# A randomised controlled trial of a self-management plan for patients with newly diagnosed angina

R J P Lewin, G Furze, J Robinson, K Griffith, S Wiseman, M Pye and R Boyle

**SUMMARY** 

Background: There are approximately 1.8 million patients with angina in the United Kingdom, many of whom report a poor quality of life, including raised levels of anxiety and depression. Aim: To evaluate the effect of a cognitive behavioural disease management programme, the Angina Plan, on psychological adjustment in patients newly diagnosed with angina pectoris.

Design of study: Randomised controlled trial.

Setting: Patients from GP practices in a Northern UK city (York) between April 1999 and May 2000.

**Method:** Recruited patients were randomised to receive the Angina Plan or to a routine, practice nurse-led secondary prevention educational session.

Results: Twenty of the 25 practices invited to join the study supplied patients' names; 142 patients attended an assessment clinic and were randomised. There were no significant differences in any baseline measures. At the six month post-treatment followup, 130 (91%) patients were reassessed. When compared with the educational session patients (using analysis of covariance adjusted for baseline scores in an intention-to-treat analysis) Angina Plan patients showed a greater reduction in anxiety (P =0.05) and depression (P = 0.01), the frequency of angina (reduced by three episodes per week, versus a reduction of 0.4 per week, P = 0.016) the use of glyceryl trinitrate (reduced by 4.19 fewer doses per week versus a reduction of 0.59 per week, P = 0.018), and physical limitations (P<0.001: Seattle Angina Questionnaire). They were also more likely to report having changed their diet (41 versus 21, P<0.001) and increased their daily walking (30 versus 2, P<0.001). There was no significant difference between the groups on the other sub-scales of the Seattle Angina Questionnaire or in any of the medical variables

**Conclusion:** The Angina Plan appears to improve the psychological, symptomatic, and functional status of patients newly diagnosed with angina.

**Keywords:** angina; self-help; disease management; randomised controlled trial.

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#### Introduction

T is known that patients with angina have a degraded quallity of life1-3 and an increased risk of anxiety and depression.4 Cardiac rehabilitation can help with these problems<sup>5-8</sup> and, in the United Kingdom (UK), the recent National Service Framework for Coronary Heart Disease has called for rehabilitation to be made available to all patients with heart disease.9 There are approximately 1.8 million people in the UK with angina, 10 of whom the great majority are treated medically in primary care.11 At present, cardiac rehabilitation is mostly provided in secondary care. It is questionable whether all patients with coronary artery disease could, would or should attend secondary care to receive their rehabilitation. It might be better if, in the main, it were delivered by those who know and see the patients most often — the staff in primary care — reserving the resources of the multidisciplinary rehabilitation team in secondary care for the more complex or treatment-resistant cases.

We have previously developed and evaluated a method of delivering post-myocardial infarction (MI) cardiac rehabilitation in the community. The Heart Manual is a home-based, self-help rehabilitation programme which the patient works through, with several brief contacts from a healthcare worker who has undergone a two-day 'facilitator' training programme. It has proved both efficacious and widely acceptable within the UK health system and has been shown to reduce anxiety and depression, visits to the general practitioner (GP), and readmissions to hospital. 12,13 lt has been recommended for use in community settings by the World Health Organization.<sup>14</sup> In the UK, more than 2000 healthcare workers have trained as 'Heart Manual Facilitators' and approximately 6000 post-MI patients a year are taking part in the programme. It is also in use in the United States of America and is the subject of ongoing randomised controlled trials in Holland and Italy (personal communication, M Ramsay 2001, the Heart Manual Project, Edinburgh Healthcare Trust, Edinburgh, Scotland EH9 2HL). The study reported here was designed to develop and evaluate a similar self-help manual for patients newly diagnosed with angina, the Angina Plan (further information about the Angina Plan is obtainable by visiting www.cardiacrehabilitation.org.uk), that could be used with the patients by a practice nurse during routine coronary heart disease secondary prevention clinics.

A hospital-based disease management programme for patients with angina can provide many benefits,<sup>7,8</sup> some of which require large numbers to demonstrate. In this, the initial study of the properties of the Angina Plan, we chose to examine its effects on anxiety and depression as previous

#### **HOW THIS FITS IN**

What do we know?

Previous work has shown that an Angina Management Programme delivered by clinical psychologists, in a hospital setting, can provide patients with significant symptomatic and quality of life benefits.

What does this paper add?

This paper demonstrates that adding a brief, low-cost, self-help angina management programme to a routine practice nurse-led CHD clinic, can also significantly reduce episodes of angina despite increasing the patients' activity levels.

experience has shown that this can be achieved with a relatively low number of participants. 12,13

## The need for early intervention

Elsewhere we have hypothesised that the reason for the commonly observed lack of association between physiological measures of disease and the extent of symptoms and disability reported by angina patients is that some patients adopt unhelpful responses, such as undue rest and withdrawing from a 'normal' life.<sup>3</sup> The cognitive-behavioural techniques used in the Angina Plan are designed to reverse the beliefs and mistaken coping efforts that we believe lead to unnecessary disability.<sup>4</sup> It may be important to change the maladaptive coping efforts before these become entrenched, therefore the Angina Plan has been designed to be used as soon after receiving the diagnosis as possible.

