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The 3D Study: improving whole person care

Submission date
18/02/2014

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Patients with long-term conditions are often managed in general practice by inviting them to practice-based clinics for each of their specific conditions (e.g. diabetes clinics), where they see a nurse who follows a checklist for that condition. However, increasing numbers of people have several long-term conditions, which is known as multimorbidity. These patients with multimorbidity often have to see different nurses and doctors at different clinics, sometimes get conflicting advice, often have to take lots of medication and can feel that no-one treats them as a whole person or takes their views into account. They also have high rates of depression which may be unrecognised. The aim of this study is to develop and test a new way for GP practices to manage people with multiple long-term conditions.

Who can participate?
Male or female, aged 18 years and over and have at least three of the following conditions: cardiovascular disease or chronic kidney disease (including coronary heart disease, hypertension, heart failure, peripheral arterial disease, CKD), stroke, diabetes, chronic obstructive pulmonary disease (COPD) or asthma, epilepsy, atrial fibrillation, severe mental health problems (e.g. schizophrenia, psychotic illnesses), depression, dementia, learning disability, rheumatoid arthritis.

What does the study involve?
The general practices are randomly allocated to either use the new way of managing patients with multimorbidity (intervention group) or to use the current management practice of treating each condition separately (usual care group). Patients in general practices allocated to the intervention group are identified and given a named nurse and doctor to manage their care. These patients are offered longer appointment times when they have to see a GP, as far as possible with their named GP. Patients are also invited for a comprehensive health review every 6 months which is designed to cover all of their health issues, focussing on the patients' concerns and priorities, as well as including a medication review to try to simplify their drug treatment and to check that their drugs are being correctly prescribed and taken, and checking for and treating symptoms of depression. The practice also has a linked general physician at the local hospital whom they can contact easily for advice about patients with complex problems. Training, feedback, financial incentives and regular meetings of practice champions are used to try to ensure that the intervention is delivered in practices as intended. Patients with general practices allocated to the usual care group continue having their care managed by their GP using

current management practices of multiple appointments and clinics for their separate conditions. Before the study starts, and at 9 and 15 months into the study, participants from both groups are asked to fill in questionnaires about their wellbeing, illnesses and treatments, their experience of their care, and what health resources they used. A small sample of patients (about 30 participants) from GP practices in the intervention group are invited to take part in qualitative interviews. Following a semi-structured interview format, participants are asked for their perspectives and experiences of changes to their care. Interviews and observation of practice staff from about five intervention practices also inform the process evaluation.

What are the possible benefits and risks of participating?
This study will help to establish what works best in planning services to manage people with multiple long-term conditions in general practice, so this will be of benefit to future patients. Using a new service or changing an established routine comes with risks. Some participants may not want to change how they are being managed. However, study participants will receive a more intensive level of monitoring and have extra points of contact (research team) in addition to what they would normally receive in primary care. Patients in intervention practices could benefit by having fewer but longer appointments and having to take less drugs. Patients may also benefit from diagnosis and treatment of depression, or being encouraged to highlight their priorities. Participants in the study would have to give up some of their time to fill out questionnaires, which may be an inconvenience. Researchers will require access to patients' medical records, which participants may be uncomfortable with. All patient information will be treated in strict confidence and in compliance of the Data Protection Act.

Where is the study run from?
The study is led by the University of Bristol, in collaboration with the Universities of Glasgow, Manchester and Dundee, the Royal College of General Practitioners and Bristol Clinical Commissioning Group. About 32 practices across England and Scotland are participating.

When is the study starting and how long is it expected to run for?
March 2014 to September 2017

Who is funding the study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
Dr Mei-See Man
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Study website
http://www.bristol.ac.uk/3d-study

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16067

Study information

Scientific Title
Improving the management of patients with multimorbidity in general practice

Acronym
3D study

Study objectives
Hypothesis: An intervention in general practice designed to improve the management of multimorbidity will improve patients' health-related quality of life, reduce their burden of illness and treatment and improve their experience of care whilst being more cost-effective than conventional service models.
Study aim: To develop and test a new way for GP practices to manage people with multiple long-term conditions.

Objectives:
1. To optimise an intervention to improve the management of multimorbidity in general practice through piloting four practices.
2. To implement this intervention in a representative range of general practices.
3. Through a cluster randomised controlled trial and economic evaluation, to assess the impact on health related quality of life, illness burden, treatment burden, patient experience, carer's burden and quality of life, and cost-effectiveness.
4. Through mixed methods process evaluation, to explore how and to what extent the intervention was implemented, the advantages and disadvantages of different models of care for patients with multimorbidity, and how and why the intervention was or was not beneficial. We will also characterise usual care and explore any changes to management practices over the duration of this study in usual care GP practices.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South West Frenchay REC, 13/03/2014, ref: 14/SW/0011

Study design
Multi-centre pragmatic practice level cluster randomised controlled trial with nested process evaluation and economic analysis of cost effectiveness

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
This is a cluster randomised trial. Clustering is at the level of the GP practice. The aim is to recruit 32 practices across England and Scotland. This is a two-arm trial with practices being randomised on a 1:1 ratio to receive the intervention or usual care.

