A patient-centred intervention to improve the management of multimorbidity in general practice: the 3D RCT

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Declared competing interests of authors: Chris Salisbury is a member of the National Institute for Health Research (NIHR) Health Services and Delivery Research (HSDR) Board. Bruce Guthrie chaired the Guideline Development Group of the National Institute for Health and Care Excellence Multimorbidity Clinical Guideline NG56 and was a member of a HSDR researcher-led panel. Polly Duncan declares a Scientific Foundation Board grant received from the Royal College of General Practitioners for the Pharmacist study, a substudy of the 3D study and a NIHR In-Practice Fellowship.

Published February 2019
DOI: 10.3310/hsdr07050

Scientific summary

The 3D RCT

Health Services and Delivery Research 2019; Vol. 7: No. 5
DOI: 10.3310/hsdr07050

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Scientific summary

Background

Health-care systems internationally have sought to improve care for patients with long-term conditions using guidelines for each condition. However, many patients have multiple long-term conditions ('multimorbidity'), and a different approach may be needed for these patients.

Patients with multimorbidity have poor quality of life owing to the impact of their health conditions ('illness burden'). They are more likely to have poor mental health, which is not always recognised. In general practice, patients with multimorbidity are repeatedly invited for reviews of their health conditions, prescribed large numbers of drugs and expected to make lifestyle changes, meaning that treatment itself is burdensome. Patients with multimorbidity also report a lack of patient-centred care. They see different health professionals, with poor continuity and co-ordination of care. Clinicians tend to focus on biomedical topics rather than addressing the problems that matter most to patients.

The number of people with multimorbidity is a major challenge to health systems worldwide, as they account for a high proportion of health and social care expenditure.

Policy documents from many different countries have recommended a new approach to care for people with multimorbidity. There is consensus that care should be based on a patient-centred model. This should incorporate an individualised approach that addresses patient needs, continuity of care, attention to quality of life and mental health as well as disease control, and a reduction in inappropriate polypharmacy. There should be greater partnership with patients to help them self-manage their conditions based on sharing information and agreeing goals and actions in a written care plan. Although these ideas are broadly accepted, there is little evidence to show their effectiveness, either as individual strategies or when used in combination to improve care for patients with multimorbidity. A recent systematic review highlighted the need for further trials of interventions in multimorbidity (Smith SM, Wallace E, O'Dowd T, Fortin M. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. *Cochrane Database Syst Rev* 2016;**3**:CD006560).

Aim and hypothesis

Our aim was to optimise, implement and evaluate an intervention to improve the management of patients with multimorbidity in general practice. We hypothesised that this intervention would improve patient health-related quality of life, reduce the burden of illness and treatment and improve patient-centred care, while being more cost-effective than current usual care.

Methods

Design

Pragmatic, cluster randomised controlled trial comparing the 3D (Dimensions of health, Depression and Drugs) approach with usual care in general practice.

We conducted a parallel mixed-methods process evaluation and an economic evaluation from the perspectives of (1) the NHS and Personal Social Services (PSS) and (2) patients.

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Setting
Thirty-three general practices in three areas of England and Scotland to maximise generalisability.

Participants
Practices used the EMIS (Egton Medical Information Systems) computer system and had a minimum of 4500 patients and two general practitioners (GPs). Eligible patients were aged ≥ 18 years with three or more long-term conditions. We kept exclusion criteria to a minimum.

Patient recruitment and practice randomisation
The target sample size was 1382 participants. We used MIQUEST (Morbidity Information Query and Export Syntax) to identify eligible patients. After screening by GPs, we invited a random sample of 150 patients per practice. The statistician used a bespoke computerised algorithm to randomly assign practices to the 3D intervention or usual care, blind to practice identifiers, with block randomisation stratified by area and minimised by practice deprivation and list size. Patients were informed of their allocation after recruitment and practice randomisation.

Intervention and comparison
Intervention design was informed by previous research, consultation with patients, clinicians and policy-makers, and international recommendations about how to organise improved care for multimorbidity. We used a logic model outlining problems experienced by patients with multimorbidity and recommended strategies to address those problems and how to operationalise those strategies in practices.

The 3D intervention was based on a patient-centred care model. This sought to improve continuity, co-ordination and efficiency of care by replacing disease-focused reviews of each health condition with one 6-monthly comprehensive review with a named GP. Each 3D review consisted of two appointments (with a nurse and then a GP) and a remote review of medication by a pharmacist. The nurse consultation focused on addressing the health problems that were most important to the patient, giving attention to quality of life and screening patients for depression. The pharmacist reviewed medication from medical records, aiming to simplify and optimise the treatment. The aim of the GP consultation was to agree a health plan with the patient, a printed copy of which was given to the patient. The 3D review used a computer template, which reinforced the patient-centred structure and was interactive, including different questions depending on a patient's combination of health conditions.

We used strategies to encourage implementation, including training, monthly feedback about implementation and financial incentives for completed reviews.

