Title Page

An evaluation of a safety improvement intervention in care homes in England: A participatory before and after mixed methods study

Submission to Journal of the Royal Society of Medicine as an original research article

Martin Marshall, *Department of Primary Care and Population Health, UCL*

Nadine Pfeifer, *UCL Partners*

Debi de Silva, *The Evidence Centre*

Li Wei, *School of Pharmacy, UCL*

James Anderson, *Anglia Ruskin Health Partnership*

Lesley Cruickshank, *Essex County Council*

Kieran Attreed-James, *Essex County Council*

Jenny Shand, *UCL Partners*

Corresponding author:

Professor Martin Marshall, Professor of Healthcare Improvement, Department of Primary Care and Population Health, University College London, Upper 3rd Floor, Royal Free Campus, Rowland Hill Street, London NW3 2PF

martin.marshall@ucl.ac.uk Mobile: 07796 993597

Running title: *'PROSPER'*

Main article: 3456 words excluding tables, figures, quotations and references

Abstract: 294 words

Objective

A growing proportion of older people live in care homes and are at high risk of preventable harm. This study describes a pragmatic evaluation of the impact of a complex safety improvement intervention, comprising training, measurement and culture-change elements, on the safety of care provided for residents.

Design

A participatory multi-method before-and-after study

Setting

90 care homes in one geographical locality in southern England.

Participants

A purposeful sample of care home managers, front-line staff, residents, quality improvement facilitators and trainers, and local government and health service commissioners.

Main outcome measures

Changes in: care home culture and work processes; the prevalence of falls, pressure ulcers and urinary tract infections; and emergency department attendances and hospital admissions. Qualitative data were collected using documentary analysis, interviews, observations and surveys, and analysed using a framework-based thematic approach. Resident outcomes data were collected by the care home staff before and after the intervention and a preliminary analysis using chi square tests was carried out.

Results

Participation in the programme appears to have led to changes in the value that staff place on resident safety and to changes in their working practices, in particular in relation to their desire to proactively manage resident risk. There was no rigorous quantitative evidence of the intervention leading to improvements in resident outcomes or hospital utilisation. The results suggest that there is a high level of commitment amongst care home staff to address the problem of preventable harm. Mobilisation of this commitment appears to benefit from external facilitation and the introduction of new methods and tools.

Conclusions

Using an evidence-based approach to reducing preventable harm in care homes can lead to changes in staff priorities and practices but there is not yet evidence that it leads to improved outcomes for care home residents.

Key words: care homes; safety; preventable harm

Introduction

In many countries, care homes, also known as medical homes or assisted living facilities, are providing a home, care and support for a growing number of older people.[1,2] In the UK, four percent of 75 to 84-year-olds and 50 per cent of 90-year-olds live in care homes.[3] A large proportion of these older people are frail and have complex health and care needs.[4,5]

Care homes in the UK are generally providing a high quality of care [6], but they have nevertheless been the subject of considerable negative publicity, including criticisms of poor care, underfunding, high staff turnover, and inadequate training and support for the workforce.[7,8] A high prevalence of preventable harm is a particular concern.[9,10] A number of programmes have been implemented in an effort to improve safety, focusing on staff education, decision support systems and better partnership working with primary care.[11-16] Their impact has been variable and often disappointing, usually as a consequence of poorly designed interventions and inadequate implementation.[17,18]

This paper describes an evaluation of a care home safety improvement programme which attempted to address these challenges by using a participatory approach to the initiative's design and implementation. PROSPER (PROmoting Safer Provision of care for Elderly Residents) was designed to reduce the incidence of three common causes of harm amongst care home residents; falls, pressure ulcers and urinary tract infections (UTIs). The programme comprised a partnership between care homes in one geographical locality, an improvement team from local government, and members of a local academic/health service network providing evidence based advice and conducting a formative evaluation. The aim of the evaluation was to assess the impact of a safety improvement intervention on care home

culture and work processes, to understand the facilitators and barriers to implementing the improvement programme, and to carry out a preliminary evaluation of the intervention on resident outcomes, accident and emergency (A&E) department attendances and hospital admissions.

