ISSN: 2059-3341

East Midlands Research into Ageing Network (EMRAN) Discussion Paper Series

ISSN [2059-3341]

Issue 22, September 2018

Statistical Analysis Plan for the Proactive Healthcare of Older People in Care Homes (PEACH) study

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East Midlands Research into Ageing Network (EMRAN) is a research collaboration across the East Midlands to facilitate collaborative applied clinical research into ageing and the care of older people. EMRAN was set up with support from NIHR CLAHRC East Midlands.

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ABSTRACT

The Proactive Healthcare for Older People living in Care Homes (PEACH) study aims to evaluate whether Quality Improvement Collaboratives can be an effective way to work with local health and social care stakeholders, including representatives of the care home sector, to implement Comprehensive Geriatric Assessment (CGA) in the care home setting. It will enlist the support of four Area Improvement Collaboratives from South Nottinghamshire, UK to make changes to enable CGA in care homes in their areas.

The primary outcome measure is health-related quality of life (HRQoL), measured using the EuroQoL 5-domain 5-level (EQ-5D-5L) index. A cluster-randomised (where care homes represent clusters) approach will be taken. Secondary outcome measures will be Health Service Resource by service category. These will be analysed using an interrupted time series approach.

The methodology is challenging and introduces the need to control for multiple sources of contamination, clustering, time effects including lag effect and measurement issues with the primary outcome variable, including the uncertain reliability of care home staff proxy responses.

This paper outlines the statistical analysis plan for the study, describing how these challenges have been addressed. It acts as reference point for further publications from the PEACH study.

INTRODUCTION

Around 425,000 people live in care homes in the UK (1). The average resident has six diagnoses, takes eight medications and is affected by cognitive impairment and functional dependency (2). Previously, the delivery of primary healthcare in UK care homes was not guided by any form of comprehensive or structured model of assessment or care management and was, therefore, inconsistent and often ad-hoc and reactive (3). Although there has been progress at policy, commissioning and service levels towards a proactive healthcare approach in care homes, these initiatives remain localized and have not been implemented at scale (4). This could be due to a number of factors including failure to work collaboratively with the care home sector, to recognise the need to prepare care homes for changes to models of care, to identify key NHS stakeholders with an established pattern of working with the care home sector, or to adequately incorporate dementia-specific considerations into models of care (5). An important contributing factor identified in research to date is that effective service delivery is predicated on using staff with the correct types of expertise – in frailty and dementia management – with referral models built around the home so that staff from different teams can communicate and co-ordinate the management of care taking account of the important structural role that the care home and it staff play in delivery (6).

Comprehensive geriatric assessment (CGA) is a model of co-ordinated and integrated multidisciplinary care for older patients which has been shown to be more effective than standard hospital approaches to care (7). It has been contended that CGA may be a useful organising framework for establishing better integration and co-ordination of healthcare in the care home sector (8). In CGA, a multidisciplinary team undertakes a comprehensive assessment with a focus on medical, psychological, functional, social, and environmental issues. This ensures recipients have clearly stated care management plans that are reviewed at intervals based on individual priorities to ensure measurable goals are attained (9). This approach has not been widely implemented in care homes in the UK.

Quality Improvement Collaboratives were developed by the Institute of Healthcare Improvement in the USA as a way of pulling together healthcare professionals and stakeholders to concentrate time and effort around iterative cycles of improvement in order to implement, embed and sustain innovations in healthcare practice (10).

The overall aim of the Proactive Healthcare of Older People in Care Homes (PEACH) study is to evaluate whether Quality Improvement Collaboratives can be an effective way to work with local health and social care stakeholders, including representatives of the

care home sector, to implement CGA in the care home setting. The study aims to do this by describing the process of implementation, testing the contextual and mechanistic factors that lead to success and measuring the health and economic consequences of changes to practice resulting from the collaborative.

The Quality Improvement Collaborative as a whole will comprise health and social care stakeholders from the geographical areas covered by four Clinical Commissioning Groups (CCGs) across South Nottinghamshire, which we have called Area Improvement Collaboratives. The Quality Improvement Collaborative, comprising all four Area Improvement Collaboratives, will meet formally four times per year to share and reflect on progress, whilst each team works on improvement projects to implement CGA in their areas between times. The Area Improvement Collaboratives are being coached by quality improvement experts to plan, design and implement their individual CGA-focused intervention. However, how they interpret CGA and eventually implement it will be determined by each Area Improvement Collaborative. This reflects the emphasis in the findings from existing research about implementing change to healthcare in care homes, which emphasizes a focus on local solutions which respect the configuration of contextual factors which influence the likelihood of positive outcomes (11).

