Geneva: World Health Organization; 2015. URL: www.ohchr.org/Documents/Issues/OlderPersons/Dementia/ThematicBrief.pdf (accessed 15 August 2017).
33. Innes A, Kelly F, Dincarslan O. Care home design for people with dementia: what do people with dementia and their family carers value? *Aging Ment Health* 2011;**15**:548–56. https://doi.org/10.1080/13607863.2011.556601

34. Dementia Alliance International. *The Human Rights of People Living with Dementia: From Rhetoric to Reality*. Ankeny, IA: Dementia Alliance International; 2016. URL: www.dementiaallianceinternational.org/wp-content/uploads/2016/04/The-Human-Rights-of-People-Living-with-Dementia-from-Rhetoric-to-Reality.pdf (accessed 15 August 2017).

35. Hare P. *Our Dementia: Our Rights*. 2016. URL: http://dementiawithoutwalls.org.uk/wp-content/uploads/2016/10/Our-dementia-Our-rights-booklet.pdf (accessed 15 August 2017).

36. O'Connor D, Phinney A, Smith A, Small J, Purves B, Perry J, *et al.* Personhood in dementia care: developing a research agenda for broadening the vision. *Dementia* 2007;**6**(Suppl. 1):121–42. https://doi.org/10.1177/1471301207075648

37. Butchard S, Greenhill B. Giving clinical psychology a backbone. *Clin Psychol Forum* 2015;**276**:16.

38. Tibbits F. Understanding what we do: emerging models for human rights education. *Int Rev Educ* 2002;**48**:159–171. https://doi.org/10.1023/A:1020338300881

39. Redman M, Taylor E, Furlong R, Carney G, Greenhill B. Human rights training: impact on attitudes and knowledge. *Tizard Learning Disability Review* 2012;**17**(Suppl. 2):80–7. https://doi.org/10.1108/13595471211218811

40. Donald A. *A Guide to Evaluating Human Rights-Based Interventions in Health and Social Care*. London: Human Rights and Social Justice Research Institute, Metropolitan University. URL: www.humanrightsinhealthcare.nhs.uk/Library/a-z/HUMAN%20RIGHTS%20IN%20HEALTHCARE%20EVALUATION%20GUIDE%20ALICE%20DONALD%20NOVEMBER%20EVENT.pdf (accessed 15 August 2017).

41. Francis R. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*. London: The Stationery Office; 2013. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/279124/0947.pdf (accessed 15 August 2017).

42. Nursing Times. *CQC Uncovers Staffing Problems at Care Homes Rated 'Inadequate'*. Nursing Times; 2016. URL: www.nursingtimes.net/news/reviews-and-reports/cqc-uncovers-staffing-issues-at-inadequate-care-homes/7009773.article (accessed 15 August 2017).

43. Comte-Sponville A. *A Short Treatise On Great Virtues: The Uses of Philosophy in Everyday Life*. London: William Heinemann; 2000.

44. McCrae N. Person-centred care: rhetoric and reality in a public healthcare system. *Br J Nurs* 2017;**22**(Suppl. 9):1125–8. https://doi.org/10.12968/bjon.2013.22.19.1125

45. Buber M, Smith RG. *I and Thou*. Edinburgh: T & T Clark; 1937.

46. Mathers N, Paynton D. Rhetoric and reality in person-centred care: introducing the House of Care framework. *Br J Gen Pract* 2016;**66**:12–13. https://doi.org/10.3399/bjgp16X683077

47. Mansell J, Beadle-Brown J. Person centred planning or person centred action? Policy and practice in intellectual disability services. *J Appl Res Intellect* 2004;**17**: 1–9. https://doi.org/10.1111/j.1468-3148.2004.00175.x

48. Community Care. *Poor Training of Care Home Staff Leaving Residents at Risk, Investigation Finds*. London: Community Care; 2015. URL: www.communitycare.co.uk/2015/10/28/training-deficit-among-care-home-staff-leaving-residents-risk-investigation-finds/ (accessed 15 August 2017).

49. NHS England. *NHS England Dementia: Good Care Planning – Information for Primary Care Providers and Commissioners*. Leeds: NHS England; 2017. URL: www.england.nhs.uk/wp-content/uploads/2017/02/dementia-good-care-planning.pdf (accessed 15 August 2017).

50. National Institute for Health and Care Excellence. *Dementia Support in Health and Social Care*. London: NICE; 2010. URL: www.nice.org.uk/guidance/QS1 (accessed 15 August 2017).

51. Langdon J, Lindow V. *Living with Risk. Mental Health Service User Involvement in Risk Assessment and Management*. Bristol: Policy Press; 2004.
52. Gould D. *Service Users' Experiences of Recovery Under the 2008 Care Programme Approach: A Research Study*. London: National Survivor User Network; 2012. URL: www.nsun.org.uk/Handlers/Download.ashx?IDMF=7d8e0ca0-98fe-432c-bb65-a7b02ed5b39b (accessed 23 January 2018).
53. May H, Edwards P, Brooker D. *Enriched Care Planning for People with Dementia: A Good Practice Guide to Delivering Person-centred Care*. London: Jessica Kingsley Publishers; 2009.
54. Zarit S, Goodman C. Decision making and dementia. *Am J Alzheimers Dis* 1990;**5**(Suppl. 5):22–8. https://doi.org/10.1177/153331759000500508
55. Local Government Association, NHS Confederation, Age UK. *Delivering Dignity: Securing Dignity in Care for Older People in Hospitals and Care Homes. A Report for Consultation*. The Commission on Dignity in Care; 2012. URL: www.ageuk.org.uk/Global/Delivering%20Dignity%20Report.pdf?dtrk=true (accessed 15 August 2017).
56. Butchard S, Pendleton J. *Getting it Right: A Human Rights Based Assessment for People with Dementia*. Liverpool: Mersey Care NHS Foundation Trust; 2012. URL: www.humanrightsinhealthcare.nhs.uk/Library/a-z/Human%20Rights%20in%20Healthcare%20Report.pdf (accessed 15 August 2017).
57. Logsdon RG, Gibbons LE, McCurry SM, Teri L. Quality of life in Alzheimer's disease: patient and caregiver reports. *J Ment Health Aging* 1999;**5**:21–32. https://doi.org/10.1186/1477-7525-1-11
58. Tennant R, Hiller L, Fishwick R, Platt S, Joseph S, Weich S, *et al.* The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007;**5**:63. https://doi.org/10.1186/1477-7525-5-63
59. Zarit SH, Reever KE, Bach-Peterson J. Relatives of the impaired elderly: correlates of feelings of burden. *Gerontologist* 1980;**20**:649–55. https://doi.org/10.1093/geront/20.6.649
60. Department of Health and Social Care. *Dementia: A State of the Nation Report on Dementia Care and Support in England*. London: Department of Health and Social Care; 2013. URL: www.gov.uk/government/uploads/system/uploads/attachment_data/file/262139/Dementia.pdf (accessed 15 August 2017).
61. West Lancashire Clinical Commissioning Group. *More Community Services for West Lancashire Dementia Patients*. Ormskirk: West Lancashire Clinical Commissioning Group; 2013. URL: www.westlancashireccg.nhs.uk/more-community-services-for-west-lancashire-dementia-patients-85831/ (accessed 15 August 2017).
62. Selwood A, Thorgrimsen L, Orrell M. Quality of life in dementia – a one-year follow-up study. *Int J Geriatr Psychiatry* 2005;**20**:232–7. https://doi.org/10.1002/gps.1271
63. Woods RT, Bruce E, Edwards RT, Elvish R, Hoare Z, Hounsome B, *et al.* REMCARE: reminiscence groups for people with dementia and their family caregivers – effectiveness and cost-effectiveness pragmatic multicentre randomised trial. *Health Technol Assess* 2012;**16**(48). https://doi.org/10.3310/hta16480
64. Hoe J, Hancock G, Livingston G, Woods B, Challis D, Orrell M. Changes in the quality of life of people with dementia living in care homes. *Alzheimer Dis Assoc Disord* 2009;**23**:285–90. https://doi.org/10.1097/WAD.0b013e318194fc1e
65. Russell D, Hoare ZS, Whitaker R, Whitaker CJ, Russell IT. Generalized method for adaptive randomization in clinical trials. *Stat Med* 2011;**30**:922–34. https://doi.org/10.1002/sim.4175

66. Moniz-Cook E, Vernooij-Dassen M, Woods R, Verhey F, Chattat R, Vugt MD, *et al.* A European consensus on outcome measures for psychosocial intervention research in dementia care. *Aging Ment Health* 2008;**12**(Suppl. 1):14–29. https://doi.org/10.1080/13607860801919850

67. Miller LA, Mioshi E, Savage S, Lah S, Hodges JR, Piguet O. Identifying cognitive and demographic variables that contribute to carer burden in dementia. *Dement Geriatr Cogn Disord* 2013;**36**:43–9. https://doi.org/10.1159/000347146

68. Brooker D, Surr C. *Dementia Care Mapping: Principles and Practice*. Bradford: Bradford Dementia Group, University of Bradford; 2005.

69. Netten A, Burge P, Malley J, Potoglou D, Towers A, Brazier J, *et al.* Outcomes of social care for adults: developing a preference-weighted measure. *Health Technol Assess* 2012;**16**:1–165. https://doi.org/10.3310/hta16160

70. Curtice M. Article 8 of the Human Rights Act 1998: implications for clinical practice. *Adv Psychiatr Treat* 2009;**15**(Suppl. 1):23–31. https://doi.org/10.1192/apt.bp.107.005462

71. Allen K. Drawing out views on services: ways of getting started. *J Dement Care* 2001;**9**:23–5.

72. Medical Research Council. *Health Services and Public Health Research Board. A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. London: Medical Research Council; 2000.

73. Hounsome N, Orrell M, Edwards RT. EQ-5D as a quality of life measure in people with dementia and their carers: evidence and key issues. *Value Health* 2011;**14**:390–9. https://doi.org/10.1016/j.jval.2010.08.002

74. Edwards RT, Hounsome B, Linck P, Russell IT. Economic evaluation alongside pragmatic randomised trials: developing a standard operating procedure for clinical trials units. *Trials* 2008;**9**:64. https://doi.org/10.1186/1745-6215-9-64

75. Glick HA, Doshi JA, Sonnad SS, Polsky D. *Economic Evaluation in Clinical Trials*. Oxford: Oxford University Press; 2014. https://doi.org/10.1093/med/9780199685028.001.0001

76. Drummond MF, Sculpher MJ, Claxton K, Stoddart GL, Torrance GW. *Methods for the Economic Evaluation of Health Care Programmes*. Oxford: Oxford University Press; 2005.

77. Brazier J. *Measuring and Valuing Health Benefits for Economic Evaluation*. Oxford: Oxford University Press; 2007.

78. Gold MR, Siegel JE, Russell LB, Weinstein MC, editors. *Cost-Effectiveness in Health and Medicine*. New York, NY: Oxford University Press; 1996.

79. Medical Research Council. *A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health*. London: Medical Research Council; 2008.

80. Curtis L, Burns A. *Unit Costs of Health and Social Care 2015*. Canterbury: Personal Social Services Research Unit, University of Kent; 2015.

81. Department of Health and Social Care. *NHS Reference Costs*. London: Department of Health and Social Care; 2015. URL: www.gov.uk/government/collections/nhs-reference-costs (accessed 15 August 2017).

82. School of Dementia Studies. *DCM8 User's Manual*. Bradford: School of Dementia Studies, University of Bradford; 2016.

83. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;**3**(Suppl. 2):77–101. https://doi.org/10.1191/1478088706qp063oa

84. Boyatzis RE. *Transforming Qualitative Information: Thematic Analysis and Code Development*. Thousand Oaks, CA: Sage; 1998.

