Implementing the Creating Learning Environments for Compassionate Care (CLECC) programme in acute hospital settings: a pilot RCT and feasibility study

Jackie Bridges,^{1,2}* Ruth M Pickering,¹ Hannah Barker,¹ Rosemary Chable,^{2,3} Alison Fuller,⁴ Lisa Gould,¹ Paula Libberton,¹ Ines Mesa-Eguiagaray,¹ James Raftery,¹ Avan Aihie Sayer,^{2,5,6,7} Greta Westwood,^{1,2,8} Wendy Wigley,¹ Guiqing Yao,¹ Shihua Zhu¹ and Peter Griffiths^{1,2}

- ¹Faculty of Health Sciences, University of Southampton, Southampton, UK ²NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Wessex, Southampton, UK
- ³Training, Development & Workforce, University Hospitals Southampton NHS Foundation Trust, Southampton, UK
- ⁴Institute of Education, University College London, London, UK
- ⁵NIHR Newcastle Biomedical Research Centre, Newcastle, UK
- ⁶Older People's Medicine, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle, UK
- ⁷Faculty of Medical Sciences, Newcastle University, Newcastle, UK ⁸Research and Innovation, Portsmouth Hospitals NHS Trust, Portsmouth, UK

*Corresponding author Jackie.Bridges@soton.ac.uk

Declared competing interests of authors: James Raftery is a member of the National Institute for Health Research (NIHR) Journals Library Editorial Group. He was previously Director of the Wessex Institute and Head of the NIHR, Evaluation, Trials and Studies Coordinating Centre (NETSCC).

Published September 2018 DOI: 10.3310/hsdr06330

Scientific summary

Pilot RCT of CLECC in acute hospital settings

Health Services and Delivery Research 2018; Vol. 6: No. 33 DOI: 10.3310/hsdr06330

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

Concerns about the degree of compassion in health care have become a focus of national and international attention. However, previous evaluations of compassionate care interventions have not provided robust assessments of their effectiveness in improving patient care, with limited use of experimental design and insufficient intervention description. Published qualitative evaluations do not examine the implementation process in depth or attempt to measure effectiveness. There is a need for high-quality mixed-methods evaluations to support health-care leaders in selecting appropriate interventions and to guide implementation.

Objectives

The Creating Learning Environments for Compassionate Care (CLECC) programme is a workplace educational intervention focused on developing sustainable leadership and work team practices theorised to support the delivery of compassionate care. This study aimed to assess the feasibility of implementing CLECC in acute hospital settings and to assess the feasibility of conducting a cluster randomised trial (CRT) with associated process and economic evaluations to measure and explain the effectiveness of CLECC.

The objectives were:

- 1. to determine the feasibility of implementing the CLECC intervention and sustaining the resulting work practices
- 2. to inform the design of a definitive evaluation of the effectiveness of CLECC
- 3. to inform the measurement of costs and benefits of CLECC in a definitive evaluation.

Methods

This mixed-methods study used two main approaches to assess feasibility: (1) a process evaluation to enable evaluation of the feasibility of implementing CLECC and (2) a pilot pragmatic CRT to inform a future evaluation of the effectiveness of CLECC. Ward nursing teams in two English NHS acute hospitals were included in the study; they were selected because they treat large numbers of older patients, and to ensure a mix of medical and surgical specialties. Six teams were randomised, with four allocated to the CLECC intervention and two to control conditions.

The Creating Learning Environments for Compassionate Care intervention

The CLECC intervention is a team-based educational programme focused on developing manager and team practices to create an expansive learning environment that enhances team capacity to provide compassionate care. Expansive (rather than restrictive) environments foster workplace learning and the integration of personal and organisational development. The implementation period of the programme is 4 months and is facilitated by a practice development nurse (PDN). CLECC is based on workplace learning theory with the ward conceptualised as a learning environment and ward team as a community of practice. It aims to embed ward-based manager and team practices including dialogue, reflective learning and mutual support, such that the team has the understanding and skills to continue to improve compassionate care following the end of the programmed activities. CLECC training consists of key activities that are combined to produce an integrated intervention over the implementation period: monthly ward leader action-learning sets; team learning activities, including local team climate analysis and values clarification; peer observations of practice and feedback to team by volunteer

team members; team study days focused on team building and understanding patient experiences; mid-shift 5-minute team cluster discussions; and twice-weekly team reflective discussions. Throughout the implementation period, ward leaders and their teams develop a team learning plan that includes a patient feedback plan and measures for continuing to develop and support leader and team practices that underpin the delivery of compassionate care.