Early work with the PEACH Area Improvement Collaboratives has recognised a spectrum of approaches to the challenge set by the Quality Improvement Collaborative. These initial approaches are outlined in table 1. Developing a typology of these approaches, as they progress, will form part of the PEACH study. Initial observations suggest, though, that they differ in the extent to which they replicate published descriptions of CGA, with some being narrower in focus than would have been expected, utilising the expertise of one professional and providing focussed assessment, for example around prescriptions or dietetics.

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Table 1: CGA interventions delivered by CCGs

CCGs	Intervention
1	Multi-Disciplinary Team (MDT) to comprehensively assess the needs of older patients living in care homes who have undergone recent deterioration. This builds on a process of comprehensive assessment at admission which is already in place.
2	Comprehensive geriatric assessment by a dietician in conversation with care home staff.
3	MDT to assess new residents admitted within 3 months to care homes.
4	The use of a standardized medication review checklist to improve the quality and safety of medication review carried out in a care home. There is also a possibility of developing a referral system between the medication review outcomes and a falls specialist.

DESCRIPTION OF THE INTERVENTION

This is not a trial of CGA but of Quality Improvement Collaboratives intended to implement CGA. This is because, as stated above, we have specified broad expectations about what should be achieved, but allowed each Area Improvement Collaborative to determine the shape that their improvement project will take. It is possible that the Quality Improvement Collaboratives will implement CGA to a greater or lesser extent, or not at all. It is possible, regardless of whether or not they effectively implement CGA, that they will influence the quality and structure of care in the care homes supported by the Area Improvement Collaborative. We have designed our evaluation plan with this in mind.

DESIGN OF THE EVALUATION

The intervention, as described above, will have effect on two levels: the effect of the Quality Improvement Collaborative at an Area Improvement Collaborative level, and the effect of the improvement plan implemented by Area Improvement Collaboratives at a care home level. The evaluation approach is designed to estimate the effect on outcomes of both the Quality Improvement Collaborative and the interventions implemented by the Area Improvement Collaboratives. The approach is intended to be pragmatic, and to include both process and outcome evaluations. The design for outcome evaluation is summarised in table 2 and involves:

- Assessment of the impact of Quality Improvement Collaborative across all 4 Area Improvement Collaboratives using interrupted times series to compare service use outcomes pre and post implementation of the Quality Improvement Collaborative.

- We will ask that our Area Improvement Collaboratives implement their improvement plans across selected care homes within their area in a stepped wedge cluster design, in random sequence order, with a new care home receiving CGA each month. The effect of the CGA will be considered overall and also at an Area Improvement Collaborative level, recognising that different Area Improvement Collaboratives may deliver CGA to a greater or lesser extent. We envisage that it may prove difficult to follow a strict stepped-wedge design for some of our Area Improvement Collaboratives, and we therefore also plan a quasi-experimental approach in which we will assess the effect of CGA models using interrupted time series to compare outcomes pre- and post-implementation of CGA across each Area Improvement Collaborative.

- Realist evaluation to understand what works, for whom, and in what ways when a Quality Improvement Collaborative intervention is used with the aim of improving delivery of CGA to people living in UK care homes. A detailed protocol for the realist evaluation has been published elsewhere (12).

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Table 2: Proposed Evaluation Framework

Evaluation question	Objective	Evaluation design
1. What is the impact of Quality Improvement Collaborative in each the four Nottinghamshire Area Improvement Collaboratives?	Utilisation of QI methodology to effect improvement in care	Comparison of service use outcomes pre- and post-implementation of the Quality Improvement Collaborative across 4 Area Improvement Collaboratives using an Interrupted Times Series (ITS)
2. How was Quality Improvement Collaborative/CGA implemented? What happened in practice with regards to implementation compared to the original plan (intervention fidelity)?	Description of process of implementation of CGA and Quality Improvement Collaborative	Process evaluation via interviews and direct observations with Quality Improvement Collaborative, care home staff and residents

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3. Was there a difference in resident/ service level outcomes in care homes that implemented the intervention according to how CGA was implemented?	To assess the effectiveness of CGA, and individual models of CGA, for Area Improvement Collaboratives with a stepped wedge design.	Stepped wedge design and analysis across and within Area Improvement Collaboratives.
4. Was there a difference in resident/ service level outcomes in care homes that implemented the intervention	To assess the effectiveness of CGA, and individual models of CGA, for Area Improvement Collaboratives where a stepped wedge design has not been possible / implemented.	Interrupted time series comparing pre and post implementation of CGA across care homes within each Area Improvement Collaborative receiving the intervention.
5. What was the cost of the relative improvement in residents?	To determine the cost of CGA/Quality Improvement Collaborative implementation using outcome estimates from the stepped wedge analysis	Economic evaluation

