Detailed Project Description

Embedding a Human Rights Based Approach to Dementia Care

Summary of Research:

This trial will employ a cluster randomised design to explore the research question; does the application of a Human Rights Based Approach to Health Care lead to improvements in the care and well-being of people with dementia in an inpatient/care home setting? In line with this, the study will aim to evaluate whether the delivery of Human Rights training to staff and the subsequent introduction of a Human Rights Based Assessment Tool impacts on both the care and well-being of individuals with dementia.

Both the Assessment Tool and Human Rights Based Training Package have been developed and piloted by Mersey Care NHS Trust. The current proposal is to extend the pilot study by implementing and further evaluating the impact of the Training Package and Assessment Tool in NHS Mental Health Trusts and care homes.

Background and Rationale:

Traditionally, people with dementia have been amongst the most devalued in our society experiencing the double stigma of old age and cognitive impairment and their human rights have been disregarded as society places emphasis on intact cognition. This has led to care practices that undermine the humanity and personhood of an individual with dementia (Kitwood, 1997). The literature highlights issues such as surrogate decision making, restraint and ‘wandering’ where human rights are not routinely considered in decision making (Robinson et al, 2007).

As society ages, dementia will become increasingly prevalent and the associated cost of the care required will become a growing burden on society. Total costs estimate that the cost of dementia to the UK is £23 billion (Luengo-Fernandez, R., Leal, J. & Gray, A., 2010). The status quo is unsustainable. In 2007 the Alzheimers society published Dementia UK, in this report they stated “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”. In 2009 The National Dementia Strategy was published outlining the government’s plan for providing quality services in dementia care.

The Prime Minister has launched a programme of work which aims to deliver major improvements in dementia care and research by 2015. The government will focus on improving the areas that matter most for dementia (DOH, 2012); awareness, quality of care and research. Much of the work currently being carried out as a response to the Prime Minister’s challenge by the Alzheimers’ society etc focuses on individuals at the early stages of dementia. Whilst this is an extremely important area, and can lead to the empowerment of people with dementia, it neglects the needs of those individuals who are at their most vulnerable, individuals at the later stages of dementia.

Person centred care is well established as being good practice in relation to delivering care for vulnerable groups such as people with dementia. It has however been criticised for being vague and difficult to research and enforce (e.g. O'Connor et al., 2007) . A Human Rights Based Approach gives backbone and a legal framework to person centred principles making them clearer to operationalise and more accessible to rigorous research. Embedding a Human Rights Approach to care planning and management will allow us, within this project, to effectively evaluate the standard of care provided.

Human Rights compel us to treat service users as human beings whilst recognising that in certain complex cases, a balance may need to be struck in order to meet competing rights. A Human Rights Approach both allows for that and provide 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 which impose an additional financial burden and undermine public confidence in services (e.g. Equality and Human Rights Commission inquiry, 2011; DOH, 2012).

The Human Rights Act (1998) is law; however within healthcare settings, it needs translating into a clear set of principles that guide everyday practice bridging the gap between the legal system and good quality health care (Roberts et. al., 2013). The Human Rights in Healthcare document (DOH, 2008) 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 (Scottish Human Rights Commission, 2009).

Table 1: Constructions of Human Rights Approach in Health Care Settings

Human Rights Based Assessment	**PANEL Principles**
Stakeholder engagement	Participation
Ensuring accountability	Accountability
Ensuring attention to vulnerable groups	Non-discriminatory
Stakeholder empowerment	Empowerment
Looking at things through a Human Rights lens	Legality

A Human Rights Based Approach has been 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 (Local Government Association et al, 2012). Embedding a Human Rights Based Approach into a dementia care setting may also provide staff with a more robust framework in which to make complex clinical decisions and drive up the quality of care provided.

Making the link between law and ethical practice is not the only step required; there is also a need to translate the concepts in a Human Rights Based Approach into practical strategies to facilitate the everyday decision making of staff. In other words to make 'choices guided by values' (Casali and Day, 2010) and guided by the more practical elements of the HRBA such as proportionality, fit with other legal frameworks, proactive strategies and balancing rights and risks. There is a clear commitment to reducing the prescription of antipsychotic medication to people with dementia (DOH, 2009). 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.

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" (Glick, 1999). This can lead to decisions which have an impact on an individual's human rights. For example, Robinson et al (2007) 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, through fear of being viewed as negligent. The implementation of the Human Rights Based assessment and learning resource would aim to provide staff with a more comprehensive and robust framework in which decision can be made drawing on the human rights principles, particularly proportionality, least restrictive practice and proactive strategies rather than relying on the most risk adverse approach.

Embedding a Human Rights Based Approach through the application of the Getting it Right Assessment Tool aims 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. Whilst there is evidence in the literature that the Human Rights of people with dementia are vulnerable to being disregarded there is little work on ways to address this. This project will build on the existing literature but expand to look at an operationalised model of providing care that embeds a Human Rights Based Approach. It is proposed that there will be a number of benefits, both to service users and services, by applying this approach. We anticipate delivery of the project will bring about changes in the way that care is delivered to people with dementia in line with the HS&DR remit.

Aims and Objectives:

Aim: To establish whether the application of a Human Rights Based Approach to Health Care leads to significant improvements in the care and well-being of people with dementia in hospital inpatient and care home settings.