Methods

Evaluation design

A multi-method before-and-after formative evaluation of the PROSPER programme was carried out using the 'Researcher-in-Residence' model,[19,20] a practical example of a participatory approach to evaluation.[21] The model positions the evaluator as an active member of an operational team with responsibility for delivering the expected outcomes of the project as well as evaluating it. The evaluator achieves this by highlighting the established evidence of what works, undertaking a pragmatic evaluation, and negotiating the meaning and utility of the findings with other members of the team. Ethics approval for the evaluation was granted jointly by the ethics committees of the participating County Council and the lead university.

The safety improvement intervention

In line with the participatory design, a complex socio-technical safety improvement intervention was co-designed by participants from the care homes, local government and the evaluation team. The development of the intervention has been described elsewhere.[18] Briefly, it comprised three complementary components. First, training in quality improvement (QI) methods was provided for the care home staff, initially by QI

experts from the local academic/health service network, then using a train-the-trainers model by members of the local government QI team. Second, data describing the incidence of falls, pressure ulcers and UTIs which had been collected by the homes themselves, was collated, analysed and fed back to the homes in graphical form by the evaluation team (for example, Figures 1a and 1b). Third, the prevailing safety culture of the homes was assessed using a version of the Manchester Patient Safety Framework (MaPSaF) [22] adapted for use in care homes.[23] The three main components of the intervention were delivered or facilitated over a six month period in each care home by members of the local government improvement team in partnership with NHS staff and the evaluation team. A strong emphasis was placed on providing support and advice, and sharing learning between the participating homes. <<Insert Figures 1a and 1b about here>>

Programme theory

A programme theory [24] devised by the PROSPER team hypothesised that the complex intervention would reduce the incidence of falls, pressure ulcers and UTIs by improving the knowledge of front line staff, changing their behaviours and providing insights into the culture of the homes with respect to safety. This in turn was expected to reduce the rates of attendance at A&E departments and unplanned admission to hospital, and thereby improve resident safety.

Setting and participants

One hundred and eighteen care homes located in one geographical area in the south east of England initially signed up for the programme. The homes either volunteered to participate or were targeted because the local government improvement team perceived that they might benefit from being involved. 28 of these homes withdrew before or shortly after

starting the programme because they felt that participation would be too time-consuming. 90 homes therefore remained actively involved to a variable extent throughout the project period. Each home signed up to one of four separate cohorts (18 homes in each of the first two cohorts, 21 in the third and 33 in the fourth) recruited at approximately six-monthly intervals starting in July 2014 and finishing in February 2016. The homes were encouraged to choose which and how many of the safety issues they wanted to prioritise.

Participating homes were representative of all care homes in the locality and across England in terms of size and type of care provided (residential or nursing). All homes were privately owned, some independently and some members of corporate groups. As for all care homes in England, they were performance managed by local government and regulated by the health and social care regulator for England, the Care Quality Commission.

Data collection and analysis

In line with the multi-method design, a combination of incidence data for the target safety incidents, routine health service utilisation data (attendances at emergency departments and hospital admissions), documentary review, participant observation, interviews, and a survey were used to evaluate the programme. Most of the data were collected by the evaluation team but, in line with the participatory approach, some were collected by the improvement team and by the care home staff. Qualitative data collection was carried out between July 2014 and March 2016, and quantitative data between July 2013 (collected retrospectively for a period of up to one year before the intervention started) and February 2016.

More than 500 documents produced by the care homes and local government staff were reviewed to provide an understanding of the local context. Twelve planning meetings

(including one workshop to adapt MaPSaF for use in care homes), training sessions and community of practice meetings were observed by the researcher-in-residence in order to understand how the participants interacted with each other in relation to safety matters. Two hundred and three semi-structured telephone interviews were carried out with the managers and front-line staff of the care homes. Twenty-three interviews were conducted with non-care home stakeholders, including health service staff and social and health care commissioners. In addition, a small number of informal discussions were held with family members and residents. All of these interviews enabled the embedded researcher to explore the participants understanding of safety and how they were responding to the safety improvement intervention. A simple structured online survey of the care home managers (one per home), based largely on the components of MaPSaF, was conducted to provide a quantitative assessment of any changes in perception of safety culture before and between eight and 20 months after the intervention. 89 percent (80/90) of the care homes provided both before and after responses to the survey.