85. Thomas DR. A general inductive approach for analyzing qualitative evaluation data. *Am J Eval* 2006;**27**(Suppl. 2):237–46. https://doi.org/10.1177/1098214005283748

86. Patton MQ. *Qualitative Evaluation and Research Methods*. 2nd edn. Thousand Oaks, CA: Sage; 1990.

87. Bass BM, Avolio BJ. *Full Range Leadership Development – Manual for the Multifactor Leadership Questionnaire*. Redwood City, CA: Mind Garden; 1997.

88. NHS Digital. *Prescription Cost Analysis, England 2015*. URL: https://digital.nhs.uk/catalogue/PUB20200 (accessed 22 January 2018).

89. Bass BM, Avolio BJ. *MLQ: Multifactor Leadership Questionnaire*. Menlo Park, CA: Mind Garden; 2000.

90. Bass BM. *Transformational Leadership: Industrial, Military, and Educational Impact*. Mahwah, NJ: Erlbaum; 1998.

91. Brooker D, Latham I. *Person-centred Dementia Care: Making Services Better with the VIPS Framework*. 2nd edn. London: Jessica Kingsley Publishers; 2016.

92. Department of Health and Social Care. *The Use of Antipsychotic Medication for People with Dementia: Time for Action*. London; Department of Health and Social Care: 2009. URL: www.gov.uk/drug-safety-update/antipsychotics-initiative-to-reduce-prescribing-to-older-people-with-dementia (accessed 15 August 2017).

93. Care Quality Commission. *Mersey Care NHS Foundation Trust CQC Inspection Report*. Newcastle upon Tyne: CQC; 2015. URL: www.cqc.org.uk/provider/RW4 (accessed 15 August 2017).

94. Rand S, Caiels J. *Using Proxies to Assess Quality of Life: A Review of the Issues and Challenges*. Canterbury: Quality and Outcome of Person-centred Care Policy Research Unit; 2015. URL: www.researchgate.net/publication/301356929 (accessed 15 August 2017).

95. Novella JL, Jochum C, Jolly D, Morrone I, Ankri J, Bureau F, Blanchard F. Agreement between patients' and proxies' reports of quality of life in Alzheimer's disease. *Qual Life Res* 2001;**10**:443–52. https://doi.org/10.1023/A:1012522013817

96. Hoe J, Hancock G, Livingston G, Orrell M. Quality of life of people with dementia in residential care homes. *Br J Psychiatry* 2006;**188**:460–4. https://doi.org/10.1192/bjp.bp.104.007658

97. Camozzato A, Roriz-Filho JS, Cruz IR, Chaves MLF, Roriz-Cruz M. Interactions Between Dementia and Depression: Causes, Consequences, and Common Mechanisms. In Abdel-Rahman E, editor. *Depression in the Elderly*. Hauppauge, NY: Nova Science Publishers; 2012. pp. 141–158.

98. Pickard AS, Knight SJ. Proxy evaluation of health-related quality of life: a conceptual framework for understanding multiple proxy perspectives. *Med Care* 2005;**43**(Suppl. 5):493–9. https://doi.org/10.1097/01.mlr.0000160419.27642.a8

99. Huang HL, Chang MY, Tang JS, Chiu YC, Weng LC. Determinants of the discrepancy in patient- and caregiver-rated quality of life for persons with dementia. *J Clin Nurs* 2009;**18**:3107–18. https://doi.org/10.1111/j.1365-2702.2008.02537.x

100. Thorgrimsen L, Selwood A, Spector A, Royan L, de Madariaga Lopez M, Woods RT, Orrell M. Whose quality of life is it anyway? The validity and reliability of the Quality of Life-Alzheimer's Disease (QoL-AD) scale. *Alzheimer Dis Assoc Disord* 2003;**17**:201–8. https://doi.org/10.1097/00002093-200310000-00002

101. Mozley CG, Huxley P, Sutcliffe C, Bagley H, Burns A, Challis D, Cordingley L. 'Not knowing where I am doesn't mean I don't know what I like': cognitive impairment and quality of life responses in elderly people. *Int J Geriatr Psychiatry* 1999;**14**:776–83. https://doi.org/10.1002/(SICI)1099-1166(199909)14:9<776::AID-GPS13>3.0.CO;2-C

102. Mahan TL. *Perceived Control in Older Adults Living in Long-term Care Facilities. Dissertation Abstracts International: Section B: The Sciences and Engineering*. 2010;**66**:1784.

103. Wang P, Yap P, Koh G, Chong JA, Davies LJ, Dalakoti M, *et al.* Quality of life and related factors of nursing home residents in Singapore. *Health Qual Life Out* 2016;**14**:112. https://doi.org/10.1186/s12955-016-0503-x

104. Fossey J, Lee L, Ballard C. Dementia Care Mapping as a research tool for measuring quality of life in care settings: psychometric properties. *Int J Geriatr Psychiatry* 2002;**17**:1064–70. https://doi.org/10.1002/gps.708

105. Bradford Dementia Group. *Dementia Care Mapping Process and Application*. Bradford: Bradford Dementia Group; 2014.

106. Royal College of Nursing. *Persistent Challenges to Providing Quality Care: An RCN Report on the Views and Experiences of Frontline Nursing Staff in Care Homes in England*. London: Royal College of Nursing; 2012. URL: https://my.rcn.org.uk/__data/assets/pdf_file/0007/438667/Persistent_challenges_to_providing_quality_care_v5.pdf (accessed 15 August 2017).

107. Surr CA, Smith SJ, Crossland J, Robins J. Impact of a person-centred dementia care training programme on hospital staff attitudes, role efficacy and perceptions of caring for people with dementia: a repeated measures study. *Int J Nurs Stud* 2016;**53**:144–151. https://doi.org/10.1016/j.ijnurstu.2015.09.009

108. INVOLVE. *What is Public Involvement in Research?* 2012. URL: www.hra.nhs.uk/resources/public-involvement-research/ (accessed 15 August 2017).

109. Swain J, Heyman B, Gillman M. Public research, private concerns: ethical issues in the use of open-ended interviews with people who have learning difficulties. *Disabil Soc* 1998;**13**(Suppl. 1):21–36. https://doi.org/10.1080/09687599826894

110. INVOLVE. *Briefing Notes for Researchers: Involving the Public in NHS, Public Health and Social Care Research*. Eastleigh: INVOLVE; 2012. URL: www.invo.org.uk/wp-content/uploads/2014/11/9938_INVOLVE_Briefing_Notes_WEB.pdf (accessed 15 August 2017).

111. Tarpey M, Bite S. *Public Involvement in Research Applications to the National Research Ethics Service: Comparative Analysis of 2010 and 2012 Data*. Eastleigh: INVOLVE; 2014. URL: www.hra.nhs.uk/documents/2015/02/involve_nres_report_2014.pdf (accessed 15 August 2017).

112. Gove D, Diaz-Ponce A, Georges J, Moniz-Cook E, Mountain G, Chattat R, Øksnebjerg L, European Working Group of People with Dementia. Alzheimer Europe's position on involving people with dementia in research through PPI (patient and public involvement). *Aging Ment Health* 2017;**17**:1–7. https://doi.org/10.1080/13607863.2017.1317334.

113. Alexander CS, Becker HJ. The use of vignettes in survey research. *Public Opin Quart* 1978;**42**:93–104. https://doi.org/10.1086/268432

114. Finger MS, Rand KL. Addressing Validity Concerns in Clinical Psychology Research. In Roberts MC, Ilardi SS, editors. *Handbook of Research Methods in Clinical Psychology*. Malden, MA; Blackwell Publishing: 2005. pp. 13–30.

115. Wallander L. Measuring social workers' judgments: why and how to use the factorial survey approach in the study of professional judgments. *J Soc Work* 2012;**12**:364–84. https://doi.org/10.1177/1468017310387463

116. Evans SC, Roberts MC, Keeley JW, Blossom JB, Amaro CM, Garcia AM, *et al.* Vignette methodologies for studying clinicians' decision-making: validity, utility, and application in ICD-11 field studies. *Int J Clin Health Psych* 2015;**15**:160–70. https://doi.org/10.1016/j.ijchp.2014.12.001

117. James IA. *Understanding Behaviour in Dementia that Challenges: A Guide to Assessment and Treatment*. London: Jessica Kingsley Publishers; 2011.

118. Royal College of Psychiatrists. *Standards for Acute Inpatient Services for Older People – 3rd Edition*. London: Royal College of Psychiatrists; 2014. URL: www.rcpsych.ac.uk/pdf/AIMS-OP%20Standards%203rd%20Edt.pdf (accessed 23 January 2018).

119. Cohen-Mansfield J, Buckwalter K, Beattie E, Rose K, Neville C, Kolanowski A. Expanded review criteria: the case of nonpharmacological interventions in dementia. *J Alzheimers Dis* 2014;**41**:15–28. https://doi.org/10.3233/JAD-132357

120. Rosen WF, Mohs RC, Davis KL. A new rating scale for Alzheimer's disease. *Am J Psychiatry* 1984;**141**:1356–64. https://doi.org/10.1176/ajp.141.11.1356

121. Nursing Times. *Concerns Over High Staff Turnover in Care Homes*. URL: www.nursingtimes.net/concerns-over-high-staff-turnover-in-care-homes/1806216.fullarticle (accessed 15 August 2017).

122. Franklin B. *The Future Care Workforce*. 2014. URL: www.ilcuk.org.uk/images/uploads/publication-pdfs/Future_Care_Workforce_Report.pdf (accessed 15 August 2017).

123. Care Quality Commission. *The State of Health Care and Adult Social Care in England in 2013/14*. Newcastle upon Tyne: CQC; 2013. URL: www.cqc.org.uk/sites/default/files/state-of-care-201314-full-report-1.1.pdf (accessed 15 August 2017).

124. Redlanders in Service. *Visiting the Lonely Ones Makes Rounds of Nursing Homes*. URL: www.redlandsdailyfacts.com/general-news/20130801/redlanders-in-service-visiting-the-lonely-ones-makes-rounds-of-nursing-homes (accessed 15 August 2017).

125. Molyneaux V, Butchard S, Simpson J, Murray C. The co-construction of couplehood in dementia. *Dementia* 2012;**11**(Suppl. 4):483–502. https://doi.org/10.1177/1471301211421070

126. Ajzen I. From Intentions to Actions: A Theory of Planned Behavior. In Kuhl J, Beckmann J, editors. *Action Control: From Cognition to Behavior*. Berlin: Springer-Verlag; 1985. pp. 11–39. https://doi.org/10.1007/978-3-642-69746-3_2

127. Sheard D. *Steering Cultural Change Matters in Dementia Care Homes: Commissioning Briefing Booklet*. Brighton: Dementia Care Matters; 2013.

128. Sheard D. Bringing relationships into the heart of dementia care. *J Dement Care* 2004;**12**:22–4.

129. Joseph Rowntree Foundation. *Improving Care in Residential Care Homes: A Literature Review*. York: Joseph Rowntree Foundation; 2008. URL: www.jrf.org.uk/report/improving-care-residential-care-homes-literature-review (accessed 15 August 2017).

130. Health Education England. *Values Based Recruitment Framework*. Leeds: Health Education England; 2016. URL: www.hee.nhs.uk/sites/default/files/documents/VBR_Framework%20March%202016.pdf (accessed 15 August 2017).

131. Sehein EH. *Organizational Culture and Leadership: A Dynamic View*. San Francisco, CA: Jossey-Bass; 1985.

132. UNISON. *Residential Care Worker Survey and Residential Care Charter Executive Summary*. 2017. URL: www.unison.org.uk/content/uploads/2017/06/residential-care-summary.pdf (accessed 15 August 2017).

