The "Mi Care HQ" Project:
Measuring and improving Care Home Quality (Mi Care HQ)

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Summary of Research

Background:
Over 300,000 older people in England live in care homes due to significant long-term health problems. Many have cognitive impairment.

In England, the Care Quality Commission (CQC) regulates care homes to ensure they provide appropriate quality of care. Since 2014, their approach has undergone substantial transformation, moving from a system based on minimum standards to one of quality ratings (outstanding, good, requires improvement and inadequate), with around a fifth of homes being rated as 'inadequate' or 'requires improvement' [1]. However, regulation is only one aspect of quality improvement and there remain questions about what 'quality' means, and how we can measure it.

The Care Act stresses that care services should improve people's 'wellbeing', which could be measured to include people's care and health-related quality of life (QoL). Rigorous, reliable and innovative approaches to measurement are required to be able to collect data about care home residents' health and care-related quality of life. Standard approaches to the measurement of patient or service-user reported outcomes rely on 'self-report' methodologies, which have repeatedly been shown to be inaccessible and inappropriate for most care homes residents [2, 3], leading to an overreliance on proxy reporting [4, 5].

Care home staff have a critical bearing on quality. Issues of the type of staff employed, training provided and how well they are able to identify and manage residents' health and care needs, are likely to influence residents' clinical and wellbeing outcomes.

Aims:

1. To develop and test new health outcome measures for pain, anxiety and depression that can be used with care home residents unable to communicate their quality of life (WP1 and 2);
2. To assess how far the regulator's (CQC) quality rating of care homes reflect residents' quality of life, by measuring the correlation between these indicators (WP2 and 3);
3. To assess how much the staff mix and employment conditions of the care workforce matter for quality: especially staff turnover rates, training provision, different contracts, pay rates etc. (WP3)

Methods:
WP1 (health measures): Conceptual development of three health-related quality of life domains (pain, anxiety and depression) that can be used alongside the mixed-methods version of the Adult Social Care Outcomes Toolkit (ASCOT) to measure both social and health-care related quality of life in care home residents. We will begin with a scoping review of existing measures, with a particular focus on tools that already incorporate observational methods, thus making them appropriate for use with people who cannot self-report. Focus groups with care home stakeholders will explore acceptability and face validity of the items, before they are cognitively tested in interviews with care staff (n=8-10) and resident representatives (e.g. family members) (n=5) using 'think aloud' and probing techniques [6]. Changes to the item wording will be made iteratively during this process, to ensure suitable beta versions of the domains for piloting in WP2.

WP2 (psychometric testing): Pilot the beta versions of the pain, anxiety and depression outcome domains, using a mixed-methods approach (interviews and observations), with a minimum of 250 care home residents from 25-30 care homes for older people (nursing and residential). Additional data about residents' care-related quality of life, needs and characteristics will also be collected to assess the construct validity of the new measures using a combination of parametric and non-parametric techniques. Appropriate psychometric techniques will be used to assess how well these domains fit with social care-related quality of life, measured by the the Adult Social Care Outcomes Toolkit (ASCOT, and to what extent they can be included alongside the overarching measure to give a comprehensive indicator of care home residents' (health and social) care-related quality of life, using a mixed-methods approach.

WP3 (care home quality ratings): Econometric analysis of secondary data to investigate the relationship between CQC quality ratings, workforce characteristics (including training provision) and residents' outcomes. Care home quality data for all homes for older people (c. 10,000) in England are available from the regulator. Data on staff characteristics and conditions are available from the National Minimum Dataset for Social Care, which includes a sample of over 6,000 care homes for older people/dementia, employing about 250,000 staff. Data on residents' outcomes will be drawn from a combination of existing datasets within the PSSRU and the data collected in WP2.

Outputs/impact:
The project will develop new, rigorously tested, outcome domains for pain, anxiety and depression, which can be used with all care home residents, even those unable to self-report. The study will add to the evidence base relating to regulator quality ratings and resident outcomes and help care homes, commissioners and regulators understand the impact of workforce policy and training, and so improve the quality of care. We will produce academic papers of the results/methods, along with reports/summaries and guides for those whose work concerns care homes. Literature for residents and carers will also be produced.

Background and Rationale

Over 300,000 older people in England live in care homes due to significant long-term health problems. Many have reduced cognitive functioning and difficulties with communication (e.g. as a result of dementia) and live with multiple long-term health conditions [7]. This places care home residents at risk of living with under reported and under managed pain, anxiety and depression [8–11].