Ten of the 90 care homes were purposefully sampled for more in-depth study by the in-residence researcher and one assistant researcher. The homes were selected to represent a range of sizes, geographical locations and levels of engagement with the initiative. These in-depth studies comprised an additional 103 individual or group interviews and 60 hours of observations of front line care and staff meetings.

Some of the interviews were audio-recorded but at the request of the care home staff most were not and so detailed notes were taken of the interviews and observations by the researchers, including verbatim quotations. All notes were typed and shared with the participants. Using NVivo the observational, interview, survey and documentary data were analysed iteratively by two researchers to extract key themes. Only those themes which

were common to, and could be triangulated between, the different data sources are presented in this paper. In line with the participatory design of the evaluation, emerging themes were shared with the care home participants at regular meetings, with the wider evaluation team and with an expert advisory group. The interpretation of these themes was negotiated between all of these stakeholders until an acceptable level of consensus was achieved.

Sixty-four organisations from the first three cohorts of care homes provided some data on the incidence of the target safety events for a period of between six and 12 months before and six months after the intervention, though only five homes were able to collect data consistently throughout this period. Data from the fourth cohort was not available for analysis by the end of the project. Rates were calculated by dividing the number of incidents by the number of residents in each home. Descriptive data were plotted as time series graphs before being fed back to the homes. Both the safety incidence and survey data were analysed with chi-squared tests using the Statistical Package for the Social Sciences (SPSS, version 9.3).

Results

Impact of the programme on working practices and safety culture

Evidence from across the different methods of data collection demonstrated that, as a consequence of participation in PROSPER, most of the care homes showed changes in their working practices, priorities and the ways in which they thought about their role with respect to safety. In particular, the emphasis changed from a focus on responding to

regulatory imperatives to reflecting on risk for their residents. At the start of the project the manager of a small home stated:

> *"Safety is about reducing our risk of safeguarding problems and making sure that we are ok when the Care Quality Commission comes."*

But a year later she recognised that her view had changed:

> *"Safety is all about trying to make life as good as possible for our residents. We work for them and we want to give them a home with dignity and respect. We want them to have quality of life."*

Another manager responsible for a medium-sized home described how participation in PROSPER had encouraged her staff to be more proactive in reducing risks and monitoring safety:

> *"It's (PROSPER) helped my staff an awful lot. We're more aware of how to prevent falls. We concentrated on UTIs. Now there are always jugs of juice around. There is a big board in the lounge with tips, the crosses, our graphs and newsletters. This sparks discussion with staff and relatives."*

Care home staff of all levels of seniority described how they felt more empowered and more confident to suggest new ideas to improve resident safety and to implement change. One home helped residents to personalise their walking frames so that they had a greater sense of ownership and were more likely to use them (a project that became known as 'Pimp the Zimmer' (Figures 2a and 2b)).

<<Insert Figures 2a and 2b about here>>

Another bought new rubber ends for walking sticks to make them less likely to slip. One home started offering jelly to residents with dementia who had problems drinking fluids and another introduced coloured drink mats to remind staff to encourage high risk patients to remain hydrated. As a carer in a medium-sized home described:

> *"We were talking about how we could adapt the red trays used in hospital, you know where people with red trays have to be given more drinks or a certain type of food or whatever. Well then we started using red doilies (mats) for hydration, to remind us to give those people more drinks."*

Several homes described how they started to involve families and residents in improving safety. About one quarter of the relatives interviewed mentioned seeing displays on notice boards relating to PROSPER. One relative stated that she felt more confident in pouring their mother a drink, rather than relying on the staff to do so.

