Goal-setting in care planning for people with multimorbidity: feasibility study and intervention refinement

Study protocol

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Abbreviations

A&E	Accident and Emergency
CA	conversation analysis
CCG	Clinical Commissioning Group
CRN	Clinical research Network
ES	enhanced service
GAS	Goal Attainment Scaling
GCP	Good Clinical Practice
GP	general practitioners
GPCOG	General Practitioner Assessment of Cognition
HEE	Health Education England
ICECAP-O	Investigating Choice Experiments CAPability measure for Older people
IMD	Index of Multiple Deprivation
IP	intellectual property
IRAS	Integrated Research Application System
KCL	Kings College London
MRC	Medical Research Council
NIHR	National Institute for Health Research
PACIC	Patient Assessment of Care for Chronic Conditions
PPI	Patient and public involvement
QALY	quality adjusted life years
R&D	Research and Development
REC	Research Ethics Committee
TDF	Theoretical Domains Framework
UEA	University of East Anglia

1. Introduction

Plain English summary

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 matter to the patient, such as getting out of the house more, or taking fewer medicines. Goal-setting is a key part of the care plan, and helps the patient and doctor agree what matters most. Nearly all general practices now offer care planning to patients at high risk of an unexpected hospital stay, but this standard approach may involve very little or no talking about patients’ goals.

We want to know if adding more goal-setting into the standard care plan will improve the health of people with more than one medical condition. However, before we can run a full trial, we need to test the ideas in this small ‘feasibility’ study. This ‘feasibility’ study will compare two groups, patients who have standard care planning, and patients who have care planning plus extra goal-setting. The study will involve 3 general practices in the ‘standard care planning’ and another 3 in the ‘care planning plus goal-setting’ arm of the study, with about 60 patients in total.

We will use a simple approach to setting goals and seeing how well goals are met, called ‘Goal Attainment Scaling’. This has been used by patients in other health care settings. We will test a short version to see if it works in general practice. We will collect information on whether patients and general practitioners (GPs) like using goal-setting and how they do it, whether they need training, how we measure patients’ health, and the likely effect of goal-setting compared to standard care planning. This research will help patients and GPs work together to better meet patients’ needs.

Scientific abstract

Personalised care planning is ‘a conversation in which patients and clinicians agree goals and actions for managing the patient's conditions’. Goal-setting, the sharing of realistic treatment goals by physicians and patients, is core to care planning, particularly for patients with multimorbidity. Goal-setting and action planning can improve physical and psychological health status and people’s capability to self-manage their condition, compared to usual care. The problem being addressed is that usual care planning rarely involves goal-setting.

Whilst developing this project, we reviewed the literature and held discussion groups with members of the public, GPs and geriatricians to identify potential barriers to goal-setting in primary care. We used the Theoretical Domains Framework to categorise barriers into domains, including lack of knowledge and skills for goal-setting, doubt about capabilities, environment (GPs can have difficulty meeting the needs of complex patients in a short consultation) and motivational and social influences on patients describing goals. We have designed the study to overcome these potential barriers. Patients with multimorbidity engage more in self-management if they have a sense of capacity, responsibility and motivation and hence may particularly benefit from a patient-centred, goal-setting intervention.

The objectives of this feasibility study are to evaluate: the acceptability of goal-setting to patients and GPs; training needed by GPs; the content of care-planning consultations; recruitment, retention and response rates; selection of primary outcome measure; and identification of statistical parameters of the primary and key secondary outcome measures to help determine the sample size for the main study.

The research plan is a cluster randomised controlled 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. The intervention has 2 stages: GP training in goal-setting as part of care planning, and then a GP care planning consultation which will use goal-setting. Assessing the achievement of diverse goals is important and we will use Goal Attainment Scaling, which gives a single outcome for the achievement of multiple goals, has an increased responsiveness to change in geriatric assessment, and is amenable to goal-setting in a person-centred manner. The control group will receive the usual care planning process.

The training and intervention will be qualitatively evaluated using video and audio-recording of consultations, transcribed for in-depth analysis. Two focus groups of GPs and patients will use vignettes to assess acceptability of the goal-setting intervention. The quantitative and qualitative data will be triangulated and 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.

NHS England is committed to care-planning for long-term conditions and proactive, personalised care has been promised for those with the most complex needs, for

example through its ‘Avoiding Unplanned Admissions’ Enhanced Service (ES) for primary care. Goal-setting is key to effective care planning, but is not specified in current care planning templates and payment schemes, such as the NHS ES. By introducing a goal-setting intervention and assessment to care planning consultations, this study has the potential to improve care planning across all patients, in addition to the 2% of patients at highest risk of unplanned hospital admission in 90% of all English practices taking part in the ES. We anticipate that this will translate into better self-management and improved measures of physical and psychological health in this group of patients, which may lead to fewer unplanned admissions and adverse effects, as well as less use of primary health care and lower costs.

Rationale & background

Personalised care planning is ‘a conversation in which patients and clinicians agree goals and actions for managing the patient's conditions’ [1]. Goal-setting, the sharing of realistic treatment goals by physicians and patients, is core to the theory and effective practice of care planning and is particularly important for patients with multimorbidity [1-3]. Medical outcomes that work well for relatively healthy patients (e.g. blood pressure control, or disease-free survival) may be inappropriate for patients with multimorbidity or severe disability [4-6]. Patients with multimorbidity have a lower quality of life and worse health than patients with single conditions, and need an integrated, person-focused approach that responds to individuals' experiences of illness, treatment effects and personal priorities [7-11].