In England, the Care Quality Commission (CQC) regulates care homes to ensure they provide appropriate quality of care. There are, nonetheless, concerns about the quality of some homes, and questions about what ‘quality’ means, and how we can measure it. Health and social care policy has emphasised the need to consider person-level outcomes as indicators of impact and quality and yet measuring these outcomes is challenging, particularly when trying to assess the quality of life of people with cognitive impairment. Most quality indicators either only capture service-level outcomes or only reflect the experiences of people who are able to engage with conventional measures, using a self-report methodology.

The Adult Social Care Outcomes Toolkit (ASCOT) was developed as a multi-attribute, preference-weighted outcome measure of social care-related quality of life (SCRQoL) and has eight conceptually distinct domains: food and drink, personal cleanliness and comfort, accommodation cleanliness and comfort, safety, social participation, occupation, control over daily life and dignity. The scale was designed to be sensitive to the impact of social care services and interventions on people’s quality of life and has sound psychometric properties [12]. Unlike many quality of life measures, ASCOT has a mixed-methods version designed to be used in care homes. Trained researchers collect evidence about each domain through observations and interviews with staff, family members and residents (where possible), which inform ratings of the person’s outcome states. This methodology enables the inclusion of people living with dementia and those who are unable to self-report and has excellent inter-rater reliability [3].

There is recent literature on measuring SCRQoL in care homes [12–14], which demonstrate high levels of unmet needs around social participation and engagement in meaningful occupation [3, 14], with residents spending long periods of time asleep or disengaged. Care staff recognise the importance of these aspects of residents’ lives but sometimes lack the training and time to understand why residents’ might be disengaged or lack motivation to participate in activities and how they might be supported to overcome these barriers [14].

The contribution of under-detected and under-managed pain, anxiety and depression to social care outcomes us currently unknown, yet likely to be highly significant. Research suggests that pain [15–17] and depression [18] are often under recognised and under treated in care homes, especially for residents living with dementia [11]. Untreated pain in older adults has been shown to exacerbate the symptoms of dementia [19, 20], as well as increasing functional decline, poor appetite and depression and being linked to poor sleep, lower levels of activity, socialising and overall quality of life [19, 21, 22]. Similarly, living with anxiety and depression can have a range of negative impacts on an older person’s life, including poorer health [23, 24], loss of independence and functional ability [25, 26], cognitive decline [27, 28], increased behavioural problems [29] and suicide [30].

The quality of care provided by care homes will affect how well residents’ care and health-related needs are met. Quality varies for many reasons, but the nature and characteristics of the workforce, and their approaches to care are likely to be major determinants. The care home sector currently has relatively high levels of staff turnover and vacancy rates [31] and there is a potential future workforce shortage [32]. Wage rates are also low. These employment conditions of the workforce could be having a negative impact on care outcomes, given that issues of pay, training, status, terms and conditions are likely to influence quality [33–35].

Evidence explaining why this research is needed now

For largely historical reasons, most public funding of care home residents in England is through local authority social care rather than the NHS, with a little over 150,000 older people supported. In addition, more than 120,000 older people pay for care home services themselves. NHS continuing care in care homes accounts for a relatively small minority of residents at somewhat over 30,000 people. Nursing care in care homes, as opposed to personal care, which is a social care responsibility, is also covered by the Registered Nursing Care Contribution paid by the NHS. Around 90 per cent of care home services are provided under contract from private and voluntary sector providers.

Care homes are regulated for standards and quality by the Care Quality Commission (CQC), but the way in which homes are inspected has changed a number of times in the last decade. The most recent system has rated around a fifth of homes as ‘inadequate’ or ‘requires improvement’ [1]. As well as on-going concerns about the quality of care, especially given the cost pressures that now exist in social care, there is uncertainty about exactly how CQC quality ratings relate to ‘final’ outcomes for care home residents. The concept of improving ‘wellbeing’ lies at the heart of the Care Act [36], defining the key purpose of the social care system, yet there is little evidence about how far care homes do improve the care-related quality of life and health of residents, and indeed the cost-effectiveness of this care.

A national study carried out under the previous care regulator, the Commission for Social Care Inspections (CSCI), found a relationship between regulator quality ratings and residents’ quality of life outcomes in residential but not nursing homes [13]. More recently, research involving a small sample of homes in England (293 residents in 34 homes) found that the new quality ratings are indicative of residents’ quality of life for both types of homes, with residents in homes rated outstanding/good having significantly better social care-related quality of life than residents in homes rated as requiring improvement/inadequate [37]. However, more evidence is required to see if these findings can be replicated in a larger sample of homes and the focus of this work was on social-care outcomes, not health.

Although measures of pain, anxiety and depression already exist for use in research or practice, unlike the ASCOT for social care, there is no equivalent way of estimating the impact of services on these outcomes. Existing measures focus on the person’s current situation or diagnosing a condition without any reference to input from services or support and without a mechanism for attributing improvements of change in outcomes to those services. There is also no evidence to suggest that tools have attempted to use innovative methods or adapted forms of communication to support the inclusion of people with cognitive or communication difficulties. This is important in care homes where we know that many have dementia and physical and sensory impairments than make self-completion or self-report challenging or impossible [2, 38].