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6. What is the evidence on the programme theories associated with CGA?	To provide evidence on methods of achieving change via CGA	Theory derived synthesis of the evidence
7. How has the intervention made a difference? • How and why have the expected outcomes resulted? • For whom has the intervention made a difference? • What factors have resulted in the observed outcomes?	To test the contextual and mechanistic that lead to improvement (Quality Improvement Collaborative and CGA in practice)	Realist evaluation: What works for who why and how?
8. Can this be expected to work elsewhere? • Can Quality Improvement Collaborative/CGA be transferred elsewhere and scaled up?	To test the contextual and mechanistic factors that lead to improvement (Quality Improvement Collaborative and CGA in practice)	Realist evaluation

• Is Quality Improvement Collaborative/CGA sustainable? What generalizable lessons have we learned from the influence of context and mechanism on the observed outcomes?		

STUDY SETTING AND POPULATION

The setting is a geographical region in the East Midlands of England covered by 4 Clinical Commissioning Groups (CCGs). Because the CCGs cover mutually exclusive geographical footprints, we will use contacts within the 4 CCGs to recruit the Area Improvement Collaboratives. In keeping with the permissive structure of PEACH, the composition of each Area Improvement Collaborative will be up to its members but we will recommend that each includes approximately 7-10 participants, with the following professional roles represented in each: general practitioner, social care staff, nursing staff, therapist, geriatrician, voluntary sector, pharmacist, dementia specialist, care home workers/managers, and members of the public. To recruit these participants, the person with responsibilities of planning/purchasing healthcare services for older people in each of the four local areas will be asked to identify the relevant local key health and social care professionals to take part.

Care homes specialising in the care of older people in the geographical area covered by each Area Improvement Collaborative, including both residential and nursing homes, will be eligible for inclusion. Area Improvement Collaboratives will be asked to provide a list of care homes eligible to benefit from their improvement initiative. Homes will be selected at random from this list.

The eligible resident population will be residents in care homes targeted by Area Improvement Collaboratives. Eligible residents in selected care homes will be those over 60 years, and not receiving end-of-life or short-term respite care. Residents who lack capacity to consent will be included under the provisions of the Mental Capacity Act for England and Wales (13) if they have a consultee. If they do not have a consultee, they will be excluded.

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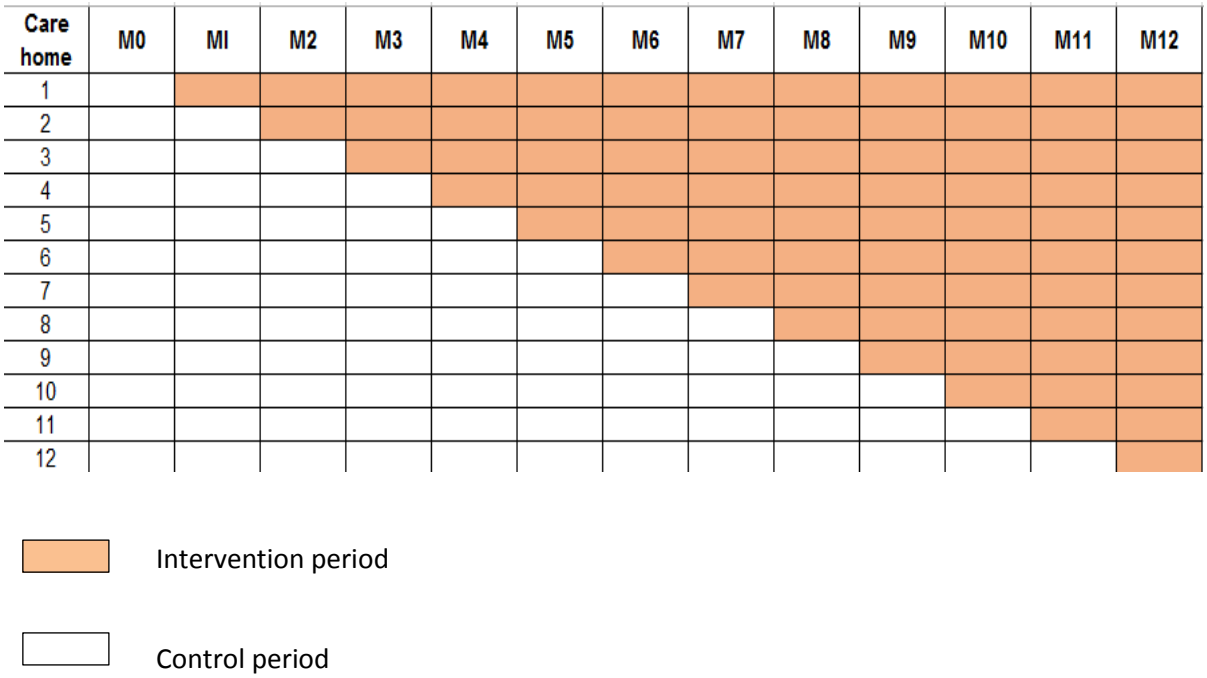
SAMPLE SIZE CALCULATION AND JUSTIFICATION