Reuben gives an illustrative example of goal-setting: ‘*A person with Parkinson’s disease may establish goals for symptoms, such as decreased rigidity and no falls; goals for functional status, such as the ability to get to the bathroom without assistance although requiring a walker; and goals for social function, such as the ability to use the Internet to communicate with a grandson at college and the ability to go to church. However, the patient may not be aiming to reduce tremor, walk without a walker, or continue to work for pay. Alternatively, he or she may prioritize being as mobile as possible even at the expense of medication-induced dyskinesia and mild confusion*.’[5]

A 2015 Cochrane review of goal-setting and action planning found 19 studies involving 10,856 participants, mainly in diabetes in primary care settings, with only one (poor quality) study of multiple conditions [1]. Physical and psychological health status improved, as did people’s capability to self-manage their condition, compared to usual care. The effects were not large, but were greater when the intervention was better integrated into routine care. Other studies have reported that goal-setting promotes progress towards mutually agreed goals and improves self-management and behaviour change, such as increased activity [12-16]. A feasibility study of goal-setting in asthma in primary care in Scotland has recently finished but results are not yet available [17]. In summary, care planning with goal-setting for patients with multimorbidity in primary care is a promising approach that has been widely advocated but not yet formally tested.

Assessing the achievement of diverse goals is important and requires a standardised scale, such as that used by Goal Attainment Scaling (GAS) to give a single outcome for the extent to which multiple goals have been achieved [18]. GAS is as sensitive as other standard scales [19] with an increased responsiveness to change in geriatric assessment, and is amenable to goal-setting in a person-centred manner [13, 14, 20]. A shorter version (GAS-Light) has been developed to reduce the time required to complete the tool so that it can be integrated into routine decision-making and review [21].

The problem being addressed by this study is that care planning rarely involves goal-setting [22]. Despite the potential benefits of goal-setting within care planning, the use

of written care plans is uncommon and 'more proactive efforts at implementation' have been called for [23]. The most recent GP Patient Survey surveyed 850,000 patients (54% of whom had a long-term condition), and only 3.1% had a written care plan [24].

NHS England has committed £162 million to care-planning for long-term conditions through the 'Avoiding Unplanned Admissions' Enhanced Service for primary care, which equates to up to £2.87 per registered patient or just over £20,000 for a practice with an average list size of 7,000 [25, 26, 27]. The ES was introduced in April 2014 and has been taken up by 90% of practices in England to provide services including a 'personalised, proactive care plan…informed by [the patient's] expectations and goals' for at least 2% of adults with complex needs [25]. Two percent of the adult population of England is approximately 700,000 people at high risk of unplanned admission, who stand to benefit from an improved care planning process involving goal-setting. Goal-setting is key to effective care planning (see 'background' section) and the ES recommends a goal setting approach [28]. However, goal-setting is not required for payment to be received, the example care planning template does not include goal-setting, and goal-setting is not mentioned in the 'guidance and audit requirements'[29], and so goal-setting is unlikely to be central to the process. The limited research evidence [22], which is supported by the views of local clinical experts, is that goal-setting is rarely used in care planning in general practice, despite being core to the theory and effective practice of care planning [1].

To inform the development of a goal-setting intervention for this project, we conducted a literature review and held discussion groups with members of the public, GPs and geriatricians. The Theoretical Domains Framework (TDF) is frequently used to explain behaviour change in implementation research [30], and we identified potential barriers to goal-setting in primary care from the literature and discussion groups, and categorised them into TDF domains. Important domains were: knowledge and skills (little information on the effectiveness and feasibility of tools to support primary care professionals in goal-setting [19], and inappropriate templates); beliefs about capabilities (health professionals' uncertainty that standard care planning would achieve immediate clinical benefits [12, 22]); environmental context (difficulty in completing separate care plans for individual conditions, poor coordination and continuity of care, and lack of time [31]); motivation and social influences (patients may feel disempowered [32] or not declare goals for social reasons [33], and discussion group patients described not mentioning their goals during consultations and wanted explicit goal-setting particularly if the clinician was not well-known to the patient).

By introducing a goal-setting intervention to the ES care planning consultations, this study has the potential to improve the effectiveness of the care planning process for 2% of patients at 90% of all English practices. Importantly, most of the patients identified by the ES are likely to have multimorbidity and hence will particularly benefit from a patient-focused, goal-setting intervention. Patients with multimorbidity are more likely to engage in self-management practices if they have a sense of capacity, responsibility and motivation [34], all of which may be enhanced through

the goal-setting process. Wide-spread adoption of a feasible goal-setting intervention during care-planning consultations with GPs will be increasingly important in the future, given the rising prevalence of multimorbidity, particularly in older age groups [35].

The ES was introduced in April 2014 and has not yet been formally evaluated. Although the policy landscape will change, the concepts of care planning for patients with chronic disease who are at risk of hospital admission will remain part of general practice for the foreseeable future. This research has been designed to focus on the theory and science of goal-setting as a part of care planning, rather than specific services that are always vulnerable to short term change. By focusing on the theory and science, this project will deliver evidence to inform future policy while being resistant to a dynamic policy context.

This study will have important implications for clinical practice in primary care. GPs sometimes struggle to meet the needs of complex patients, particularly within the constraints of the 10 minute consultation [36, 37]. By testing the effectiveness of collaborative goal-setting within care planning and offering an effective way to deliver this, this study has the potential to shift the model of care planning within GP consultations. We hypothesise that this could increase patients' motivation, self-efficacy and self-management, improve treatment concordance, reduce adverse effects and encourage earlier appropriate contact with primary care, which will translate into improved physical and psychological health in this group of patients and may lead to fewer unplanned admissions (the intended outcome of the ES) as well as less use of primary health care and lower costs.

Study goals and objectives

This feasibility study aims to estimate important parameters that are needed to design the main study. The subsequent main study will determine if a goal-setting intervention during care planning consultations can improve health for general practice patients with multimorbidity and at high risk of hospital admission.

The research question for the subsequent definitive trial will be: 'does goal-setting in a care planning consultation improve health for patients with multimorbidity and at high risk of hospital admission, compared with usual care planning?'