Finally, although a small literature exists on the impact of workforce characteristics, e.g. staff turnover, on care home quality [33, 39, 40], most of this literature is US-based and focuses on clinical markers of quality or other process measures, not final outcomes or quality of life. Furthermore, there is very little statistical evidence in England linking skill mix and training levels to care quality outcomes [41–44].

Care home services remain highly labour-intensive, and as such the nature and training of the care home workforce is expected to be a highly significant factor for overall care home quality, and on the effectiveness of care on residents. The focus of this study is on the relationship between workforce employment conditions and training, CQC quality ratings and the care- and health-related quality of life of care home residents.

We hypothesise that where the workforce has good employment conditions, including relatively high wage rates, and where policies are in place to reduce vacancy rates and staff turnover, this will have a positive effect on quality of care and support, which will in turn lead to comparatively better outcomes for care home residents.

Aims and objectives

This research aims to:

1. Measure the health and quality of life (QoL) of care home residents, particularly for people with impaired mental capacity (WPs 1 and 2). The specific objective is to develop new health outcome measures for pain, anxiety and depression that can be used alongside the Adult Social Care Outcomes Toolkit (ASCOT) with care home residents unable to communicate their SCRQoL.
2. Assess how far CQCs quality ratings of the home are consistent with indicators of residents’ QoL (WPs 2 and 3). The objective is to: (a) understand how indicators assessed at the home

level (CQC quality ratings) relate to the care- and health-related quality of life of sample individuals; and (b) to assess how far operational measures such as CQC quality ratings can be used as summary statistics of resident QoL.

3. Assess how much the skill mix and employment conditions of the care workforce matter for quality, including factors such as training provision, staff turnover rates, staff qualifications etc (WP3). The objective is to assess how much these factors – some under the home's control (e.g. training and skill mix) and some outside (direct) control (e.g. local labour market conditions) are associated with indicators of quality. The intention is to understand how policies that change these factors might be implemented to improve the quality of care.

Research Plan / Methods

The research plan comprises three interlinked work packages, which taken together seek to address the aims outlined above. The underlying theme is to assess how care home quality is affected by the way the care home workforce is organised, supported and managed. There are a number of ways to measure and assess care home quality that might be combined to measure quality more comprehensively. Our plan is to use an outcomes-focused indicator in the form of the Adult Social Care Outcomes Toolkit (ASCOT), measuring quality as the extent to which care can improve patient quality of life. ASCOT was designed to measure social care-related quality of life and has a version that can estimate quality of life for people who cannot use self-completion methods. WP1 (measures) will explore how key elements of health-related quality of life, such as pain, anxiety and depression, can be combined with ASCOT to provide a more comprehensive measure of quality and cognitively test the question wording and response options ahead of piloting.

WP2 will consist of a primary data collection with a minimum of 250 care home residents in 25-30 homes. We will collect data about residents' needs, characteristics and care and health outcomes and use this data to psychometrically test the validity, reliability and dimensionality of the new domains (pain, anxiety and depression). We will also record home-level quality indicators, such as the homes' CQC ratings, which will feed into WP3.

In WP3, we propose two general approaches to assessing the relationship between quality and workforce characteristics and deployment, one drawing on resident outcomes data collected in WP2, the other drawing on secondary data. First, while primary data collection is underway (WP2), we will conduct an analysis of existing data on around 6,000 care homes to model the relationship between CQC quality ratings and the following workforce characteristics: skill mix, training provision to staff, input of support from the community, such as by volunteers and staff terms and conditions (turnover/vacancy rates, and wages). All these variables, which can be affected by policy, are expected to be important determinants of quality. Second, once the primary data collection is complete, we will merge this data with comparable existing data held within the unit and collected as part of the measuring Outcomes of Care Homes (MOOCH) project [37], to examine the relationship between CQC quality ratings and resident outcomes in a larger sample of homes. The combined datasets will provide data for approximately 550 care home residents in 60 homes (residential and nursing).

The flow diagram in Annex 1 gives details of these processes.

The above is an overview of how the WPs fit together. Specific details for each are described below.