133. Killett A, Bowes A, Brooker D, Burns D, Kelly F, La Fontaine J, *et al. What Makes a Real Difference to Resident Experience? Digging Deep into Care Home Culture: The CHOICE (Care Home Organisations Implementing Cultures of Excellence) Research Report*. Cambridge: Cambridge University Press; 2013. URL: www.worcester.ac.uk/documents/CHOICE_final_report.pdf (accessed 15 August 2017).

134. Donald A, Watson J, McClean N, Leach P, Eschment J. *Human Rights in Britain Since the Human Rights Act 1998: A Critical Review*. Manchester: Equality and Human Rights Commission; 2009. URL: www.equalityhumanrights.com/en/publication-download/research-report-28-human-rights-britain-human-rights-act-1998-critical-review (accessed 23 January 2018).

135. Kinderman P, Butler F. *Implementing a Human Rights Approach Within Public Services: An Outline Psychological Perspective*. London: Department for Constitutional Affairs; 2006. URL: www.researchgate.net/publication/255579672_Implementing_a_Human_Rights_Approach_within_Public_Services_An_Outline_Psychological_Perspective (accessed on 8 February 2018).

136. Matthews L, Sanz R. *Older People and Human Rights*. London: Age UK/British Institute of Human Rights; 2011. URL: www.ageuk.org.uk/Documents/EN-GB/For-professionals/Equality-and-human-rights/Older_People_Human_Rights__Expert_series_pro.pdf?dtrk=true (accessed 15 August 2017).

137. All-Party Parliamentary Group on Dementia. *Prepared to Care. Challenging the Dementia Skills Gap*. London: The Stationery Office; 2009. URL: www.alzheimers.org.uk/download/downloads/id/735/appg_report_prepared_to_care.pdf (accessed 15 August 2017).

138. Health Education England. *Dementia Core Skills Education and Training Framework*. Leeds: Health Education England; 2015. URL: www.skillsforhealth.org.uk/images/projects/dementia/Dementia%20Core%20Skills%20Education%20and%20Training%20Framework.pdf (accessed 15 August 2017).

139. Surr C, Gates C, Irving D. *What Works in Dementia Training and Education? A Critical Interpretive Synthesis of the Evidence*. Leeds: Leeds Beckett University; 2017. URL: www.heacademy.ac.uk/system/files/downloads/surr_what_works_in_dementia_training.pdf (accessed 15 August 2017).

140. Kirkpatrick DL. *Evaluating Training Programs: The Four Levels*. San Francisco, CA: Berrett-Koehler; 1984.

141. James I. *Understanding Behaviour in Dementia That Challenges: A Guide to Assessment and Treatment (Bradford Dementia Group Good Practice Guides)*. London: Jessica Kingsley Publishers; 2011.

142. Caddell LS, Clare L. The impact of dementia on self and identity: a systematic review. *Clin Psychol Rev* 2010;**30**:113–26. https://doi.org/10.1016/j.cpr.2009.10.003

143. Sabat SR, Harre R. The construction and deconstruction of self in Alzheimer's disease. *Ageing Soc* 1992;**12**:443–61. https://doi.org/10.1017/S0144686X00005262

144. Roberts A, Greenhill B, Talbot A. Standing up for my human rights: a group's journey beyond consultation towards co-production. *Br J Learn Dis* 2011;**40**:292–301. https://doi.org/10.1111/j.1468-3156.2011.00711.x

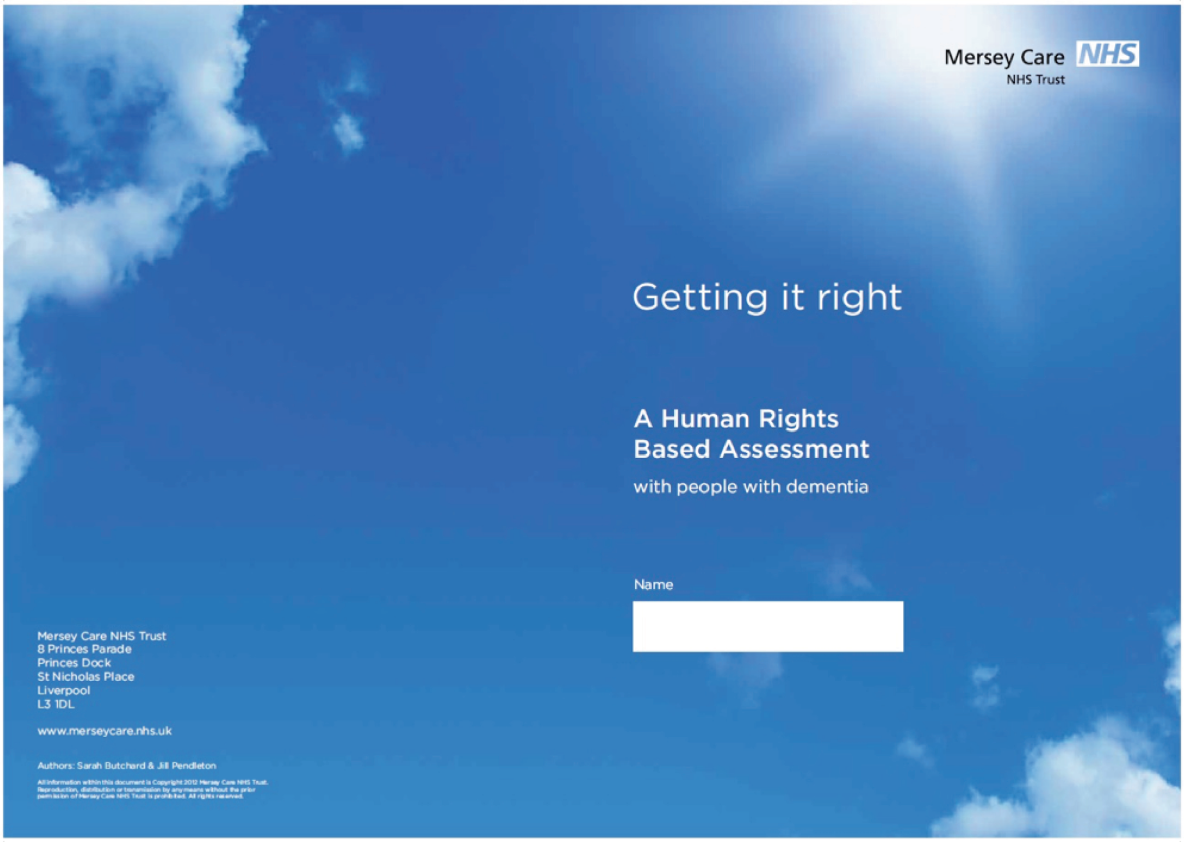
145. Dementia Engagement and Empowerment Project. *Dementia Words Matter: Guidelines on Language About Dementia*. URL: http://dementiavoices.org.uk/wp-content/uploads/2015/03/DEEP-Guide-Language.pdf (accessed 15 August 2017).

146. Health Education England. URL: https://hee.nhs.uk/ (accessed 15 August 2017).

147. Bloom BS, editor. *Taxonomy of Educational Objectives, Handbook I: The Cognitive Domain*. New York, NY: David McKay Co., Inc.; 1956.

148. The King's Fund. *Transforming the Delivery of Health and Social Care: The Case for Fundamental Change*. London: The King's Fund; 2012. URL: www.kingsfund.org.uk/sites/files/kf/field/field_publication_file/transforming-the-delivery-of-health-and-social-care-the-kings-fund-sep-2012.pdf (accessed 15 August 2017).
149. Innovations in Dementia. *Making an Impact Together*. 2015. URL: https://dementiawithoutwalls.org.uk/wp-content/uploads/2016/10/Making-An-Impact-Together.pdf (accessed 15 August 2017).
150. Curtis L. *Unit Costs of Health and Social Care 2015*. Canterbury: Personal Social Services Research Unit, University of Kent; 2015.

Appendix 1 'Getting it Right' assessment tool



Mersey Care NHS Trust

Getting it right

A Human Rights
Based Assessment

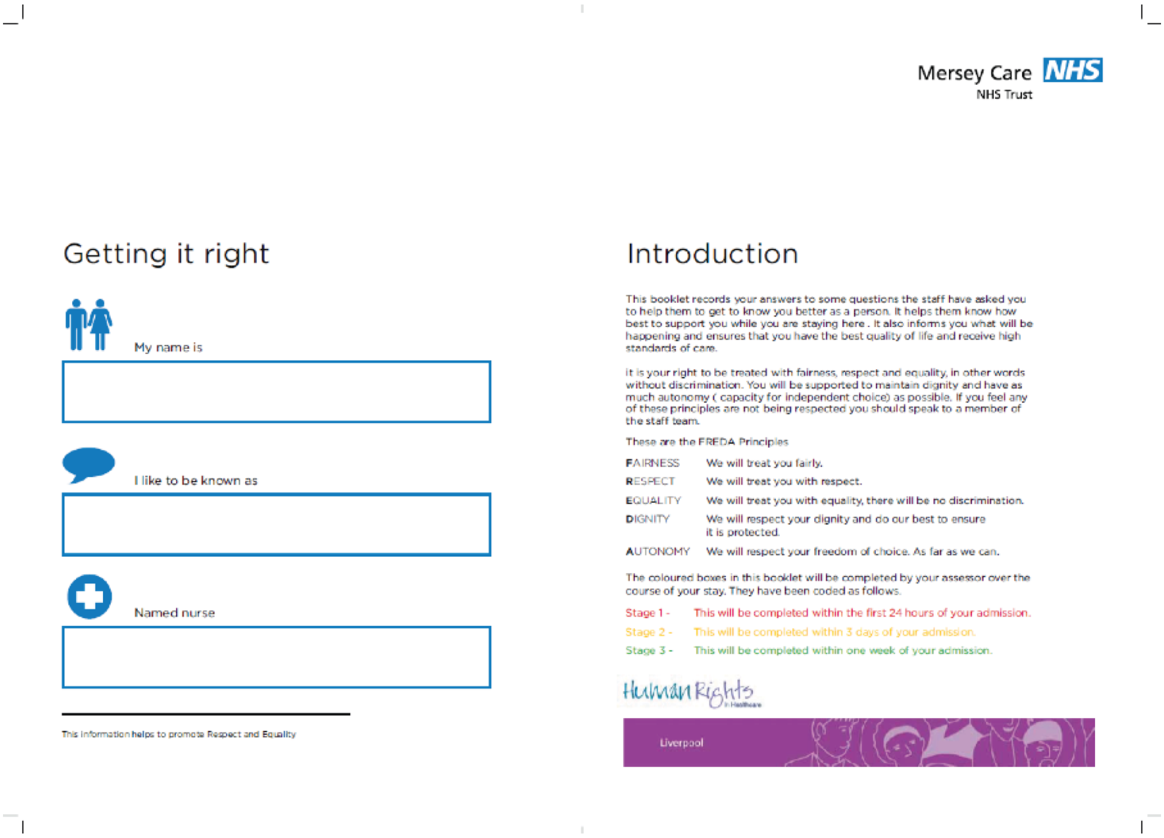
with people with dementia

Name

Mersey Care NHS Trust
8 Princes Parade
Princes Dock
St Nicholas Place
Liverpool
L3 1DL

www.merseycare.nhs.uk

Authors: Sarah Butchard & Jill Pendleton



Mersey Care NHS
NHS Trust

Getting it right

My name is

I like to be known as

Named nurse

This information helps to promote Respect and Equality

Introduction

This booklet records your answers to some questions the staff have asked you to help them to get to know you better as a person. It helps them know how best to support you while you are staying here . It also informs you what will be happening and ensures that you have the best quality of life and receive high standards of care.

It is your right to be treated with fairness, respect and equality, in other words without discrimination. You will be supported to maintain dignity and have as much autonomy (capacity for independent choice) as possible. If you feel any of these principles are not being respected you should speak to a member of the staff team.