The objectives of the feasibility study are to evaluate:

- acceptability of the goal-setting intervention (GAS-Light) to patients
- acceptability of goal-setting to general practitioners (GPs)
- training needed by GPs to use goal-setting in care planning
- the content of 'usual' care planning consultations in the control group
- recruitment rate for both primary care practices and patients
- retention rates of participants and response rates to questionnaires
- data availability for cost and outcome measures, and time needed to collect
- selection of primary outcome measure for the main subsequent trial
- identification of statistical parameters (i.e. mean, variance, intra-class correlation coefficient) of the primary and key secondary outcome measures to help determine the sample size for the main study

The quantitative, qualitative and health economic data 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.

2. Methods

Study Design

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. The intervention has 2 stages: GP training in goal-setting as part of care planning, and then a GP care planning consultation which will use goal-setting. The control group will receive the usual care planning process. 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.

Inclusion and exclusion criteria for general practices:
Inclusion criterion for general practices:

- Participating 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) [25], or similarly using risk stratification to identify patients at high risk of unplanned admission
- At least one GCP trained GP (to be site Principal Investigator) and one GCP trained nurse for data collection
- GPs must be available to attend pre-arranged goal-setting training in the event that their practice is randomised to the intervention group

Exclusion criterion for general practices:

- Single handed practice

Inclusion and exclusion criteria for patients from each of the recruited practices:

Inclusion criteria for patients:

- Age 18 or over
- In the top 2% for risk of unplanned admission, e.g. on the practice register for 'Avoiding Unplanned Admissions' ES or similar, and eligible for a new or review care planning consultation during the data collection period
- Diagnosed with at least two of 40 morbidities in Barnett's analysis of multimorbidity, which includes conditions in the Quality and Outcomes Framework [35].

Exclusion criteria for patients:

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

Recruitment

Six practices will be recruited from the Clinical Research Network (CRN) in the East of England. The CRN will invite practices from all 5 Clinical Commissioning Groups (CCGs) (West Norfolk CCG, South Norfolk CCG, Great Yarmouth and Waveney CCG, North Norfolk CCG and Norwich CCG) and seek to include at least one practice with more than 10,000 patients on its practice list. The Research Information Sheet for Practices (RISP) and email of invitation (Appendix A and B) will be used to inform practices about the study.

Each practice will aim to recruit 10 patients (60 in total). Eligible patients in each practice will be identified from the practice ES register (or similar risk stratification approach) for care planning with assistance from the project research associate, and screened for comorbidity using Barnett's analysis of multimorbidity [35]. A copy of Barnett's co-morbidity list will be provided to participating practices for this purpose. The project research associate will visit practices to help with developing the search where needed. The GP will screen the list of all eligible patients to check for appropriateness as per exclusion criteria prior to the stratification and selection of 100 patients to be invited.

To identify the 100 patients an index of multiple deprivation (IMD) score will be attributed to each eligible patient using their postcode and the list of eligible patients will be stratified into deprivation quartiles. Patients in each quartile will be listed alphabetically, and a random number generator (for example in Microsoft Excel) will be used to select 20 patients from the most affluent quartile, 20 from the second most affluent, 20 from the third most affluent and 40 from the least affluent quartile, making 100 patients in total from each practice, list size allowing. This oversampling from the least affluent quartile is to increase participation from harder to reach deprived populations. Participants will additionally be opportunistically invited to participate by clinicians during the same time period. The practice notes will already flag the electronic record of those on the ES register for a care plan, and the GP will check that they meet the study inclusion and exclusion criteria, including having two comorbid conditions, prior to inviting them to take part.

Patients selected for invitation will be sent a letter by the practice (Appendix C) with a patient information sheet (Appendix D) and number to call or Expression of Interest form to post (Appendix E) if they wish to participate. The invitation mailing will also include an additional patient information sheet about the audio- and video-recording options (Appendix F). Patients will be recruited on a 'first come first served' basis, aiming to recruit the required number from each practice.

The practice will assign each invited patient a unique study ID with help from the project research associate if required. The names and dates of births of patients with their unique study ID will be held by the practice. The practice will provide five year age band, sex and deprivation quartile data for all 100 invited patients. These anonymised data will be used by the research team to compare responders with non-responders, to inform development of the future trial.

After practice recruitment, the research associate will obtain consent from participating GPs in each practice on the basis of the information provided in the RISP (Appendix A) and GP participant information sheet (Appendix G), plus reading the content of the consent form (Appendix H). An additional GP participant information sheet detailing the audio- and video-recording options will also be provided (Appendix I). The research associate will contact the practice by phone to check whether the GP or other practice staff have any questions before the study gets underway, and to prompt return of the consent form (by post or email) to UEA, and will visit the practice if requested.

Randomisation

Three practices will be randomly allocated to the intervention and three to the control group using simple block randomisation by the UEA Clinical Trials Unit. Invitation mailings will be sent by a practice prior to randomisation of that practice. Randomisation will occur when the research team have received at least 10 expressions of interest from a practice's invited patients, or by a defined cut-off date a minimum of one week prior to the scheduled GP training, whichever occurs first. No opportunistic recruitment will occur after randomisation, in order to minimise bias. Participants and those involved in managing the study and analysing the qualitative data cannot be blinded to randomisation. The researchers performing quantitative data analysis will be blinded unless this is not possible, for example when assigning costs associated with the intervention.

Care pathway for patients (procedures)

Interested patients will be asked to contact the research team for more information. The researcher will answer any questions the patient may have at this stage. If the patient agrees to take part, the researcher will visit the potential participant to seek consent. This will involve completion of: the main study consent form (Appendix J) and the baseline questionnaires (Appendices K-O). The practice will be informed (Appendix P) when their patients are recruited to the study. Details of the procedures involved, including the use of questionnaires, will be explained. The number declining to take part will be recorded.

After the baseline researcher visit, the patient will be asked to book a care planning appointment at their surgery with assistance from the researcher, as required. The consultations may be arranged in one surgery session, or mixed in with a 'routine' surgery, or done during a home visit if the participant is unable to attend the surgery, at the practice's discretion.