WP1: measures

The Adult Social Care Outcomes Toolkit (ASCOT) is a well-established set of tools for measuring outcomes in social care [45]. Its focus is on the social care-related quality of life (SCRQoL) of individuals. SCRQoL refers to those aspects of a person's quality of life that are relevant to, and the focus of, social care interventions. ASCOT uses an innovative approach to estimating the impact services are having on people's quality of life [45]. This approach broadly involves asking two questions. The first asks about the person's situation now (often with services already in place). We call 'current SCRQoL'. The second asks what the situation would be if services were not in place to support the person and nobody else stepped in. We call this 'expected SCRQoL'. Expected SCRQoL is, therefore, highly correlated with functional ability [45]. By taking the 'expected' scores away from the 'current' scores, we can estimate the impact the service(s) are having on the person's QoL.

The care home version of ASCOT uses a mixed-methods approach comprising observation of lived experience alongside interviews (staff, family and residents) to rate individual residents' SCRQoL [3, 13]. Although the tool can be used alongside other measures, including health-related quality of life (HRQoL) tools, the ASCOT tool itself does not include HRQoL domains. A mixed-methods approach is important for the high proportion of people in care home that are unable to use self-completion tools [2]. Up to 80% of care home residents [46] are believed to have dementia. QoL measures need to be designed for use in these settings and must address these challenges.

In order to better reflect the overall wellbeing of those who live in care homes, we propose to develop three new HRQoL domains; pain, anxiety and depression, which could be collected using a mixed-methods approach. They would sit alongside existing SCRQoL domains. Both of these outcome domains have been shown to be highly relevant to the lives of people living in older adult care homes [9, 47]. Whilst there are other areas of health related quality of life that are of relevance to older adults in care homes, for example usual activities and self- care as included in EQ-5D [48], aspects of these are included in the existing SCRQoL measure.

The first stage of this work package (aim 1) would concentrate upon the conceptual development of the three additional domains and conduct a scoping review of existing measures, with a particular focus on tools that already incorporate observational methods. The scoping review would feed into the development of draft tools. For each domain, drafts would include:

- Observational guidance;
- Two questions per domain (current and expected) with fixed response options to gather proxy (staff and family members) perspectives (to go into a structured interview schedule);
- One question with fixed response options to gather an individual’s current experience (to go into a structured interview schedule);
- A set of prompts for use in a semi-structured interview schedule for use with care home residents.
- Guidance for rating evidence gathered.

The initial inclusion criteria for the scoping review will be (1) English language tools (2) validated in populations over the age of 65 years of age (3) using observational or mixed-methods, however, in line with previous research [49], it is likely the final criteria will be amended post-hoc. For example, while the focus of the search is on measures used with older populations (and in particular older people living with dementia) and observational tools, if the initial search finds few tools, a broadening of the search criteria will be considered. Subsequent searches may include other populations (such as adults with intellectual disabilities) and methods (such as face to face interviews).

In the second stage, the draft tools will be shared with stakeholders (including care home staff) in three to four focus groups in order to explore the face and construct validity of the items. If significant issues are identified, a further period of adaptation and development will be carried out, followed by another two focus groups. It is in this stage that the research team will work in partnership with lay research advisors who will be peer researchers, assisting with the design, conduct and analysis and focus group interviews.

Following revision, the structured questions with fixed response options (see above), will be cognitively tested with a sample of staff (n=8-10) and family members of care home residents (n=5).. These new domains are being developed specifically to measure pain, anxiety and depression in a population who cannot self-report (due to cognitive impairment or communication issues), therefore data will mostly be collected by observing residents and speaking to staff and/or family members. As such, the structured questions and response options need to be tested with these potential proxy informants. Cognitive testing will not be done with care home residents, as this method is not suitable for people with cognitive impairments or communication difficulties and it is unlikely structured self-report questions will be used with this population. Staff and family members will be asked to reflect on the process of answering these two questions. This will be done via a combination of verbal probing techniques and the other main cognitive interview technique of thinking aloud [50].

WP2: psychometric testing

This work package aims to pilot and psychometrically test the properties of the new pain, anxiety and depression measures developed in WP1 and collect information about care home residents’ care and health-related quality of life outcomes to feed into analysis in WP3. A primary data collection will be required.

Recruitment of homes and residents

We propose to recruit around 25-30 care homes to the study. We will conduct a ‘filtering’ survey of all care homes for older people on the CQC register in six local authorities in the South East of England (n=circa 1242 homes). Homes will be sent a (paper or online) survey questionnaire gathering some local context, such as whether they follow any specific care philosophies or have particularly strong links with their local communities, as these are also factors that might influence care quality and would be helpful to describe and possibly control for in the analysis in WP3. The survey will ask for expressions of interest in taking part in future research and those who express an interest will become our eligible sample of homes. We estimate a 10-15% response rate to the survey, which would yield an eligible sample size of 124-186 homes, which should be enough to recruit our required sample size of 250 care home residents, powered to assess the construct validity, reliability and scale dimensionality of the new measures.

Once a home has agreed to take part in the research, the Clinical Research Network (who have agreed to support recruitment of residents in this study) and/or the research team will visit the home and explain the recruitment process to the home manager. We are aiming to recruit a mean of 10 residents per care home to the research, with a minimum of five in any one home. In homes with distinct units/hubs, catering for residents with different care needs, we will try to recruit five residents per participating hub/unit. This has been a successful strategy in recent research [37], providing a more representative sample of residents in larger homes and also having practical advantages in terms of economies of scale for fieldwork.

All permanent (long-stay) residents are eligible to take part in the study and managers will be asked to randomly select every nth resident from an alphabetical list and continue selecting/inviting until we achieve the desired sample size in each home. We will rely on the professional judgement of the manager as to whether the resident has the capacity to consent or requires the involvement of a personal consultee. This approach has been employed successfully in previous research by the research team [38, 51, 52] and received ethical approval from the REC. Where residents have the capacity to consent, the CRN will support the study by inviting them to participate and collecting informed consent. In cases where the person lacks the capacity to consent, the registered manger will be asked to forward information to an appropriate personal consultee, such a close family member or friend. If no such person exists, the resident will be excluded from the research as we will not have the capacity to consult professional consultees within this timeframe.

Instruments and data collection

Care staff will be asked to complete a questionnaire about each participating resident's needs and characteristics. As well as basic demographic and health information (e.g. diagnosis of dementia), the questionnaire will contain validated scales and items asking about the person's health-related quality of life (EQ5d), functional abilities (activities of daily living) and cognitive state (e.g. the Cognitive Performance Scale). These have been used extensively by the research team in previous care home research and staff have no difficulty completing them on the resident's behalf. In order to explore the content validity of the new domains of pain, anxiety and depression, these questionnaires will also now contain staff-rated, validated scales relating to these concepts so that we can explore hypothesised relationships with the new attributes in the analysis. Which scales are included will be informed by the reviews being undertaken in WP1.

Depending on the number of residents taking part in each home, one or two researchers will visit the service to pilot the new domains (pain, anxiety and depression) and collect social care-related quality of life (SCRQoL) using the ASCOT. As outlined in our original proposal, the ASCOT uses a mixed-methods approach to collecting SCRQoL data in care homes, which includes structured observations, interviews with residents and interviews with staff and family members. Evidence from these sources is then triangulated and used to inform a researcher/fieldworker 'rating' of the person's outcomes in each of the ASCOT domains. The approach is described in full elsewhere [38] but uses a systematic approach following a hierarchy of evidence to deal with any conflicts in ratings. The hierarchy gives precedence to the residents' own view, where the person has been able to give it. However, as outlined above, in most cases care home residents are unable to self-report in this way, so the researcher will draw on their own observational evidence (notes taken on each outcome domain during a structured 2 hour observational period) and also the views of staff and family members. All ratings are supported by the rich qualitative evidence gathered during the data collection. The hierarchy of evidence and systematic approach to ratings has led to excellent inter-rater reliability in previous research [38].

We propose a similar approach for the new domains and will be piloting these alongside the main ASCOT measure. Where possible, data collection will be assisted through the use of the Open Data Kit

(ODK) an android-enabled platform that enables researchers to enter data directly onto a mobile device, where it can be encrypted and stored securely before being uploaded to a secure server.

*Analysis (*psychometric testing)

To assess construct validity, we will test the hypothesised relationships between the new domains and the other scales, using a combination of non-parametric (e.g chi-squared tests for unordered or ordered categorical variables)) or parametric tests (e.g. one-way analysis of variance (for continuous variables)). For chi-squared tests, one-sided probability exact tests will be used when computationally feasible; where this is not possible, data will be recoded to increase numbers in individual cells or Fisher's exact test will be used instead. Associations significant at the 1% level will be taken to be strongly suggestive of a relationship between the attribute and the variable; relationships significant at between the 1% and 5% level will be taken to be moderately suggestive of a relationship between the attribute and the variable; and relationships significant at between the 5% and 10% level will be taken to be weakly suggestive of a relationship between the attribute and the variable. We will also consider the patterns of relationships as well as the p-value to assess the direction of the relationships rather than significance alone.

To explore the dimensionality of ASCOT after including the new domains, exploratory factor analysis will be used (principal axis factoring (PAF)). Suitability for PAF will be assessed using Bartlett's test of sphericity (significance $p < 0.001$) and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy (>0.6). Factors will be retained via the Kaiser criterion (eigenvalue >1.0) and variances of each factor >5%. The factor structure of ASCOT will then be further examined using Rasch analysis (partial credit model), a more modern psychometric approach. Item goodness-of-fit will be measured by infit mean square $\geq$ 1.2. For dimensionality, the variance for the Rasch model is expected to explain at least 50%, with the remaining components explaining $\leq$ 5% of the variance (eigenvalue $\leq$ 2.0). To assess reliability, we will test the internal consistency of participants' responses across the ASCOT items (including new domains) using Cronbach's alpha coefficient. A high Cronbach's alpha coefficient indicates that items in the measure are measuring the same construct.