These are the FREDA Principles

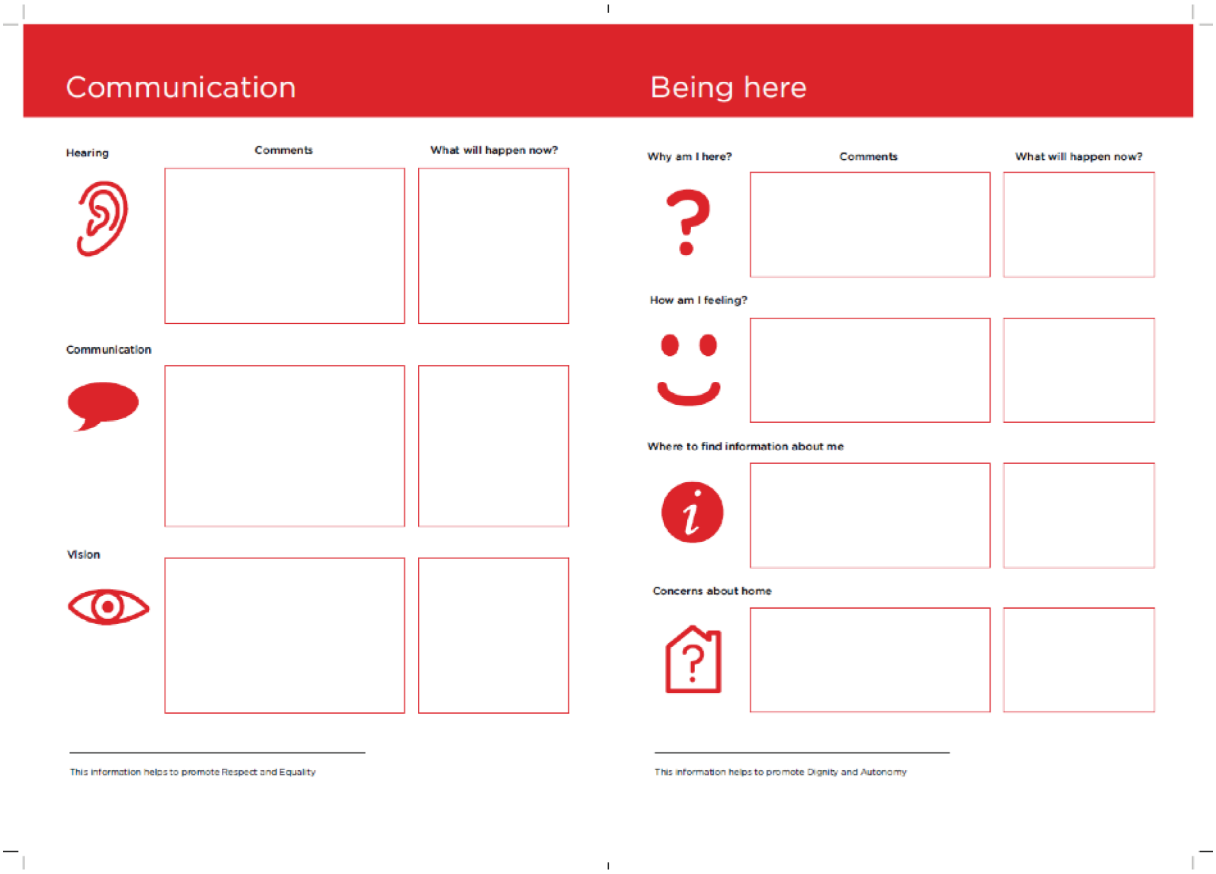
FAIRNESS	We will treat you fairly.
RESPECT	We will treat you with respect.
EQUALITY	We will treat you with equality, there will be no discrimination.
DIGNITY	We will respect your dignity and do our best to ensure it is protected.
AUTONOMY	We will respect your freedom of choice. As far as we can.

The coloured boxes in this booklet will be completed by your assessor over the course of your stay. They have been coded as follows.

Stage 1 -	This will be completed within the first 24 hours of your admission.
Stage 2 -	This will be completed within 3 days of your admission.
Stage 3 -	This will be completed within one week of your admission.

Human Rights in Healthcare

Liverpool



Communication

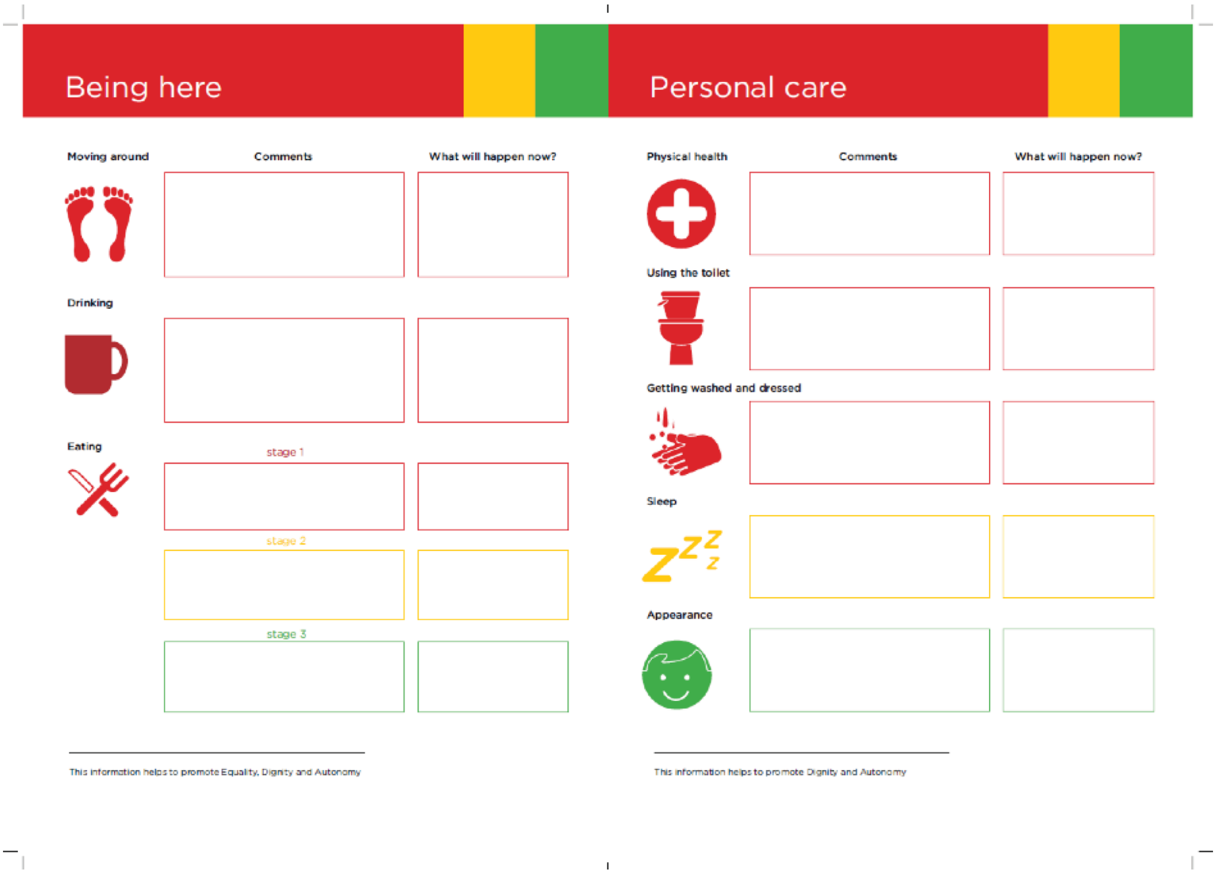
	Comments	What will happen now?
Hearing		
Communication		
Vision		

This information helps to promote Respect and Equality

Being here

	Comments	What will happen now?
Why am I here?		
How am I feeling?		
Where to find information about me		
Concerns about home		

This information helps to promote Dignity and Autonomy



Being here

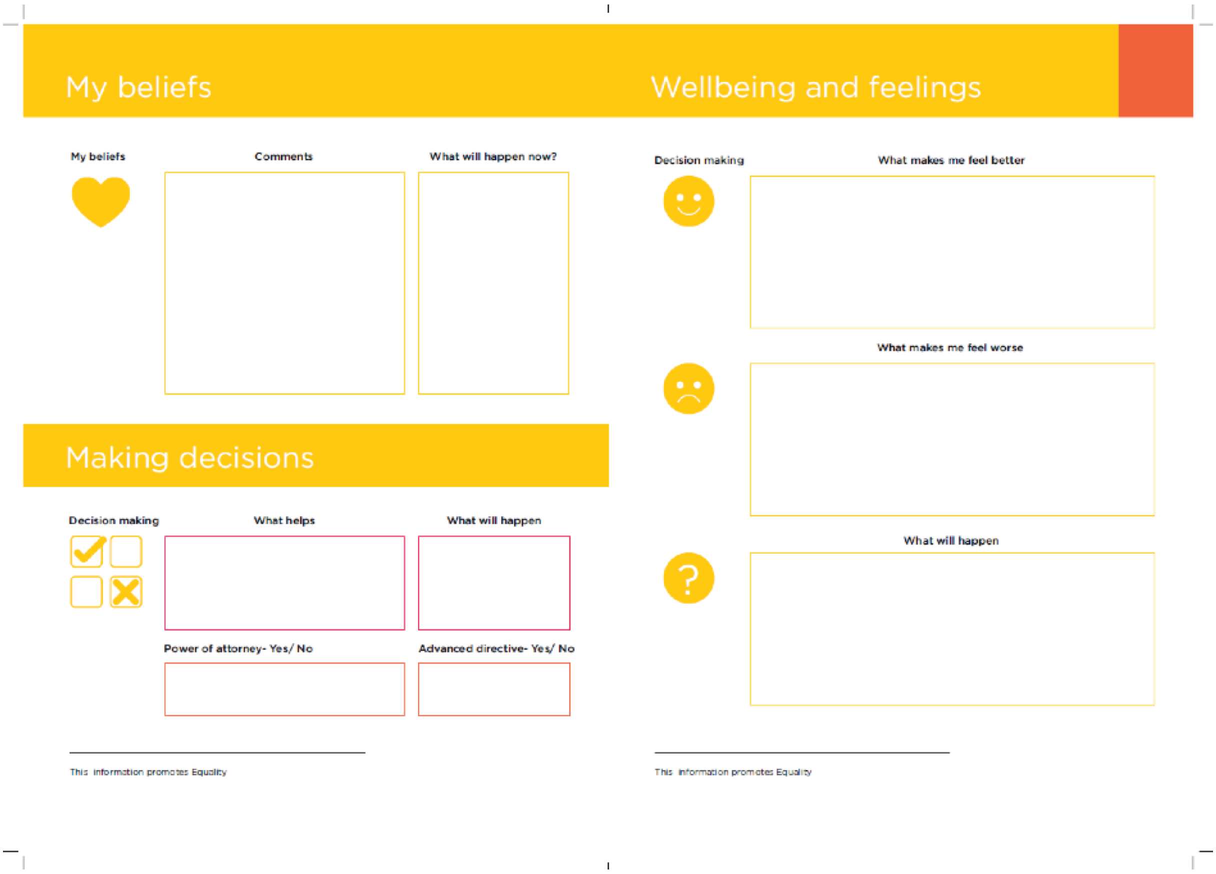
Moving around	Comments	What will happen now?
Drinking		
Eating	stage 1	
	stage 2	
	stage 3	

This information helps to promote Equality, Dignity and Autonomy

Personal care

Physical health	Comments	What will happen now?
Using the toilet		
Getting washed and dressed		
Sleep		
Appearance		

This information helps to promote Dignity and Autonomy



My beliefs

My beliefs ♥

Comments

What will happen now?

