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Living well with multiple morbidity

Submission date
28/11/2012

Recruitment status
No longer recruiting

Registration date
14/01/2013

Overall study status
Completed

Last Edited
23/06/2016

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Scotland has increasing numbers of people with long-term conditions such as heart disease, diabetes, obesity, and arthritis. The challenge of managing long-term condition is of huge concern to policy makers, the National Health Service (NHS) and to our wider society because of the rising costs of healthcare and their impact on both quality and quantity of life. Inequalities in health and healthcare are also a major problem; people living in poorer areas have worse health and die at a younger age on average than people living in richer areas. In these areas the provision of healthcare does not match the need for it.
Long-term conditions often come together; and multimorbidity (the coexistence of two or more long-term conditions in an individual) is becoming the norm rather than the exception and in deprived areas occurs at a younger age. Primary health care teams general practitioners (GPs), primary and community care nurses and other health professionals are often in a good position to help people manage their complex multiple health problems but there is very little research evidence about what kind of help is most likely to work and why. The current application is the third phase of a programme of research which aims to develop and test a primary care whole-system intervention to help people with multimorbidity to more effectively manage their problems. Our overall aim of the programme of research is to test the feasibility of a primary care-led whole system intervention that helps people in deprived areas to live well with multiple morbidity. That is, to test a complex intervention for patients living in deprived areas with multiple long-term conditions aimed at improving their quality of life and wellbeing. Our hypothesis is as that a whole system intervention which gives GP and/or practice nurses a limited amount of extra time in consultations, together with training in delivering a patient-centred approach aimed at enhancing patient well-being, plus suitable self-help material for patients, will over time lead to improvements in quality of life and wellbeing.

Who can participate?
Patients will be recruited form general practices in Glasgow that serve the most deprived areas. Patients with two or more long-term conditions will be eligible, aged from 30-65 years of age. We are aiming to be as inclusive as possible, but patients who are unable to give informed consent in English, or are terminally ill will not be included.

What does the study involve?
GPs will be asked to identify suitable patients for the study, and will make contact with those patients to see if they would be interested in hearing more about the study. If the patient

agrees, information on the study will be sent to the patient and a few days later, the patient will be phoned by a member of the research team to make an appointment to meet the research nurses at the practice. The nurse will then explain the study and the process of randomisation and answer any queries, and then gain informed consent if the patient wishes to take part. It will be made clear that the patient is free to withdraw from the study at any time. The research nurse will also collect baseline information and data from the patient by questionnaire. Once this data is collected, the practices will be randomly allocated to control or intervention group, and patients will be notified by letter as to which group they are in. If they are in the control practices they will receive their usual care from their GP. If they are in the intervention group, they will receive the CARE Plus intervention. This will involve longer consultations with their GP or nurse. The aim of the longer consultations are to discuss the patients problems from their viewpoint, regarding how their conditions affect their life (and how their life circumstances may be affecting their conditions), and make a list of priorities. The patients and GP (or nurse) will then set specific goals which may be things the GP will do and things the patient will do. GPs and nurses in the intervention group will receive some extra training and support over the 12 months of the study. Patients will also have access to a self-help pack which contains a booklet on living well with chronic illness, and CDs to help relaxation and stress management. Patients will be contacted by the research team at 6 months and 12 months to complete another questionnaire. A small number of patients will also be invited to take part in a longer interview with a researcher to discuss their views on the intervention. The study will also require access to individual patients records to supplement the analysis of electronic records by the research nurse and will thus require informed consent by patients.

What are the possible benefits and risks of participating?
For patients in the control group, receiving usual care, we do not foresee any particular benefits or risks beyond that encountered in normal primary care. For patients in the intervention group, benefits may include improvements in quality of life, well-being, mental and physical functioning. In terms of risks, we do not foresee any increased risks in the intervention group. Given that patients with multiple physical conditions often have associated mental health problems such as stress, we may identify patients in both groups at risk of suicide, harm to themselves, or harm to others, either though the questionnaire feedback or the qualitative interviews. We have thus included a suicide protocol within the study which will ensure the safety of patients, practitioners, and research staff involved.

Where is the study run from?
The study is being conducted by Professor Stewart Mercer and colleagues in General Practice and Primary Care, Institute of Health and Wellbeing, Glasgow University. Patients will consult healthcare staff in their usual general practice, and data collection by the research nurses will also take place in their own practice, or in their home if they prefer.

When is the study starting and how long is it expected to run for?
The study started in October 2012 and data collection and analysis will continue until May 2013

Who is funding the study?
The study is funded by the Chief Scientist Office of the Scottish Government

Who is the main contact?
Professor Stewart Mercer
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
12939

Study information

Scientific Title
Living well with multiple morbidity: the development and evaluation of a primary care-based complex intervention to support patients with multiple morbidities

Study objectives
The key research questions to be answered in this phase are:
1. Is the sampling, recruitment, retention and data collection of practices, practitioners and patients feasible in this target group?
2. What are the patients' and practitioners' views on the intervention?
3. What is the likely cost effectiveness of the intervention when trialled in a future large, definitive, cluster randomised trial?

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Service, 09/09/2011, ref: 11/WS/0031

Study design
Randomised trial

Primary study design

Interventional

Secondary study design
Randomised controlled 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Generic Health Relevance

Interventions
CARE Plus, Exploratory cluster RCT to test feasibility of carrying out complex intervention in high deprivation setting; Follow Up Length: 12 months

Randomisation at practice level will then take place after baseline measurements are completed, with four practices randomised to control group and four to intervention.