Care homes compete for business and do not have a tradition of collaboration but PROSPER encouraged the homes to be more outward-looking and more willing to learn from and with each other. As one carer from a small home described:

> *"We've found it really useful to listen to feedback from other homes. For example, we found out we had a local falls prevention team. She (a member of the team) then did assessments on our residents and we made changes in the care plans. We wouldn't have known about that service if other homes didn't mention it."*

The homes also described how as a consequence of participating in PROSPER they learnt how to work more effectively with the NHS, a relationship which had previously been fractious. In addition, they forged a more constructive and mutually appreciative

relationship with their local councils. Overall, the homes described a sense of pride associated with being part of the programme.

Impact of the programme on resident outcomes and use of NHS services

Sixty-four care homes from the first three cohorts provided outcome data. Four of these homes focused mainly on reducing pressure ulcers, 17 on reducing falls and 13 on reducing UTIs. Four homes focused on both falls and pressure ulcers and the remaining homes did not specify a focus. Two different analyses were carried out, one aggregating data provided by homes which provided any data (n=64) and one from the more limited set of homes that provided both pre- and post-intervention data (n=18 of which only 5 provided complete data for the pre and post phases).

When using all available data (table 1) the programme was associated with small but statistically significant reductions in the rates of falls (23.7% to 20.9%, $p<0.01$) and pressure ulcers (5.2% to 3.9%, $p<0.01$) and statistically significant increases in UTIs (4.4% to 5.1%, $p<0.01$), A&E attendances (2.6% to 3.3%, $p<0.01$) and all hospital admissions (2.5% to 3.2%, $p<0.01$). There was a non-significant increase in hospital admissions resulting from a fall (1.0% to 1.2%, $p=0.16$).

<<Insert Table 1 about here>>

When analysed only using data for the homes which focused on reducing specific safety events, the results were similar to that of all data analysis. When analysed using data only from those care homes providing both pre- and post-intervention data, no statistically significant changes in safety events or hospital utilisation were found. No differences in

impacts on resident outcomes were associated with geographic area, home size or cohort size.

Factors enabling the PROSPER programme

The participants identified a number of factors which they thought contributed to PROSPER's impact. They placed a high value on the encouragement, support and practical help provided by local council quality improvement facilitators and the in-residence evaluator. In particular, they appreciated the ways in which the PROSPER team introduced them to a range of specific improvement methods and tools, including data displays and the principles of the Plan-Do-Study-Act cycle. A manager of a large home stated:

> *"The tools have helped us to stop behaving like robots, to stand back and think about things."*

Feedback of data demonstrating changes in the prevalence of safety events over time were particularly highly valued by the staff. Graphical displays of the data catalysed more informed and often more challenging conversations amongst the staff, and sometimes with relatives. As one senior carer described:

> *"[PROSPER] is making carers think outside of the box and consider all the reasons for things. Like falls is not just about mobility, there may be other reasons people fall. We started to analyse the falls to see whether it is to do with capacity and weakness. We look at how often people fall, how many people fall and when. We look at what precautions are needed."*

The care home staff particularly appreciated the training that they received as part of the PROSPER programme. They enjoyed learning in groups, within or between organisations,

and established several communities of practice to develop their thinking and exchange ideas.

Factors acting as a barrier to the PROSPER programme

The participants also identified a number of constraints to PROSPER having an impact, most of which were a consequence of the environment within which care homes currently operate in the UK. Local government interviewees felt that the high level of turn-over of senior managers in the homes was a notable barrier to successful engagement. About half of the care homes complained that they did not have time to fully commit to the programme and about one-third of homes did not feel that they gained much from taking part. One-quarter of homes complained about the quality and consistency of the support from the improvement team. Such comments reduced in later cohorts, reflecting changes in the knowledge, capacity and capability of the improvement team as the programme developed.

Discussion

Participation in the PROSPER programme appears to have led to notable changes in the value that care home staff place on resident safety, and to changes in their working practices. Whilst not universal, these improvements were reported by the majority of participating homes. The intervention appears to be associated with small but inconsistent reductions in falls and pressure ulcers and an increase in UTIs, the latter probably the result of increased reporting. It had no impact on the steady rise in A&E attendances and hospital admissions. However, the quantitative findings should be interpreted cautiously given the amount and poor quality of the data and the consequential decision to carry out only simple statistical analyses.