Usual practice continued on control wards, that is, there was no planned team-based educational activity for staff.

Process evaluation

The feasibility of implementing CLECC into practice with the four intervention ward teams was assessed through a process evaluation using normalisation process theory as a framework. Qualitative interviews with nursing staff and managers during implementation and follow-up phases (n = 33 interviewees), observations of learning activities (n = 7) and ward leader questionnaires (n = 12) aimed to identify and explain the extent to which the CLECC intervention was implemented into practice, enabling an assessment of its workability and integration into existing work practices.

Pilot cluster randomised trial

In order to prepare for a definitive multicentre evaluation, the feasibility and piloted procedures for a pragmatic CRT of effectiveness were assessed. Cluster randomisation of staff and patients at ward nursing team level was undertaken. Outcomes were assessed at baseline and at 4 months after completion of the CLECC implementation period. The measurement of compassionate care was assessed across three complementary core outcomes: (1) researcher-rated observations of the quality of staff–patient interactions using the Quality of Interaction Schedule (QuIS), (2) patient-reported observations of emotional care using the Patient Evaluation of Emotional Care during Hospitalisation (PEECH) and (3) nursing staff self-reported empathy using the Jefferson Scale of Empathy (JSE). Baseline and follow-up data were also gathered on individual and ward team characteristics.

All trial analyses were carried out on an intention-to-treat basis. Possible QuIS ratings are positive social, positive care, neutral, negative protective and negative restrictive. The proportion of QuIS interactions rated for each of the five QuIS categories was analysed, including a further analysis for total positive ratings (the sum of positive social and positive care ratings) and total negative ratings (sum of negative protective and negative restrictive ratings). The frequencies of patients with the lowest (most negative) scores for each PEECH subscale were calculated. The differences between groups were tested using the chi-squared test. A three-level mixed-effects logistic regression model was fitted to investigate the effect of the CLECC intervention on the likelihood of a negative interaction. Predictive factors were included as fixed effects and presented as odds ratios (ORs) with 95% confidence intervals (CIs), after adjustment for baseline and ward consecutively. Mean PEECH and JSE scores were calculated by subscale and in total, and differences between groups at follow-up were tested using the Mann–Whitney *U*-test. Estimates of intracluster correlation were generated for each outcome measure.

Economic evaluation

The economic component of the study aimed to explore how costs and benefits might best be measured in a definitive evaluation. The feasibility of using EuroQol-5 Dimensions, five-level version (EQ-5D-5L), as a patient-based outcome measure at ward level was assessed. The likely training costs of the CLECC intervention and its implementation (through qualitative interviews with staff) were also explored.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Bridges *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Results

Feasibility of implementing and sustaining Creating Learning Environments for Compassionate Care

Staff were generally keen to participate and valued the positive contribution of CLECC not only to their own well-being but also to supporting good patient care. Many original CLECC practices were possible to implement as planned. Although practices did not always continue beyond the implementation period in their original form, staff reported that the philosophy and associated culture that CLECC had nurtured continued to guide their practice. Sustainability was strongly linked by staff to the extent to which the ward leader understood and valued CLECC.

Creating Learning Environments for Compassionate Care had some coherence for staff in that they appreciated its potential value, but their understanding was often limited to the concrete activities they had direct experience of. This may have then limited the development of participants' own practice in relation to CLECC, but interview data reflect extensive participation by staff, suggesting that engaging in CLECC was not limited by lack of coherence. Although it was often the concrete activities that were used by staff to explain CLECC, its role as a broader stimulus to action, and accompanying expectations that each team would use CLECC in their own way, developed cultures in which reflection, learning, mutual support and innovation were legitimised. In short, CLECC appears to have moved all of the participating teams further along the continuum to becoming more expansive learning environments.