The difference between the intervention and control groups will be the use of goal-setting with GAS-Light to inform the care plan in the intervention group. The control group will receive care planning consultations as normally conducted in that practice, which may or may not involve goal-setting. The content and duration of care planning consultations in both intervention and control groups will be recorded and compared, as little is known about the content of 'usual' care planning consultations.

The Goal-Setting intervention

The intervention has 2 stages: GP training in goal-setting with assessment using GAS-Light, and the use of goal-setting by patients and GPs during care-planning consultations.

GP training

One of the barriers to goal-setting that emerged from our literature review and analysis using the Theoretical Domains Framework (TDF) was the lack of GPs' knowledge and skills in goal-setting. The two participating GPs from each of the three intervention practices will be required to attend one of two half-day training workshops, each with only 3 GPs to ensure an opportunity for all to role play with professional actors, held within four weeks of randomisation. Training will be underpinned by the Calgary Cambridge communication skills model [38, 39] taught at Norwich Medical School.

GPs will be introduced to the theory and research context for involving patients in goal-setting in the care planning context using material from GAS-Light. This will include the role of patient engagement in healthcare [40] and research on health literacy, shared decision making and self-management of chronic conditions for patient enablement [41]. The use of the goal-setting intervention (GAS-Light) will then be introduced, including discussion, demonstration and practice using video-recorded role-play, playback and feedback. Some GPs may not have used goal-setting before, so the close relationship with shared decision making, including key steps [42], will be discussed and rehearsed during role-play. Feedback will be given using an analytical framework for goal-setting activity that combines Edwards' recommendations [43] for shared decision making with the approach used to teach communication skills at Norwich Medical School. This innovative analytical framework will include shared decision making skills such as: eliciting the patient's agenda, problem definition, equipoise and preference, option portrayal, information provision, checking understanding, exploration of ideas, concerns and expectations, checking preferences, decision making and review. In addition, areas specifically pertaining to goal-setting such as GP and patient initiation and engagement in goal-setting, goal formulation and quality of goal statements will be included in the analytical framework. The training will be evaluated as described in the 'qualitative evaluation' section below.

Patient participation in goal-setting

The goal-setting intervention (GAS-Light) will involve goals being set at baseline, and then reviewed and scored at 6 months, by the patient and GP together. Both the initial and 6-month follow-up consultations in the intervention group will be booked for 20 minutes (if in GP surgery). Participants in both intervention and control groups will be free to arrange any further consultations and changes. Patients in the intervention arm will be given an information sheet (Appendix Q) and a brief introduction to goal-setting by the researcher at the baseline data collection visit if the

practice has been randomised or over the telephone if the practice is randomised after the baseline visit. The researcher will provide a sheet to the patient with 3 questions on it (Appendix R), and ask the patient to think about the questions with their family or carer before their care planning consultation with the GP. The three questions are standard goal-setting questions that underpinned a previous goal-setting intervention in asthma [17]:

- What's important to you and what would you like to achieve over the next 6 months?
- Why is it important to you?
- What are the first steps you would like to take towards achieving this goal or goals?

GAS-Light will involve six key steps with the GP, the first five at the initial appointment and the final step at the 6-month follow-up appointment [21]:

1. Identify the principle patient-defined problems and GPs will be encouraged to ask patients to share the answers to their 3 goal-setting questions

2. What does the patient expect to be able to achieve? Broadly define one primary goal and 2-3 secondary goals

3. Are the patient/carer and doctor agreed on the expected outcome? Refine goals to be SMART (specific, measurable, achievable, realistic & timed)

4. How will outcome be assessed? Record baseline measures for each goal (e.g. distance walked, etc.)

5. Plan treatment in the context of a care plan to be delivered over a 6-month period

6. Review and record level of achievement for each goal as GAS-Light scores.

Goals may cover anything agreed by the patient and doctor, e.g. reducing falls, being able to go shopping, being on fewer medications. Goal achievement will be scored at the 6-month follow-up by the GP using a simple 5-point scale from -2 to +2, depending on the extent to which the goal was achieved. Recording of goal achievement will be facilitated by providing a GAS-Light record form to GPs (Appendix S). The collaboRATE scale (Appendix T) [44] will measure the level of shared decision making in the clinical encounter from the patient's perspective; the Dyadic OPTION scale (Appendix U) will assess this aspect from the GP's perspective [45].

Outcome measures

This feasibility study will collect data to inform a subsequent full trial. A key outcome for the subsequent full trial is expected to be unplanned hospital admission as defined

by NHS England [46] and in accordance with the ES [25]. Data will be collected from the general practice, from routinely available national data, by participating GPs, and from patients by the research associate.

Practice level data collected at baseline for all participating practices using a standardised spreadsheet (Appendix V) will be:

- Number of patients on practice list
- Number of GPs in practice
- Risk prediction tool used in the Enhanced Service
- Usual method of care planning (to comply with the Enhanced Service if relevant – free text entry)
- Characteristics of the participating GPs, including:
    - part-time/full-time
    - role (salaried/partner/locum)
    - sex
    - year of qualification
    - age

Publicly available Health and Social Care Information Centre (HSCIC) classification of rurality and deprivation will be added to this practice level data.

