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Goal-setting in care planning for people with multimorbidity

Submission date
21/11/2016

Recruitment status
No longer recruiting

Registration date
21/12/2016

Overall study status
Completed

Last Edited
05/07/2019

Condition category
Other

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

Plain English summary of protocol

Background and study aims
A care plan is an agreement between a patient and doctor that helps them both to look after the patient's health from day to day. A good care plan is owned by the patient and includes goals that are important to the patient and that they want to work towards, such as getting out of the house more, or taking fewer medicines. Over the past 3 years, nearly all general practices have offered care planning to patients at high risk of an unexpected hospital stay. Usual care planning may involve very little or no talking about patients' goals, even though previous research has found that goal-setting can improve health. In this study, patients who have usual care planning, and those who have care planning with goal-setting will be compared. The aim of this study is to find out whether a full-scale study looking at the effectiveness of a goal-setting intervention (program) would be possible.

Who can participate?
General practices and adult patients who attend these practices who are at risk of having unplanned admissions to hospital.

What does the study involve?
Participating practices are randomly allocated to one of two groups. Participants attending practices in the first group receive the goal-setting intervention. This involves two care planning appointments with a GP from their general practice, to set goals and then to later review progress that has been made on the goals set. Participants in this group may also be invited to attend a focus group to give their opinions about the intervention. Participants attending practices in the second group continue their usual treatment according to the standard care planning process. At the start of the study and after six months, participants have their quality of life and mental processing assessed using questionnaires. In addition, patient notes are reviewed to find out how much they are using healthcare and how many are still living. The number of participants who took part in the study is also recorded to see if conducting a larger study would be possible.

What are the possible benefits and risks of participating?
There are no guaranteed benefits however patieents who take part in the goal-setting may feel more involved, and may benefit from discussing their health care needs with their GP; GPs in

turn may feel that more patient-centred discussion is achieved. There are no anticipated risks to health, however patients and GPs in the care plan with goal-setting group may find the goals they set are difficult to achieve. Patients and GPs may be disappointed if their practice is not in the goal-setting group. Some participants may feel uncomfortable about the consultations being recorded.

Where is the study run from?
The study is run from Norwich Medical School and takes place in six GP practices (UK)

When is the study starting and how long is it expected to run for?
March 2015 to July 2018

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

Who is the main contact?
Professor Nick Steel
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(updated 12/06/2019, previously:
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Public

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Additional identifiers

Protocol serial number
31936

Study information

Scientific Title
Goal-setting in care planning for people with multimorbidity: Feasibility study and intervention refinement

Study objectives
The aim of this study is to investigate the feasibility of conducting a substantive randomised controlled trial to determine if a goal-setting intervention during care planning consultations can improve health for general practice patients with multi-morbidity and at high risk of hospital admission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Leicester South Research Ethics Committee, 19/10/2016, ref: 16/EM/0411

Study design
Randomised; Interventional; Design type: Treatment, Process of Care, Education or Self-Management, Psychological & Behavioural, Management of Care

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Primary Care, Primary sub-specialty: Primary care; UKCRC code/ Disease: Other/ General symptoms and signs

Interventions

This is a six practice cluster randomised controlled mixed-methods feasibility trial, to test the feasibility of goal-setting as part of the care planning process in 60 patients with multimorbidity and at risk of unplanned hospital admission. Three practices will be randomly allocated to the intervention and three to the control group using simple block randomisation by Norwich Clinical Trials Unit.

Intervention group: Participants receive a goal-setting intervention, comprising two care planning appointments with a GP from their general practice. The first of these appointments will involve goal-setting, and the second will be to review the goals agreed and any progress made with them. Intervention group participants may also be invited to attend a focus group to discuss their experiences of goal-setting.

Control group: Participants receive treatment as usual for patients included in the care planning process.

The duration of participation for patients from practices in both groups will be 10 months, including consent, baseline data collection, up to two care planning consultations, and follow-up data collection at 6 months post-baseline. For those patients and GPs that opt to take part in subsequent focus groups, the overall duration will be approximately 18 months. The quantitative, qualitative and health economic data gathered during the study will be triangulated and emerging findings discussed with patients and GPs at a workshop to refine the intervention if required, and estimate the key parameters for a subsequent definitive randomised controlled trial of goal-setting within care planning consultations.

Intervention Type
Other

Primary outcome(s)
1. Recruitment rate (practice level) is measured as the number of general practices that consent to participate at 3 months
2. Recruitment rate (patient level) is measured as the number of eligible patients that consent to participate in the study by 6 months
3. Quality of life is measured using the EQ-5D questionnaire and the ICECAP-O questionnaire at baseline and 6 months
4. GAS-Light goal achievement is measured for intervention group patients after the second care plan consultation
5. Patient involvement with care planning and goal-setting is measured using the Dyadic OPTION and CollaboRATE scales after the initial care plan consultation, and the Patient Assessment of Care for Chronic Conditions (PACIC) 20-item questionnaire at baseline and 6 months
6. Cognition is measured using the General Practitioner Assessment of Cognition (GPCOG) Score at baseline and 6 months
7. Healthcare resource use is measured by the number of hospital admissions, A&E and outpatient contacts, and primary care staff contacts at 6 months, by reviewing patient notes
8. Number and type of prescribed medications will be measured at 6 months, by reviewing patient notes
9. Mortality will be measured at 6 months by reviewing patient notes

Key secondary outcome(s))
No secondary outcome measures

Completion date

31/07/2018

Eligibility

Key inclusion criteria
Inclusion criteria for practices:
1. In the 'Avoiding Unplanned Admissions Enhanced Service (ES): proactive case finding and care review for vulnerable people for general practice' (over 90% of practices in England), or similarly using risk stratification to identify patients at high risk of unplanned admission
2. At least one GCP trained GP (to be site Principal Investigator) and one GCP trained nurse for data collection
3. GPs must be available to attend pre-arranged goal-setting training in the event that their practice is randomised to the intervention group

Inclusion criteria for patients:
1. Age 18 or over
2. In the top 2% for risk of unplanned admission, e.g. on the practice register for 'Avoiding Unplanned Admissions' ES or similar, and so eligible for a new or review case planning consultation during the data collection period
3. Diagnosed with at least 2 of 40 morbidities in Barnett's analysis of multimorbidity, which includes diseases in the Quality and Outcomes Framework

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
52

Key exclusion criteria
Exclusion criteria for practices:
1. Single handed practice

Exclusion criteria for patients:
1. Not able to participate in goal-setting in GP's professional opinion (e.g. advanced dementia or acute psychosis)
2. Received care planning consultation in previous three months
3. Require translation services to communicate verbally

Date of first enrolment

01/11/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norwich Medical School
University of East Anglia
Chancellors Drive
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United Kingdom
NR4 7TJ

Sponsor information

Organisation
NHS South Norfolk CCG

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The quantitative data generated by the study will be made available from the principal investigator Professor N Steel. A summary of the qualitative data will also be available on request. Please note that the video recordings of care planning consultations will not be made available, as participant consent does not cover this level of general dissemination.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative analysis results	01/07/2019	05/07/2019	Yes	No
Results article	results	03/06/2019	05/07/2019	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes