

1 **Title**

2 **Can goal-setting for patients with multimorbidity improve outcomes in primary care?: cluster**
3 **randomised feasibility trial**

4

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29 [df/86549c5b-c4ed-435b-8719-4c3160f9793f](http://www.uea.ac.uk/documents/246046/14839702/GoalPlan+Research+Protocol+v1.2+170316.pdf/86549c5b-c4ed-435b-8719-4c3160f9793f)

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34 trial

35

36 **Abstract**

37 Introduction

38 Goal-setting is recommended for patients with multimorbidity, but there is little evidence to support
39 its use in general practice.

40 Objective

41 To assess the feasibility of goal-setting for patients with multimorbidity, before undertaking a
42 definitive trial.

43 Design and setting

44 Cluster-randomised controlled feasibility trial of goal-setting compared to control in six general
45 practices.

46 Participants

47 Adults with 2 or more long term health conditions and at risk of unplanned hospital admission.

48 Interventions

49 General Practitioners (GPs) underwent training and patients were asked to consider goals before an
50 initial goal-setting consultation and a follow-up consultation six months later. The control group
51 received usual care planning.

52 Outcome measures

53 Health-related quality of life (EQ5D5L), capability (ICEpop CAPability measure for Older people
54 (ICECAP-O)), patient assessment of chronic illness care (PACIC) and health care use. All consultations
55 were video or audio-recorded, and focus groups were held with participating GPs and patients.

56 Results

57 Fifty-two participants were recruited with a response rate of 12%. Full follow-up data were available
58 for 41. In the goal-setting group, mean age was 80.4 years 54% were female and the median number
59 of prescribed medications was 13, compared to 77.2 years, 39% female and 11.5 medications in the
60 control group. The mean initial consultation time was 23.0 minutes in the goal-setting group and
61 19.2 in the control group. Overall 28% of patient participants had no cognitive impairment.
62 Participants set between one and three goals on a wide range of subjects, such as chronic disease
63 management, walking, maintaining social and leisure interests, and weight management. Patient
64 participants found goal-setting acceptable and would have liked more frequent follow-up. GPs
65 unanimously liked goal-setting, felt it delivered more patient-centred care and highlighted the
66 importance of training.

67 Conclusions

68 This goal-setting intervention was feasible to deliver in general practice. A larger, definitive study is
69 needed to test its effectiveness.

70 **Strengths and limitations of this study**

71

72

73 • General practitioners and patients with multimorbidities both benefit from preparation before
74 setting goals

75 • Recruitment reached target levels in five of six practices, but the patient response rate of 12%
76 means that a definitive study will need sufficient numbers of patients with multimorbidity

77 • Existing measures of patient centred care are usually designed for a single specific treatment
78 decision and were difficult to apply to goal setting consultations, where several goals were
79 discussed

80 • The most relevant outcome measure for goal setting was the patient assessment of chronic
81 illness care (PACIC), which includes a sub-scale for goal setting

82 • Qualitative data from video-recorded consultations and focus groups were vital to understand
83 how goal-setting was implemented in practice, and how acceptable it was to GPs and patients.

84 Introduction

85 The rising number of long-term conditions and prescribed medications has increased the burden of
86 treatment for patients [1 2]. People with multimorbidity (defined as two or more chronic conditions
87 [2]) tend to have a lower quality of life and worse health than those with single conditions [3].
88 Medical outcomes that work well for relatively healthy patients (e.g. blood pressure control, or
89 disease-free survival) may be inappropriate for patients with multimorbidity or severe disability [4
90 5], and the use of current single-disease guidelines in this group can encourage harmful
91 polypharmacy with resulting drug-drug and drug-disease interactions [6].

92 The National Institute for Health and Care Excellence (NICE) recommends an approach to care that
93 takes account of multimorbidity by establishing patient goals, values and priorities [7]. Goal setting is
94 the sharing of realistic goals by health professionals and patients and agreement of the best course
95 of action [8]. Goal setting enables patients and doctors to focus health care on the outcomes that
96 are most important to the patient. Examples of outcomes that matter to patients may include
97 maintaining independence, undertaking paid or voluntary work, preventing adverse outcomes (e.g.
98 falls) and reducing treatment burden [7]. Despite the recommendation that health professionals
99 should establish patient goals with individuals with multimorbidity, there is little evidence to support
100 the use of goal-setting between general practitioners and patients, and it is rarely used in primary
101 care [8-10]. The goal setting approach is more likely to be effective if it incorporates shared decision
102 making, the process by which health professionals and patients make decisions together based on
103 the best available evidence [11], because the goals and actions agreed will be more patient-centred
104 leading to greater engagement in the process by patients. The difference is that shared decision
105 making is usually concerned with specific clinical treatment decisions, whereas goal setting usually
106 involves a wider discussion around ways to deliver outcomes that matter to the patient.

107 Goal-setting should be, but rarely is, an important element of the care planning process in the UK.
108 For the purposes of this study, we define care planning as 'a conversation in which patients and
109 clinicians agree on goals and actions for managing the patient's conditions' [8]. For patients with
110 long term health conditions, personalised care planning has been found to improve physical and
111 psychological health, in addition improving capability to self-manage, compared to usual care [8]. A
112 recent systematic review highlighted the need for evidence exploring 'the effects of personalised
113 care planning on goal-attainment, especially patient's personal goals as opposed to goals
114 determined by clinicians or researchers' [12].

115 Our goal-setting intervention was designed within the context of a national recommendation that
116 the top 2% of patients at risk of unplanned hospital admission should have a care plan [13]. We
117 wanted to find out if a consultation focussed on goal-setting would improve outcomes for this
118 patient group, compared to control consultations (the usual care planning process undertaken in UK
119 primary care which rarely includes goal setting). Before we could conduct a full trial to answer this
120 question, we needed to answer questions about the feasibility of such a trial. We aimed to assess
121 the feasibility of goal-setting for patients with multimorbidity, at high risk of hospital admission and
122 eligible for a care planning consultation, with a view to undertaking a future definitive randomised
123 controlled trial. Our objectives were to assess participant recruitment and retention, the
124 acceptability of a goal-setting intervention to patients and GPs, the training needs of GPs, the
125 content of control consultations, goal-setting and the feasibility of collecting relevant outcome
126 measures.

127 **Methods**

128 We undertook a cluster randomised controlled feasibility trial of goal-setting compared to usual care
129 in six general practices in the United Kingdom, with six months follow-up. Six months was long
130 enough for patients and GPs to work towards the agreed goals, but not so long that the goals would
131 have been forgotten. There were no significant changes to the protocol [14]. Research ethics
132 approval was obtained from the NHS Research Ethics Committee (16/EM/0411). Participants were
133 recruited between April and May 2017 and follow-up completed in February 2018.

134
135 General practices were invited via two emails through the East of England Clinical Research Network
136 and recruited on a first-come first-served basis. To be eligible, practices had to be using risk
137 stratification to identify patients at high risk of unplanned admission (for example by participating in
138 the Avoiding Unplanned Admissions Enhanced Service: proactive case finding and patient review for
139 vulnerable people [13]), have at least one Good Clinical Practice trained GP and nurse, be able to
140 nominate two GPs to attend the goal-setting training and not be a single handed practice. Practices
141 were reimbursed for staff time and travel to undertake the research and deliver the intervention.
142 Patients were eligible if they were aged 18 or over, identified as in the top 2% for risk of unplanned
143 admission and diagnosed with at least two of 40 morbidities in Barnett's analysis of multimorbidity
144 [2]. Patients were excluded if they were deemed to be unable to participate in goal-setting in the
145 GP's professional opinion (e.g. advanced dementia or acute psychosis), had received a care planning
146 consultation in the previous three months, or required translation services to communicate verbally.

147 Practice administrators searched their electronic patient register according to the eligibility criteria,
148 and a GP then checked the resulting patient list for exclusion criteria. Eligible patients were sent a
149 letter of invitation and participant information leaflet, with the intention of recruiting 10 patients
150 per practice. The number of eligible patients ranged from 47 to 124 and all were invited. The
151 protocol allowed GPs to opportunistically invite patients they thought might be interested, however
152 no patients were recruited through this process. A study researcher visited interested patients at
153 home to discuss the study and obtain written informed consent.

154 The Norwich Clinical Trials Unit independently randomised three practices to goal-setting and three
155 to control, by simple block randomisation using a 1:1 ratio and sealed opaque envelopes. Practices
156 were randomised after at least 10 expressions of interest were received from patients. It was not
157 possible to blind participants, health professionals or researchers due to the nature of the
158 intervention, with the exception of the statistician undertaking the analysis, who was blinded to the
159 allocation.

160 *Intervention*

161 Both intervention and control practices identified two GPs to either attend the training and deliver
162 goal setting consultations or deliver control consultations, although in one intervention practice
163 (Practice 3) only one GP was able to attend. Therefore five participating GPs from practices allocated
164 to goal-setting (see Table 1) received training in a three hour experiential workshop, led by senior
165 consultation skills tutors (CS and SW) and a GP with experience in communication skills training (AS).
166 One other GP attended the training but withdrew prior to delivering the intervention for personal
167 reasons. The training model we developed for goal setting adapted relevant elements of the work of
168 Elwyn and colleagues on shared decision making [15 16] and of patient-centred care in the leading
169 training model in clinical communication (the Calgary Cambridge Guide [17]). Our model adopted a
170 structured, patient-centred stepped approach. Steps included preparation, goal elicitation, assessing

171 options, making goals smart, decision-making and evaluation. Following an introduction to the
172 study, the training was mainly experiential to enable GPs to rehearse existing skills and integrate
173 additional skills for facilitating the goal-setting process. Experiential methods included role-play,
174 video analysis and interactive skill spotting . GPs were trained in groups of three and were given a
175 detailed handbook in advance. The handbook contained information about the study and a “how to”
176 guide for goal-setting, including theoretical background and examples of goal setting. The control
177 group GPs received no training for this study and were asked to undertake a care planning
178 consultation as they would usually do in routine clinical practice. This may have involved a national
179 care planning template, which does not include goal setting, from the Avoiding Unplanned
180 Admissions Enhanced Service [13].

181 A study researcher discussed goal-setting and the associated paperwork with participants during the
182 face-to-face baseline visit, which lasted approximately 15 minutes. The researcher gave all patient
183 participants a patient-held goal-setting sheet (PGS), with questions to consider prior to their
184 consultation. The questions (Supplementary Appendix 1) were:

- 185 • What are your goals? What is important to you? What do you really want to achieve over
186 the next six months?
- 187 • Why are these goals important to you?
- 188 • What are the first steps you would like to take towards achieving this goal or goals?