#### Objective

To evaluate the effect of the Angina Plan on the psychological status of patients diagnosed with angina in the preceding 12 months.

## Method

## Patients and recruitment

We asked all of the GP practices in the city of York, UK if they would identify patients for the study. Those who agreed searched their prescribing records for patients prescribed nitrates for the first time in the previous 12 months. The GP wrote to these patients asking their permission to pass their name on to the researchers. Patients who assented received a written description of the research and their case notes were searched for any mention of the following exclusion criteria: angina for more than 12 months; serious co-morbidity likely to be life-threatening; a dementing illness or mental confusion. Those who appeared to be eligible were invited to attend a specially established assessment clinic run by a GP in the cardiology department of a local district hospital. The purpose of the clinic was to confirm that they met the inclusion criteria and to undergo a symptom-limited exercise tolerance test to check that they were not in need of an urgent interventional treatment. Those meeting the criteria and giving consent completed a number of baseline questionnaire measures and were block randomised, stratifying for age and sex, to the Angina Plan or Educational session treatment. The randomisation lists were held by a secretary at a remote site, who was blinded to the patients and not otherwise involved in the study.

#### **Treatments**

Patients were informed that the purpose of the study was to establish which of two possible methods of helping them — either a self-help manual (the Angina Plan) or a nurse education session with additional booklets — would be more helpful. A practice nurse who had extensive experience of running primary care secondary prevention clinics was recruited and employed for one day a week, to deliver the treatments in a room close to the assessment clinic. She took no part in designing the research or collecting or analysing any measures.

# The Angina Plan

'The Angina Plan' consisted of a 70-page, patient-held 'work-book' and an audio-taped relaxation programme which was introduced to the patient and, when possible, his or her partner during a 30 to 40-minute structured interview. Before commencing, the nurse asked the patient to complete a questionnaire designed to establish if he or she had any of the common misconceptions about angina (for example, each episode is a 'mini-heart attack', or, 'angina is caused because your heart is worn out'). Any misconceptions revealed in this way were discussed with the patient (and, if possible, his or her partner) in an effort to correct their understanding of the illness and to explain how such beliefs can lead to undue invalidism. The nurse then worked with the patient to identify all of his or her personal risk factors for coronary heart disease in the normal manner. A method of gradually and systematically reducing these and increasing activity levels, 'goal setting and pacing' that we have developed in previous research with angina patients.8 was used to negotiate gradual return to abandoned activities or to increase the patients' capacity for that activity. The same method was used to introduce lifestyle change; for example, by adding one portion of fruit or vegetables to the patients diet each day for the following week. Most patients wished to increase their exercise capacity and chose to walk a certain distance each day. Patients were asked to practice relaxation, using the audio cassette, for 20 minutes each day. The nurse contacted the patient with a brief (five to ten minutes) phone call at the end of weeks 1, 4, 8, and 12. During these phone calls, any success with the goals the patients had set was rewarded with praise and encouragement and they were asked if they wished to extend the goal. The Plan also contained written information about the role of frightening thoughts and misconceptions in triggering adrenaline release and anxiety and how this can result in poor coping strategies (such as the 'overactivity-rest cycle'), as well as an explanation of the symptoms of hyperventilation and panic. Standard advice on risk factors, medication, and what to do in the event of a suspected heart attack were also included.

#### Educational sessions

The nurse identified the patients' risk factors for coronary heart disease from the research clinic measurements and a personal history and discussed ways in which each of them could be reduced. Patients were invited to ask questions about each risk factor and about angina or heart disease in general. They were also encouraged to discuss how it had affected their lives. Any questions they had were answered in an honest and factual manner by the nurse. If she did not know the answer at the time then she found it later and telephoned or wrote to them. Every patient was given a package of written information, designed for patients with coronary heart disease and angina and produced by authoritative sources, including the British Heart Foundation, the Chest Heart and Stroke Association, and the Family Heart Association.

#### Baseline and outcome measures

Demographic and medical data gathered included social class, <sup>15</sup> marital status, co-existing illnesses, Canadian Angina Class, <sup>16</sup> blood pressure, medication, body-mass index (BMI), cholesterol level, smoking history, diet and daily activity levels (DINE), <sup>17</sup> and a symptom-limited exercise stress test.