Overall, the study suggests that despite considerable economic and workforce pressures in the care home sector, there is a high level of commitment and innovative thinking amongst care home staff to address the problem of preventable harm. Mobilisation of these assets appears to benefit from external facilitation and the introduction of new methods and tools. These results are consistent with the growing body of theoretical and empirical evidence that improvement starts to happen when multi-faceted interventions containing both technical and social components are combined with rigorous methods of implementation and an enabling environment.[18,25] The participatory nature of the programme and the formative orientation of the evaluation both promoted a high level of engagement and commitment on the part of the care home staff.[26] The lack of clinically important improvements in resident or health service outcomes may be disappointing to some observers but is consistent with programme theory suggesting that changes in behaviour have to precede measurable changes in outcomes.[27-29] Indeed, there is a growing view that it is inappropriate to evaluate the outcomes of improvement interventions until the nature and the mechanism of action of the intervention are fully understood.[29]

The results should be viewed in light of a number of features which are an inherent consequence of the formative and participatory design, and the pragmatic quantitative evaluation.

Firstly, the quality and the quantity of outcomes data varied substantially between care homes. Whilst some homes provided both pre- and post-intervention data, many provided only one or the other and some provided none, limiting the conclusions that could be drawn from a pre/post design. In addition, most care homes do not have experience of collecting high quality data and there were some inconsistencies in the data provided by some of the homes. Secondly, the lack of controls does not lend itself to providing robust conclusions,

and other factors, including simply taking part in the initiative, might account for some of the observed changes.[30] Thirdly, the evolving nature of the intervention and its multifaceted design make it difficult to attribute changes to specific elements of the intervention. Finally, the cost-effectiveness of any improvement intervention is important but this was not formally evaluated in this study.

The findings of this study have useful implications for those leading quality improvement work in care homes. Well-designed improvement programmes with a focus on sharing ideas and using data to enable change appear to engage care home staff and can lead rapidly to changes in working practices. Such programmes may be more likely to work if they are delivered using a participatory methodology by multi-disciplinary teams bringing expertise in the local context, quality improvement, evidence-based change management, and a formative approach to evaluation. The potential tensions between regulatory and performance management drivers on one side, and an improvement philosophy on the other, need to be managed carefully.

The study also contains important learning for researchers and research funders interested in the care home sector. More thought, effort and time needs to go into the co-design of improvement programmes. Once the programme is optimally designed, larger scale, more methodologically rigorous and longer term evaluations are needed before a definitive judgement about the effectiveness and value of a programme can be made. Given that the most effective interventions are likely to be multifaceted, studies need to be of sufficient scale to explore the relative effectiveness of the different components of the intervention.

Conclusion

PROSPER is a rare example of a participatory, evidence-informed and rigorous improvement programme carried out in the care home sector. There remains a lack of robust evidence that such programmes have an impact on clinical outcomes for older people, or on health service utilisation and further methodologically rigorous research is required to answer these questions. However, this study provides robust qualitative evidence that well-designed improvement programmes can result in changes in what care home staff value and in their working practices. Together these offer considerable hope to the growing number of older people living in care homes and guidance to practitioners and policy makers.

Figure legends

Figure 1a: Run chart of rates of falls over time for 3 cohorts of care homes

Figures 1b: Run chart of rates pressure ulcers over time for 3 cohorts of care homes

Figure 2a: Personalised walking frames (1)

Figure 2b: Personalised walking frames (2)

Table 1: Number of events and event rates among the 64 care homes

Competing interests

The authors declare that there is no conflict of interest.

Funding

This work was supported by the Health Foundation, an independent charity based in London, England.

Guarantor

MM is the guarantor

Author contributions

MM, LC and JS designed the original study protocol. LC and KAJ were responsible for recruiting and supporting the participating homes. DdS led the qualitative data collection and analysis working in particular with MM, JA and JS. LW led the quantitative data collection and analysis working in particular with JA, JS, and LC. KAJ and NP worked with the lead analysts of the quantitative and qualitative data on the interpretation of the data. MM and NP wrote the first draft of the paper and all authors contributed to subsequent drafts.