189 The goal-setting consultations were held with the participating GPs even if they were different from
190 the patient’s usual GP. During the initial goal-setting consultation GPs, in partnership with
191 participants, documented the goals which had been agreed. GPs then provided support, within their
192 clinical expertise and with the help of other health care professionals, to help patients achieve their
193 goals, for example by providing information on local groups and services. Participants in both the
194 goal-setting and control groups had an initial consultation which lasted about 20 minutes, but only
195 patients in the goal-setting arm were invited back for a follow-up consultation after six months to
196 discuss their goal attainment.

197 *Data and statistical analysis*

198 We collected quantitative and qualitative data to meet the feasibility study objectives. Data
199 collected from patients during a researcher visit at baseline and six months were: health-related
200 quality of life (EQ-5D-5L [18]); capability (as measured through the five attributes of attachment,
201 security, role, enjoyment and control in the ICEpop CAPability measure for Older people
202 questionnaire (ICECAP-O) [19])(ICEPOP is the name of the UK MRC-funded programme through
203 which the index was developed), cognition (general practitioner assessment of cognition scale (GP-
204 COG) [20]) and patient centred care (patient assessment of care for chronic conditions scale (PACIC)
205 [21]). Data collected from the electronic patient record included age, sex and postcode Index of
206 Multiple Deprivation (IMD) score (baseline only), medications on repeat prescription, diagnoses,
207 achievement of relevant quality of care indicators in the Quality and Outcomes Framework [22] and
208 primary and secondary care use (see health economic section below for more details). Practice data
209 were collected before randomisation and patient data were collected after.

210 GPs and patient participants were asked to complete an assessment of shared decision making
211 during each consultation using the CollaboRATE scale [23] for patients and dyadic OPTION scale [24]
212 for GPs. GPs and patients in the goal-setting group were asked to discuss and complete a goal
213 attainment scaling (GAS-Light) questionnaire [25] (See Supplementary Appendix 2) at the second

214 consultation. Goal attainment was scored using the following system: -1 = worse than expected, 0 =
215 no change, 1 = partially attained, 2 = as expected, 3 = a little more and 4 = a lot more than expected.

216 All initial consultations were video (n=41) or audio (n=4) recorded and transcribed. Three team
217 members scored the consultations using the observer OPTION measure to assess shared decision
218 making [26]. One focus group was held with patients and one with GPs from the goal-setting group
219 at the end of the six month follow-up period to discuss perspectives, experiences and overall
220 acceptability of the goal-setting intervention. All patients in the intervention group were sent a letter
221 of invitation to the focus group, except two who indicated at the researcher visit they did not want
222 to take part. Both focus groups lasted about 90 minutes, were held at the university, guided by a
223 topic guide, audio-recorded and transcribed. Patient or GP participants unable to attend the focus
224 groups were interviewed by phone or face-to-face using the same topic guide.

225 We calculated the recruitment rate by practice and by randomisation group. Demographic variables
226 were compared for those recruited and those not recruited. The characteristics of baseline
227 consultations were summarised both by practice and by intervention group.

228 The change in outcome measures from baseline to follow-up was summarised using descriptive
229 statistics by randomisation group. We estimated the difference between randomisation groups using
230 a linear mixed model with practice included as a random effect. This would allow the estimation of
231 potential differences in a full-scale trial. The intra cluster correlation coefficient was estimated for
232 each outcome, however great care should be taken in the interpretation of these due to the small
233 number of clusters [27]. All statistical analyses were undertaken using Stata version 15.

234 *Health economic evaluation*

235 Data were collected on resource use from an NHS perspective to test data collection processes and
236 to inform a future health economic evaluation estimating quality adjusted life years (QALYs). A
237 record was kept of resources required to provide GP training, as well as the length of initial and
238 follow-up goal-setting consultations. Additional health care resource use was extracted from
239 electronic health records by practices supported by a study researcher (EL) for the six-months prior
240 to randomisation and from randomisation to follow-up. Health care use was collected for: day-case
241 and inpatient hospital admissions; outpatient visits; accident and emergency visits (A&E);
242 consultations at the GP practice (GP, practice nurse, health care assistant, nurse practitioners); and
243 other contacts, such as district nursing, allied health professional contacts, ambulance call outs, and
244 specialist nursing contacts.

245 Resource use was costed using the NHS reference costs [28] for secondary care and a published
246 source for primary care contacts [29]. NHS reference costs were used to estimate a weighted
247 average cost for day cases, non-elective short stay, non-elective long stay, and elective admissions.
248 For longer stays, additional days were costed using a weighted average of all excess bed day costs.
249 For the first and second GP consultations in the goal-setting group, we had data on length of
250 consultation and setting. The cost of providing training was estimated from a description given by
251 the study researcher of duration and required staff. The cost of academic staff time was estimated
252 using University pay scales (including employer's national insurance and superannuation payments).
253 As the training would have relevance beyond the duration of the study, we estimated a useful life of
254 3 years and calculated an annual equivalent cost [30]. All costs are in 2015/16 UK pounds sterling. As
255 the duration of the study was six-months, we did not discount costs and benefits. As the study size
256 was very small with great variability in estimates of cost and effect, we did not estimate formal cost-
257 effectiveness.