WP3: care home ratings

Aim 2: Assess how far CQCs quality ratings of the home are consistent with indicators of residents' QoL (WPs 2 and 3)

Drawing on the data collected in WP2, the comparison of CQC quality ratings and resident outcomes will use (multi-level) regression analysis to estimate the correlation between sample SCRQoL and the care home's CQC quality rating. The estimation will use SCRQoL data from the 250 residents in WP2, supplemented by comparable data from the *Measuring the Outcomes of Care Homes* (MOOCH) project [37]. The MOOCH study assesses the relationship between CQC quality ratings and residents' SCRQoL and has data on 293 care home residents in 34 care homes in England. Both datasets will have information about residents' age, gender, needs levels, etc., and care home-level data, such as registration category, size and CQC quality rating, which can be used in the analysis.

Aim 3: Assess how much the skill mix and employment conditions of the care workforce matter for quality.

We propose to use the National Minimum Data Set for Social Care (NMDS-SC)and econometric modelling to investigate the relationship between care home quality – as measured by the Care Quality Commission (CQC) quality rating of the home – and workforce characteristics, training provision and community engagement of care homes for older people in England. This analysis, which will mainly inform aim 3, will focus on the effects of workforce skill mix (e.g. share of registered nurses in total direct care staff), staff terms, conditions and training provision, as well as community engagement (e.g. volunteers, and employment of community support and outreach staff as well as activity workers). This would complement research by the Economics of Social and Health Care Research Unit (ESHCRU) using the NMDS-SC, which examined the impact of local labour market characteristics and staff terms and conditions. The ESHCRU work – which involves a number of current co-applicants – has provided valuable understanding of the dataset and the feasibility of our proposed analyses.

We propose to assess determinants of CQC quality rating overall and also the components that underpin the overall rating (i.e. safe, effective, caring, responsive, and well-led). The components analysis should reveal whether some care outcomes are more strongly related to staff characteristics, training and engagement than others.

We will use a range of econometric methods to account for selection in the data, including multi-level modelling to account for selection on observables and instrumental variables to account for selection on unobservables [53]. There are several factors that may affect care home ratings. These confounding factors can be classified into resident characteristics (or case mix), care home characteristics, and market characteristics [35, 53, 55, 56]. Resident characteristics (e.g. age, ADL function, mobility, mental status, long-term conditions, etc.) may provide some indication of care need and the amount of staff required to meet the care demand. Care home characteristics are often associated with nurse staffing levels and skill mix, but also include for example the type of ownership (i.e. for profit and not-for-profit status), group size, care home size (i.e. number of beds), work environment, payer mix (i.e. share of self-funders), and geographical location. Market characteristics usually capture the level of supply in the local area (e.g. number of beds) and indicators of the local labour market (e.g. unemployment rate). Data on care home characteristics including beds, type and sector are available in the NMDS-SC, but measures of resident characteristics are not available. We will therefore match indicators of need, as well as measures of demand and supply, to the dataset at local area-level.

We will also explore the possibility of a longitudinal aspect to the analysis if a large enough subset of homes has been inspected on more than one occasion over the period January 2015 to April 2017. Compared to cross-sectional analysis, a longitudinal analysis would provide stronger evidence of causation.

The NMDS-SC is a rich source of information on care provider staff characteristics and staffing levels in England. Social care provider registration and data input for the NMDS-SC are voluntary. Providers are encouraged to participate through: personalised staffing reports, local market comparisons, training incentives, and information held on NMDS-SC can be used to automatically update the staffing section of Provider Information Returns (PIRs), a legal requirement to their CQC registration. Despite the voluntary nature of the data provision, the NMDS-SC includes data for a large proportion of social care establishments [54]. In detail: the NMDS-SC as of April 2016 has data for more than 22,000 social care establishments (all establishments, including domiciliary care providers, and not just care homes). Over 16,000 of these are in the independent sector (for profit and voluntary sectors), of which nearly 10,000 are care homes. From these, there are nearly 6,000 care homes for older people and/or those living with dementia. A minority of these care homes may not be suitable for the analysis as they are aimed at specific clients, e.g. older people with brain injuries. Further refinement of the sample may be necessary based on when the staffing data was entered – if using only care homes that have updated information in the last year, we anticipate a sample of 3,500-5,000 care homes. The sample of about 6,000 care homes for older people/dementia employ more than 250,000 staff. We will initially focus on independent sector homes (to have a more homogenous dataset given that, for example, competitive forces in both the labour and care homes market are less likely to impact on LA homes), but will also run analyses with LA homes included.