Patient participant data collected from practices using a spreadsheet (see Appendix W and X for two draft forms (baseline & 6-month version)) and completed by a Good Clinical Practice trained nurse (with help if needed from the research associate) will be:

- Age (baseline only)
- Sex (baseline only)
- Postcode (baseline only)
- Presence of a care plan in the notes (baseline only)
- Mention of patient goals in the care plan (baseline only)
- Healthcare resource use during trial - hospital admissions, A&E and outpatient contacts, primary care staff contacts (6 months only)
- Number and type of prescribed medications (baseline and 6 months)
- Number and type of diagnosed conditions on Barnett list [35] (baseline and 6 months)
- Routinely recorded biometric data and clinical disease progression for each condition present in the Quality and Outcomes Framework (baseline and 6 months)
- Mortality (6 months only)
- Participation and retention

Data collected in all participants' homes (or another location of their choosing) by the researcher:

- General Practitioner Assessment of Cognition (GPCOG) Score, calculated from Step 1 of assessment (Informant interview will not be used) [47-49] (Appendix K, baseline and 6 months)
- Patient Assessment of Care for Chronic Conditions (PACIC), a 20-item questionnaire that measures patient involvement with care planning and goal-setting [50] (Appendix L, baseline and 6 months)
- Quality of life using 2 complementary measures:
    - EQ5D [51], a short questionnaire to assess mobility, self-care, activities, pain and anxiety, (Appendix M, baseline and 6 months)
    - ICECAP-O (Investigating Choice Experiments CAPability measure for Older people) which covers attributes of wellbeing found to be important to older people in the UK such as attachment, security, role, enjoyment and control (Appendix N, baseline and 6 months) [52]
- Social care and related data (Appendix O)
    - Marital status, type of accommodation (e.g. private home/care home/sheltered housing), if any social care is received and the frequency of this care (baseline only)

Data collected by general practitioners:

- Dyadic OPTION Scale [46] (Appendix U) for all patients after initial care plan consultation
- GAS-Light goal achievement (Appendix S) for intervention group patients after second care plan consultation

Data completed by patients:

- CollaboRATE scale [45] (Appendix T) by all patients after initial care plan consultation

Data collected by researchers and PPI representative

- Observer version of OPTION-5 [54] (Appendix Y)

Statistical analysis

One aim of this feasibility study is to estimate important parameters required for the sample size estimation for a full trial. These will be used in conjunction with data from other sources, due to the expected uncertainty of the estimates [54]. Rates of drop-out, outcome measures completion and retention will be estimated. Formal statistical analysis comparing the intervention and control group will be undertaken using random effect modelling.

Health economic evaluation

We will monitor resource-use, health related quality of life, completion rates, outcome measure performance and seek to identify the key drivers of cost, to inform the decision as to how costs and benefits would be measured in the future definitive study. The resource required to provide GAS-Light will be measured, including GP training, additional GP consultation time and associated management. As part of the study a log will be kept of all resources required to provide the training. This will include any time of staff, both giving and receiving training. Costs incurred in providing the training will be recorded. We will use the video and audio recordings to measure the length of the initial care planning consultation in both arms of the feasibility study, and of the consultation to review goals 6 months later in the intervention arm only, and then specify the length for the main trial.

Data will be collected from practices on health care resource use in both arms of the study. This will include: contact with practice staff; inpatient and day case episodes; visits to A&E and outpatients. We will also collect data on prescribed medicines. We will monitor the time taken to perform this data collection in order to assess the resource implications of collecting data in this way for a future study. All contacts recorded will be costed using appropriate unit costs data. Examples would include: NHS reference costs [55]; published unit cost data for health and social care [56]; and the BNF [57] for medicine costs.

Two outcome measures that have the potential to be used in a future trial will be evaluated in this patient population. The EQ-5D-5L [52] is a widely used measure of health related quality of life, often used in economic evaluations. This instrument will be used to estimate quality adjusted life years (QALYs) [58]. Additionally, the ICECAP-O [52] to measure aspects of well-being important to older people. We will evaluate the use of these two measures in this study to inform the choice of measure in the future study.

As this study is to investigate the feasibility of the GAS-Light intervention the study will not be adequately powered to demonstrate effectiveness. For this reason it is unlikely to show cost-effectiveness. However, we will use the data collected to conduct a preliminary analysis. This will enable us to explore the potential for the intervention to be cost-effective, explore what are the key drivers of cost, and inform the design of any future study.

Qualitative evaluation

Qualitative evaluation will be an iterative analysis of recorded consultations, participant and researcher ratings of consultations, and focus groups. Video analysis will be in two steps: firstly we will adopt a pragmatic method to compare content and duration of the ‘usual’ control practice care planning consultation with ‘care planning plus goal-setting’ in the intervention practices, and assess overall fidelity to the intervention. Secondly, we will use a conversation analytic approach [59] in order to

explore in-depth the key aspects of the care planning and goal-setting consultations including verbal and non-verbal behaviours.

i. Training

Evaluation of the training workshop will be based on the 'four levels' theory of evaluation in training [60]. This process will capture initial responses and acquisition of core knowledge and skills relating to goal-setting through interaction, role-play and formal feedback at the training session. We will employ a before-and-after training evaluation of experience, knowledge and self-efficacy pertaining to goal-setting and working with individually tailored patient-centred goals. Later detailed analysis of recorded consultations will enable continued evaluation of the training and communication skills through analysis of the application and outcome of goal-setting. Focus groups, as described below, will enable further review and ensure the feedback cycle informs training for the definitive trial.

ii. Implementation

Step 1. Pragmatic analysis to compare care planning consultations in intervention and control groups:
All 60 baseline care-planning consultations will be video or audio recorded in both control and intervention groups. Video recordings are preferable as they show non-verbal communication and reveal more about the dynamics of the consultation but not essential, and audio recording will be used if GP or patient prefers, and for home visits (unless the GP wishes to use video recording for home visits as well). Validated scales will be completed by patient and doctor after the consultation, to rate patient involvement in the goal-setting and care-planning process, and compare control and intervention groups. Specifically, the CollaboRATE scale (Appendix T) [44] will be completed by the patient; the Dyadic Option scale (Appendix U) by the GP Research observers plus PPI representative will also rate involvement using the observer version of OPTION-5 (Appendix Y) [53] with video playback. This inter-rater involvement will add to the credibility, validity and transferability of the analysis and findings. Thus this three-way analysis of communication in the intervention and control consultations, and recordings produced during training, will enable the team to assess the influence of the goal-setting training and intervention from the patient's perspective as well as the health professionals' and researchers'.