Making decisions

Decision making ☑ ☐ ☐ ☒

What helps

What will happen

Power of attorney- Yes/ No

Advanced directive- Yes/ No

This information promotes Equality

Wellbeing and feelings

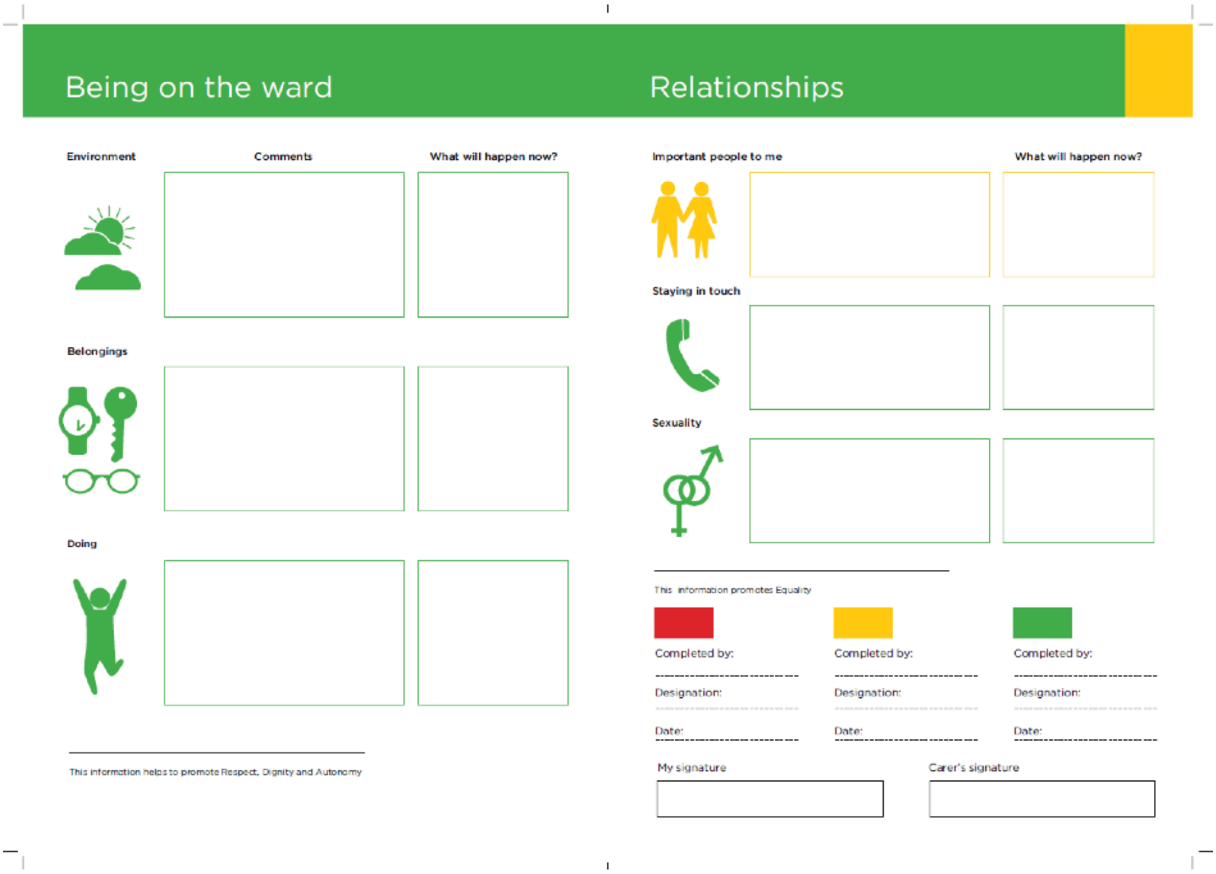
Decision making

☺ **What makes me feel better**

☹ **What makes me feel worse**

? **What will happen**

This information promotes Equality



Being on the ward

Environment	Comments	What will happen now?
Environment		
Belongings		
Doing		

This information helps to promote Respect, Dignity and Autonomy

Relationships

Important people to me		What will happen now?
Important people to me		
Staying in touch		
Sexuality		

This information promotes Equality

🟥	🟨	🟩
Completed by:	Completed by:	Completed by:
Designation:	Designation:	Designation:
Date:	Date:	Date:

My signature

Carer's signature

Appendix 2 Supplementary tables

TABLE 37 List of job roles of the staff interviewed for the study

Job title	Group, *n* (%)	
	Control	Intervention
Acting senior carer		1 (0.8)
Activities co-ordinator	2 (1.6)	
Activity co-ordinator	2 (1.6)	1 (0.8)
Apprentice clinical support worker		1 (0.8)
Assistant practitioner	2 (1.6)	
Assistant support worker	1 (0.8)	
Care assistant	18 (14.5)	27 (21.8)
Care assistant and acting senior		1 (0.8)
Care assistant/driver		1 (0.8)
Care home manager		1 (0.8)
Care worker	2 (1.6)	2 (1.6)
Carer	3 (2.4)	6 (4.8)
Clinical lead		2 (1.6)
Clinical specialist physiotherapist	1 (0.8)	
Clinical support worker		19 (15.3)
Deputy manager	2 (1.6)	
Deputy ward manager	1 (0.8)	1 (0.8)
Domestic		1 (0.8)
Gardener/domestic		1 (0.8)
General nurse	2 (1.6)	
Health-care assistant	42 (33.9)	8 (6.5)
Health-care assistant: training to be assistant practitioner	1 (0.8)	
Health-care support worker	1 (0.8)	
Housekeeper/carer	1 (0.8)	
Health support worker		1 (0.8)
Hotel services manager		1 (0.8)
Kitchen assistant	1 (0.8)	
Maintenance lead		1 (0.8)
Manager		1 (0.8)
Mental health nurse	1 (0.8)	
Nurse	6 (4.8)	3 (2.4)
Nurse practitioner		2 (1.6)
Nursing assistant	2 (1.6)	1 (0.8)
Occupational therapist		2 (1.6)

continued

TABLE 37 List of job roles of the staff interviewed for the study (*continued*)

Job title	Group, *n* (%)	
	Control	Intervention
Occupational therapist assistant	1 (0.8)	1 (0.8)
Occupational therapist assistant/care assistant	1 (0.8)	
Physical health nurse	1 (0.8)	
Physiotherapist	1 (0.8)	
Physiotherapy assistant	1 (0.8)	
Registered manager	1 (0.8)	
Registered mental health nurse	2 (1.6)	1 (0.8)
Senior care assistant	2 (1.6)	6 (4.8)
Senior carer	4 (3.2)	3 (2.4)
Senior health-care assistant	1 (0.8)	
Senior unit manager		1 (0.8)
Staff nurse	3 (2.4)	4 (3.2)
Supervised practice nurse	2 (1.6)	
Supervised practitioner nurse	1 (0.8)	
Supervisor		1 (0.8)
Support worker	8 (6.5)	13 (10.5)
Team leader	2 (1.6)	1 (0.8)
Trainee assistant practitioner	1 (0.8)	1 (0.8)
Unit manager		1 (0.8)
Unit manager/nurse		1 (0.8)
Ward manager		2 (1.6)
Total	124 (100.0)	124 (100.0)

TABLE 38 Mean values for the two treatment groups at the two assessment points for the ADAS-Cog

Assessment point	*n*	Minimum	Maximum	Mean (SD)
Group 1				
Pre	8	13.67	46.33	31.17 (10.52)
Post	1	27.33	27.33	27.33 (N/A)
Group 2				
Pre	5	16.33	44.33	29.53 (11.97)
Post	0	N/A	N/A	N/A
Total				
Pre	13	13.67	46.33	30.54 (10.63)
Post	1	27.33	27.33	27.33 (N/A)
Did not complete				
Pre	319	N/A	N/A	N/A
Post	435	N/A	N/A	N/A

N/A, not applicable.

TABLE 39 Mean values for the two treatment groups at the two assessment points for the IDEA proxy questionnaire

Assessment point	*n*	Minimum	Maximum	Mean (SD)
Group 1				
Pre	3	31.00	37.00	34.00 (3.00)
Post	N/A	N/A	N/A	N/A
Group 2				
Pre	2	29.00	33.14	31.07 (2.93)
Post	2	36.00	41.00	38.50 (3.54)
Total				
Pre	5	29.00	37.00	32.83 (3.04)
Post	2	36.00	41.00	38.50 (3.54)
Did not complete				
Pre	318	N/A	N/A	N/A
Post	421	N/A	N/A	N/A

N/A, not applicable.

TABLE 40 Mean values for the two treatment groups at the two assessment points for the WEMWBS

Assessment point	*n*	Minimum	Maximum	Mean (SD)
Group 1				
Pre	3	41.00	47.00	44.00 (3.00)
Post	0	N/A	N/A	N/A
Group 2				
Pre	3	48.00	52.00	50.33 (2.08)
Post	2	38.00	48.00	43.00 (7.07)
Total				
Pre	6	41.00	52.00	47.17 (4.17)
Post	2	38.00	48.00	43.00 (7.07)
Did not complete				
Pre	317	N/A	N/A	N/A
Post	421	N/A	N/A	N/A

N/A, not applicable.

TABLE 41 Mean values for the two treatment groups at the two assessment points for the ZBI

Assessment point	*n*	Minimum	Maximum	Mean (SD)
Group 1				
Pre	3	28.00	37.00	33.03 (4.59)
Post	0	N/A	N/A	N/A
Group 2				
Pre	3	8.38	34.00	19.71 (13.06)
Post	2	10.00	30.38	20.19 (14.41)
Total				
Pre	6	8.38	37.00	26.37 (11.40)
Post	2	10.00	30.38	20.19 (14.41)
Did not complete				
Pre	317	N/A	N/A	N/A
Post	421	N/A	N/A	N/A

N/A, not applicable.

TABLE 42 Outcome measures for all available participants at both time points

Outcome measure	*n*	Minimum	Maximum	Mean (SD)
T1 ASCOT total	85	0.22	1.0	0.86 (0.14)
T2 ASCOT total	70	0.09	1.0	0.85 (0.18)
T2 ASCOT proxy total	147	0.16	1.0	0.81 (0.17)
T2 ASCOT proxy total	176	0.2	1.0	0.81 (0.17)
T1 EQ-VAS	71	50.0	100.0	78.23 (16.77)
T2 EQ-VAS	62	0.0	100.0	74.19 (24.23)
T1 EQ-VAS proxy	202	5.0	100.0	62.71 (19.99)
T2 EQ-VAS proxy	236	10.0	100.0	60.53 (19.57)
T1 EQ-5D-3L total	101	–0.043	1.0	0.743 (0.27)
T2 EQ-5D-3L total	86	–0.077	1.0	0.714 (0.28)
T1 EQ-5D-3L proxy total	202	–0.371	1.0	0.35 (0.34)
T2 EQ-5D-3L proxy total	233	–0.536	1.0	0.381 (0.34)
T1 QOL-AD total	103	26.00	51.00	36.56 (5.46)
T2 QOL-AD total	93	22.75	45.00	35.33 (5.57)
T1 QOL-AD proxy total	183	14.08	47.67	30.89 (7.27)
T2 QOL-AD proxy total	224	13.00	46.09	31.69 (6.72)
T1 WEMWBS total	6	41.0	52.0	47.17 (4.17)
T2 WEMWBS total	2	38.0	48.0	43.00 (7.07)
T1 ZBI total	6	8.381	37.00	26.37 (11.40)
T2 ZBI total	2	10.00	30.38	20.19 (14.41)

T, time; VAS, visual analogue scale.