Acknowledgments

The authors would like to thank the participating care homes, including the staff, managers, residents and their families and the home owners, as well as the local government officers and staff. We are also indebted to the PROSPER Advisory Group comprising of Professor Bryony Dean Franklin, Professor Claire Goodman, Professor Steve Iliffe, Dr. Yogini Jani, Dr. James Mountford, Professor Maxine Power and Professor Mike Roberts. Zahraa Mohammed Ali, Chris Singh and Clem White provided additional research expertise for the evaluation.

References

1. Office of National Statistics, National Population Projections, 2014: https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/datasets/tablea21principalprojectionukpopulationinagegroups Accessed [13.12.2016]
2. OECD, Historical population data and projections (1950-2050): https://stats.oecd.org/Index.aspx?DataSetCode=POP_PROJ Accessed [13.12.2016]
3. The National Care Homes Research and Development Forum. My Home Life, Quality of life in care homes, A review of the literature. London: Help the Aged, 2007.
4. Office of Fair Trading. Survey of Older People in Care Homes. London: Office of Fair Trading, 2005.
5. Laing W. Care of Elderly People: UK Market Survey 2010-11. London: Laing and Buisson, 2010.
6. Care Quality Commission. The state of adult social care services 2014 to 2017: http://www.cqc.org.uk/publications/evaluation/state-adult-social-care-services-2014-2017 Accessed [07.07.2017]
7. Eborall C, Fenton W, Woodrow S. The State of the Adult Social Care Workforce in England 2010. London: Skills for Care, 2010.
8. Franklin B. The future care workforce. London: ILCUK, 2014: http://www.ilcuk.org.uk/images/uploads/publication-pdfs/Future_Care_Workforce_Report.pdf Accessed [09.01.2016]
9. Stubbs B, Denkinger MD, Brefka S, Dallmeier D. What works to prevent falls in older adults dwelling in long term care facilities and hospitals? An umbrella review of meta-analyses of randomised controlled trials. Maturitas 2015; 81(3):335-342.

10. Mody L, Krein SL, Saint S, Min LC, Montoya A, Lansing B, McNamara SE, Symons K, Fisch J, Koo E, Rye RA, Galecki A, Kabeto MU, Fitzgerald JT, Olmsted RN, Kauffman CA, Bradley SF. A targeted infection prevention intervention in nursing home residents with indwelling devices: a randomized clinical trial. JAMA Intern Med 2015; 175(5):714-723.
11. Buljac-Samardzic M, van Wijngaarden JD, Dekker-van Doorn CM. Safety culture in long-term care: a cross-sectional analysis of the Safety Attitudes Questionnaire in nursing and residential homes in the Netherlands. BMJ Quality & Safety 2015; Jul 24(1): 1-0.
12. Mody L, Meddings J, Edson BS, McNamara SE, Trautner BW, Stone ND, Krein SL, Saint S. Enhancing Resident Safety by Preventing Healthcare-Associated Infection: A National Initiative to Reduce Catheter-Associated Urinary Tract Infections in Nursing Homes. Clin Infect Dis 2015; 61(1):86-94.
13. Lim RH, Anderson JE, Buckle PW. Work Domain Analysis for understanding medication safety in care homes in England: an exploratory study. Ergonomics 2016; 59(1):15-26.
14. Marasinghe KM. Computerised clinical decision support systems to improve medication safety in long-term care homes: a systematic review. BMJ Open 2015; 5(5):e006539.
15. Zúñiga F, Ausserhofer D, Hamers JP, Engberg S, Simon M, Schwendimann R. The relationship of staffing and work environment with implicit rationing of nursing care in Swiss nursing homes-A cross-sectional study. Int J Nurs Stud 2015; 52(9):1463-1474.
16. Jiang T, Yu P. The impact of electronic health records on client safety in aged care homes. Stud Health Technol Inform 2014; 201:116-123.
17. Enabling Research In Care Homes (ENRICH). A toolkit for care home research: http://enrich.nihr.ac.uk Accessed [07.07.2017]