The primary outcome measure for the stepped wedge analysis is the EuroQoL-5 domain-5 level (EQ-5D-5L) Health Related Quality of Life Measure, described in greater detail below. A conservative intra-cluster correlation coefficient for EQ-5D-5L in care homes was assumed to be 0.05. The power calculation was based on at least 25 participants per care home with implementation carried out in 12 steps (a new care home per CCG receiving the intervention per month). Taking alpha as 0.05, with 12 care homes per CCG, and a 90% power, it will be possible to detect an effect size of 0.2 standard deviations difference between intervention and control periods for each CCG (14,15). This sample size is therefore 920 care home residents.

RANDOMISATION

Homes will be randomly selected from a list of care homes provided by each CCG. This will involve allocation of a study number to each home, and care homes will then be randomised using Stata v15 (Statacorp LLC, 2015) to the order in which they would receive the intervention in a stepped wedge design as shown below, with each step being one month in duration.

Figure 1: Proposed Evaluation Framework



BLINDING

Blinding is not feasible within this study design.

RECRUITMENT

All care homes will be recruited before they were randomised to start the intervention.

OUTCOMES

Outcomes measured in PEACH comprise a series of service and resident level outcomes summarised in tables 3 and 4 respectively. The rationale is that these reflect measurable differences in the patient experience that may translate, with some interpretation, into an understanding of how the Area Improvement Collaboratives, and the interventions they introduce, influence quality of care, quality of life, and resident satisfaction with care provided. In addition, we will consider whether the Quality Improvement Collaborative approach is cost-effective.

As described above, the primary outcome measure for the stepped-wedge analysis is the EQ-5D-5L. This is a widely-used preference-based health-related quality of life (HRQoL) measure suitable for use in economic evaluations. The EQ-5D-5L version measures HRQoL across five domains (mobility, self-care, usual activities, pain, anxiety/depression) with the scale for each domain ranging from level 1 (no problems) to level 5 (extreme problems). The responses from the five domains are converted to QoL index scores (utilities) generated from a given country's general population (16).

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Table 3: Service Level Outcomes

Outcome	Data source	Type of variable
Hospital admission rates (primary outcome)	Emergency hospital admissions to Nottingham University Hospitals (NUH)	Counts per care home per month
Hospital length of stay (secondary outcome)	Emergency admissions to NUH	Proportion <=2 days and >2 days (binary outcome coded 0/1) per care home per month
30-day readmission rates (secondary outcome)	Emergency hospital admissions to NUH which were a 30-day readmission	Binary outcome: proportion of admissions that were a 30-day readmission per care home per month
Ambulance consultations (secondary outcome)	East Midlands Ambulance Service (EMAS)- all types i.e. Hear & Treat, See & Treat and Conveyance Including contact type and consultation time.	Counts per care home per month
GP out of hours consultations (secondary outcome)	Nottingham Emergency Medical Service (NEMS)- both home visits & telephone consultations Including contact type and consultation time.	Counts per care home per month

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Table 4: Resident Level Outcomes

Outcome(tool)	Data source*	Type of variable
Quality of life (EQ-5D-5L)	Primary data collection from residents consented to PEACH in participating care homes	Domain levels- categorical Index scores- count/continuous QALYs- count/continuous EQ-5D-VAS- continuous/count
Quality of life (HowRu)		Categorical
Patient satisfaction (HowRwe)		Categorical

STATISTICAL ANALYSIS

Descriptive analysis

Baseline characteristics of care homes and their residents will be described using means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. Baseline care home variables will be type of care home (nursing or residential), latest Care Quality Commission (CQC) rating, number of beds and number of staff. Baseline resident variables will be age, gender, mental capacity status, ethnicity and length of stay in a care home, current medications, current medical diagnosis and Charlson Comorbidity Index. The Charlson Index records the presence or absence of 19 conditions which are weighted according to how strongly they predict mortality (17).

A summary of the missing data in each variable will also be reported.