258 *Qualitative analysis*

259 The video and audio recordings of control and goal-setting consultations were compared by the
260 research team (CS, EL, AS, JM and RH) to measure duration and explore the content and
261 methodological implications for a future study. An in-depth analysis of the consultations using a
262 conversation analytic informed approach [31] is reported elsewhere [32].

263 A thematic framework-based analysis was used to analyse the focus groups recordings and
264 transcripts [33] to assess the acceptability of the goal-setting intervention to patients and GPs and
265 possible future improvements to the goal-setting intervention, training and trial design.

266 *Patient and Public Involvement (PPI)*

267 Four individuals contributed to patient and public involvement (CG, RH, AM, HS). Two PPI
268 representatives contributed to the design of the research as co-applicants on the initial application
269 for funding (AM and HS) and steering group membership (AM and CG). PPI members contributed to
270 the analysis and interpretation of the results, with one PPI representative reviewing and scoring
271 video consultations using OPTION (RH) and a further two reviewing a selection of video consultation
272 transcripts (AM and CG). Two PPI members reviewed and commented on the manuscript and are co-
273 authors (AM and CG).

274 **Results**

275 *Recruitment and retention*

276 Sixty general practices were invited with seven expressing interest and six being recruited (Figure 1).
277 Across the six practices (Table 1), 550 patients met the eligibility criteria and were invited. In total,
278 52 patients were recruited with 24 belonging to practices randomised to goal-setting and 28 to
279 practices in the control group. Thirteen patients were held in reserve from three practices which had
280 recruited enough patients. The response rate was 12% $((52+13)/550)$. There was little variation in
281 age, sex and deprivation between those who participated and those who did not (Supplementary
282 Table 1). Two participants in the goal-setting group and five in the control group did not receive the
283 initial consultation because they declined to attend, were unavailable or withdrew consent. Four
284 participants in the goal-setting group did not receive the follow-up consultation because of ill health
285 or death. Data collected directly from participants were available for 18 participants in the goal-
286 setting group and 23 in the control group. Participant data collected from practices were available
287 for 23 participants in the goal-setting group and 28 in the control group. Recruitment of practices
288 took place between December 2016 and February 2017 and recruitment of patients between April
289 and May 2017.

290 The control practices were in more urbanised areas with larger practice populations and more
291 female GPs participating compared to goal-setting practices (Table 1). The goal-setting group,
292 compared to control (see Table 2), had more patient participants who were female (54% compared
293 to 29%), older (80 years old compared to 77), with a higher number of health problems (5 compared
294 to 4) and medications (13.0 compared to 11.5), but similar quality of life. The control group had
295 participants spread across all four IMD quartiles, whereas the goal-setting group had participants in
296 only the second and third quartiles. All participants were white British and retired, except for one
297 participant in the goal-setting group who was of working age but not employed and one in the
298 control group who was self-employed. There was variation in participant baseline characteristics
299 between practices in mean age (range 69.5 to 85.8 years old), proportion of females (range 25% to
300 73%), number of medications (range 10.0 to 15.5) and number of health problems (range 3.0 to 7.5)
301 across participating practices.

302 The mean initial consultation time in the goal-setting group was 23.0 minutes and in the control
303 group was 19.2 minutes (Table 3). GPs in the intervention group saw a mean of 4.4 patients (range 4
304 to 5), whereas GPs in the control group saw a mean of 3.8 patients (range 2 to 7). Patients spoke
305 more in the goal-setting group initial consultation (mean GP:patient word count ratio (WCR) 1.35)
306 than the control group (WCR 1.52), but this was not statistically significant. Dyadic OPTION scores for
307 GPs perceptions of shared decision making were not statistically significantly higher in the goal-
308 setting group compared to the control group, and collaboRATE scores were similar. Observer
309 OPTION scores showed large variation and inconsistency in scoring between the three research team
310 members (data not presented).

311 Most patients set two or three goals (Table 4) in the goal setting intervention arm, with GPs and
312 patients setting on average one more goal in Practice 1 than in Practice 3. The commonest types of
313 goals were related to management of chronic conditions, walking, maintaining social and leisure
314 interests and weight management (Table 5). Forty-two of the 50 goals were scored with a mean
315 attainment score per patient of 1.45 (1= partially attained and 2= as expected) with 'partially
316 attained' being the commonest outcome (Table 4).

317 In the control arm, goals were rarely mentioned. Four usual-care GPs followed the care planning
318 template recommended within the Avoiding Unplanned Admissions enhanced service [13], one GP
319 appeared to treat it as a normal problem-focused consultation and another GP focused solely on end
320 of life issues.

321 *Outcome measures*

322 As expected in this small feasibility study, there were no statistically significant differences between
323 goal-setting and control from baseline to follow-up in PACIC score, health-related quality of life as
324 measured by EQ5D, number of medications or GPCOG score (Table 6 which also shows the intra-
325 class correlation coefficients). Capability as measured by ICECAP-O at six months, improved slightly
326 more in the control group than in the goal-setting group, but the 95% confidence interval includes
327 zero (mean difference between groups -0.08, 95% CI -0.15 to -0.00).

328 There was considerable variation in health care use in the six months prior to randomisation and six
329 months follow-up (Table 7). Most health care contact increased in both the control and goal-setting
330 groups, but district nurse contacts increased and inpatient admissions decreased only in the goal-
331 setting group. Quality and Outcomes Framework data were collected at baseline and follow-up, but
332 the results were uninformative due to low numbers and low variability (Supplementary Table 2).

333 There was one death in the goal-setting group due to cancer, which was judged to be unrelated to
334 the intervention. The estimated cost of the goal-setting was £147 per patient, of which £95 related
335 to costs of providing initial and follow-up GP consultations, and £43 related to the cost of GP
336 training. There was a small cost for the study researcher to explain goal-setting. A mean cost of £50
337 per patient was incurred in the control group for the initial consultation. The single largest cost for
338 the six-months prior to recruitment and the six-months of follow-up was inpatient stays (Table 7).
339 There were also substantial costs in other settings, for example in general practice contacts and
340 district nurse services. The types, number and associated costs of health service use varied
341 considerably, as would be expected in a feasibility study.

342 *Acceptability*

343 Eleven patients expressed interest in the focus group but only six were able to attend on the
344 selected date. Two patients who were unable to attend took part in a telephone interview. Of the
345 five GPs who deliver the intervention, four attended the focus group and one was unable to attend,
346 so was interviewed face-to-face at the GP surgery. All six patient participants attending the focus
347 group reported positive experiences and views of the intervention, particularly regarding the
348 different emphasis of the consultation. Participants spoke of goal setting providing clarity about
349 what mattered to them, and helping them to plan and focus their lives

350 *"[Goal-setting] gives he or she a much better understanding of particularly what is worrying*
351 *you, what your aims are, the things that you miss being able to do and to be able to actually*
352 *explain it where [GPs] have time, because very often the GPs, you know, you've only got ten*
353 *minutes. But with these consultations, you're actually able to talk to a doctor, as you would*
354 *indeed a friend almost" (Patient 107)*

355 Goal-setting appeared to function as a mechanism for helping make consultations patient-centred.
356 This was reflected in the unanimous support for the intervention amongst the four GPs who
357 attended the GP focus group and one GP who was interviewed by phone. GPs described the goal-
358 setting consultations as *more patient-centred and reflected on its 'therapeutic powers'* (GP10)
359 compared to day-to-day general practice, which GPs felt could be dominated by *'box-ticking'* and
360 *'target driven'* (GP018) medicine.

361 *"I felt almost as if I was trying to put on a different hat, you know, trying not to constantly*
362 *interrupt them or to sort of sway them in any way, I was trying to give them the opportunity*
363 *to just say what they wanted to say and set any goal that they wanted to and I, and it made*
364 *me reflect on actually what I do during the day to day when I've got ten minutes with a*
365 *patient and I'm very aware of the sort of pressure of, oh I've got to do a medication review*
366 *and I've got to do this and oh no, their cholesterol's now 7 and oh gosh I've, have my*
367 *colleagues already spoke to them about this and are they aware of X, Y and Z and actually it*
368 *was quite nice in a way just take a step back and think, um I don't have to do that with this*
369 *consultation, let's see what happens when the patient has more control over it"* (GP025)

370 Patient participants spoke positively about the baseline researcher visit because it helped them
371 understand the study and encouraged them to reflect on what was important. However, when
372 discussing wider implementation across the health service, participants acknowledged that a home
373 visit for each patient may be too costly and alternative provision would be acceptable to most
374 people. Patients were reluctant to receive more paperwork as they felt that it was a burden for
375 some people. When asked by the moderator to consider the acceptability of a group session to
376 introduce people to the study and to the concept of goal-setting, all but one of the patient
377 participants at the focus group felt this would be acceptable.

378 Continuity of care was a concern for patient participants. While one person was disappointed not to
379 see their own GP, three were positive about consulting with a different doctor, especially if it was
380 difficult to see their usual GP. However, participants spoke of wanting more follow-up and
381 consistency amongst the health care team in relation to their goals in the future; some participants
382 felt there was a disconnection between the activity of goal setting and their subsequent treatment
383 by staff within the practice.

384 GPs stated that the experiential work, especially role play and skill spotting, was the most useful
385 aspect of training. When discussing delivering training at scale, GPs felt e-training with opportunities
386 to watch '*other people role-play*', would fit in with their busy schedules. In addition, multiple shorter
387 e-training modules, using a '*step-by-step*' approach (GP014) that contributed to continuing
388 professional development, would be attractive to GPs when implementing the intervention more
389 widely.

390 Discussion

391 The process of setting goals in a GP consultation and follow-up over six months was acceptable to
392 patients and unanimously supported by participating GPs. Recruitment and retention of practices
393 and patients was achieved. A wide range of goals were set and, as expected with a feasibility study,
394 there were no statistically significant differences in the main outcomes. Goal setting consultations
395 were a similar length to control consultations. The qualitative findings were that goal-setting helped
396 patients and GPs focus on what was important and supported GPs to deliver more patient-centred
397 care. Patient preparedness, continuity of care and being able to deliver training at scale were
398 important considerations for future studies of goal setting. Data on the number of health problems
399 were not sufficiently robust for analysis because they were extracted from practice records using
400 different processes. Asking GPs in the non-intervention group to undertake a video-recorded usual
401 care planning consultation is likely to have altered practice compared to what would have happened
402 within the enhanced service. An intention-to-treat analysis was undertaken to reduce the impact of
403 protocol violations (e.g. patients not receiving the pre-specified intervention).