TABLE 43 Community and hospital services: all participants available at both time points ($n = 172$)

	Time point							
	T1				T2			
Service accessed	Minimum	Maximum	Mean	SD	Minimum	Maximum	Mean	SD
Alternative therapist	0	1	0.01	0.076	–	–	–	–
Care manager	0	2	0.01	0.152	–	–	–	–
Community nurse	0	14	0.69	1.909	0	8	0.67	1.351
CPN	0	10	0.20	0.885	0	3	0.19	0.500
Dentist	0	2	0.06	0.268	0	2	0.03	0.200
Dietician	0	2	0.17	0.447	0	3	0.18	0.515
GP	0	6	0.84	1.138	0	5	0.94	1.066
Mental health team worker	0	1	0.03	0.184	0	1	0.02	0.131
Optician	0	2	0.18	0.429	0	2	0.15	0.370
Occupational therapist	0	1	0.01	0.076	0	1	0.02	0.151
Physiotherapist	0	4	0.08	0.433	0	5	0.08	0.446
Practice nurse	0	1	0.03	0.184	0	1	0.02	0.151
Psychiatrist	0	4	0.12	0.521	0	2	0.16	0.410
Social worker	0	2	0.10	0.369	0	3	0.08	0.375
Chiropodist	0	2	0.40	0.598	0	3	0.38	0.736
A&E visits	0	23	0.23	1.800	0	29	0.57	2.940
Inpatient nights	0	35	0.42	3.074	0	33	0.44	2.995
Outpatient visits	0	3	0.06	0.300	0	2	0.09	0.311

Service use

Service use data was collected using an adapted CSRI, which recorded participants' frequency of contacts with hospital services and selected community-based services at T1 and T2. Participants' medication usage was also recorded. Service use was costed using national unit costs for the price year 2014–15.[80,81]

TABLE 44 Community and hospital services cost: all participants available at both time points ($n = 172$)

	Time point							
	T1				T2			
Service accessed	Minimum (£)	Maximum (£)	Mean (£)	SD	Minimum (£)	Maximum (£)	Mean (£)	SD
Alternative therapist	0.0	17.0	0.10	1.2962	–	–	–	–
Care manager	0.0	78.0	0.45	5.9474	–	–	–	–
Community nurse	0.0	938.0	45.97	127.8901	0.0	536.0	44.80	90.5172
CPN	0.0	750.0	15.26	66.3617	0.0	225.0	14.39	37.4643
Dentist	0.0	178.0	5.69	23.8662	0.0	178.0	2.59	17.8191
Dietician	0.0	76.0	6.41	16.9719	0.0	114.0	6.85	19.5828
GP	0.0	270.0	37.67	51.2088	0.0	225.0	42.12	47.9675
Mental health team worker	0.0	42.0	1.47	7.7289	0.0	42.0	0.73	5.5143
Optician	0.0	42.0	3.79	9.0007	0.0	42.0	3.05	7.7628
Occupational therapist	0.0	44.0	0.26	3.3550	0.0	44.0	1.02	6.6508
Physiotherapist	0.0	152.0	2.87	16.4429	0.0	190.0	2.87	16.9487
Practice nurse	0.0	56.0	1.95	10.3052	0.0	56.0	1.30	8.4647
Psychiatrist	0.0	556.0	16.91	72.4343	0.0	278.0	21.82	57.0064
Social worker	0.0	158.0	7.81	29.1737	0.0	237.0	5.971	29.6069
Chiropodist	0.0	62.0	12.26	18.5328	0.0	93.0	11.90	22.8215
A&E visits	0.0	2461.0	24.26	192.6203	0.0	3103.0	60.97	314.5914
Inpatient	0.0	13,930.0	168.92	1223.5115	0.0	13,134.0	173.55	1192.1741
Outpatient	0.0	372.0	7.21	37.2346	0.0	248.0	11.54	38.5317
Total	0.0	13,930.0	349.28	1254.3541	0.0	13735.0	405.46	1292.1842

TABLE 45 Community and hospital services: group 1 complete-case participants ($n = 76$)

Service accessed	Time point							
	T1				T2			
	Minimum	Maximum	Mean	SD	Minimum	Maximum	Mean	SD
Alternative therapist	0	1	0.01	0.115	–	–	–	–
Care manager	–	–	–	–	–	–	–	–
Community nurse	0	3	0.25	0.676	0	4	0.46	0.930
Community psychiatric nurse	0	2	0.12	0.364	0	2	0.30	0.589
Dentist	0	1	0.01	0.115	–	2	0.03	0.229
Dietician	0	2	0.12	0.364	0	2	0.13	0.442
GP	0	6	0.66	1.114	0	4	0.76	0.922
Mental health team worker	0	1	0.03	0.161	–	–	–	–
Optician	0	1	0.08	0.271	0	1	0.16	0.367
Occupational therapist	–	–	–	–	–	–	–	–
Physiotherapist	0	4	0.14	0.605	0	5	0.14	0.647
Practice nurse	0	1	0.04	0.196	0	1	0.03	0.161
Psychiatrist	0	3	0.17	0.575	0	2	0.24	0.513
Social worker	0	2	0.12	0.431	0	3	0.08	0.392
Chiropodist	0	2	0.17	0.413	0	1	0.21	0.410
A&E visits	0	23	0.34	2.641	0	14	0.42	1.995
Inpatient nights	0	35	0.64	4.304	0	14	0.46	2.346
Outpatient visits	0	1	0.03	0.161	0	2	0.13	0.377

TABLE 46 Community and hospital services cost, group 1 complete-case participants ($n = 76$)

	Time point							
	T1				T2			
Service accessed	Minimum (£)	Maximum (£)	Mean (£)	SD	Minimum (£)	Maximum (£)	Mean (£)	SD
Alternative therapist	0.0	17.0	0.22	1.9500	–	–	–	–
Care manager	–	–	–	–	–	–	–	–
Community nurse	0.0	201.0	16.75	45.2767	0.0	268.0	30.86	62.3168
Community psychiatric nurse	0.0	150.0	8.88	27.2959	0.0	150.0	22.70	44.1923
Dentist	0.0	89.0	1.17	10.2090	0.0	178.0	2.34	20.4180
Dietician	0.0	76.0	4.50	13.8299	0.0	76.0	5.00	16.8143
GP	0.0	270.0	29.61	50.1382	0.0	180.0	34.34	41.4837
Mental health team worker	0.0	42.0	1.11	6.7677	0.0	–	–	–
Optician	0.0	21.0	1.66	5.7004	0.0	21.0	3.32	7.7084
Occupational therapist	–	–	–	–	0.0	–	–	–
Physiotherapist	0.0	152.0	5.50	22.9716	0.0	190.0	5.50	24.5908
Practice nurse	0.0	56.0	2.21	10.9767	0.0	56.0	1.47	9.0236
Psychiatrist	0.0	417.0	23.78	79.8919	0.0	278.0	32.92	71.3055
Social worker	0.0	158.0	9.36	34.0516	0.0	237.0	6.24	30.9700
Chiropodist	0.0	62.0	5.30	12.7948	0.0	31.0	6.53	12.7221
A&E visits	0.0	2461.0	36.61	282.5841	0.0	1498.0	45.05	213.4737
Inpatient	0.0	13930.0	256.61	1713.0393	0.0	5572.0	183.29	933.8243
Outpatient	0.0	124.0	3.26	19.9809	0.0	248.0	16.32	46.8018
Total	0.0	13930.0	399.61	1727.8158	0.0	6764.0	395.87	1042.8599

TABLE 47 Community and hospital services: group 2 complete-case participants ($n = 96$)

Service accessed	Time point							
	T1				T2			
	Minimum	Maximum	Mean	SD	Minimum	Maximum	Mean	SD
Alternative therapist	–	–	–	–	–	–	–	–
Care manager	0	2	0.02	0.204	–	–	–	–
Community nurse	0	14	1.03	2.434	0	8	0.83	1.594
Community psychiatric nurse	0	10	0.27	1.138	0	3	0.10	0.397
Dentist	0	2	0.10	0.340	0	1	0.03	0.175
Dietician	0	2	0.21	0.501	0	3	0.22	0.566
GP	0	5	0.98	1.142	0	5	1.07	1.154
Mental health team worker	0	1	0.04	0.201	0	1	0.03	0.175
Optician	0	2	0.26	0.508	0	2	0.14	0.373
Occupational therapist	0	1	0.01	0.102	0	1	0.04	0.201
Physiotherapist	0	2	0.02	0.204	0	1	0.02	0.144
Practice nurse	0	1	0.03	0.175	0	1	0.02	0.144
Psychiatrist	0	4	0.08	0.474	0	1	0.09	0.293
Social worker	0	2	0.08	0.313	0	3	0.07	0.363
Chiropodist	0	2	0.57	0.661	0	3	0.52	0.894
A&E visits	0	4	0.14	0.555	0	29	0.69	3.519
Inpatient nights	0	11	0.25	1.522	0	33	0.42	3.436
Outpatient visits	0	3	0.08	0.375	0	1	0.06	0.243

TABLE 48 Community and hospital services cost, group 2 complete-case participants ($n = 96$)

	Time point							
	T1				T2			
Service accessed	Minimum (£)	Maximum (£)	Mean (£)	SD	Minimum (£)	Maximum (£)	Mean (£)	SD
Alternative therapist	–	–	–	–	–	–	–	–
Care manager	0.0	78.0	0.81	7.9608	–	–	–	–
Community nurse	0.0	938.0	69.09	163.0914	0.0	536.0	55.83	106.7878
Community psychiatric nurse	0.0	750.0	20.31	85.3254	0.0	225.0	7.81	29.7606
Dentist	0.0	178.0	9.27	30.2274	0.0	89.0	2.78	15.5666
Dietician	0.0	76.0	7.92	19.0333	0.0	114.0	8.31	21.4983
GP	0.0	225.0	44.06	51.4030	0.0	225.0	48.28	51.9252
Mental health team worker	0.0	42.0	1.75	8.4368	0.0	42.0	1.31	7.3461
Optician	0.0	42.0	5.47	10.6622	0.0	42.0	2.84	7.8396
Occupational therapist	–	44.0	0.46	4.4907	0.0	44.0	1.83	8.8385
Physiotherapist	0.0	76.0	0.79	7.7567	0.0	38.0	0.79	5.4559
Practice nurse	0.0	56.0	1.75	9.7947	0.0	56.0	1.17	8.0402
Psychiatrist	0.0	556.0	11.58	65.8692	0.0	139.0	13.03	40.7285
Social worker	0.0	158.0	6.58	24.7619	0.0	237.0	5.76	28.6444
Chiropodist	0.0	62.0	17.76	20.4866	0.0	93.0	16.15	27.7196
A&E visits	0.0	428.0	14.49	59.3619	0.0	3103.0	73.56	376.5659
Inpatient nights	0.0	4378.0	99.50	605.6652	0.0	13,134.0	165.83	1367.3781
Outpatient	0.0	372.0	10.33	46.4547	0.0	124.0	7.75	30.1732
Total	0.0	4901.0	309.44	686.7635	0.0	13,735.0	413.05	1465.1972

TABLE 49 Other community services: all participants

	Sum of other visits	
Community services	Clinic	Home
Visit 1		
Anticoagulation service	0	3
Audiology	2	1
Cardiology	0	1
Care home liaison	0	4
COPD nurse	0	1
Diabetes nurse	0	1
DWP	0	1
Eye clinic	1	0
Falls team	0	1
Geriatric consultant	0	1
Health-care assistant	0	1
Memory clinic	6	4
Pharmacist	0	1
Phlebotomist	0	10
Solicitor	0	1
Speech and language	1	16
Urologist	1	0
Warfarin nurse	0	1
Equipment/wheelchair services	0	5
Visit 2		
Anticoagulation service	0	2
Audiology	0	1
Care home liaison	0	7
Community liaison	0	1
Community matron	0	4
Consultant geriatrician	0	1
Dermatologist	1	0
Diabetes nurse	0	3
Falls team	0	8
Health-care assistant	0	2
Memory clinic	0	3
Parkinson’s nurse	0	1
Pension advisor	0	1

continued

TABLE 49 Other community services: all participants (*continued*)