Effectiveness analysis

Early work with the Area Improvement Collaboratives has suggested that deviation and variation in their chosen interventions may be as a result of broader resource and organisational constraints which may also impact on their ability to implement a stepped wedge approach to roll-out. This would, in turn, influence our ability to analyse the impact and effectiveness of each Quality Improvement Collaborative using a stepped wedge approach. In response to this likely and possible variation in approaches, we have identified a multi-tiered approach to analysis which includes an element of contingency so that varying approaches can be accommodated.

We will record the chronology and nature of clinical interventions with sufficient accuracy to verify whether a stepped wedge or quasi-stepped wedge approach was adopted. Where stepped wedge methodology cannot be used we will use an interrupted time series approach.

Stepped wedge analysis

A Generalized Linear Mixed Model (GLMM) will be used to adjust for clustering of the data. EQ-5D-5L utilities, EQ-5D-VAS and QALYs will be analysed using a linear mixed-effects regression model adjusted for care home and resident level characteristics. Emergency hospital admission, ambulance consultation and GP out-of-hours attendance rates will be analysed using a Poisson/negative binomial regression model. Hospital length of stay and readmission rates will be analysed using a logistic regression. A similar approach, using GLMM, will be taken for using costs as the outcome to calculate

incremental costs associated with the intervention. We will carry out an intention-to-treat analysis, assuming that each care home had the intervention implemented in the appropriate month for that care home and that each consenting resident in each of the care homes was delivered the intervention in the appropriate month.

The following equations show the statistical model to be fitted for the primary outcome of admission rates (15).

$$Log(E[Y_{ijk}]) = \beta_0 + \beta_j + W_{ik} + \theta X_{ij} + \alpha_i + \gamma_{ik} + e_{ijk}$$

The right side of the equation is connected to the mean of the outcome via a natural logarithm link function.

Y_{ijk}, is the rate of admission of a resident k at time j from care home i;

β_0, is the baseline rate of being admitted from a care home at time$j$ without the intervention.

β_j , is the fixed effect adjusting for being in time point j

W_{ik} , is adjusting for individual and cluster level baseline covariates

X_{ij}, is a fixed effect for whether or not care home $i$has the intervention at time$j$ (0 for no CGA, 1 for having CGA)

θ, is the log rate ratio for the effect of CGA on emergency hospital admissions

$\alpha_i \sim N(0, \tau^2)$ is the random effect for clusters (care homes)

$\gamma_{ik} \sim N(0, \emptyset^2)$ is the random effect for each resident; and

$e_{ijk} \sim N(0, \sigma^2)$ is the error term for each admission record.

Unit of analysis will be care home-month.

For our EQ-5D-5L data, we will assume that the data is missing completely at random and carry out a complete case analysis. All available data for each individual will be used. We are expecting no missing values on our routinely collected service level outcome variables.

To assess for balance at baseline, we will compare the baseline characteristics of the care homes.

Fidelity to the intervention

Area Improvement Collaboratives will be asked to record and share with the study team when the intervention was delivered, to which care homes and residents and when any changes to the intervention took place. This will be used as a proxy to measure intervention fidelity

Sensitivity analysis

We will conduct sensitivity analysis to explore whether effect estimates change if those residents with high proportions (greater than 25%) of missing data on an outcome are excluded.

Allowing for intervention effect heterogeneity across CCGs using fixed effects

The impact of the intervention at a care home level (CGA) will be estimated for the Area Improvement Collaboratives that employed the stepped wedge design combines as well as for individual Area Improvement Collaboratives using the following equation:

$$Log\ (E[Y_{i(c)jk}]) = \mu + \beta_j + W_{ik} + \theta X_{i(s)j} + \theta_s X_{i(c)j} Z_{i(c)} + \alpha_i + \gamma_{ik} + e_{ijk} \quad (18)$$

$Z_{i(c)}$, An indicator for Area Improvement Collaborative and θ_s a fixed interaction effect between treatment status and Area Improvement Collaborative.

Allowing for the variation of secular trends across CCGs using fixed effects

Because of the difference in the intervention between areas, it might be reasonable to expect a different secular trend in each Area Improvement Collaborative. This will be done by adding a fixed interaction between time and CCG to the basic model. This model extension only modifies the fixed effects component in the model and does not affect the correlation structure.

$$Log\ (E[Y_{i(c)jk}]) = \beta_0 + \beta_j + W_{ik} + \theta X_{i(s)j} + \delta_{jc} Z_{i(c)} + \alpha_i + \gamma_{ik} + e_{ijk} \quad (18)$$

δ_{jc} , represents the fixed time by CCG interaction.

Sub-group analysis

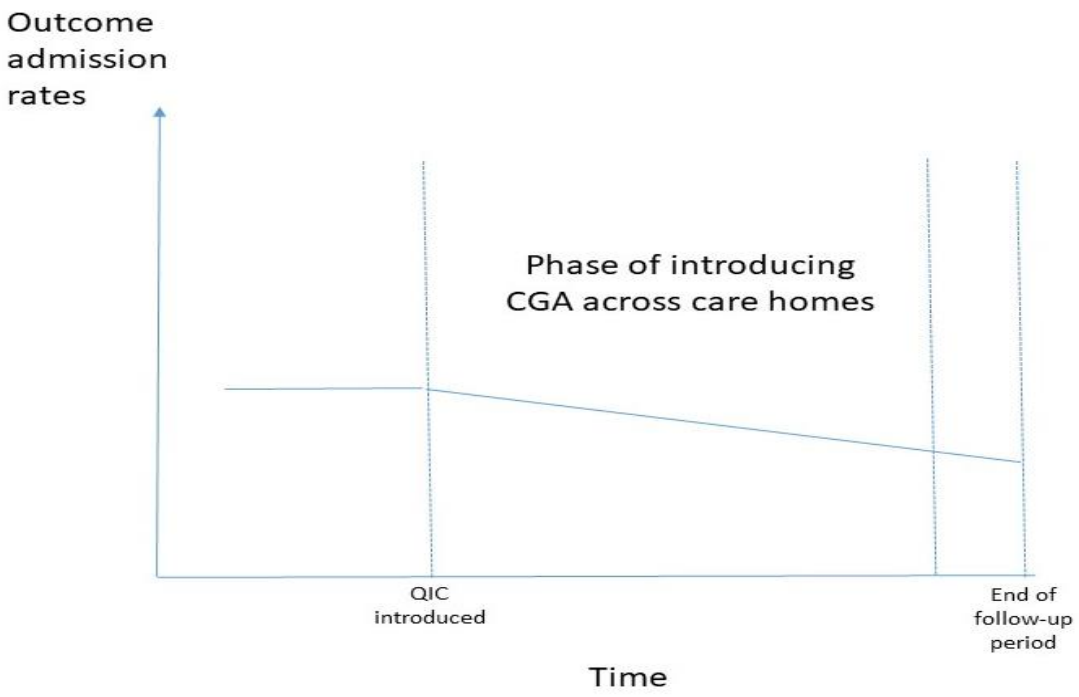
To investigate proxy-response bias, a pre-planned sub-study will be conducted to test the level of agreement between resident and proxy staff-responses for Health-related Quality of Life measures (HRQoL) – the Assessing Proxy Reliability In Care home Outcome Testing (APRICOT) study. A full protocol for this has been published elsewhere (19). This will help inform whether resident or staff values should be used where both are available. Assuming that resident values are used where these are available, with proxy values used only where resident values are not available, we will conduct sensitivity analysis to explore the effect of including only those with sufficient resident data.

Interrupted times series

Descriptive analysis - In addition to the summary statistics described above, time series of rates and proportions over time (25 months) with indicators of implementation of the Quality Improvement Collaborative and the CGA will be plotted across and within Area Improvement Collaborative areas.

Interrupted Time Series (ITS) assume a counterfactual situation whereby in the absence of the intervention or policy change, pre-existing trends remain unaffected. Therefore, any changes that do occur in the post-intervention period can be attributed to the intervention (20). ITS requires a hypothesis of how the intervention will impact on the chosen outcomes if effective. In particular, it requires the hypothesis to state whether the change will be a gradual change in the gradient of the trend, a change in the level, or both, and whether the change will follow the intervention immediately or there will be a lag period before any effect is expected. Our study hypotheses can be seen in figures 2 and 3 below.

Figure 2: Impact model for Quality Improvement Collaborative impact across Area Improvement Collaboratives



We hypothesise that there will be a downward trend in rates of admissions following the Quality Improvement Collaborative across the 4 CCGS.