Dissemination and projected outputs

In addition to the final report and PowerPoint slides (i.e. the required project outputs), we intend to inform a wide audience about the progress and results of the project.

First, we will produce interim reports and papers/articles on the results and methods. We expect to produce three papers in academic journals (e.g. NIHR HS&DR Journal, Health Economics and Ageing and Society) to engage with a wide range of disciplinary scholars (e.g. Social Policy, Economics, Gerontology and Geriatrics). We also expect to produce two articles in professional magazines (e.g. Community Care) to engage with the broader health and social care professionals.

Second, reports/summaries and tools/guides for those working in the care sector will also be produced. These will be concise papers or blogs focusing on the implications of the results. Where appropriate, these will be co-authored and disseminated in collaboration with PPI members of the advisory group.

Third, we will produce literature for residents and carers, developed, as far as possible, in conjunction with the co-researchers taking part in the study and experts in communication with people with limited mental capacity. These will likely take the form of digestible pamphlets, with the emphasis on key messages, such as what to look for when choosing homes

Fourth, we will have a project website which will contain all the project's outputs (e.g. reports and discussion papers, recordings/slides from webinars/presentations etc.). A range of social media, including Twitter and blogging, will be utilised to broadcast the main findings.

Fifth, we expect to report the results at: academic conferences (e.g. HESG, BSG), regional feedback sessions with those who took part in the study, CPD registered events (e.g. the National Care Forum and the Margaret Butterworth Care Home Forum) and also at stakeholder events, subject to invitations, e.g. Care England events. We will also present the findings to an international audience of policy makers, academics and providers through the annual ASCOT workshop and/or webinar series.

We aim to also work with stakeholder networks and policy makers to disseminate research findings. Care England and other care home representative organisations are concerned with these issues. Regarding policy, employment conditions form part of the new market-shaping responsibilities for local authorities as laid down by the Care Act 2014. We will build on our Policy Research Unit (QORU) networks to disseminate relevant findings from the research.

The project should help providers, commissioners and regulators to improve quality of care through developing new health outcome measures for care home residents and understanding the impact of workforce policy and training.

Specific impacts include:

First, the research will provide stakeholders with tools to measure relevant health outcome measures for pain and anxiety/depression when used alongside care-related quality of life indicators. These measure could be used with care home residents, especially those unable to communicate effectively how they feel because of dementia or very poor health in relation to promoting an effective workforce.

Second, the results will aim to influence the care sector regarding (a) employment practice e.g. staff recruitment and training etc., and (b) policy seeking to affect the operation of local labour markets. For example, the results might help shape DH guidelines or regulatory practices regarding staffing practice in care homes where that is linked to improved quality. These factors are important because the Care Act requires local authorities to foster a workforce that is able to deliver high-quality services. Where appropriate, we would develop benchmarking templates for this purpose.

Third, by drawing on two comparable datasets, we aim to improve understanding of how well CQC quality ratings reflect care homes residents health and care-related quality of life.

Timetable

The research project will start in July 2017 and runs for 36 months.

Months	*Activity*	*Work Package(s)*
1-8	Rapid review of existing measures of pain and anxiety	1
	Literature and scoping review informing study design	2
	Design of filter survey	2
	Ethical review of focus groups, secondary data analysis and filter survey	1, 2 and 3
	Preliminary analysis of secondary data	2
9-13	Development of new, “mixed-methods” pain and anxiety domains	1
	Filter survey of care homes	2
	Ethical review of primary data collection (Health Research Authority (HRA)	2
	Begin secondary data analysis	3
14-20	Focus groups of pain and anxiety domains with care home staff	1
	Cognitive interviews of pain and anxiety domains	1
	Substantial amends for ethics, Research governance and HRA ethics review	2
	Selection and recruitment of care homes begins	2
	Primary data collection in care homes begins	2
	Secondary data analysis finished	3

21-27	Recruitment, primary data collection and entry continues	2
28-36	Data analysis	all
	Dissemination	all

Project management

Prof Jackie Cassell (PI) will provide overall management of the project, produce analyses, and oversee the drafting of the progress reports and final report. JC will also provide links to relevant NHS projects and health and residential care networks.

Mr Nick Smith (Co-I) will lead the WP1 (measures) and the drafting of the Interim Report 1. He will co-lead the analysis and paper relating to the development and cognitive testing of the new domains.

Dr Max Cooper (Co-I) will advise the project and enable access to general practitioners advice on health related measures through his undergraduate teaching networks.

Dr Stephen Allan (Co-I) will co-lead WP3, (care home ratings) drafting of Interim Report 2 and a research paper on the results of the secondary data analysis in WP3.