Community services	Sum of other visits Clinic	Home
Pharmacist	0	5
Phlebotomist	0	12
Solicitor	0	2
Speech and language	2	7
Stoma nurse	0	1
Warfarin nurse	0	2
Equipment/wheelchair services	0	1

TABLE 50 Unit costs and sources for the community and hospital data

Item	Unit	Cost (£)	Source/notes
District/community nurse	Per hour	67	Community nurse home visit, including qualification and travel costs (*Unit Costs of Health and Social Care 2015*,[80] p. 169)
GP	Per visit	45	Per contact lasting on average 11.7 minutes. Includes qualification costs and direct care staff costs (*Unit Costs of Health and Social Care 2015*,[80] p. 177)
Community mental health team worker	Per hour	42	(CMHT) for older people with mental health problems (*Unit Costs of Health and Social Care 2015*,[80] p. 199)
Community psychiatric nurse	Per hour	75	Nurse, mental health, per hour of face-to-face contact (*Unit Costs of Health and Social Care 2015*,[80] p. 170)
Practice nurse	Per hour	56	Assumed home visit is the same as clinic visit. Per hour of face-to-face contact, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 174)
Psychiatrist	Per hour	139	Consultant: psychiatric cost per hour of face-to-face patient contact, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 237)
NHS physiotherapist	Per hour	38	Per physiotherapist hour, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 217)
NHS occupational therapist	Per hour	44	NHS community occupational therapist, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 191)
NHS chiropodist/podiatrist	Per hour	31	Assumed home visit and clinic visit the same. Per hour, community chiropodist (*Unit Costs of Health and Social Care 2013*,[150] p. 178), inflated to 2015 prices using the Bank of England calculator
NHS dietician	Per hour	38	Per hour, hospital-based dietician including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 220)
NHS optician	Per contact	21	NHS sight test fee for Optometrists and Ophthalmic Medical Practitioners (URL: www.fodo.com/resource-categories/nhs-sight-test-fees; accessed 8 March 2018)
NHS dentist	Per hour	89	NHS dentist-performer only, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 180)
Social worker	Per hour	79	Per hour of face-to-face contact (adult services), including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 188)

TABLE 50 Unit costs and sources for the community and hospital data (*continued*)

Item	Unit	Cost (£)	Source/notes
Care manager	Per hour	39	Per hour, including qualification costs (*Unit Costs of Health and Social Care 2015*,[80] p. 193)
Alternative therapist	Per hour	17	Taken as mid-point of NHS pay band 5, including National Insurance and pension
A&E	Per visit	107	*NHS Reference Costs*,[81] T01NA, type 1 non-admitted, VB09Z, emergency medicine, category 1 investigation with category 1–2 treatment
Inpatient services	Per night	398	*NHS Reference Costs*,[81] nonEI, HE11H, hip fracture without interventions, with a CC score of 0–3
Outpatient services	Per visit	124	*NHS Reference Costs*,[81] WF01A non-admitted face-to-face attendance, follow-up, general surgery 100

TABLE 51 Breakdown of the medications prescribed for participants ($N = 254$) at baseline

Type of medication	*n*
Anaesthesia	
General	1
Local	4
Cardiovascular system	
Anticoagulants and protamine	22
Antiplatelet drugs	83
Beta-adrenoceptor blocking drugs	42
Diuretics	55
Hypertension and heart failure	42
Lipid-regulating drugs	78
Nitrates, calcium channel blockers and other antianginal drugs	42
Positive inotropic drugs	13
Central nervous system	
Analgesics	171
Antidepressant drugs	147
Antiepileptics	30
Drugs for dementia	113
Drugs used in nausea and vertigo	9
Drugs used in Parkinsonism/related disorders	8
Drugs used in psychoses and related disorders	92
Drugs used in substance dependence	2
Hypnotics and anxiolytics	150

continued

TABLE 51 Breakdown of the medications prescribed for participants ($N = 254$) at baseline (*continued*)

Type of medication	*n*
Ear, nose and oropharynx	
Drugs acting on the nose	1
Drugs acting on the oropharynx	1
Other appliances	1
Endocrine system	
Corticosteroids (endocrine)	12
Drugs affecting bone metabolism	25
Drugs used in diabetes	34
Sex hormones	3
Thyroid and antithyroid drugs	31
Eye	
Anti-infective eye preparations	8
Miscellaneous ophthalmic preparations	6
Treatment of glaucoma	15
Gastrointestinal system	
Acute diarrhoea	4
Antisecretory drugs and mucosal protectants	96
Antispasmodics and other drugs altering gut motility	5
Chronic bowel disorders	2
Dyspepsia and gastro-oesophageal reflux disease	6
Laxatives	184
Infections	
Antibacterial drugs	23
Antifungal drugs	2
Antiprotozoal drugs	4
Malignant disease and immunosuppression	
Sex hormones and antagonists in malignant disease	1
Musculoskeletal and joint diseases	
Drugs used in neuromuscular disorders	5
Drugs used in rheumatic diseases and gout	11
Soft-tissue disorders and topical pain relief	3
Nutrition and blood	
Anaemias and other blood disorders	62
Base/dil susp agents/stabilisers	3
Minerals	7
Oral nutrition	42
Vitamins	97

TABLE 51 Breakdown of the medications prescribed for participants ($N = 254$) at baseline (*continued*)

Type of medication	*n*
Obstetrics, gynaecology and urinary tract disorders	
Drugs for genito urinary disorders	16
Respiratory system	
Antihistamines, hyposensitisation and allergic emergencies	15
Bronchodilators	28
Corticosteroids (respiratory)	11
Cough preparations	1
Mucolytics	2
Skin	
Anti-infective skin preparations	2
Emollient and barrier preparations	7
Emollients	4
Preparations for eczema and psoriasis	2
Skin cleansers, antiseptics and desloughing agents	6
Skin fillers and protectives	6
Sunscreens and camouflagers	1
Topical corticosteroids	4
No medication	
No medication	7
Sterile water	
Waters	1
Grand total	1911

dil, dilute; susp, suspension.

Appendix 3 Outcome measures

IDEA

Please think about the care you receive at/ from ___________ and answer the following questions. Please choose only one answer for each question.

1. Do people here treat you with dignity?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

2. Do people here treat you with respect?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

3. Do people here treat you as an individual?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

4. Do people here treat you as if you are important?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

5. Are you made to feel silly or stupid here?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

6. Do people here involve you in decisions about your care?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

7. Are you ignored here?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

8. Do people here talk down to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

9. Do people look at you when they speak to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

10. Do people here talk to you in a way that you can understand?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

11. Are your views ignored when decisions need to be made?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

12. Do people here show an interest in you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

13. Do people here take time to get to know you?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

14. Do people here make assumptions about you?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

15. Do people here help you make decisions for yourself?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

16. Are you able to choose how you spend your time?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

17. Do you have to do what you are told here?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

18. Do people here know who’s important to you and respect this?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

19. Are people you trust involved in decisions about your care when you need them to be?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

20. Do people here give you the time to do things?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

21. Do people here seem to understand your problems?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

22. Do people here take you seriously?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

23. If you get angry or upset do you think it will be held against you?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

24. Are you treated fairly here?

Yes	Sometimes	No	Couldn’t Answer
1	2	3	9

25. Do people here help you live as normal a life as possible?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

26. Do people here respect your choices in how you want to live your life?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

27. Do people treat you differently now?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

28. Are you supported to do lots of the things you used to do?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

29. Do you still have contact with the people who are important to you?

Yes	Sometimes	No	Couldn't Answer
1	2	3	9

Care Plan Audit

Instructions for use:

Delete the appropriate response for each of the listed items to record if there is/is not evidence of the item in the care plan. Write any other comments in the space provided.

Patient Identifier:
……….

Date of admission:
………....

Date of discharge:
……

1. General Items	Please circle appropriate answer	Comments:
Existence of a care plan?	Yes No	
Type of documentation	Paper Electronic Both	
Named Signed Dated	Yes/No Yes/No Yes/No	
Care plan completed by (please only state profession)		____________________
Review date of care plan	Yes No	
End date of care plan (if applicable)	Yes No	
Diagnosis	Yes No	
Unexplained jargon/abbreviations	Yes No	If present how many occurrences:
Risk Assessment	Yes No	
Risk Management Plan	Yes No	
Goals Action Plan	Yes No	
Discharge Plan	Yes No	
Understanding of why they are on the ward/in the care home	Yes No	
Deprivation of Liberty Safeguards	Yes No	
Mental Capacity Act decisions	Yes No	

Mental Health Act Status	Yes No
Collaboration – mention of who was involved in creating the care plan	Yes No
If yes who was involved:	
Person with dementia	Yes/No
Relative/Family member	Yes/No
Professional	Yes/No
Other	Yes/No
Was the person with dementia asked if they wanted a copy	Yes No
Who else has copies:	
Person with dementia	Yes/No
Relative/Family member	Yes/No
Professional	Yes/No
Other	Yes/No
Person with dementia's preferred name recorded	Yes No
Preferred language recorded	Yes No
Any reference to Human Rights/FREDA	Yes No
Record any instances of Human Rights language:	

2. Physical Health	Yes/No	Comments:
Current health issues	Yes No	
List of treatments	Yes No	
Current weight/BMI – happy with this?	Yes No	
Smoking	Yes No	Amount per day:
Alcohol consumption	Yes No	Amount per day:
Blood pressure recorded	Yes No	
Do they wear glasses	Yes No	
Do they use a hearing aid	Yes No	
Special needs: (Eating, drinking, communication, moving about, using the toilet, sleeping etc)	Yes No	
Pain	Yes No	Where:
Risk of falling	Yes No	
Other Comments:		

3. Mental Health	Yes/No	Comments:
Depressed feelings	Yes No	

(Any formal assessments e.g. Cornell Scale for Depression in Dementia)		
Anxious feelings (Any formal assessments e.g. Beck Anxiety Inventory)	Yes No	
Experience of other unpleasant feelings	Yes No	
Particular symptoms relevant to individual’s diagnosis	Yes No	
Other Comments:		

4. Cognitive Ability	Yes/No	Comments:
Visual processing problems	Yes No	
Ability to manage personal care	Yes No	
Memory issues	Yes No	
Communicating issues	Yes No	
Difficulties with planning/judging/controlling	Yes No	

5. Capacity for doing	Yes/No	Comments:
Predominant way of engaging with the world at the current time	Yes No	
Please circle person's level of ability: **Eating/Drinking** Automatic responses only Requires assistance to begin task Requires prompt to begin task Goal directed action		
Please circle person's level of ability: **Walking** Automatic responses only Requires assistance to begin task Requires prompt to begin task Goal directed action		

Please circle person's level of ability:

Personal Care

Automatic responses only

Requires assistance to begin task

Requires prompt to begin task

Goal directed action

Please circle person's level of ability:

Activities

Automatic responses only

Requires assistance to begin task

Requires prompt to begin task

Goal directed action

6. Personal Preferences	Yes/No	Comments:
Food and drinks that the person likes	Yes No	
When and how the person likes to eat	Yes No	
Clothes the person likes to wear/how the person likes to look	Yes No	
Routines for Activities of Daily Living	Yes No	
Work-like activities that the person needs to do routinely	Yes No	
How the person relaxes	Yes No	
People, places or objects that the person feels attached to/are important/want with them	Yes No	
Spirituality	Yes No	
Cultural beliefs	Yes No	
Sexuality (Orientation, sexual needs and preferences)	Yes No	

7. Personality	Yes/No	Comments:
Comments or statements on personality dimensions	Yes No	

8. Life History	Yes/No	Comments:
Early Years		
Memories of family and friends	Yes No	

Memories of schooling and education (Interests, friends, teachers, achievements)	Yes No

Stories from early years	Yes No
Middle Years	
Memories of family and friends	Yes No
Memories of things the person did (Work, hobbies, holidays)	Yes No
Stories from middle years	Yes No
After Retirement	
Memories of family and friends	Yes No
Memories of things the person enjoyed (Hobbies, travel etc)	Yes No
Stories from after retirement	Yes No
Now	
Who and what I think about (People close to me, proudest achievements, regrets, happiest memories)	Yes No
Recent stories	Yes No
Activities/hobbies I enjoy	Yes No

9. Life at the moment	Yes/No	Comments:
Well-being/ill-being – how the person feels	Yes No	

Carer or significant other's satisfaction with the care (Any comments from carers)	Yes No	
Person with dementia's satisfaction with the care (Any comments from person with dementia)	Yes No	
Psychological needs (Comfort, occupation, attachment, identity, inclusion)	Yes No	

10. Future Wishes	Yes/No	Comments:
Plans for inability to communicate wishes in the future (Lifestyle preferences, treatments and support the person would/would not accept, list of people to consult regarding treatment and support decisions)	Yes No	
Mention of Advanced Directive or Living Will	Yes No	
Attorney's appointed (For property, welfare, Lasting Power of Attorney)	Yes No	

IDEA - proxy

Please think about the care your relative receives at the care home / ward and answer the following questions. Please choose only one answer for each question.