Practices in the control arm continued to provide care as usual. Patients' reviews mainly focused on meeting the requirements of the Quality and Outcomes Framework (QOF).

Outcome measures
Outcomes were collected at baseline and at 9 and 15 months after patient recruitment. The primary outcome was health-related quality of life measured by the Euroqol-5 Dimensions, five-level version (EQ-5D-5L) at 15 months. Secondary outcomes included measures of illness burden, treatment burden and patient-centred care. Key measures of the process of care, such as continuity, were included as intermediate outcomes. We also collected quantitative data about implementation of the intervention. We investigated the cause and expectedness of deaths and any possible association with the intervention. Outcomes were collected and analysed blind to allocation when possible.

Analysis
Patients were analysed in the groups in which their participating practices were allocated ('intention to treat'). For analysis of the primary outcome, deceased patients were given an EQ-5D-5L value of zero and missing data were imputed. All outcomes were analysed in multilevel regression models, which included adjustment for baseline measures of the outcome, stratification and minimisation variables and practice as a random effect.

Economic analysis

In a cost–consequences analysis we related the cost of the intervention or usual care to changes in a range of outcomes; the cost-effectiveness analysis from the NHS and PSS perspective estimated the incremental cost per quality-adjusted life-year (QALY) gain and the net mean benefit at a threshold of £20,000 per QALY. Uncertainty was addressed in sensitivity analyses.

Process evaluation

Our process evaluation explored the initial response of the practices to the training, the delivery of the intervention to patients, patient and professional perceptions of the intervention, the maintenance of the intervention over time and how practice context influenced these issues. We combined quantitative data about intervention delivery with qualitative data from various sources, including patients (and carers), health professionals and administrative staff, and commissioners. We undertook a case study design to understand how the intervention was delivered at five practices, as well as more focused qualitative data collection at five additional practices. We undertook postal and telephone surveys of all practices to understand usual care at baseline.

Patient and public involvement

An active group of up to 14 patients and carers provided a service user perspective, contributing to the refinement of the research questions, the design of the intervention, the design of outcome measures, the analysis of qualitative data, patient newsletters, the study website and the interpretation of findings.

Results

Recruitment and baseline characteristics

Between May and December 2015, 33 practices (1546 patients) were randomised [16 practices (797 patients) to the 3D intervention, 17 practices (749 patients) to usual care].

Primary outcome

Primary outcome data were provided by 1346 (88%) participants at 15 months. There was no evidence of difference between trial arms in health-related quality of life [adjusted difference in means 0.00, 95% confidence interval (CI) –0.02 to 0.02; p-value = 0.93]. This finding was robust to a range of sensitivity analyses. In a complier-average causal effect analysis we found no evidence that the intervention was more effective in patients who received two 3D reviews as planned. We found no evidence that the effect was moderated by patient age, deprivation, baseline quality of life or number of long-term conditions.

Illness burden

There was no evidence of difference between intervention and usual-care arms in respect of self-rated health, anxiety or depression, or illness burden.

Treatment burden

Using a new measure of treatment burden developed for this study, we found no evidence that the intervention reduced treatment burden. There was no evidence of difference in medication adherence, the number of drugs prescribed or the number of indicators of potentially inappropriate prescribing.

Patient-centred care

All measures of patient-centred care showed benefits from the intervention after 15 months. These benefits included the Patient Assessment of Chronic Illness Care Scale (PACIC) measure (adjusted mean difference 0.29, 95% CI 0.16 to 0.41; $p < 0.001$), the Consultation and Relational Empathy (CARE) measure of relational empathy (adjusted mean difference 1.44, 95% CI 0.47 to 2.41; $p = 0.01$ for GP and adjusted mean difference 1.11, 95% CI 0.03 to 2.19; $p = 0.043$ for nurse), the proportion of patients reporting care related to their priorities [odds ratio (OR) 1.85, 95% CI 1.44 to 2.38; $p < 0.001$], those reporting care as

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joined up (OR 1.48, 95% CI 1.18 to 1.85; $p = 0.001$), those reporting a written care plan (OR 1.97, 95% CI 1.32 to 2.95; $p = 0.001$) and overall satisfaction with care (OR 1.57, 95% CI 1.19 to 2.08; $p = 0.001$).

Process measures

There was an improvement in continuity of care in the intervention arm compared with in the usual-care arm, which was statistically significant using the Continuity of Care index (adjusted mean difference 0.08, 95% CI 0.02 to 0.13; $p = 0.004$) but not using the newer Visit Entropy measure ($p = 0.065$). There was no evidence of difference between intervention and usual care in QOF indicators.

Patients in the intervention arm had more nurse consultations and slightly more GP consultations over 15 months than patients in the usual-care arm (incident rate ratios – nurse 1.37, 95% CI 1.17 to 1.61, $p < 0.001$; and GP 1.13, 95% CI 1.02 to 1.21, $p = 0.021$). There was no evidence of difference in the number of hospital admissions or outpatient attendances.