In terms of cognitive participation, ward teams varied in the extent to which individual members saw it as their role to ensure that CLECC happened. Furthermore, there was uncertainty as to the role of matrons in supporting CLECC. Collective action to implement CLECC was dependent on the extent to which CLECC activities harmonised with the priorities of the wider organisation. Findings strongly reflect extremely busy hospital environments in which, without the right support for staff, care approaches tend to be very task focused. Staff flagging up what they valued about CLECC highlighted what nursing work can be like in contexts of this kind. The stress is not related only to barriers to satisfactory patient care. Ward staff valued CLECC because it refocused them on patients as people and because it involved sharing working time and space with other team members, promoting the feeling of being part of a team.

Our findings reflect the fact that, if the ways of working that CLECC promotes are not seen as valued or if this value is not indicated to frontline workers by managers, then these practices do not routinely occur. The findings also show, however, that it is possible to introduce practices at a local work team level that promotes relational ways of working between staff, albeit constrained in the absence of restructuring of the wider system. Findings point to refinements needed for CLECC and to the contexts in which it will be implemented to improve the prospects for its impact and sustainability. These focus on wider system restructuring to support work team conditions that enable the relational aspects of caring and working.

Informing future Creating Learning Environments for Compassionate Care evaluation

The findings from this study indicate that the use of experimental design to evaluate the effectiveness of compassionate care interventions within the context of a mixed-methods study is feasible, as is a focus on patient-based outcomes. Staff were amenable to the prospect of randomisation to either experimental condition. All wards recruited remained in the study throughout data collection, and all clusters randomised to the intervention went on to receive it. Blinding of patients and visitors to ward allocation appeared successful, although strategies to blind researchers gathering data need further development in a future trial. Evidence of pathways through which the CLECC intervention had the potential to influence practice in other wards in both of the participating organisations was found.

The recruitment rate for observations at baseline was 97% (i.e. 152 out of 157 approaches to eligible patients), and at follow-up was 90% (i.e. 157 out of 175 approaches). Some patients were approached and consented more than once, and some recruited patients were not observed. Overall, 273 patients were observed (i.e. 133 at baseline and 140 at follow-up). The mean age of patients was 82 years and 25% of patients observed had

evidence of cognitive impairment, suggesting that our sample was representative of the wider hospital population. Acceptability of the QuIS tool was high, and reliability between observers was acceptable. We did not find any evidence that staff changed their behaviour as a result of being observed. These findings support the selection of quality of staff–patient interaction, as measured by QuIS, as a candidate primary outcome in a future trial. With regard to clustering, there was a clear design effect apparent with QuIS at the observation session level.

The recruitment rate for patient questionnaires at baseline was 80% (i.e. 173 out of 217 eligible patients) and at follow-up was 75% (i.e. 186 out of 247 eligible patients). In total, 354 completed questionnaires were returned. Of these respondents, 83% were aged > 70 years and 12% had cognitive impairment. Most patients needed researcher help with questionnaire completion and the questionnaire was too long for some.

The recruitment rate for nursing staff questionnaires at baseline was 37% (i.e. 91 returned out of 249) and at follow-up was 35% (i.e. 87 out of 247). Overall, 178 questionnaires were returned. Respondents represented a range of ages, ethnic groups, job roles and experience. There was a perception that questionnaires were lengthy to complete and that staff were too busy.

Findings reflect a range of ward contexts at baseline, with similarities across some dimensions (e.g. bed numbers and staff views on relational care) and differences across others (e.g. staffing levels and duration of ward leadership). Using QuIS, staff–patient interactions observed at baseline were rated as total positive (73%), neutral (17%) or total negative (10%), but there was some variation in these proportions between wards. Using the PEECH questionnaires (with higher scores representing better experiences), patients at baseline tended to rate wards relatively positively {total mean PEECH score of 48.9 on a scale of 0–66 [standard deviation (SD) 11.7]}, although less so on the connection subscale [i.e. 1.66 out of 3 (SD 0.78)]. Results from the baseline nursing questionnaires showed variations between teams in nursing staff mean reported empathy levels (ward mean range = 107-120 out of a possible range of 20-140; higher mean scores indicate higher empathy).