1. Do people here treat (name) with dignity?

Yes	Sometimes	No
1	2	3

2. Do people here treat (name) with respect?

Yes	Sometimes	No
1	2	3

3. Do people here treat (name) as an individual?

Yes	Sometimes	No
1	2	3

4. Do people here treat (name) as if he/she is important?

Yes	Sometimes	No
1	2	3

5. Is (Name) made to feel silly or stupid here?

Yes	Sometimes	No
1	2	3

6. Do people here involve (name) in decisions about his/her care?

Yes	Sometimes	No
1	2	3

7. Is (Name) ignored here?

Yes	Sometimes	No
1	2	3

8. Do people here talk down to (name)?

Yes	Sometimes	No
1	2	3

9. Do people look at (name) when they speak to him/her?

Yes	Sometimes	No
1	2	3

10. Do people here talk to (name) in a way he/she can understand?

Yes	Sometimes	No
1	2	3

11. Are (Name's) views ignored when decisions need to be made?

Yes	Sometimes	No
1	2	3

12. Do people here show an interest in (name)?

Yes	Sometimes	No
1	2	3

13. Do people here take the time to get to know (name)?

Yes	Sometimes	No
1	2	3

14. Do people here make assumptions about (name)?

Yes	Sometimes	No
1	2	3

15. Do people here help (name) to make decisions for himself / herself?

Yes	Sometimes	No
1	2	3

16. Is (Name) able to choose how he/she spends their time?

Yes	Sometimes	No
1	2	3

17. Does (Name) have to do what he/she is told here?

Yes	Sometimes	No
1	2	3

18. Do people here know who’s important to (name) and respect this?

Yes	Sometimes	No
1	2	3

19. Are people (name) trusts involved in decisions about his/her care when he/she needs them to be?

Yes	Sometimes	No
1	2	3

20. Do people here give (name) the time to do things?

Yes	Sometimes	No
1	2	3

21. Do people here seem to understand (name's) problems?

Yes	Sometimes	No
1	2	3

22. Do people here take (name) seriously?

Yes	Sometimes	No
1	2	3

23. If (name) gets angry or upset do you think it will be held against him/her?

Yes	Sometimes	No
1	2	3

24. Is (Name) treated fairly here?

Yes	Sometimes	No
1	2	3

25. Do people here help (name) live as normal a life as possible?

Yes	Sometimes	No
1	2	3

26. Do people here respect (name's) choices in how he/she wants to live his/her life?

Yes	Sometimes	No
1	2	3

27. Do people treat (name) differently now?

Yes	Sometimes	No
1	2	3

28. Is (Name) supported to do lots of the things he/she used to do?

Yes	Sometimes	No
1	2	3

29. Does (Name) still have contact with the people who are important to him/her?

Yes	Sometimes	No
1	2	3

Interview Schedule

We are interested in asking you about how you make decisions in your day to day working life. There are no right or wrong answers and the information you give will not be shared with managers or supervisors. You are free to leave at any time. Do you have any questions?

Working within dementia care we are aware that you will regularly be in situations where you have to make complex clinical decisions about an individual's care. Could you tell us about some of the clinical situations that you find most challenging on a day to day basis?

I would now like to ask you about some specific situations you may encounter in your day to day working practice. Again there are no right or wrong answers we are just interested in your opinion.

Vignette 1

What would you do?

How would you come to this decision?

What would help you or support you in making this decision?

Vignette 2

What would you do?

How would you come to this decision?

What would help you or support you in making this decision?

Etc….

That is all the clinical situations we would like to ask you about. Do you think that the situations we have asked about reflect your day to day work?

Thank you for participating in this study. We will make you aware of any results from the work. Do you have any questions you would like to ask?

Vignettes set 1

Life History

Freedom of Expression – Anne is a married woman with a diagnosis of frontal temporal dementia. Since being admitted to the ward she has formed a close friendship with a male service user, John. John and Anne often sit together in the day room and have been seen holding hands and hugging each other. What would you do?

Neurological Impairment

Discrimination – Nadia has a diagnosis of Alzheimer's. Her son lives in Spain but has come over to visit her. 10 minutes before he is due to arrive you noticed that Nadia is soaked in urine. You encourage her to go for a wash and explain it is because her son is coming to visit. She refuses and does not seem to understand what you are telling her. What would you do?

Personality

Liberty – George has a diagnosis of Alzheimer's and has been on the ward for several weeks. His family report that he has always been an active man who has enjoyed the outdoors. It has been noticed that George spends long periods of time pacing around the ward. At times this irritates other service users. George can become tired after pacing and at times he has stumbled but never fallen. Because of this a member of staff needs to accompany him when he walking around the ward. What would you do?

Health

Degrading Treatment – Sheila was admitted to the dementia ward from the nursing home she lives in as they had noticed an increase in her levels of agitation. She recently had a fall whilst she was going to the toilet. Despite this she insists that she does not want someone to assist her and can go to the toilet on her own. What would you do?

Social Psychology

Peaceful enjoyment of possessions – Rajesh has always been interested in music and listening to it often calms him down. His family have brought him in a CD player and a selection of CDs. There has been an issue with another service user going into people's rooms and taking their personal possessions. Rajesh's family have asked whether his CDs will be safe. What would you do?

Vignettes set 2

Life History

Discrimination – Frank is an ex-boxer and despite his diagnosis of vascular dementia he is still extremely physically fit. It has been recorded that at times he has hit out at both staff and other service users on the ward. When this is discussed with his family at ward round they confide that he has a history of violence within the home and they do not want him to return home. What would you do?

Neurological Impairment

Liberty – Desmond has been admitted to the dementia ward on an informal basis. He is often observed rattling the front door and asking to go out. His family question this. They are told that all service users who are on the ward on an informal basis are given the code to the door. His family state that because of his memory problems he would be unable to retain this information. What would you do?

Personality

Freedom of expression – Ping is a 75 year old lady with a diagnosis of vascular dementia. She has been prescribed a variety a medications to help control multiple physical problems and also to help with her agitation. Every day at medication time Ping states that she has always been a fit and healthy woman and does not need to take any medication. She then refuses to take it. What would you do?

Health

Right to life – Norman has a diagnosis of Alzheimer's but also suffers with an undiagnosed medical condition resulting in urinary retention. The urinary retention requires the insertion of a catheter at the local acute hospital and some further investigations to diagnose the condition. The family have asked that whilst Norman is on the dementia ward could the staff accompany him to these appointments. When staff have attended with him in the past he has become very agitated and distressed and one occasion slid out of his wheelchair onto the floor. What would you do?

Social Psychology

Private family life – Joan has a diagnosis of Alzheimer's and has been becoming increasingly distressed on the ward. During the afternoon she becomes increasingly aggressive with both staff and other services users, eventually hitting another female service user. The decision is made to give Joan PRN medication and she then goes to sleep. When her family come to see her she has been asleep for about 30 minutes. What would you do?

Attitudes Quiz

Please circle your answer to the following questions.

1. I feel I understand the idea of human rights.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

2. Human rights are important for everyone.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

3. It is important to protect a person's human rights, regardless of who they are.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

4. The idea of human rights is something I do not consider important as part of my own values, attitudes and beliefs.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

5. The idea of human rights fits well with my understanding of the core values, aims and objectives of the NHS.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

6. Human rights are not useful or relevant to my day-to-day work.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

7. Human rights are about doing what is decent and fair.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

8. I feel that my own human rights are respected and I am treated well within my organisation.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

9. When people talk to me about human rights I feel pressured to work in a way I don’t like.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

10. Positive change can happen at work using human rights values and approaches.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

11. Other people in my team at work do not have a strong belief in human rights.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

12. My family and friends have a strong belief in human rights.

Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree

Knowledge Quiz

Please circle one correct answer for each of the following questions

1. Human rights:

a) Belong to certain groups at certain times
b) Can be taken away from any of us
c) Are claimed and cannot be taken away

2. In the United Kingdom who is protected by the Human Rights Act?

a) Everyone who works for a government organisation (e.g. nurses, teachers and civil servants)
b) Everyone who has the right to vote
c) Everyone regardless of status
d) Everyone who is a UK citizen

3. In which of the following circumstances do the NHS and its staff have a responsibility to act in relation to human rights?

a) Preventing breaches of human rights; for example, intervening to protect one individual from the actions of another
b) Informing individuals when their rights may be at risk - so they can make decisions to protect their own rights
c) Responding to breaches of human rights, including investigating what has happened
d) All of the above

4. The framework that gives the rights contained in the European Convention on Human Rights direct effect in UK law is:

a) The Bill of Rights
b) The UK constitution
c) The Human Rights Act

5. FREDA stands for:

a) Freedom, Respect, Equality, Diversity, Autonomy
b) Fairness, Rights, Equality, Dignity, Autonomy
c) Fairness, Respect, Equality, Dignity, Autonomy

6. Non– absolute rights can be interfered with if the action/decision is:

a) In pursuit of a legitimate aim
b) Lawful
c) Necessary

d) Proportionate
e) All of the above
f) Only b and d

7. Which one of the following rights is absolute?

a) The right to respect for private and family life, home and correspondence
b) The right to be free from inhuman or degrading treatment
c) The right to freedom of expression
d) The right to manifest one's religion or belief.

8. The right to respect for private life and family life, home and correspondence includes which of the following?

a) Physical wellbeing
b) Psychological wellbeing
c) The right to a house
d) Not having your post intercepted
e) a, b and d
f) a, b and c

9. When a person lacks the capacity to give informed consent to treatment Deprivation of Liberty Safeguards (DoLS) should be applied for:

a) Whenever something is to be done to an individual which is outside of usual working practice
b) As part of best practice, as soon as someone is admitted to a ward environment
c) Whenever something is to be done to an individual which deprives them of their liberty.

10. Which of the following is not part of a human rights based approach:

a) Putting human rights at the heart of policy and planning
b) Empowering staff & service users
c) Ensuring clear accountability
d) Non-discrimination and attention to vulnerable groups
e) Ensuring you always do what the service user wants
f) Enabling meaningful involvement and participation of all key people

11. A proactive strategy is primarily a response that aims to minimise harm by acting:

a) Before an event
b) During an event
c) After an event

12. Proportionality means the same as:

a) Using the least restrictive strategy
b) Using common custom and practice
c) Doing what the person and their family want

13. Which of the following people's human rights might need to be taken into account when making decisions in a healthcare organisation?

a) Service users
b) Carers
c) Staff
d) The wider community
e) All of the above

EME
HS&DR
HTA
PGfAR
PHR

Part of the NIHR Journals Library
www.journalslibrary.nihr.ac.uk

Published by the NIHR Journals Library