Dr Florin Vadean (Co-I) will co-lead WP3, (care home ratings) organise and manage the filter survey (WP2 (psychometric testing). He will co-lead the drafting of Interim Report 2, a research paper on the results of the secondary data analysis in WP3 (care home ratings), and conduct the analysis for the research paper on the results of the primary data collection relating to CQC ratings and residents' outcomes.

Ms Ann-Marie Towers (Co-I) will provide day-to-day management of the project at Kent and also lead on the completion of the ethical review at PSSRU/University of Kent, manage the primary data collection (WP2) (psychometric testing), and co-lead drafting the research paper on the results of the primary data relating to CQC ratings and residents' outcomes. She will also lead the paper relating to the psychometric properties of the new measures.

Dr Henglien Lisa Chen (Co-I) was formerly lead for WP4 which has been removed at the request of NIHR. She will contribute to the analysis and interpretation of primary data collected in WP1 and WP2.

Prof Julien Forder (Co-I) will support the research work and provide advice about social care policy.

Communication and coordination of activities between the two teams at the PSSRU/University of Kent and the University of Sussex will be mainly through contact by email and phone. Four face-to-face team meetings are planned at key stages of the project: a kick-off meeting in the first month of the project; a meeting on the selection/recruitment of care homes for the primary data analysis (WP2 (psychometric testing)) around month 11; and two meetings during the drafting of the interim and final reports. We also anticipate monthly project meetings by video/audio conference that will involve all or some subset of the research team. In addition, specific meetings will occur as required regarding the business of individual work packages.

Liaison and reporting to NIHR will be via the project HS&DR research liaison officer.

Data and information governance will be managed in line with PSSRU/University of Kent and University of Sussex data and IG policy.

Study steering committee and data management and ethics committee

We can confirm that we have already begun identifying suitable experts for these two committees, with a view to appointing members if we are successful with this application.

Study Steering Committee

The PI (Professor Cassell) will sit on the steering committee and other work package leads will be invited to present their contributions to the project to the committee at relevant stages of the research. In addition, we aim to appoint an independent chair with expertise in research in care homes, and a further three independent members consisting of a minimum of one: statistician/health economist;; service user recruited via the University of Sussex's public involvement group; and care home manager.

The steering group will meet at the very start of the project and at least another 3 times (annually) after that.

Data management and ethics committee

We will invite a member of the data management team from the PSSRU, a member of the QORU public patient involvement group, a representative from the care regulator and at least one academic with expertise in the ethics of care homes research to sit on this independent committee.

By agreement with the Steering Committee and NIHR, there no separate Data Management and Ethics has been convened and the Steering Committee will address relevant issues. .

Approval by ethics committees

Ethics and research governance approval will be sought in two stages to insure an early start of the project work: (1) we will apply at an early stage (months 4-8) with University of Kent Faculty of Social Sciences Research Ethics Advisory Group for ethic clearance for the stakeholder focus groups (WP1 (measures)), secondary data analysis (WP3 (care home ratings)) and filter survey (WP2 (psychometric testing)); (2) once filter survey is completed and the care homes for primary data analysis (WP2 (psychometric testing)) are identified, we will seek ethical approval from the Health Research Authority (HRA) as well as the appropriate research governance consent in the LAs sampled for the project (months 10 to 12).

Patient and Public Involvement

In relation to the commissioned call for research, the specific aims and methods of this research proposal, as laid out in plain English summary, have been considered by five members of the public. We have also revised the following sections based on comments and feedback from two members of QORU's Research Advisory Group: Plain English Summary, Dissemination and Outputs, and Patient and Public Involvement.

PPI input will be delivered in four ways:

- The study steering group and data management and ethics group will include PPI representatives. We plan to include one member of the QORU Public Patient Involvement Group and one or more service users recruited via the University of Sussex's public involvement group. Members of the steering group will review project plans and outputs for written quality and clarity, attend meetings and give a public/patient perspective on any issues that may arise.
- We will recruit lay research advisors from QORU's research advisors panel (RAP) to help us conduct WPs 1 and 2 e.g. to comment on study materials and specific design issues. There are 25 RAP members with various backgrounds in, and experience of, the workings of health and social care services.
- We propose to involve two members of the RAP in our fieldwork data collection activities in WP1. These persons will be given training through participation on our ASCOT courses. We propose that these people work as part of the research team for these activities.
- Finally, we will invite PPI members as co-authors on reports and summaries and tools/guides.

Formal support and training for PPI reps will be offered through PSSRU's QORU programme. The two RAP members recruited to be directly involved with fieldwork will be trained and supported by the research team to assist with the focus groups in WP1.

NEW UPDATED REFS (2018)

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Annex 1. Flow diagram