GP practices will be randomly allocated to intervention or usual care arm.
Intervention arm has four main components:
1. Identification and prioritisation of patients with multimorbidity: Flagged on GP computer systems and participants will carry a 3D study card to enable identification by GP reception staff who will offer longer appointment times.
2. Continuity of care: allocated a named usual GP and usual practice nurse and practices trained in strategies to promote continuity of care
3. '3D' assessments and care plan; one by usual nurse and one by usual doctor every 6 months, instead of separate clinics for each condition. The 3 'D's are:
3.1. Dimensions of health - focus on quality of life issues and patients' priorities before disease measures
3.2. Depression - assessment and treatment
3.3. Drugs - drugs review by pharmacist, simplify drugs regime and addressing adherence
Care will be supported by a bespoke computer template. Patients will be given a care plan which addresses their main problems and priorities.
4. Practice linked hospital general physician who is available for advice about complex problems and to try to coordinate hospital investigations and appointments for multiple diseases

Usual care arm:
Patients attend disease-specific clinics often with different specialist nurses for each of their long-term conditions. Nurses will follow disease-specific computerised protocols, focussing on collecting data for pay-for-performance targets instead of improving quality of life or addressing patients' priorities.

Follow Up Length: 12 months
Updated 19/01/2016: Follow Up Length: 15 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health related quality of life, measured using EQ-5D; Timepoint(s): 12 months
Updated 19/01/2016: 15 months

Secondary outcome measures
Current secondary outcome measures as of 02/02/2017:
1. Illness burden, measured using the Bayliss measure of illness burden in multimorbidity; Timepoint(s): 9 and 15 months
2. Consultation empathy, measured using the CARE measure. Timepoint(s): GP consultations, 9 and 15 months; nurse consultations, 15 months only
3. Carer experience, measured using the Carer Experience Scale; Timepoint(s): 9 and 15 months
4. Hospital admission and outpatient rates, measured using patient records and questionnaire; Timepoint: 15 months
5. Anxiety and depression, measured using the Hospital Anxiety Depression Scale (HADS); Timepoint(s): 9 and 15 months
6. Management of LTCs, measured using PACIC; Timepoint(s): 9 and 15 months
7. Medication adherence, measured using the Morisky Medication Adherence Scale; Timepoint (s): 9 and 15 months
8. Number of drugs prescribed, measured using patient records; Timepoint: 15 months
9. Quality of disease management, measured using the Quality Outcomes Framework indicators; Timepoint(s): 15 months
10. Self-rated health, measured using single question item; Timepoint(s): 9 and 15 months
11. Treatment burden, measured using the Multimorbidity Treatment Burden Questionnaire; Timepoint(s): 9 and 15 months
12. Use of health services, measured using patient records and questionnaire; Timepoint: 15 months
13. Overall satisfaction, measured using single question item; Timepoint 9 and 15 months
14. Health related quality of life, measured using EQ-5D; Timepoint 9 months
15. Care which is joined up and related to patients' priorities, measured using two questions from the LTC6 questionnaire; Timepoint(s) 9 and 15 months
16. Number of high risk prescribing indicators, measured using POEMS study indicators; Timepoint 15 months
17. Continuity of care, measured using COC and visit entropy measures; Timepoint 15 months
18. Cost effectiveness, measured as cost per QALY; Timepoint 15 months
Please note that the EQ-5D at 9 months is a secondary outcome, while EQ5D at 15 months is the primary outcome.

Secondary outcome measures from 19/01/2016 to 02/02/2017:
1. Bayliss measure of illness burden in multimorbidity; Timepoint(s): 9 and 15 months
2. CARE measure. Timepoints relating to GP consultations, 9 and 15 months; nurse consultations, 15 months only
3. Carer Experience Scale; Timepoint(s): 9 and 15 months
4. Hospital admission and outpatient rates; Timepoint(s): 9 and 15 months
5. Hospital Anxiety Depression Scale (HADS); Timepoint(s): 9 and 15 months
6. Management of LTCs (PACIC); Timepoint(s): 9 and 15 months
7. Morisky Medication Adherence Scale; Timepoint(s): 9 and 15 months
8. Number of drugs prescribed; Timepoint(s): 9 and 15 months
9. Quality of disease management; Timepoint(s): 15 months
10. Self-rated health; Timepoint(s): 9 and 15 months
11. Brief Treatment Burden Questionnaire; Timepoint(s): 9 and 15 months
12. Use of health services; Timepoint(s): 9 and 15 months
13. Overall satisfaction (single item); timepoint 9 and 15 months
14. EQ-5D. Timepoint: 9 and 15 months