Step 2. In-depth analysis to assess fidelity and effectiveness of goal-setting processes in care planning consultations in intervention groups:
We will assess the extent to which the intervention is being delivered as intended and consider the need to refine the intervention for the future definitive trial, following the MRC guidance on developing and evaluating complex interventions [61]. All 60 consultations will be transcribed verbatim using basic transcription conventions and read and reread to ensure familiarisation. Initial analysis using the analytical framework for goal-setting activity described under 'GP training' above will be informed by the findings of the Observer OPTION (Appendix Y) and Dyadic OPTION (Appendix U) to rate patient involvement. This will facilitate the sampling

of a reliable selection of up to 30 short (approximately 3 minutes) intervention consultation sequences that include goal-setting activity. These will be selected for further in-depth analysis, after transcription using full conventions for Conversation Analysis [62]. Conversation analysis (CA) is a recognised inductive approach for transcribing, extracting and analysing sequential patterns and turn taking in recording of interactional data [63]. As an intensive method CA enables detailed analysis and will focus on patterns of interaction [64] and enable identification of how goal-setting is attempted and achieved and how communication challenges are surmounted [65]. It will ultimately inform refinement of the intervention and training for the definitive trial, and enable the production of a unique analytical framework for assessment of goal-setting in primary care consultations with patients with multimorbidity.

iii. Focus groups

The acceptability of the goal-setting intervention to patients and GPs will be assessed using focus groups with one group of approximately 6 GPs (letter of GP invitation Appendix Z, GP participant information sheet Appendix AA), and one group of approximately 8 patients from the study, using anonymised vignettes from a range of goal-setting consultations based on a topic guide (Appendix AB). Up to six patient participants selected at random from each of the three intervention practices (up to 18 in total) will be invited to take part in the focus group (letter of patient invitation, Appendix AC, and patient participant information sheet, Appendix AD). Up to eight patients will be recruited on a first-come, first-served basis. All GPs who have received the training will be invited to take part in the GP focus group. Consent forms will be sent to patient and GP participants (Appendices AE and AF respectively) in advance, and signed at the time of the focus group. The experience of patients and doctors with care planning, and particularly goal-setting and using GAS-Light to score achievement of goals will be sought, as will barriers and enablers to the intervention, and unexpected benefits and potential harms will be explored. Study findings will inform further topics to be explored and interactive discussion will be encouraged to uncover a range of issues and unique perspectives. Focus groups will be audio-recorded and transcribed, field notes kept and a thematic framework analysis used [66]. Data will be analysed using the principles of framework analysis [67], which is a suitable method for the management and analysis of qualitative data in applied health research with mixed data from different participants and vignettes. It enables a structured summarised overview of a large qualitative dataset. It has been designed to facilitate evaluation of health and social care interventions (such as GAS-Light) and will allow comparison across, between and within cases. It will enable the analysis to focus on the core issues explored in the focus groups and take into account the in-depth analysis of the care-planning consultations whilst offering the flexibility to explore new themes. All audio recordings will be transcribed verbatim and supported by NVivo. Data will be indexed, charted, summarised and linked, resulting in a series of intuitively structured themed matrices. Each case (e.g. participant, vignette, etc) will be displayed by theme enabling analysis thematically and across the whole dataset.

Triangulation of data and workshop to refine intervention

We will triangulate both the quantitative and qualitative findings from the study with the data generated collaboratively through the focus groups. This is a key step in the process evaluation and will enable further refining of the intervention and training for the future definitive trial. A half day workshop will be held with patients, commissioners, GPs from both intervention and control practices, and other service providers to review the emerging qualitative and quantitative findings and consider the need for the intervention to be refined prior to use in the future definitive trial (dissemination workshop letter Appendix AG). The primary outcome measure to be used for the main subsequent trial will also be discussed at this workshop.

3. Research governance

Ethics

Confidentiality:
Participants may discuss sensitive matters during recorded consultations or focus groups. This will be managed through close attention to confidentiality, and participants will be made aware of their right to withdraw from the study at any point. The reporting of results (including quotations) will be fully anonymised and excerpts from consultations will only be used with the explicit consent of participants.

Potential harms to patients:
There is a possibility of inappropriately raising expectations of health care and patients feeling disappointed if they fail to achieve the goals that they set. However, as they will set the goals together with a GP it is more likely that the goals will be realistic, and the GP will be able to help them deal with situations when not all goals are achieved. Patient goals could involve the reduction or cessation of potentially effective treatment. This would be negotiated with a GP as part of a usual clinical consultation, during which the patient and GP would agree on the management that is in the patient's best interests.

Consent/capacity:
Although the recruitment procedure aims to exclude patients that GPs feel are unable to take part in a goal planning consultation, there is a small risk of recruiting patients who lack capacity to take part in a one-to-one goal-setting care planning consultation (e.g. due to a new health condition, such as a stroke). For the purposes of this feasibility study (where we aim to test the intervention within a one-to-one consultation, not including carers/translators) these patients may need to be excluded. The GP and, if required, the research team will discuss the situation with the participant and withdraw the participant from the trial if needed.

Research team:
The baseline and 6 month follow-up patient data collection will be carried out by the researcher at a home visit (or at a place of the participants' choosing). There is a potential physical risk from visiting patients in their own homes. Given that the patients will be screened for suitability for participation by their own GPs (who should know the patient) the risk will be small. All researchers will comply with safe working practices which includes carrying a mobile phone and sharing details of visits with other members of the research team.

Study management

Some patients may prefer not to be videoed during their appointment with their GP, and even if the patient is willing there may be problems with the video equipment. For this reason we will ensure all GPs have an audio-recorder as a default option for recording the consultation.

Transfer of the recorded consultation to the research team at the University will need to take place as soon as possible after the consultation. The practice will be asked to store the memory file/audio tape or audio recorder in a locked filing cabinet in the practice and to notify the research team when the consultation is completed. A member of the research team will then visit the practice as soon as practicable to collect the recording in person and bring it to the university for secure storage.