Specific Objectives:

1. To investigate whether the application of a Human Rights Based Approach to Health Care, as opposed to treatment as usual, leads to significant improvements in the

quality of life of people with dementia in hospital inpatient and care home settings, as measured by scores on the QoL-AD (the Quality of Life in Alzheimers Disease scale).

2. To explore whether training on the application of a Human Rights Based Approach to Health Care leads to identifiable improvements in the quality of staff decision making 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, 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) and the Zarit Burden Interview (ZBI).

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 a hospital and care home setting in terms of patient reported well being, care plan development, staff stress, family member well being and overall quality of care, as compared to usual patient management.

Detailed Description of the Intervention

The planned intervention for this trial is to introduce a novel Human Rights based assessment tool, 'Getting it Right', into dementia wards. This tool is rooted in the principles of person centred care and has been especially developed in order to improve the person centred nature of the creation of care plans and ensure that the Human Rights of the service user are considered. The tool is designed to be completed by a staff member and the service user together, and thus, should encourage both individuals to consider the different Human Rights that should be recognised during the service users stay in care. More specifically, the tool maps these Human Rights on to a wide range of areas of care including, preferences of food and drink, prefered name and access of visitors. Whilst filling out the assessment tool, the staff are able to utilise a corresponding manual. This takes staff though the tool, reminding them of questions to ask and details to complete. After the tool has been completed it functions as the individuals care plan and is able to be kept by the service user as a personal record of the care they should be being provided with during their stay.

To aid the implementation of the Assessment Tool a Training Package has also been developed for staff working in inpatient dementia units. This takes 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 assessment tool. The training package includes a specially designed and commissioned DVD, containing dramatised ward-based scenarios, which encourage interactive learning of

Human Rights based approaches when making clinical decisions. During the training, participants will be encouraged to engage in discussion around how to respond to clinical situations from a Human Rights focused approach. This will be achieved through providing a DVD which shows situations being acted out which may present difficulties within inpatient dementia care. Staff will then be encouraged by the trainers to discuss the situations in light of the training they will receive on the application of Human Rights.

The exact composition of staff to be trained will be determined by the service in which the training is delivered but staff from all grades and disciplines will be included in the training. This is the model used in the pilot phase where staff attending training encompassed a range of grades and professions e.g. ward manager, registered nurses, support workers, domestic staff, occupational therapists, physiotherapist. The key issue is that training is provided for 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 intervention site will also be offered 3 sessions of 2 hour monthly booster sessions to help build their confidence in embedding a Human Rights based approach to care. These sessions will be delivered by the initial trainers.

Development and Piloting of the Assessment Tool and Training Package

Following Human Rights training by the British Institute of Human Rights, the Getting it Right Assessment was developed by a Project Team at Mersey Care NHS Trust consisting of service user representatives, carers, researchers and staff from different disciplines including nursing, clinical psychology, occupational therapy and psychiatry. There were several steps in the development of the initial constructs for the Assessment Tool. First a list of general topic areas were generated via a literature review of the area. Focus groups were then run with staff, service users and carers to gather information about potential violations of Human Rights during an individual's dementia journey. As the assessment tool is designed to be used on inpatient assessment wards and in care home settings it was felt that it was vitally important to also elicit the opinions of this population. Historically, people with later stages of dementia are excluded from consultation on service development matters due to difficulties with communication and the cognitive load involved in some tasks. In this situation a method previously outlined and found to be useful in eliciting the views of people with later stages of dementia by Allen (2001) was employed. This involved more indirect investigation by showing people on the inpatient ward a picture of a person and asking them what they would say to this person if they were considering staying on the ward. Useful and relevant information was generated in this way. The themes from all of the methods above were then combined to create the domains for the Getting it Right Assessment tool.

The function of the tool is to generate a person centred care plan that will maximise the person's quality of life whilst they are on the ward and help to ensure that their Human Rights are acknowledged and upheld. The design of the tool is inherently service user inclusive, in that the assessment document is completed by the individual with dementia alongside a staff member. The staff member is supported by a corresponding manual and the end product is a care plan which can be kept by the service user as well as serving as the basis for the subsequent care the person will receive. The tool has been designed to be user friendly with bold print, pictorial representations and clear colour coded sections.

Alongside the tool, the Project Team developed a one day staff Training Package. In addition to training in the use of the Assessment Tool, the Training Package consists of information about the Human Rights Act including the legal requirements of the NHS and guidance in implementing a Human Rights Based Approach to Dementia Care. The training package includes a specially designed and commissioned DVD, containing dramatised ward-based scenarios, which encourage interactive learning of Human Rights based approaches when making clinical decisions.

The Getting it Right tool and associated Training Package were piloted within Mersey Care NHS Trust, and underwent an evaluation using a number of outcome measures; a specifically designed audit tool, vignette based semi-structured interviews and Human Rights knowledge and attitude quizzes.

Firstly, the quality of care plans was measured by conducting a care plan audit. This revealed that care plans were generic in nature with little emphasis on the particular needs of the person. As such they would be considered to be non person centred.

Secondly, staff decision making was explored via semi-structured interviews. The interviews used vignettes which prompt discussion around clinical situations which may impact on service users' Human Rights. Thematic analysis, as described by Braun and Clarke (2006), was conducted in order to identify the semantic themes which explain the decision making frameworks used within clinical scenarios. Themes emerging from this showed that staff had limited frameworks in which to make the complex clinical decisions they were faced with. Rather they relied on common sense and local practices, not based on any consideration of the effects their decisions may have.