Carers

We recruited 145 carers of patients participating in the trial and explored the impact of the intervention on carers' quality of life, experience and treatment burden. In this small substudy (which had limited power to detect differences between trial arms), no differences were observed in respect of carers' quality of life or treatment burden. However, carers in the 3D intervention arm reported improved experience of caring using a scale that measures topics such as feeling supported with caring, feeling in control and fulfilment from caring.

Patient safety

During the trial 5.0% (78/1546) of patients died. There was no evidence of difference in the number of deaths between the intervention and usual-care arms and none of the deaths appeared to be related to the intervention.

Implementation of the intervention

Implementation of the intervention was incomplete. Half (49%) of the patients received two complete 3D reviews over 15 months as intended, whereas another 26% had one review. Three-quarters (76%) of patients had a review of medication and 77% of those who had a GP review were given a printed health plan.

Economic analysis

The economic evaluation confirmed that patients with multimorbidity require considerable expenditure from the NHS and social services. There were small and not meaningful or statistically significant increases in both cost and QALYs in the intervention arm compared with the usual-care arm [mean cost £6140 intervention, £6014 usual care; adjusted mean difference £126 (95% CI £–739 to £991); adjusted mean QALY difference 0.007 (95% CI –0.009 to 0.023)]. The incremental cost-effectiveness ratio was £18,499 with a 50.8% probability that the intervention was cost-effective at a threshold of £20,000 per QALY. This provides evidence that the intervention was unlikely to be either more or less cost-effective than usual care at this cost-effectiveness threshold.

There was no significant difference in the costs incurred by patients from the intervention compared with usual care (mean difference £33, 95% CI –£35 to £101).

Process evaluation

Patients and practice staff were generally supportive of the 3D intervention. Qualitative data suggested that both patients and staff welcomed the patient-centred approach. However, practices found it difficult to organise the paired doctor and nurse consultations. Some patients received 3D reviews as well as, rather than instead of, usual disease-focused reviews. Patients strongly appreciated continuity of care, and practice staff agreed in principle but found this difficult to organise. Staff also questioned the appropriateness and feasibility of offering more time to multimorbid patients. Patients valued the comprehensive 3D reviews,

although practice staff had mixed views, particularly nurses who had training only in specific long-term conditions. Many nurses felt uncomfortable screening for depression. The pharmacist review was valued by patients and doctors, although pharmacists tended to ensure that treatment followed guidelines rather than simplifying medication as intended. Agreeing health plans was unfamiliar for both patients and doctors, and plans tended to be driven by a GP's agenda. Practice staff found it difficult to adjust to the 3D template and the need to concentrate on the computer tended to mitigate against a patient-centred consultation. Several doctors and nurses questioned the need for a 3D review every 6 months.

Conclusions

This is the largest trial conducted of an intervention to improve the management of multimorbidity in general practice. The 3D intervention is based on patient-centred principles that are widely recommended in international guidelines. Our rigorous, pragmatic trial provides robust evidence about effectiveness.

The 3D trial achieved the aim of delivering more patient-centred care, but this was not associated with improvements in health-related quality of life, illness burden or treatment burden. However, it was delivered at no significant increase in cost and was similarly cost-effective to usual care.

The 3D intervention was not fully implemented, with only about half of the participants receiving two 3D reviews as intended. Some problems with implementation were caused by a new approach being delivered to a small number of patients in each practice for a limited time within the context of a trial. To assess fully the benefits of 3D may require a whole-practice organisational change sustained over several years.

Implications for health care

The 3D intervention was designed to implement a range of strategies that are widely advocated to improve the management of multimorbidity. In conjunction with findings from earlier studies, we can conclude that these approaches are likely to have little impact on health-related quality of life in the short term, although they do improve patient-centred care. Some have argued that providing patient-centred care in a way that patients prefer, and which addresses the problems that matter to them most, should be a priority on ethical grounds, and we have shown that this approach can be delivered at little additional cost. The effectiveness of 3D could probably be improved through refinement of the intervention, better training for practice staff and better patient targeting. Effectiveness in terms of quality of life may also become apparent over time, as changes in treatment and self-management have an impact.

Recommendations for research

1. Future studies to determine the impact of new systems of care for multimorbidity should be based on whole-system change and long-term patient follow-up.
2. Interventions to effectively simplify drug regimes in patients with polypharmacy need to be developed and evaluated.
3. Research is needed to test the effectiveness of interventions to reduce treatment burden.
4. There is a need for new measures of benefit from improved management in primary care, which reflect outcomes that are important to patients and sensitive to change.
5. Evidence synthesis is needed to understand the features of organisational interventions to improve primary health care that are associated with an impact on quality of life.
6. Research is needed to understand the extent to which patients value concepts, such as patient-centred care compared with quality of life, and the trade-offs they are prepared to make between them.

Trial registration

This trial is registered as ISRCTN06180958.

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Funding

Funding for this study was provided by the Health Services and Delivery Research programme of the National Institute for Health Research.

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/).

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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 12/130/15. The contractual start date was in March 2014. The final report began editorial review in October 2017 and was accepted for publication in April 2018. 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.

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