There is a risk of GPs not wanting to take part fully with this intervention as they are already time-pressured and may feel overburdened by the need for a longer consultation. They may be concerned about enabling patients to take more control of the consultation, or even about their performance being scrutinised as part of a research study. However, this risk should be small as all participating GPs will have volunteered for the study. Participating GPs receive funding to pay for their time to take part in the study and deliver the intervention, and in most cases the intervention will be an extension of usual care already being provided by the GP, so should not be a large addition to usual practice. Moreover, each GP will be carrying out between 5 – 10 consultations each (depending on if they are in the control or intervention arm), so the numbers will be small. In the unlikely event that any potentially unprofessional behaviour is observed, then this will be followed up with standard clinical governance procedures.

Feedback of data from research team to general practices

The UEA research team will inform the relevant GP if their patient's GPCOG score is below 5 (indicating cognitive impairment) at the baseline researcher visit, so that clinical follow-up may be undertaken, as required.

Informed Consent Forms

A participant consent form will be used for all patient and GP participants in the study and focus groups (Appendices H, J, AE and AF). Consent will be taken by a member of the research team when they make their first visit to patients to obtain the baseline data. All research team members taking consent will be at least Good Clinical Practice trained and familiar with the process of taking consent.

Potential participants will be sent an information sheet about the main study (Appendix D) plus an information sheet about video- and audio-recording options (Appendix F) together with a letter (Appendix C) and asked to contact the research team if they are interested in participating. Patients recruited in this way will thus be given several days to decide if they wish to take part.

The research associate will obtain informed consent from participating GPs in each practice on the basis of the information provided in the RISP and reading the content of the consent form (Appendix H), plus the GP participant information sheets for the main study and (Appendix G) and video- and audio- recording options (Appendix I). The research associate will contact the practice by phone to check whether the GP or

other practice staff have any questions before the study gets underway, and to prompt postal return of the consent form to UEA, and will visit the practice if requested.

The few participants that we anticipate will be opportunistically recruited when they visit the practice will be given the main study information sheet (Appendix D) and invitation letter (Appendix C) during their appointment and asked to contact the research team to express an interest.

Safety Considerations and monitoring of adverse events

As this is a feasibility study and unlikely to produce significant risks of harm we will not have a formal data monitoring committee, however the research team and, in particular, the Study Steering Group will monitor trial data. Data will be reviewed at Steering Group meetings. Participating practices will be asked to report any significant events (including those that relate to patient safety) that arise during the trial.

It is not thought likely that significant information will become available during the course of the research that will affect continued participation given the small scale of the study and the fact that we are not looking for statistically significant outcomes. However, should any significant events occur that require an evaluation of continued participation, then participants will be notified via a direct letter or telephone call from the research team.

In health services research projects of this type, the Health Research Authority defines a serious adverse event (SAE) as an untoward occurrence that:

(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect; or
(f) is otherwise considered medically significant by the investigator

Point e) above is not applicable to the GoalPlan study.

In accordance with HRA guidance, any SAEs occurring to a research participant (patient or GP) that come to the attention of the Chief Investigator will be recorded as such by the research team and reported to the Research Ethics Committee **only if the event in question was**:-

(a) related – that is, it resulted from administration of any of the research procedures, and was
(b) unexpected – that is, the type of event is not listed in this protocol as an expected occurrence.

Any SAEs that meet the above criteria will be reported to the REC within 15 days of the CI becoming aware of the event.

Patient and focus group disclosures

The focus group facilitators will be experienced qualitative researchers. They will open the focus group with a description of what is expected during the discussion and make sure participants are aware of the need for confidentiality and mutual respect. They will make it clear that participants are able to take a break from the focus group if personal, sensitive issues have been raised that they do not feel comfortable discussing.

Personal information may also be shared during focus group discussions. If it is apparent that a participant becomes distressed during a focus group the researcher will intervene and suggest a short break before recommencing when the participant feels ready (or allowing them to withdraw from the study if they wish). A debrief with the researcher will also be offered to the participant at the end of the session.

If the researcher remains concerned about participant distress or unprofessional behaviour they will seek further guidance from their colleagues. They will also reflect on the experience and consider the factors that gave rise to the situation, to assist in managing further similar instances.

Data Management

The patient's usual health care professionals - as per usual care - will have access to participant's health care data. It will only be the participant's usual health care professionals who will access their medical records to obtain data. The members of the research team will have access only to data released by the health care professionals in accordance with the study protocol or provided by participants. Personal identifiers will be removed and the data will be coded using participants' unique study IDs for analysis. One member of the research team will collect personal demographic data. They will need the demographic data and personal details to be able to invite participants to the focus groups and visit them at home.

Consent for data collection will include consent to use the data for future research, including research not directly related to the study (but about GP-patient communication). The data will be kept for 15 years (including audio and video recordings). In addition, with appropriate anonymisation and appropriate ethics approval the data would be usefully employed by future researchers investigating consultations about care planning and GP-patient interaction, saving the need for future potentially invasive and time-consuming data collection.

Sensitive data may be recorded on camera/audio tape when consultations are recorded. If the patient preferred for information not to be recorded then they have the right to withdraw from the study. The reporting of results (including quotations) will be non-identifiable and video or audio excerpts from consultations would only be used in dissemination or teaching with the explicit consent of participants.

Personal data about participants will usually be collected by a member of the research team at the time that the participant calls to express an interest in being part of the study. This will be stored in a database on a University computer's hard drive. The database will be password protected and accessible only to members of the research team. Paper documents will be stored in a locked filling cabinet. A secure NHS to NHS email will be used to transfer data securely from practices to the University.

Arrangements for patients who do not understand English

In this feasibility study we will test goal-setting amongst patients who can communicate in English (as good communication is essential for the tool to work). Patients who require translation services will therefore be excluded, but other patients with special communication needs (e.g. deafness, blind) will be included as long as they are able to conduct a one-to-one consultation with their GP.

We will record the number of people who are excluded because of the inability to conduct a one-to-one consultation (including those who would have required an interpreter), and the reason for exclusion.