Finally, staff were given a Human Rights Knowledge quiz both before and after the training to assess knowledge of Human Rights. This demonstrated an increase in knowledge post training. Staff also completed an attitudes questionnaire and this showed a more positive attitude towards a Human Rights Based Approach following training.

The intervention will be piloted again, using all the proposed measures, prior to the start of the trial. A dementia inpatient ward in Mersey Care NHS Trust has been identified. This will allow for a more practical consideration of the feasibility of the suggested measures to evaluate the intervention.

Outcome Measures

Service user well being**:** The primary outcome measure used in the research will be the Quality of Life in Alzheimer's disease (QOL-AD; Logsdon, Gibbons, McCurry & Teri, 1999) to assess the subjective well being of the person with dementia. The European consensus on outcome measures for psychosocial intervention research in dementia care (Moniz-Cook et al., 2008) states that the QOL-AD 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 MMSE scores as low as 3. The QOL-AD proxy version will also be used with both staff and family caregivers to elicit the views of a person supporting the individual with dementia.

Family Carer well being: It is recognised that caring for someone with dementia can be a stressful role (e.g. Miller et al., 2013). It is therefore suggested that carer well being will also be assessed to explore whether the application of a Human Rights Based Approach on a unit improves the well being of the family carer. Family carer well being will be assessed via the Warwick Edinburgh Mental Well-Being Scale (WEMWBS) and the Zarit Burden Interview (ZBI) will explore their perception of caring responsibilities.

Standard of Care: A care plan audit will be conducted at each site to provide a measure of the documented plan of care for each service user. An audit tool has been specifically designed for the study, based on the gold standards of person centred care in dementia care settings and with a Human Rights Based focus. This will aid in establishing whether Human Rights Based training is an explanatory variable in any changes in care and well-being observed over and above a standard training package as it allows for 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 will be assessed via Dementia Care Mapping (DCM; Bradford Dementia Group, 1997) - an observational assessment yielding quantitative measures of well-being and ill-being for the individual with dementia.

Staff decision making: Decision making will be explored via vignette based interviews with staff at various grades on the participating sites. It was felt that this qualitative element of the study served several purposes. It is hoped that it will provide an outcome in its own right in that it will explore how staff make decisions in difficult complex situations. This was a useful part of the pilot phase. The interviews will also provide more information on the mediators of any effect observed as it asks directly about decision making and what assists with this. If the intervention is successful more human rights based language and a clearer framework for decision making should been seen in the post intervention interviews.

Knowledge of Human Rights: In order to assess knowledge acquisition during the training pre and post-training measures of Human Rights knowledge will be collected via the Human Rights Knowledge Quiz, as recommended by “A Guide to Evaluating Human Rights Based Interventions in Health and Social Care” (Donald, 2012). This data will be collected on the day of the training. A Human Rights Attitude Quiz will also be used to look at changes in attitude pre and post training. Again this data will be collected on the day of training.

Health Economics: The trial will also conduct a cost consequence analysis where consequences include: patient reported health related quality of life (EQ-5D), patient reported well being (QoLAD), care plan development and adherence to care plans by staff, staff stress, family member well being (self efficacy measure) and overall quality of care (ASCOT).

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 which would capture the information required, that is 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 the Enhanced Care Planning for dementia document derived from Kitwood's principles of person centred care.

A 'tick box' format applies and therefore data can be expressed as a percentage as well as a raw number for pre- and post-intervention and then compared formally, using either paired sample t-tests or analysis of covariance, as appropriate. There is however also the capability to capture more qualitative data which will allow reflection on the person centred nature of care plans and the inclusion of Human Rights Based language in care plans. If the intervention was successful it would be anticipated that care plans post training would be more person centred and include more Human Rights Based language. An independent consultant, who is an expert in the field of dementia care, will also be asked to judge whether they can tell the difference between a selection of pre and post training care plans.

Vignette based interviews - Interview schedules were developed by combining the areas of enhanced care planning from Kitwood's model of dementia care and the Human Rights considered to be most relevant to health care . Ten vignettes were constructed which, between them, covered all relevant areas using examples from clinical practice. Using hypothetical examples such as these avoids asking directly about care provision which may not lead to responses that reflect true practise due to demand characteristics and staff concerns about the perceived potential repercussions of their responses.

Knowledge and Attitudes questionnaire - The Human Rights Knowledge and Attitudes Quizzes were adapted from the original learning disabilities questionnaires outlined in "A Guide to Evaluating Human Rights Based Interventions in Health and Social Care" (Donald, 2012).

Issues of Specificity

It is important that the outcome measures utilised allow 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 will measure the documented standard of care that a person should be receiving but will also tap into increases in Human Rights based language and concepts which would be suggestive of the Human Rights Based nature of the intervention having an effect over and above simply providing generic training.