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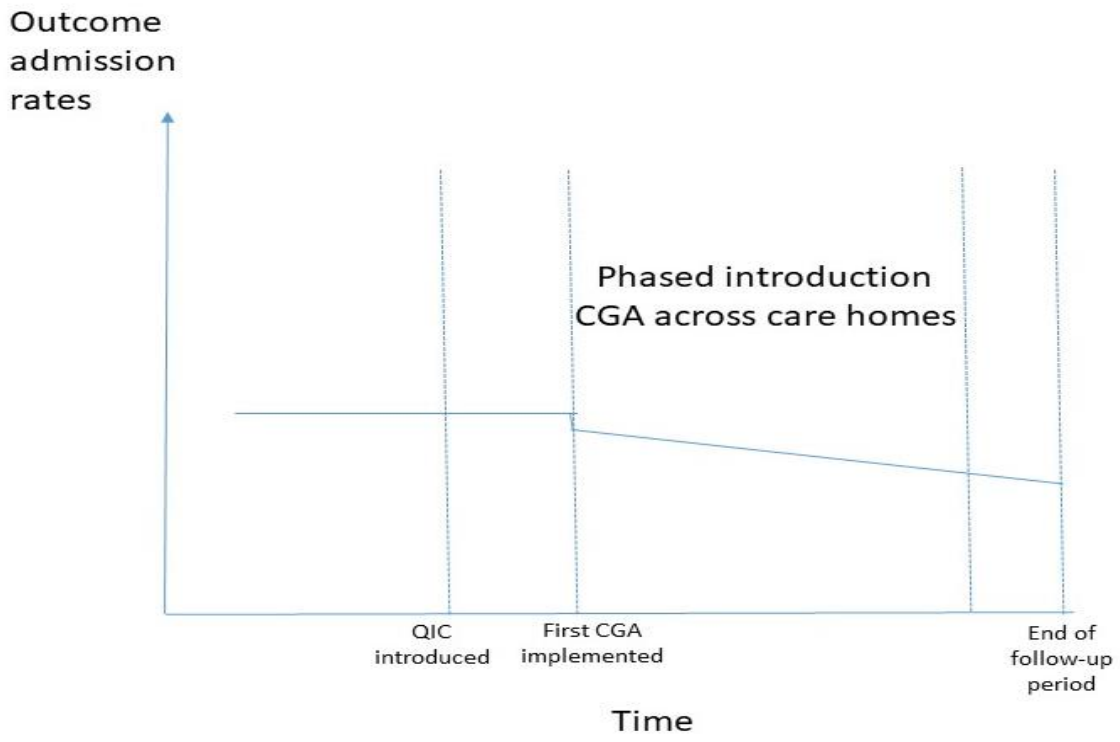
Figure 3: Impact model for CGA impact within Area Improvement Collaboratives



We hypothesise that there might be a lag period after the commencement of the Quality Improvement Collaboratives till CGA is phased in across each Area Improvement Collaborative area, that there might then be an immediate change in rates when implementation of CGA starts in a CCG and that there may be a gradual change in the trend in rates of admissions over the time period of the introduction of CGA across the care homes.

Method of analysis

Segmented regression analysis will be used. We will conduct a separate regression model for each CCG, and then estimate an overall effect by fitting a single model with data from all Area Improvement Collaboratives and account for the heterogeneity across Area Improvement Collaboratives by fitting random effects for CCGs.

Model for individual CCG

$$Y_t = \beta_0 + \beta_1 T + \beta_2 X_t + \beta_3 T X_t \quad (20)$$

The basic equation where:

- T: The months elapsed since the start of the study
- X_t: A dummy variable indicating the pre-intervention period (coded 0) or the post-intervention period (coded 1);
- Y_t: The outcome at time t;
- b_0: The baseline level at T = 0;
- b_1: The change in outcome associated with a time unit increase (representing the underlying pre-intervention trend);
- b_2: The level change following the intervention; and
- b_3: The slope change following the intervention (using the interaction between time and intervention: TX_t)

The unit of analysis will be monthly outcome per Area Improvement Collaborative for the Quality Improvement Collaborative intervention and monthly outcome per care home for CGA.

Addressing methodological issues to improve the robustness of the results

Adjusting for seasonality and long-term trends

We will use Fourier terms to adjust for seasonality plus a linear function of time to adjust for non-seasonal trends.

Accounting for over dispersion

We will allow for over dispersion by including a scaling parameter to avoid the incorrect estimation of standard errors.

Model checking and autocorrelation

Although in most cases autocorrelation is explained by factors such as seasonality and adjusting may account for this effect. Nevertheless, it is worth assessing residual autocorrelation. We will assess autocorrelation by examining a plot of residuals against time and partial autocorrelation. If we observe residual autocorrelation we will adjust for this using autoregressive integrated moving average (ARIMA).

ACKNOWLEDGEMENTS

The authors would like to acknowledge the broader PEACH study team: Mr Zimran Alam, Ms Anita Astle, Professor Tony Avery, Dr Jaydip Banerjee, Professor Clive Bowman, Mr Michael Crossley, Professor Claire Goodman, Professor Pip Logan, Professor Finbarr Martin, Professor Julienne Meyer, Professor Dominick Shaw, Professor David Stott and Dr Maria Zubair.