404 A Cochrane review, published in 2015, assessed the effects of personalised care planning (defined as
405 goal-setting and action planning), for adults with long term health conditions compared to usual care
406 [8]. Whilst 19 RCTs were included, all except for one focused on single conditions. The one multiple
407 condition study included patients who had high health care use and focused on care planning, with
408 goal-setting as part of the process, across the wider health care system to reduce unplanned
409 admissions [34]. The authors found an increase in quality of life (measured by SF36) in the
410 intervention compared to control, however with 50% of participants lost to follow-up and intention
411 to treat not undertaken, there is a possibility of a lost to follow-up bias in favour of the intervention.
412 Our study has focused on goal-setting specifically in primary care.

413 A systematic review of randomised and non-randomised studies, published in 2017, looked at
414 collaborative goal-setting or health priority setting for elderly people with a chronic condition or
415 multimorbidity [12]. The authors found that in four of eight intervention studies, multifactorial
416 approaches improved goal-setting or care planning, but the review did not assess health outcomes
417 or quality of life. The authors concluded that future research was needed to determine the “mix of
418 essential elements within a multifactorial intervention to provide recommendations on daily
419 practice”. Our study helps to answer this question by identifying some key requirements of goal-
420 setting in primary care.

421 This was a feasibility study and the main implications are for the design of a subsequent definitive
422 trial. Our objectives were to assess participant recruitment and retention, the acceptability of a goal-
423 setting intervention to patients and GPs, the training needs of GPs, the content of control
424 consultations, goal-setting and the feasibility of collecting relevant outcome measures.

425 We set out to recruit six practices, and seven (out of 60 invited) were willing to take part after one
426 initial email invitation. Participant recruitment and retention was sufficient overall, but low in one
427 practice (which recruited four out of a target of ten). Reminder letters were not sent, but these may
428 help all practices to recruit larger numbers if required in a future study. Seven participants, five from
429 the control and two from goal-setting, did not receive the initial consultation because they declined
430 the consultation, withdrew consent or were not able to attend. Possibly some were disappointed to
431 be allocated to the control group.

432 Goal-setting was acceptable to participating patients and GPs, albeit a self-selecting group who were
433 willing to take part in research into goal-setting. Goal setting is unlikely to be relevant to everyone,

434 but the positive response of participants in this feasibility study suggests that it is likely to have
435 wider acceptability in general practice. Further research is needed to understand which patients will
436 benefit most from goal setting. The readiness of patients to undertake goal-setting appeared to be
437 important. Although several goals were only partially attained, GPs and patients still felt them to be
438 worthwhile, suggesting that the process of goal setting has benefits, apart from the achievement of
439 goals.

440 Training participating GPs in goal-setting was important, and participating GPs thought that the face-
441 to-face training with role play used in the feasibility study could be replaced with online e-learning to
442 allow delivery at scale to a wider GP workforce. The initial researcher visit was important to
443 participants and the key elements of this visit would be delivered in a future trial using video and
444 leaflet-based patient information aids, again to be developed using material collected during this
445 feasibility study.

446 Goal setting consultations were more focussed on what matters to the patient than the control
447 consultations. Key challenges in goal setting included preparation and agreeing goals and we explore
448 these further elsewhere [32]. Some patients were concerned that their goals were not considered in
449 future consultations, which suggests that better communication of goals with the rest of the health
450 care team will be needed. Planned follow-up of goals with the GP sooner than six months if needed
451 would improve continuity of care, which is associated with lower mortality [35].

452 We collected a wide range of outcome measures in order to assess their feasibility and suitability for
453 use in a future trial. Both EQ-5D-5L and the ICECAP-O should be used in a future economic
454 evaluation but would not be the best primary outcome measure for a trial of goal setting. A recent
455 study which aimed to improve the management of patients with multimorbidity, the 3D study, used
456 the EQ5D5L as a primary outcome, but did not find any significant difference between arms [36]. It
457 may be that the domains within the EQ5D5L are insensitive to changes in care for patients with
458 multimorbidity and a measure of patient centred care such as PACIC is a more appropriate primary
459 outcome measure as it contains a sub scale to measure goal setting. Baseline and follow-up data
460 were collected during researcher visits, which could be replaced by postal questionnaires as the
461 amount and complexity of data to be collected would be reduced. Postal questionnaires are widely
462 used in research and could either increase or reduce the completeness of follow-up data, depending
463 on the preference of individuals for a visit rather than a postal form to complete.

464 Quality and Outcomes Framework data did not prove useful because of the small numbers and low
465 variation. The observer OPTION scoring, initially developed within a rehabilitation context, had low
466 consistency between researchers and therefore was not useful. A possible reason for this lack of
467 consistency was that OPTION was developed for specific clinical decisions, and not for goal setting
468 which often involved multiple complex decisions.