The completion of Human Rights knowledge and attitude quizzes measures changes in these areas pre and post training but does not look at the impact this has on staff in their everyday working lives and how it affects service user well being. Staff interviews will be conducted to explore whether the introduction of a Human Rights Based Approach leads to differences in their decision making processes when considering care issues. Again this will be evaluated through the identification of key phrases and concepts in the transcripts which would point to the specificity of a Human Rights Based Approach having a direct influence on daily decision making. The FREDA based questionnaire will allow the team to explore whether service users feel that their Human Rights are respected and upheld more after the intervention.

Taken together these elements will allow evaluation of the proposal that the Human Rights Based Approach outlined in this proposal has benefits that would not be seen by generic training.

Development and Validation of the FREDA Assessment tool

Although there is recognition that violations of human rights can occur in healthcare settings little has been done to attempt to quantify the extent to which this occurs. It is perhaps understandable that health care settings do not want to ask about the Human Rights act directly due to fear of litigation if they are found to be failing in their legal duty. Given, however, that the NHS has a responsibility to ensure that an individual's rights are upheld whilst in their care it is important that there is a robust method to evaluate the extent to which this occurs. To this end, work has been undertaken to develop and begin validating a FREDA tool in order to assess how well individuals subjectively experience their Human Rights to be being upheld.

The FREDA principles have been used elsewhere within healthcare to aid individuals' understanding of their Human Rights (Curtice, 2010). 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 via focus groups with individuals with dementia and their carers. Participants came to one of two focus groups to discuss the care they had received in relation to their human rights. The main aims of the focus groups were to see if 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 to be used in relation to develop of the human rights agenda.

Following initial construction of items face validity will be tested by giving the provisional items to those individuals who participated in the focus groups. Informal, open ended interviews will be undertaken to determine relevance of questions to the original constructs. Additionally, the provisional questionnaire items will be piloted to ensure that it understandable for and accessible by people with dementia. In particular at this stage it will be essential that people at varying stages of dementia are consulted to clarify that the wording and layout of the questionnaire best facilitate its completion. Following this stage, any necessary adjustments will be made to the questionnaire items and a pilot run of the questionnaire will be administered to a sample of older people from the voluntary sector e.g. Age UK, reader organization and an older adult service user sample.

Sample size will be dependent on number of participants necessary to test number of items generated for each domain of questionnaire. Vignettes will be designed reflecting common clinical situations which will represent human rights being either upheld or disregarded. Participants will be asked to complete the questionnaire in accordance with their given vignette. In order to assess content validity, an exploratory factor analysis will be employed to statically test whether the number of domains within the questionnaire are suitable.

Additionally, a test of internal consistency will be conducted to explore if items measuring each construct (fairness, respect etc) correlate with other items measuring the same construct. Lastly, in order to test concurrent validity, the questionnaire will assessed as to whether it could distinguish between the hypothetical situations of the vignettes wherein human rights were upheld or not.

Research Plan/ Methods:

Search & Review Strategy

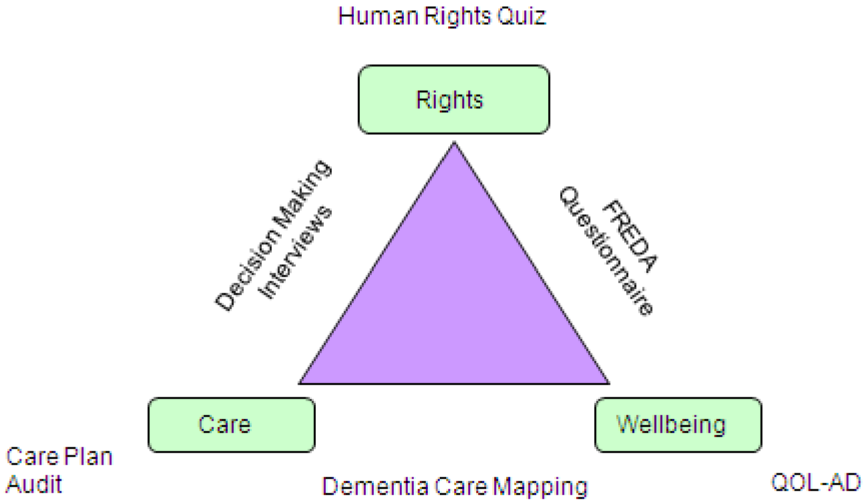
A preliminary literature review has been undertaken in the area of Human Rights within dementia care. Key search databases were used (AMED, EMBASE, HMIC, MEDLINE, PsycINFO, BNI, CINAHL, HEALTH BUSINESS ELITE) to look for keywords of dementia and/or alzheimer* and "human right*". The results were then limited to those which were conducted in the previous decade. A full search strategy will include a search of the above databases, widening the search terms to include those which may describe concepts connected to Human Rights, without explicitly naming so, (e.g. restraint, wandering and tagging).

To date, 64 journal articles have been published which specifically mention Human Rights in relation to dementia care.

Design and theoretical/conceptual framework

The research will use a cluster randomised design to compare the impact of implementing the intervention, i.e. the training package, Assessment Tool, and booster sessions on 10 intervention sites as compared to 10 control sites. The control sites will continue with treatment as usual. No active placebo is indicated. Control sites will receive the training following the conclusion of the research.