Intellectual property (IP) considerations

The results of the Project, including any intellectual property rights and commercially valuable know-how, but excluding Background Intellectual Property ("Arising Intellectual Property") shall vest in SNCCG including any modification to GAS-Light and development of any training materials. All collaborators in the project will be granted "an irrevocable, non-transferable, royalty-free right to use all arising intellectual property generated in the course of the Project for non-commercial, academic and research purposes". To further assist with the dissemination the Parties agree that Kings College London (KCL) shall be given a non-exclusive royalty free licence to use the foreground IP. It is likely that if we were to disseminate the foreground IP, and it contained portions of the GAS-Light tool we may require a formal waiver or confirmation allowing the new material to be distributed, acknowledging both KCL and the contributors within this application.

Continued provision after completed research

All GPs are expected to provide care planning where indicated as part of usual practice. The goal-setting aspect of the consultation may be something that GPs and patients wish to continue using as part of their usual practice, but no specific arrangements are being made to ensure this continuous provision, which will be a matter of personal choice for each GP and patient.

4. Project management

A project steering committee will comprise representation from NHS England, NHS South Norfolk CCG, two public involvement members, and members of the research team. The steering committee will meet every 12-16 weeks. The main role of the steering committee will be to oversee project management, and ensure that the project is proceeding as expected within time and financial constraints.

The principal investigator (Prof Nick Steel) will be the project manager and responsible for ensuring that the project is conducted within the timelines described above and within budget. He will chair the steering committee meetings. The research associate and research team will be responsible to Prof Steel as the lead investigator. The research associate will be responsible for data extraction, maintenance, entry and analysis, under supervision of members of the research team as appropriate. Prof Steel will be responsible for the financial management in collaboration with the R&D office at NHS South Norfolk CCG, and the finance office at the UEA.

The research team will keep in contact with the sponsor throughout the trial, especially in relation to recruitment of practices.

Research timetable

See Appendix AH for a Gantt Chart illustrating the timeline of the project. The entire project is expected to last 21 months.

Patient and public involvement

Patient and public involvement (PPI) will be provided by a co-applicant on the research who will contribute to steering group meetings and the management and interpretation of the research, and by an additional member of the steering group.

Withdrawal procedure

Participants will have the right to withdraw from the study at any time without giving reason. Identifiable data already collected with consent would be retained and used in the study. No further data would be collected or any other research procedures carried out on or in relation to the participant. Should the participant wish their data to be withdrawn from the study as well, this will be undertaken if it has not already been processed and analysed.

If a practice withdraws before GP training has been delivered and/or patients have been recruited another practice will be recruited. If this happens the interested practices will not be informed if they are joining the intervention or control arm. Should a practice wish to withdraw after training and recruitment of patients identifiable data already collected with consent would be retained and used in the

study. All participants would be informed of the practices decision to withdraw and would themselves be withdrawn from the study. No further data would be collected or any other research procedures carried out on or in relation to the practice and their participant.

Should a GP wish to withdraw from the study the practice will be able to remain in the study unless it no longer meets the inclusion and exclusion criteria as outlined above. GPs will have the option of withdrawing their data (such as material from video or audio recordings) from the study unless it has already been processed and analysed.

5. Dissemination

The findings will be disseminated to NHS England (commissioners of the enhanced service which involves care planning) through our co-applicant. General practices will be informed of the results through their respective Clinical Commissioning Group.

The regional NIHR Clinical Research Network will disseminate the results to the East of England Clinical Commissioning Groups. A summary of the results and implications for clinical practice, aimed at GPs and commissioners, will be published on the University of East Anglia website. Results will be disseminated to the contributors of the research (including patients who wish to be informed of the results) through a mailing list.

Results will be disseminated to academics through peer reviewed publication. We will present the findings to the national Society for Academic Primary Care conference or similar suitable academic meeting.

1. Main feasibility paper
    - Target Journal: Journal of Clinical Epidemiology or BMJ Open
2. Goal planning in clinical (shared) decision making: a new framework / grid for analysis of patient involvement and engagement with goal-setting
    - Target Journal: Patient Education and Counselling
3. Whose Goals Are They Anyway? Asymmetry and ownership in care planning consultations between doctors and their patients with multimorbidity in primary care
    - Target Journal: Social Science & Medicine

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Appendices

Appendix A: Research Information Sheet for Practices

Appendix B: Invitation email to general practices

Appendix C: Letter of invitation to GoalPlan study to patients from practice

Appendix D: Patient participant information sheet for trial

Appendix E: Expression of Interest form

Appendix F: Patient participant information leaflet about audio- and video-recording options

Appendix G: GP participant information sheet for trial

Appendix H: GP consent for trial

Appendix I: GP participant information leaflet about audio- and video-recording options

Appendix J: Patient consent for trial

Appendix K: GPCOG questionnaire

Appendix L: PACIC questionnaire

Appendix M: EQ5D questionnaire

Appendix N: ICECAP-O questionnaire

Appendix O: Patient social factors baseline questionnaire

Appendix P: Letter to inform GP of patient participation

Appendix Q: Information sheet to intervention patients about goal setting

Appendix R: Three question information sheet

Appendix S: GAS-Light goal achievement record form for completion by GPs

Appendix T: CollaboRATE scale

Appendix U: Dyadic OPTION scale

Appendix V: Practice level data collection spreadsheet

Appendix W: Spreadsheet for collecting patient data from routine practice data BASELINE

Appendix X: Spreadsheet for collecting patient data from routine practice data FOLLOW-UP

Appendix Y: Observer OPTION version (http://www.optioninstrument.org/raters-manual.html)

Appendix Z: Letter of invitation to GP focus group

Appendix AA: GP participant information sheet for focus group

Appendix AB: Focus group topic guide

Appendix AC: Letter of invitation to patient focus group

Appendix AD: Patient participant information sheet for focus groups

Appendix AE: Patient participant consent form for focus groups

Appendix AF: GP participant consent form for focus group

Appendix AG: dissemination workshop letter

Appendix AH: Gantt chart