469 Goal-setting can be valuable for GPs and patients seeking to agree the desired outcomes of care,
470 particularly for older patients with multimorbidity. This study has demonstrated that it is acceptable
471 and feasible in general practice, and a full trial is now needed to assess whether goal setting
472 improves important clinical outcomes for patients.

473

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475

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478 undertook the statistical analysis. DT undertook the economic analysis. All authors contributed to
479 the interpretation of the results. JF drafted the initial manuscript. All authors revised the manuscript
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481

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494

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496 Dataset of quantitative data and statistical code is available from the corresponding author.

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596

Table 1: Baseline characteristics of participating practices and patients, by practice

	Goal-setting			Control		
	Practice 1	Practice 2	Practice 3	Practice 4	Practice 5	Practice 6
Practice characteristics						
Practice rurality*	Village	Town and fringe	Town and fringe	Urban >10K	Urban >10K	Urban >10K
Patient population	5000 to 9,900	10,000 to 14,900	5000 to 9,900	>14,900	10,000 to 14,900	10,000 to 14,900
IMD practice decile	7	5	7	9	5	5
Characteristics of participating GPs	n=2 both male, partners and working part-time	n=2 one male, one female, both partners and working full-time	n=1 male, partner working part-time	n=2 One male, one female, both partners, one working full-time and one part-time	n=2 both female, partners and working part-time	n=2 both female, partners and working part-time
Years qualified of participating GPs	GP014 = >20 yrs; GP018 = 10 to 20 yrs	GP025 = <10 yrs; GP026 = 10 to 20 yrs	GP038 = 10 to 20 yrs	GP046 = >20 yrs; GP047 = >20 yrs	GP053 = >20 yrs; GP055 = >20 yrs	GP061 = 10 to 20 yrs; GP067 = 10 to 20 yrs
Practice recruitment						
Patients assessed for eligibility, n	9067	14845	6791	18540	10381	13439
Patients invited, n (% assessed)	77 (0.8)	108 (0.7)	47 (0.7)	108 (0.6)	124 (1.2)	86 (0.6)
Recruited, n (% invited)*	11 (14.3)	9 (8.3)	4 (8.5)	8 (7.4)	10 (11.6)	10 (11.6)

*ONS indicator 2011 [37], ** = based on Barnett list [2] IMD = Index of Multiple Deprivation (1= most deprived and 10 least deprived), partner = GP with responsibility for the practice, n= number, SD = standard deviation, IQR = Interquartile Range, n= number, *=does not include those on the reserve list (see Figure 1)

Table 2: Baseline characteristics of patient participants

Variable		Control	Goal-setting
Number		28	24
Female n (%)		11 (39%)	13 (54%)
Age mean (SD)		77.18 (9.42)	80.42 (8.72)
GPCOG category n (%)	Impairment and further investigations implied	1 (4%)	0 (0%)
	Informant interview required	17 (61%)	19 (79%)
	No cognitive impairment	10 (36%)	5 (21%)
Number of diagnoses* median (IQR)		4.00 (3.00, 5.00)	5.00 (3.00, 6.00)
IMD national quartile n (%)	1	5 (18%)	0 (0%)
	2	9 (32%)	14 (58%)
	3	3 (11%)	10 (42%)
	4	11 (39%)	0 (0%)
Marital status n (%)	Divorced	0 (0%)	2 (8%)
	Living with partner	0 (0%)	2 (8%)
	Married	12 (43%)	10 (42%)
	Single	2 (7%)	4 (17%)
	Widowed	14 (50%)	6 (25%)

N= number, SD = standard deviation, IQR = Interquartile Range, GPCOG = General Practitioner assessment of Cognition, PACIC = Patients Assessment Chronic Illness Care, EQ-5Q-5L = 5 level EQ-5D, ICECAP-O = ICEpop CAPability measure for Older people, * = based on Barnett list [2], IMD = Index of Multiple Deprivation

Table 3: Characteristics of initial consultations

	Intervention group				Control group				Mean difference between intervention and control (95% CI)
	Practice 1 (n = 10)	Practice 2 (n = 8)	Practice 3 (n = 4)	Intervention total (n = 22)	Practice 4 (n = 7)	Practice 5 (n = 9)	Practice 6 (n = 7)	Control total (n = 23)	
Duration of initial consultation (mins) mean (SD)	24.1 (4.0)	23.3 (4.4)	19.9 (6.2)	23.0 (4.6)	14.3 (4.8)	25.2 (5.7)	16.3 (4.1)	19.2 (6.9)	3.88 (-3.25,11.01)
Dyadic OPTION scores mean (SD)	65.3 (9.0)	63.2 (6.4)	62.5 (3.6)	64.0 (7.2)	63.5 (13.0)	62.7 (4.0)	42.1 (20.4)	56.6 (16.2)	7.57 (-6.37,21.50)
CollaboRATE scores mean (SD)	7.8 (1.0)	8.5 (0.9)	8.8 (0.2)	8.2 (1.0)	7.0 (2.6)	8.6 (0.7)	8.7 (0.6)	8.1 (1.8)	0.20 (-1.06,1.47)
GP:patient word count ratio mean (SD)	1.23 (0.40)	1.41 (0.78)	1.50 (1.05)	1.35 (0.67)	1.13 (0.45)	1.92 (0.75)	1.39 (0.52)	1.52 (0.67)	-0.14 (-0.65,0.37)

SD= standard deviation, n= number, 95%CI = 95% confidence interval

Table 4: Patient participants, goals set and attainment scores by practice

		Practice 1	Practice 2	Practice 3	Overall
Number of patients		10	8	4	22
Number of patients setting 1, 2 or 3 goals	1 goal	0	2	1	3
	2 goals	3	4	3	10
	3 goals	7	2	0	9
Number of goals set		27	16	7	50
Number of goals with data available for attainment scoring		21	15	6	42
Number of goals in each attainment score category (category score) n (%)	worse than expected (-1)	1 (4.8)	2 (13.3)	1 (16.7)	4 (9.5)
	no change (0)	4 (19.0)	0 (0.0)	2 (33.3)	6 (14.3)
	partially attained (1)	9 (42.9)	5 (33.3)	1 (16.7)	15 (35.7)
	as expected (2)	2 (9.5)	3 (20.0)	1 (16.7)	6 (14.3)
	a little more (3)	2 (9.5)	4 (26.7)	0 (0.0)	6 (14.3)
	a lot more than expected (4)	3 (14.3)	1 (6.7)	1 (16.7)	5 (11.9)
Mean goal attainment score per patient (range -1 to 4)		1.43	1.67	1.0	1.45

Table 5: Categories of goals set

Goal categories	Number of goals
Management of chronic condition (non-medication)	9
Walking-related	8
Maintain interests	5
Management of chronic condition (medication-related)	5
Gain weight	4
Social participation	3
Healthy living	3
Balance/mobility	3
Gardening-related	3
Manual dexterity	3
Mental health	2
End of life management	1
Cooking/food preparation	1
Grand Total	50

Table 6: Change in outcome measures between groups at six months

Variable	Control				Intervention				Mean difference-in-difference between goal-setting and control (95% CI)	Intraclass correlation coefficient (95% CI)
	n	Baseline, mean (SD)	Follow-up, mean (SD)	Difference, mean (SD)	n	Baseline, mean (SD)	Follow-up, mean (SD)	Difference, mean (SD)		
Number of medication	28	12.5 (8.19)	12.79 (7.25)	0.29 (2.65)	23	13.61 (4.56)	14.65 (4.44)	1.04 (3.21)	0.76 (-0.85,2.37)	0.00*
GPCOG	23	7.35 (1.70)	6.78 (2.19)	-0.57 (2.02)	19	7.58 (1.30)	7.00 (2.26)	-0.58 (2.29)	0.09 (-1.65,1.84)	0.08 (0.00,0.77)
PACIC	23	1.45 (0.30)	1.85 (0.77)	0.40 (0.69)	18	1.94 (0.76)	2.25 (0.70)	0.31 (0.98)	-0.09 (-0.60,0.42)	0.00*
EQ-5D-5L	23	0.54 (0.34)	0.52 (0.35)	-0.02 (0.19)	18	0.56 (0.25)	0.55 (0.28)	-0.01 (0.15)	0.02 (-0.11,0.13)	0.05 (0.00,0.94)
ICECAP-O	22	0.72 (0.26)	0.78 (0.20)	0.06 (0.14)	17	0.78 (0.12)	0.77 (0.13)	-0.02 (0.06)	-0.08 (-0.15,-0.00)	0.00*

SD = standard deviation, GPCOG = General Practitioner assessment of Cognition, PACIC = Patients Assessment Chronic Illness Care, EQ-5Q-5L = 5 level EQ-5D, ICECAP-O = ICEpop CAPability measure for Older people, 95%CI = 95% confidence interval

*The confidence interval was not reported in cases when the ICC is zero as the standard error is undefined in these cases

Table 7: Costs associated with health care use in

Resource use	6-months prior to recruitment						Recruitment to 6-month follow-up					
	Total contacts n	Control Total cost £	Mean cost £ (SD)	Total contacts n	Goal-setting Total cost £	Mean cost £ (SD)	Total contacts n	Control Total cost £	Mean cost £ (SD)	Total contacts n	Goal-setting Total cost £	Mean cost £ (SD)
Community based services												
GP	157	4,636	166 (164)	89	2,464	107 (115)	177	5,150	184 (150)	124	4,002	174 (145)
Other practice based	97	922	33 (42)	108	1,080	47 (30)	152	1,823	65 (58)	149	1,529	66 (53)
District Nurse	148	3,582	128 (546)	198	6,450	280 (1297)	100	2,879	103 (321)	241	7,450	324 (1384)
Other	72	1,434	51 (132)	72	2,601	113 (193)	189	7,652	273 (355)	97	5,510	240 (224)
All community based	474	10,575	378 (778)	467	12,594	548 (1520)	618	15,681	560 (719)	611	16,962	737 (1537)
Inpatient	4	11,291	403 (1113)	16	28,054	1220 (2584)	12	35,055	1252 (2203)	13	39,889	1734 (4815)
Outpatient	45	4,848	173 (208)	51	7,381	321 (397)	41	4,424	158 (202)	52	6,295	274 (329)
A&E	1	138	5 (26)	6	826	36 (74)	15	2,066	74 (109)	16	2,204	96 (128)
Total for all costs		26,853	959 (1776)		48,856	2124 (4031)		57,226	2044 (2665)		65,349	2841 (4968)

SD = standard deviation, A&E = Accident and Emergency