The underlying conceptual framework for the study is that the introduction of a Human Rights Based Approach to health care will lead to improvements in the well being of people with dementia and the care they receive. This is summarised in the figure below and highlights how the outcome measures proposed allow us to investigate these areas and the links between them. Specifically, the QOL-AD will allow measurement of changes in subjective well being but will not explain why these changes take place. The care plan audit will measure the documented standard of care that a person should be receiving and will also tap into increases in Human Rights based language etc which would be suggestive of the Human Rights Based nature of the intervention having an effect over and above simply providing generic training. Care plans do not however capture the actual care that is delivered and how it affects well being. Dementia Care Mapping will be used to discover whether care provided on a unit changes and the effect this has on well being of service users on the unit. The completion of Human Rights knowledge and attitude quizzes measures changes in these areas pre and post training but does not look at the impact this has on staff in their everyday working lives and how it affects service user well being. Staff interviews will be conducted to explore whether the introduction of a Human Rights Based Approach leads to differences in their decision making processes when considering care issues. Similarly the FREDA based questionnaire will allow the team to discover whether service users are feeling that their Human Rights are respected more after the intervention.



The project flow chart attached sets out the time points at which outcome measures will be administered.

Randomisation

Randomisation of the clusters will be undertaken by NWORTH using an adaptive, dynamic web based randomisation service (Russell et al., 2011). The clusters will be stratified for by geographical location and size.

It is recognised that randomisation would usually take place after baseline measures had been completed in order to avoid any biases generated by knowing which group you are in. In this case, however, this will not be possible. Sites will need to know in advance when their training will take place in order to make the practical arrangements to attend the training e.g. ensuring adequate staff cover for the site. Similarly, if baseline measures are completed too far in advance of the training taking place there is a risk that factors other than the intervention may influence any chance identified. For this reason sites will be randomised prior to baseline measures being taken. In order to minimise the effects of allocation to group prior to baseline measures being taken the information given about the exact nature of the training provided, particularly its focus on Human rights, will only be revealed to those staff who need to know this in order to plan e.g. ward manager and it will be made clear at this point that all staff will receive the training at some point.

Sample Size

The sample size is based on the primary outcome measure; the QOL-AD and is based on conservative figures on several parameters.

Effect size- The literature has indicated that previous similar research has yielded effects sizes of 0.6 (Selwood, Thorgrimsen & Orrell, 2005) but we feel that we should be a bit more conservative given practical experience hence we have powered for an effect size of 0.5.

Intraclass correlation coefficient (ICC) - Other trials utilising the QOL-AD have applied an ICC of 0.02 based on pilot work (Woods, Bruce, et al, 2012). As this is a different intervention and the differences between groups/clusters is the important aspect we have chosen to apply a more conservative ICC of 0.05.

Sample size – A sample size of 10 clusters with 11 individuals per group achieves 80% power to detect an effect size of 0.5 using QoL-AD when the ICC is 0.05 using a 2 sided t-test with a significance level of 0.05. Taking a retention rate of 77% (Hoe et al, 2009) into account requires 14 participants to be recruited per cluster. This results in a total sample size of 280 participants.

Family carer well being is being explored via the WEMWBS. We would aim to recruit a family care giver for each participant but acknowledge that in reality this will not be possible. The sample size for this group will therefore be dictated by the number of participants who have a family carer willing to take part in the trial. Staff vignette based interviews will be analysed qualitatively and saturation point will therefore be taken as a sample size indicator. Similarly, as the care plan audit has been designed specifically for this trial a more pragmatic approach to sample size will need to be taken.

Setting & Target Population

The proposed research will be conducted in dementia inpatient wards set with NHS Trusts and care homes. The lead Trust will be Mersey Care NHS Trust. Expressions of interest have also been received from Greater Manchester West, Lancashire Care and 5 Boroughs

The population to be investigated during this study is that of service users and staff of inpatient dementia wards. All service users will be either existing residents or new admissions to the dementia units.

Initial expressions of interest to be involved in the study were based on the understanding that staff would need to be released for training and the demands on staff time have been discussed. Whilst commitment is not in the form of formal contracts a clear, strong interest and commitment has been expressed from a number of organisations. Having presented the package at a variety of events, including the launch of the Human Rights in Healthcare document, interest has been high from both NHS Trusts and care home settings. Mersey Care NHS Trust has been approached by other local NHS Trusts interested in implementing the package and they are clearly interested in being involved in this study. Similarly, contact has been made with clinicians, the relevant senior managers and research departments in the local NHS Trusts to assess interest – it was found to be high. There are many personal contacts and agreements amongst this which are based on previous collaborations and joint working. The research team will work closely with the DeNDRoN ERICH (Enabling Research in Care Homes) programme to support care homes in being involved in the study.

Inclusion/Exclusion Criteria

Inclusion criteria will be broad and are outlined below in relation to both sites and individuals at these sites.

a) Clusters – All NHS sites will be dementia specific wards. It would be unlikely that all the care homes will be caring for people with dementia exclusively. Care homes will be included if caring for people with dementia is part of the facilities core business and they have enough residents with dementia to fulfil the needs of the study.

b) Individuals within clusters – the main inclusion criteria for individuals within the cluster is a diagnosis of dementia. Issues such as age, severity of dementia, length of time at the setting will be recorded but are not inclusion/ exclusion criteria in themselves.

The main exclusion criteria would be an individual who does not have capacity to consent and has no proxy available to support them in this.