At follow-up there were more positive (78% vs. 74%) and fewer negative (8% vs. 11%) QuIS ratings for the intervention wards than for the control wards. Once other variables were accounted for, the odds of a negative interaction were not significantly reduced because of the CLECC intervention (adjusted OR 0.30, 95% CI 0.07 to 1.32). In total, 63% of intervention ward patients indicated the lowest (i.e. more negative) scores on the PEECH connection subscale, compared with 79% of control group patients. However, the odds of a negative score were not significantly reduced because of the impact of CLECC once other variables were factored into the analysis (adjusted OR 0.47, 95% CI 0.14 to 1.59). Despite this, these are promising results given that data were gathered 4 or more months after the end of the implementation period, indicating that, if there is an effect, it is sustainable beyond the period in which CLECC is being actively facilitated. We found no evidence that nursing staff empathy may be improved because of CLECC, but these results have to be viewed in the context of a low response rate to nursing surveys.

Informing the measurement of Creating Learning Environments for Compassionate Care costs and benefits

Our findings have established the feasibility of estimating the cost of a CLECC-type intervention. Intervention costs were calculated as training costs (PDN time and staff time attending study day) and ongoing implementation costs (cost of staff engaging in CLECC activities on the ward). Findings show that, aside from initial CLECC training costs, the implementation of concrete CLECC activities by ward teams was not associated with additional resource use.

Use of the EQ-5D-5L was shown not to be feasible, mainly because different patients with different ailments and severity were involved at baseline and follow-up. We found that an impact inventory would provide estimates of both costs and benefits of CLECC with a focus on those associated with providing the intervention, but set within a wider context that includes effects on staff and on patients. Cost per change in each of the primary and secondary outcomes could also be estimated and compared with other studies.

[©] Queen's Printer and Controller of HMSO 2018. This work was produced by Bridges *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

Findings are not generalisable outside hospital nursing teams and this feasibility work is not powered to detect differences attributable to CLECC.

Conclusions

- 1. Compassionate care interventions, such as CLECC, should define the role of health-care leaders in mobilising structural capacity to support relational team working of staff in frontline caring roles.
- 2. The use of structured observations of staff–patient interaction quality is a candidate primary trial outcome measure but requires further testing and development.
- 3. A definitive evaluation of the implementation, effectiveness and cost-effectiveness of CLECC, drawing on experimental design in the context of a mixed-methods evaluation, is feasible.

Future work

Further funding is being sought to continue this research. In the first instance, this will focus on establishing the validity of QuIS in relation to people with cognitive impairment, and on establishing the organisational contexts in which CLECC is likely to achieve high impact and sustainability.

Trial registration

This trial is registered as ISRCTN16789770.

Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research. The systematic review reported in *Chapter 2* was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (Wessex), the University of Örebro and the Karolinska Institutet.

Health Services and Delivery Research

ISSN 2050-4349 (Print)

ISSN 2050-4357 (Online)

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

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

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

Criteria for inclusion in the Health Services and Delivery Research journal

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

HS&DR programme

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

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

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

This report

The research reported in this issue of the journal was funded by the HS&DR programme or one of its preceding programmes as project number 13/07/48. The contractual start date was in December 2014. The final report began editorial review in March 2017 and was accepted for publication in November 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HS&DR editors and production house have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the final report document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HS&DR programme or the Department of Health and Social Care.

© Queen's Printer and Controller of HMSO 2018. This work was produced by Bridges *et al.* under the terms of a commissioning contract issued by the Secretary of State for Health and Social Care. This issue may be freely reproduced for the purposes of private research and study and extracts (or indeed, the full report) may be included in professional journals provided that suitable acknowledgement is made and the reproduction is not associated with any form of advertising. Applications for commercial reproduction should be addressed to: NIHR Journals Library, National Institute for Health Research, Evaluation, Trials and Studies Coordinating Centre, Alpha House, University of Southampton Science Park, Southampton SO16 7NS, UK.

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

NIHR Journals Library Editor-in-Chief

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

NIHR Journals Library Editors

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

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

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

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

Dr Tessa Crilly Director, Crystal Blue Consulting Ltd, UK

Dr Eugenia Cronin Senior Scientific Advisor, Wessex Institute, UK

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

Ms Tara Lamont Scientific Advisor, NETSCC, UK

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

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

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

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

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

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

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

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

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

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

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

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

Please visit the website for a list of editors: www.journalslibrary.nihr.ac.uk/about/editors

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