ETHICS

The Proactive Healthcare of Older People in Care Homes (PEACH) study was reviewed by both the UK Health Research Authority and the University of Nottingham Research Ethics Committee and determined by both to be a service development and evaluation project (London Bromley REC ref: 205840; University of Nottingham ref: LT07092016). The PEACH study protocol has been reviewed as part of good governance by the Nottinghamshire Healthcare Foundation Trust.

FUNDING

This work has been conducted as part of the Proactive Healthcare of Older People in Care Homes (PEACH) study, supported by the Dunhill Medical Trust, award number FOP1/0115.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare

REFERENCES

1. Laing & Buisson. Care of the Elderly People Market Survey, 2009. London: Laing and Buisson; 2010.

2. Gordon AL, Franklin M, Bradshaw L, Logan P, Elliott R, Gladman JRF. Health status of UK care home residents: a cohort study. Age Ageing. 2014; 43(1):97–103.

3. Iliffe S, Davies SL, Gordon AL, Schneider J, Dening T, Bowman C, et al. Provision of NHS generalist and specialist services to care homes in England: review of surveys. Prim Health Care Res Dev. 2015; 17(2):122-37

4. NHS England. New Care Models: The Framework for enhanced health in care homes, available online at https://www.england.nhs.uk/wp-content/uploads/2016/09/ehch-framework-v2.pdf (last accessed 24th April 2018).

5. Gladman JRF, Conroy SP, Ranhoff AH, Gordon AL. New horizons in the implementation and research of comprehensive geriatric assessment: knowing, doing and the "know-do" gap. Age Ageing. 2016; 45(2):194–200.

6. Goodman C, Davies SL, Gordon AL, Dening T, Gage H, Meyer J, et al. Optimal NHS service delivery to care homes: a realist evaluation of the features and mechanisms that support effective working for the continuing care of older people in residential settings [Internet]. Optimal NHS service delivery to care homes: a realist evaluation of the features and mechanisms that support effective working for the continuing care of older people in residential settings. NIHR Journals Library; 2017. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29091374

7. Welsh TJ, Gordon AL, Gladman JR. Comprehensive geriatric assessment - a guide for the non-specialist. Int J Clin Pract. 2013; 68(3):290-293

8. Gordon AL. What is the case for care home medicine? The geriatrician's perspective. J R Coll Physicians Edinb. 2015; 45(2):148-53

9. Ellis G, Langhorne P. Comprehensive geriatric assessment for older hospital patients. Br Med Bull. 2005;71(1):45–59.

10. Nadeem E, Olin SS, Hill LC, Hoagwood KE, Horwitz SM. Understanding the Components of Quality Improvement Collaboratives: A Systematic Literature Review. Milbank Q. 2013; 91(2):354–94.

11. Gordon AL, Goodman C, Davies SL, Dening T, Gage H, Meyer J, et al. Optimal healthcare delivery to care homes in the UK: a realist evaluation of what supports effective working to improve healthcare outcomes. Age Ageing. 2018; 47(4): 595-603

12. Devi R, Meyer J, Banerjee J, Goodman C, Gladman JRF, Dening T, et al. A Quality Improvement Collaborative Aiming for Proactive HEAlthcare of Older People in Care Homes (PEACH): a realist evaluation protocol. BMJ Open, *in press.*

13. Mental Capacity Act 2005. London: Stationery Office; 2005.

14. Woertman W, de Hoop E, Moerbeek M, Zuidema SU, Gerritsen DL, Teerenstra S. Stepped wedge designs could reduce the required sample size in cluster randomized trials. J Clin Epidemiol. 2013; 66(7):752–8.

15. Hussey MA, Hughes JP. Design and analysis of stepped wedge cluster randomized trials. Contemp Clin Trials. 2007; 28(2):182–91.

16. Devlin NJ, Shah KK, Feng Y, Mulhern B, van Hout B. 2018. Valuing health-related quality of life: An EQ-5D-5L value set for England. Health Econ; 27(1):7–22.

17. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. J Chronic Dis.1987; 40(5):373–83.

18. Hemming K, Taljaard M, Forbes A. Analysis of cluster randomised stepped wedge trials with repeated cross-sectional samples. Trials. 2017;18(1):101.

19. Usman A, Lewis S, Hinsliff-Smith K, Long A, Housley G, Jordan J, et al. Measuring health related quality of life of care home residents, comparison of self-report with staff proxy responses for EQ-5D-5L and HowRu: Protocol for Assessing Proxy Reliability In Care home Outcome Testing. BMJ Open. 2018: 8.

20. Lopez Bernal J, Cummins S, Gasparrini A. Interrupted time series regression for the evaluation of public health interventions: a tutorial. Int J Epidemiol. 2016; 46(1): 348-355