Data Collection

Baseline measures will be completed 1 week prior to an intervention site receiving training. Demographic data and an assessment of cognitive impairment, as measured by the Alzheimer's Disease Assessment Scale (ADAS-Cog; Rosen, Mohs & Davis, 1984), will be completed to ensure that the participants from hospital inpatient and care home settings are comparable on these factors. Demographic data will also be collected from staff at the sites to compare level of training and experience.

In order to minimise factors other than the intervention impacting on the results the pre-training interviews will be conducted the week before the training takes place. The post-training interviews will take place a month after the third booster session to allow time for the Human Rights Based Approach to be embedded into the culture of the service.

Adherence checks will be made at booster sessions to ensure that the assessments are being completed. This will involve looking at a selection of completed Getting it Right Assessments at the site to check that they have been completed, completed accurately and within the given time frames.
Subsequent to the final booster session post-intervention measures will be taken.

The time frame of 3 months has been chosen as the scope of the study is to evaluate the immediate impact of introducing a Human Rights Based Approach to care. Whilst it would be possible to extent the follow up period it is felt that this may lead to higher attrition rates due to high turnover rates on dementia inpatient wards. There is also a risk that extending the follow up period would result in individual participants experiencing clinically significant changes in their cognitive ability over the course of the study, thereby making pre and post comparisons more problematic.

The participant data will be collected and inputted by the research team and managed through MACRO an electronic data capture system provided by NWORTH. MACRO is an electronic data capture system which meets regulatory compliance for designing electronic case report forms, data entry, data monitoring and data export, and good practice guidelines. MACRO has built in systems for an audit trail and quality assurance.

Data Analysis

Quantitative Analysis: A multi-level ANCOVA, Analysis of covariance, will be used to compare groups on continuous quantitative scores collected. This model will take account of the cluster design and use baseline scores as covariates.
Other standard covariates, including the stratification variables will be considered for inclusion in the model.

Qualitative Analysis: Thematic analysis as outlined by Braun & Clarke (2006) will be used to analyse data from the vignette based semi-structured interviews. The pre-intervention themes will be compared to the post-intervention themes using constant comparative method (Glaser, 1965) in order to assess any changes in light of the training and tool use.

Economic Evaluation

Economic Research Question: What are the costs and consequences of human rights training for staff looking after patients with dementia in a hospital and care home setting in terms of patient reported well being, care plan development, staff stress, family member well being and overall quality of care, as compared to usual patient management?

Based on the MRC's guidelines for the evaluation of complex interventions (MRC 2008) and our Standard Operating Procedure for economic evaluation alongside pragmatic RCTs, and experience in the conduct of economic evaluation alongside trials of psychosocial interventions in dementia care (Hounsome et al 2010; Woods et at 2012) we will, from a public sector, multi-agency perspective (Edwards et al 2008, Glick et al 2007, Drummond et al 2005, Brazier et al 2007, Gold et al 1996, MRC 2008):

1. Fully cost the human rights staff training programme, distinguishing between set up/training costs and running costs, with the former amortized over 3 years.
2. Record study participant medication, primary and secondary care health service use and social care , focussing on intensity of nursing care on wards and on admissions and readmissions to hospital for participants in care homes (using where possible, routine hospital and care home data, costed using National unit costs 2012).
3. Conduct a cost consequence analysis where consequences include: patient reported well being (QoLAD), care plan development and adherence to care plans by staff, staff stress, family member well being (self efficacy measure) and overall quality of care (ASCOT).

We suggest the inclusion of EQ-5D 3L for participants with mild to moderate dementia, for comparison with other published studies, and our previous trials, but have opted for a cost consequence approach rather than cost utility analysis 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. This is a study where the economic evaluation will need to take account of clustering, particularly between hospital setting and care home setting (Sculpher et al 2004).

Dissemination and projected outputs:

We will adopt a range of dissemination methods to publicise our findings.
We plan a series of peer reviewed publications in International Journals reporting the outcomes of the study (for instance; Ageing and Society, Dementia). Presentations will also be given at appropriate, leading, academic and service-provider conferences.
Reports describing the research and implications for care will be made available to participating organisations.
If proven successful, the training package and the 'Getting it Right' Assessment Tool will be disseminated to service providers through the NHS and social care providers.
The pilot project was part of the national Human Rights in Health Care project (www.humanrightsinhealthcare.nhs.uk) coordinated by the Department of Health and we will continue to use our links with the project to facilitate wider dissemination of the project. We will also utilise existing links and networks to ensure service users and carers are included among those who get to hear of our findings.

During the dissemination phase we will also explore other possible uses of the intervention e.g. use in learning disabilities or brain injury populations; expansion for use in community settings.

The principal outputs from the research will include the training package, the 'Getting it Right' Assessment Tool and the FREDA questionnaire, in addition to academic papers. This will be used to inform better-quality care for people with dementia.

With appropriate tools, the care workforce are more likely to be able to offer high-quality, human rights compliant care. If successful, the materials developed through this research will replace other outdated assessment tools that are not fit for purpose for the target population. With appropriate support, staff will feel more able to face complex clinical decisions, thus raising their sense of empowerment and improving the person centred nature of care plans.

If the research reveals measurable and significant improvements in the care of people with dementia can be achieved through the intervention described here, roll-out to the wider health care system could have a significant benefit for service-users, especially if further developments ensue.