The CARE PLUS Intervention: core components
The CARE Plus consultation is the core of the intervention. The ingredients are an empathic person-centred approach, a holistic assessment, and a specific and agreed plan of action. It will be based on a simple model, called the CARE Approach.1 The CARE Approach consists of;
1. Connecting with the person (not just the patient or the diseases)
2. Assessing issues holistically (using a bio-psycho-social framework)
3. Responding empathically and positively (validating suffering, identifying individual strengths)
4. Empowering and enabling (making a SMART plan of action based on patients priorities)

The CARE Plus consultation is not designed as a tick box exercise, though there will be required documentation of what was discussed, prioritised, and planned. An essential component will be the formation of an agreed list of priorities based on the patients needs and views, and a documented plan of action (which may include things that the practitioner will do in addition to the patient) with SMART objectives (Specific, Measurable, Achievable, Realistic, Time-bound). As much as possible, practitioner will be encouraged to link patients with relevant local resources and community services, including the third sector. However an essential component of the intervention is also follow-up, to review progress against the plan, help problem solve, and to repeat the process of the CARE Plus Consultation, moving prioritised items up the agenda to be tackled in the revised plan of action.

The number of longer consultations that each patient will receive will be agreed between the practitioner and patient, but we envisage a minimum of two extended consultations per patient over the 12 month study period. The length of the initial and follow-up consultations will also be flexible according to need, but based on pilot work we have advised practitioners that the initial consultation will require 30-45 minutes.
All patients will also receive a self-management pack, which will include simple written material,

talking book, and cds/dvds. Given the generic problems of multimorbidity in the context of deprivation, and the very high levels of emotional distress and mental health issues, the material will be based around mindfulness-based stress reduction techniques, provided by the charity Mindfulness Scotland.

Additional material will include generic cognitive behavioural therapy (CBT)-based advice on self-management in long-term conditions in the form of a booklet, Reclaim Your Life by Professor Chris Williams.

Training and support for the practitioners forms the third essential part of the intervention. Here will be 3 half-day meetings of all the participating healthcare staff from the 4 practices together, one at the start of the intervention, and the other two spaced out over the remaining 12 months.
The training and support will be provided by two experienced practitioners, one an academic GP with expertise in the consultation and deprivation, and the other a psychiatrist skilled in problem solving, CBT, and mindfulness.

The first training and support meeting will include an introduction to the intervention, its empirical and theoretical underpinning, an outline of the CARE Approach, including the holistic assessment, and the SMART Plan of action. There will be an introduction to mindfulness-based stress reduction and the material that self-management material that the patients will receive. Participants will be encouraged to make a personal learning plan, based on their perceived gaps in knowledge and/or skills. The session will end with a mindfulness practice, and feedback. The practitioners will also be given the same self-help pack that patients receive, plus an additional information pack relating to the study to take away and read.

The second training and support meeting will begin with the group setting their own shared goals for the session, and then we will review progress in the intervention, and discuss problems and issues. Case-based discussions will be encouraged to facilitate shared learning. The session will end with a mindfulness practice and feedback.

The third training and support meeting will follow the same format as the second. The session, as it will be the last one, will also serve as a time to reflect on the intervention, and beyond. The session will end with a mindfulness practice.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Health-related quality of life (Euro-Qol 5D-5L)
2. Well-Being (W-BQ12)

Measured at baseline, 6 months, 12 months

Secondary outcome measures
1. Hospital Anxiety and Depression Scale (HADS)
2. Self-efficacy
3. Self-esteem: The questionnaire will also include demographic and socio-economic status

items, self-rated multimorbidity burden
4. Self-rated general health
5. Compliance with medication
6. CARE measure and Patient Enablement Instrument (PEI) will be used at the first consultation in both groups, and then retrospectively at 6 and 12 months on the participating patients (n=200). Practices will also collect 100 such measures on consecutive adult patients not in the study at baseline, 6 months and 12 months to ascertain any effects of the intervention on consultation quality in general.

An economic analysis will also be carried out, based on the EQOL utility scores, and health service utilisation in control and intervention groups.

Overall study start date
23/07/2012

Completion date
04/10/2012

Eligibility

Key inclusion criteria
For participating practices, the inclusion criteria are: NHS Greater Glasgow and Clyde general medical practices serving socio-economically deprived populations that have previously registered interest in the study. For participating patients, the inclusion criteria are:
1. Males and females who are aged between 30 and 65 years
2. Who have two or more long term conditions
3. Whose healthcare provider believes are likely to benefit from and participate in the intervention for the duration of the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 160

Key exclusion criteria
Practices will be excluded in the majority of the GP principals:
1. Do not agree to deliver the intervention
2. Cannot attend the first Care PLUS training session

Patients will be excluded if they are:
1. Unable to give informed consent to participate, including those with severe learning disability, severe active mental health problems (active psychosis, schizophrenia, bi-polar illness, psychotic depression, severe depression including active suicideality), severe dementia or other cognitive

impairments.
2. Terminally ill or considered by GP as likely to die within next 12 months.
3. Unable to understand spoken and written Eglish, as we do not have the finances available to pay for translators.

Date of first enrolment
23/07/2012

Date of final enrolment
04/10/2012

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Glasgow
Glasgow
United Kingdom
G12 8QQ

Sponsor information

Organisation
NHS Greater Glasgow & Clyde (UK)

Sponsor details
Tennent Building
38 Church Street
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Scotland
United Kingdom
G11 6NT

Sponsor type
Hospital/treatment centre

Website
http://www.nhsggc.org.uk/

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/06/2016		Yes	No