18. Marshall M, de Silva D, Cruikshank L, Shand J, Wei L, Anderson J. What we know about designing an effective improvement intervention (but too often fail to put into practice). BMJ Qual Saf 2016 Dec 16:bmjqs-2016.
19. Marshall M, Pagel C, French C, Utley M, Allwood D, Fulop N, Pope C, Banks V, Goldmann A. Moving improvement research closer to practice: the Researcher-in-Residence model. BMJ Qual Saf 2014 Jun 3:bmjqs-2013.
20. Marshall M, Eyre L, Lalani M, Khan S, Mann S, de Silva D, Shapiro J. Increasing the impact of health services research on service improvement: the researcher-in-residence model. Journal of the Royal Society of Medicine 2016 Jun; 109(6):220-5. doi:10.1177/0141076816634318
21. Cornwall A, Jewkes R. What is participatory research? Soc Sci Med 1995; 41(12):1667-76.
22. Kirk S, Parker D, Claridge T, Esmail A, Marshall M. Patient safety culture in primary care: developing a theoretical framework for practical use. Qual Saf Health Care 2007; 16(4):313-320.
23. Marshall M, Cruickshank L, Shand J, Perry S, Anderson J, Wei L, Parker D, de Silva D. Assessing the safety culture of care homes: a multi-method evaluation of the adaptation, face validity and feasibility of the Manchester Patient Safety Framework. BMJ Qual Saf 2017 Apr 19:bmjqs-2016.
24. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. BMJ Qual Saf 2015 Jan 23:bmjqs-2014.
25. Grol R, Wensing M, Eccles M, Davis D. Improving patient care: the implementation of change in health care. John Wiley & Sons 2013 Mar 18.
26. Vindrola-Padros C, Pape T, Utley M, Fulop NJ. The role of embedded research in quality improvement: a narrative review. BMJ Qual Saf 2017 Jan 1; 26(1):70-80.

27. Welsh European Funding Office. Introduction to soft outcomes and distance travelled. In A Practical Guide to Measuring Soft Outcomes and Distance Travelled – Guidance Document. Cardiff: Welsh European Funding Office, 2003: http://www.networkforeurope.eu/files/File/downloads/A%20Practical%20Guide%20to%20Measuring%20Soft%20Outcomes%20and%20Distance%20Travelled%20-%20Guidance%20Document%202003.pdf Accessed [13.12.2016]
28. Butcher B, Foster H, Marsden L, McKibben J, Anderson C, Mazey R. The Soul Record. Summary Report. Soft Outcomes for Universal Learning: A practical framework for measuring the progress of informal learning. Norwich: Norwich City College of Further and Higher Education: https://soulrecord.org/sites/default/files/fields/publication/file/SOULFeb006.pdf Accessed [13.12.2016]
29. Parry GJ, Carson-Stevens A, Luff DF, McPherson ME, Goldmann DA. Recommendations for evaluation of health care improvement initiatives. Academic pediatrics 2013 Dec 31; 13(6):S23-30.
30. Carlopio J. The Hawthorne Effect: Awareness of Experimental Participation or Experimental Demands?. Manitoba: University of Manitoba, 1982.

Table 1. Number of events and event rates among the 64 care homes

	No of events	No of residents	Rate of events	p value
Falls				
Pre	3058	12884	23.7%	<0.01
Post	4714	22564	20.9%	
Pressure Ulcers				
Pre	644	12367	5.2%	<0.01
post	858	22157	3.9%	
UTIs				
Pre	484	10934	4.4%	<0.01
post	1073	20900	5.1%	
Hospital Admissions				
Pre	297	11935	2.5%	<0.01
post	704	21731	3.2%	
A&E attendances				
Pre	312	11932	2.6%	<0.01
Post	729	21839	3.3%	
Hospital admissions due to a fall				
Pre	122	12363	1.0%	0.16
Post	252	21875	1.2%	