Predicted benefits

The main benefits expected as a result of the research are: Increased subjective and objective well being of people with dementia in inpatient wards or care settings. This will be seen in an increased standard of care for people with dementia in inpatient or care settings and reported increases in well being from those with dementia. Additionally, we predict that a successful intervention will result in staff working on dementia inpatient wards or care settings having a more robust framework in which to make complex clinical decisions on a day to day basis. The additional validation of the FREDA questionnaire would also permit staff or researchers to assess service user's opinion on the level to which their basic Human Rights are respected. This will have significant utility in future research and care management.

Many of the concepts covered in the Getting it Right Assessment Tool map directly onto the standards of the Accreditation for Inpatient Mental Health Services (AIMS) process and therefore allow wards to meet the required the standards more readily. Again this may reduce the duplication of paperwork required.

There is currently no measure to directly explore the FREDA principles. An objective of this study is to validate such a measure. The validation of the FREDA questionnaire will permit staff or researchers to assess service user's opinion on the level to which their basic Human Rights are respected. This could have significant utility in future research and care management.

It is suggested that, if successful, the intervention could have generalisability to other areas. If the Getting it Right Assessment Tool was to be completed with people with dementia at an earlier stage whilst they are still in community settings the assessment document could follow them throughout their journey. There are particular issues with the treatment of people with dementia in general hospital wards and this assessment may allow a more thorough understanding of the person to guide care in this setting. During the pilot stage there have been preliminary discussions with learning disability services to explore the utility of the intervention with this population.

Plan of investigation and timetable:

Initial pilot work has already been completed and it is proposed that a further pilot phase will be conducted prior to the start date of May 2014.

Work is also underway to develop a FREDA questionnaire. The development and initial validation of this questionnaire will be completed between July 2013 and November 2013.

The study will be approved through the appropriate multicentre research ethics committee and research governance procedures after notification but prior to the start date.

May 2014 - July 2014. Research Assistants will need to complete Dementia Care Mapping training at this stage so that they can use the technique in the study. Site allocation to clusters will also take place at this stage.

July 2014 - January 2016. Delivery of intervention. For each site baseline measures will be completed 1 week prior to the intervention being delivered and 4 months post intervention.

January 2016 – March 2016 Deliver training to the control sites.

January 2016 – April 2016 Final analyses, writing report and papers, dissemination and conferences

Project Management:

A Programme Steering Committee (PSC) will be set up to oversee the study with a Data Monitoring and Ethics Committee (DMEC) as a subcommittee of the PSC. In addition to the independent members of the PSC, it will be comprised of key co-applicants, PPI Lead and the PPI representatives. The PPI Steering Group reports to the PSC. The PSC and DMEC meet biannually.

The Programme Management Group (PMG) meets quarterly with operational responsibility for delivery of the Programme (CI, programme coordinator, operational team members, trial statistician and PPI representative, utilising teleconferencing/ videoconferencing as necessary and appropriate.).

We will arrange monthly team and PI meetings once established, recognising that these may need to be more frequent in the early stages.

Staff management- Research assistants will be line managed within the University by the PI. They will be employed for 2 years.

Ethical Considerations and Data Management Protocols

The study will be approved through the appropriate multicentre research ethics committee and research governance procedures. The study will be compliant with Good Clinical Practice (GCP) standards, with staff trained accordingly. Accurate records will be kept, in accordance with the protocol, and data will be collected and managed in a systematic and verifiable manner. Standard good governance and practice procedures will be followed using GCP guidelines and the standard operating procedures adopted from NWORTH where appropriate.

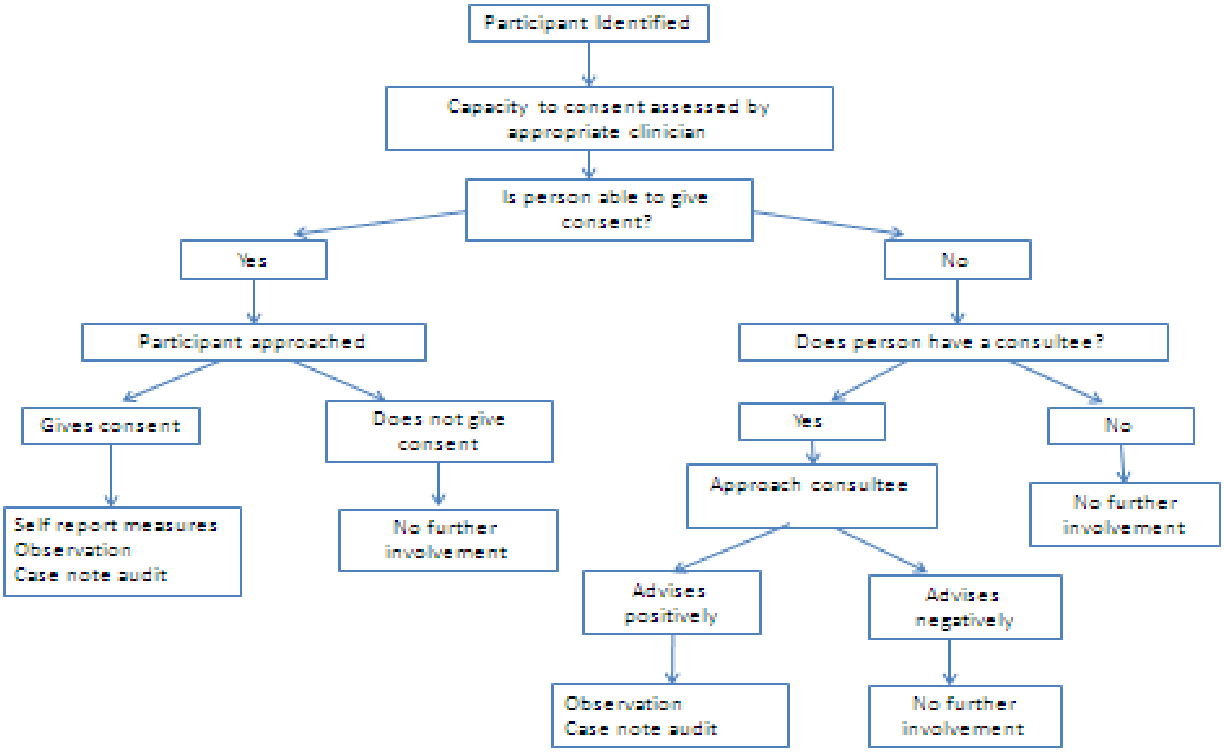
The pilot phase was granted ethical approval by the local Trust research and Governance department. Ethical approval for the trial will be sought after notification of success.