Secondary outcome measures from 28/04/2015 to 19/01/2016:
1. Bayliss measure of illness burden in multimorbidity; Timepoint(s): 6 and 12 months
2. CARE measure; Timepoint(s): 6 and 12 months
3. Carer Experience Scale; Timepoint(s): 6 and 12 months
4. Hospital admission and outpatient rates; Timepoint(s): 6 and 12 months
5. Hospital Anxiety Depression Scale (HADS); Timepoint(s): 6 and 12 months
6. Management of LTCs (PACIC); Timepoint(s): 6 and 12 months
7. Morisky Medication Adherence Scale; Timepoint(s): 6 and 12 months
8. Number of drugs prescribed; Timepoint(s): 6 and 12 months
9. Quality of disease management; Timepoint(s): 12 months
10. Self-rated health; Timepoint(s): 6 and 12 months
11. Brief Treatment Burden Questionnaire; Timepoint(s): 6 and 12 months
12. Use of health services; Timepoint(s): 6 and 12 months
13. Overall satisfaction (single item); timepoint 6 and 12 months

Original secondary outcome measures:
1. Bayliss measure of illness burden in multimorbidity; Timepoint(s): 6 and 12 months
2. CARE measure; Timepoint(s): 6 and 12 months
3. Carer Experience Scale; Timepoint(s): 6 and 12 months
4. Coordination of care (LTC6 QIPP); Timepoint(s): 6 and 12 months
5. Hospital admission and outpatient rates; Timepoint(s): 6 and 12 months
6. Hospital Anxiety Depression Scale (HADS); Timepoint(s): 6 and 12 months
7. Management of LTCs (PACIC); Timepoint(s): 6 and 12 months
8. Morisky Medication Adherence Scale; Timepoint(s): 6 and 12 months
9. Number of drugs prescribed; Timepoint(s): 6 and 12 months
10. Quality of disease management; Timepoint(s): 12 months
11. Self-rated health; Timepoint(s): 6 and 12 months
12. Tran Measure of Treatment Burden; Timepoint(s): 6 and 12 months
13. Use of health services; Timepoint(s): 6 and 12 months
14. Overall satisfaction (single item); Timepoint 6 and 12 months

Overall study start date
01/03/2014

Completion date
30/09/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/04/2015:
1. Male and female, aged 18 and over
2. Three or more long term conditions from the following list of conditions:
2.1. Cardiovascular disease (CVD) or chronic kidney disease (CVD) including heart disease, hypertension, heart failure, peripheral arterial disease, chronic kidney disease stage 3 to 5
2.2. Stroke
2.3. Diabetes
2.4. COPD or asthma
2.5. Epilepsy
2.6. Atrial fibrillation
2.7. Severe mental health problems (eg. Schizophrenia, psychotic illnesses)
2.8. Depression
2.9. Dementia
2.10. Learning disability
2.11. Rheumatoid arthritis

Previous inclusion criteria:
1. Male and female, aged 18 and over
2. Three or more long term conditions from the following list of conditions:
2.1. CVD: coronary heart disease, hypertension, heart failure, peripheral arterial disease
2.2. Stroke
2.3. Diabetes
2.4. Chronic kidney disease
2.5. COPD or asthma
2.6. Epilepsy
2.7. Atrial fibrillation
2.8. Severe mental health problems (e.g., schizophrenia, psychotic illnesses)
2.9. Depression
2.10. Dementia
2.11. Learning disability
2.12. Osteoporosis
2.13. Rheumatoid arthritis

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 1383; UK Sample Size: 1383

Key exclusion criteria
Current exclusion criteria as of 28/04/2015:
1. Life expectancy of less than 12 months
2. Serious suicidal risk
3. Known to be leaving practice within 12 months
4. Cannot complete questionnaires in English (themselves or with the help of carers)
5. Adults lacking capacity to consent (Scotland only)

Previous exclusion criteria:
1. Life expectancy of less than 12 months
2. Serious suicidal risk
3. Known to be leaving practice within 12 months
4. Cannot complete questionnaires in English (themselves or with the help of carers)

Date of first enrolment
01/05/2015

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
School of Social and Community Medicine
Canynge Hall,
39 Whatley Road
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BS8 2PS

Study participating centre
Centre for Primary Care
Institute of Population Health,
University of Manchester,
Williamson Building,
Oxford Road
Manchester

United Kingdom
M13 9PL

Study participating centre
Institute of Health and Wellbeing
College of Medical, Veterinary and Life Sciences,
University of Glasgow,
1 Horslethill Road
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United Kingdom
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Sponsor information

Organisation
University of Bristol (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research Programme; Grant Codes: 12/130/15

Alternative Name(s)

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to publish the main findings in high-impact peer reviewed journals, and a longer report in the NIHR journals library within a year of project completion.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Chris Salisbury (c.salisbury@bristol.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2016		Yes	No
Protocol article	protocol for process evaluation	04/05/2016		Yes	No
Results article	results	07/07/2018		Yes	No
Results article	baseline results	29/08/2018		Yes	No
Other publications	process evaluation	06/11/2019	11/11/2019	Yes	No
Other publications	cost-effectiveness evauation	19/01/2020	12/02/2021	Yes	No
HRA research summary			28/06/2023	No	No