The trial will be registered with www.controlled-trials.comand allocated an ISRCTN number. There are unlikely to be any harmful side-effects, and participants will be fully informed of the potential risks/benefits of the project. The potential risks are not likely to be any different between the usual care and the intervention groups. We follow the National Research Ethics Authority guidance on including people who lack capacity. We follow the Mental Capacity Act Code of Practice for participant's whose level of cognitive impairment is severe (or increases) so they are unable to give adequate consent. The research will follow the Data Protection Act 1998 guidance on confidentiality.

There are two main ethical considerations predicted to be issues in this study.

Capacity to give consent - Obtaining informed consent will always be an ethical dilemma when working in dementia care, particularly when working at the later stages of dementia. By the fact that people are in care homes or on a dementia ward they are likely to be at later stages of dementia. The team acknowledge that people at later stages of dementia, and particularly those without carers, are vulnerable and it is therefore important that they are included in study. Every attempt will be made to obtain informed consent with every potential participant in line with the Mental Capacity Act. Experienced clinical staff will assess the capacity of each potential participant, in line with best practice in research governance and the recommendations of the Mental Capacity Act, and individuals will give (or withhold) consent if they are able to consent themselves. If people are not able to give informed consent they will not be asked to complete the self report measures. Although the QOL-AD has been chosen specifically because it is suitable for people at later stages of dementia it is reasonable to assume that if people are unable to give informed consent completion of the measure will be difficult. There is no reason that people without a family caregiver should be excluded from the study if they can give informed consent to participate.

If someone is unable to give informed consent, and therefore not included in the self-report element of the study they may still however be included within Dementia Care Mapping in cases where a Personal Consultee can be identified and consulted. If it is not possible to identify a Personal Consultee, or if the Consultee advises against including the individual in the study, the person will not be included in any aspect of the research. A flow chart outlining these issues is included below.



Care Standards - A potential ethical issue is that the nature of observing and questioning people about the delivery of care may identify care practices which are considered to be below minimum standards. In these circumstances the formal, established procedures of the relevant site will be followed.

Patient and Public Involvement:

Meaningful service user involvement fits well with key aims of the project to ensure dignity and respect whilst remembering that the individuality of human needs does not diminish with the passage of time or diagnosis. We aim to follow the lead of others who have worked within the arena of Human Rights research by fostering meaningful inclusion of service users and carers through co-production (Roberts, Greenhill, Talbot & Cuzak, 2012).

Previous to this application, service users and carers have been included in the development of measures, project design and their views sort during consultation at a Mersey Care NHS Trust Research Conference.

As outlined above service users and carers have been fully involved in the development of both the Getting it Right Assessment Tool and FREDA questionnaire.

It is proposed that service users and/or carers will continue to contribute to this proposed research at all levels. At the outset of the proposed project a service user or carer will be recruited as an integral member of the research team, provided with training and be paid for their time, a cost accounted for in the budget. We would anticipate that in addition to contributing to the development of the project they will be involved in elements of the research and training delivery.

Alongside this, a PPI reference group will be set up including service users, carers and other interested stakeholders. The large membership of this group will provide diverse opinions which will benefit each stage of the process. Additionally we will link with the Mersey Care Service User Research and Evaluation (SURE) group and the Mersey Care Applied Research Innovation and Service Evaluation (ARISE) group who bring an excellent track record of PPI involvement in research and have numerous service users and carer representatives on their steering groups.

We aim to disseminate the findings of our study as widely as possible to feedback the outcomes of this proposed research to service users and their carers. The pilot work conducted has already been presented at Mersey Care NHS Trust Service Users in Research Conference in March 2013. During this event, service users and carers were invited to comment on the pilot work and the proposed study. Similarly,, communication of the study results will be ensured through the service user and carer communication channels available to Mersey Care NHS Trust.

Expertise and justification of support required:

The project team consists of experts within the field of both dementia care and human rights including service users/carers, clinicians and academics, alongside individuals qualified to assist in the conducting and analysing of the research such as a statistician and qualitative research consultant.

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