The principle outcome measures were anxiety and depression from the Hospital Anxiety and Depression Scale (HADS).<sup>18</sup> This measure, designed especially for medically-ill patients, has been widely used and found to be valid for use with cardiac patients.<sup>19</sup>

Additional outcome measures included an angina diary kept by the patient for one week for recording the frequency of episodes of angina and the number of short-acting glyceryl trinitrate (GTN) pills or 'puffs' of sub-lingual spray taken each day. Patients rated each episode of angina for severity using a scale from 1 to 100, with 100 being 'worst possible pain' and the duration of the episode in minutes.

A disease-specific health-related quality-of-life measure, the Seattle Angina Questionnaire, <sup>20</sup> was completed.

Baseline and follow-up measures were collected, scored, and entered into the computer by research staff blinded to group allocation. The data were analysed by a medical statistician not otherwise involved in the research.

#### Statistical analysis

An initial power calculation, based on a within-group standard deviation for HAD anxiety score of 0.97 in an earlier study of angina patients, showed that 75 patients per group would give approximately 80% power to detect a true mean difference of 0.5 units on the HAD scale. An intention-to-treat analysis — where missing final scores were replaced with the baseline value for that subject — was used throughout. Differences between groups were tested for categorical variables using  $\chi^2$ . All of the other results were tested for group differences using analysis of covariance adjusting for baseline scores.

#### Results

## Recruitment

Between April 1999 and May 2000, of the 25 GP practices

asked to take part in the study, 20 (80%) agreed to participate and conducted a search. The number of patients who: (a) were discovered in the computer search; (b) responded to the request to take part; (c) were suitable for recruitment; (d) excluded; (e) lost to the study; and (f) reaching the sixmonth endpoint, are shown in Figure 1. Of the 187 who underwent the research assessment, four (2%) were found to require further cardiological investigation and were withdrawn and eight (4%) were regarded by a consultant cardiologist as probably having been wrongly diagnosed as having angina. Of the 398 patients identified and written to by the GP, 211 did not meet the entry criteria or did not reply to our letter (Figure 1). Of the 187 assessed at the clinic, 57 did not meet the entry criteria (Figure 1), thus of 142 patients 68 were randomised to the Angina Plan and 74 to the educational session, of whom 130 (91%) completed the follow-up assessment.

#### Baseline measures

There were no significant differences at baseline between the two groups on any demographic or medical variable or in the use of cardiac drugs. The mean baseline values for the whole sample are shown in Table 1.

Of those entered into the study, 91% were available at the six-month follow-up. Mean change scores were calculated

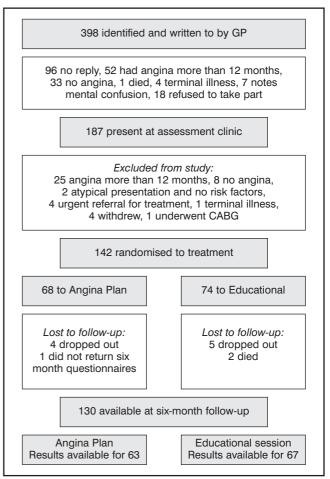


Figure 1. Recruitment flow chart.

Table 1. Demographic and medical variables at baseline. All comparisons are non-significant, P>0.05.

Demographic variables	Angina Plan patients	Educational session patients
Mean age in years on entry to the study (SD)	66.74 (9.37)	67.64 (9.01)
Number (% group) of men	39 (57)	46 (62)
Number (% group) married	51 (75)	49 (66)
Number (% group) in classes 3m, 4 and 5 [Registrar General Social Class]	25 (37)	25 (34)
Mean number of years in full-time education	10.98 (2.12)	10.95 (2)
Illness measures	,	` '
Mean number of episodes of angina a week	7.55 (10.11)	6.29 (8.87)
Canadian angina class: number (% group)	, ,	, ,
1	29 (43)	27 (36)
2	31 (46)	40 (54)
2 3	8 (12)	7 (9)
4	O	Ô Î
NYHA Cardiac Failure class: number (%) scoring >1	28 (41)	37 (50)
Number (%) with positive exercise test	27 (53)	23 (47)
Mean number of minutes (SD) on treadmill	5.09 (2.26)	5.04 (2.17)
History of acute events		
Number (%) previously referred to cardiology	30 (44)	28 (38)
Number (%) with previous myocardial infarction	16 (24)	25 (34)
Number (%) with previous angiogram	9 (13)	16 (22)
Number (%) with previous PTCA	7 (10)	5 (7)
Cardiac risk markers		
Number (%) with recorded hypertension	29 (43)	36 (49)
Mean (SD) systolic blood pressure	144 (25.92)	141 (23.53)
Number (%) with recorded diabetes	5 (7)	11 (15)
Number (%) with cholesterol >5.2 at some time	57 (84)	57 (77)
Number (%) with family history in near relative	29 (43)	42 (57)
Number (%) of current or previous smokers	49 (72)	52 (70)
Mean (SD) body-mass index	26.4 (3.77)	27.66 (4.25)

for the psychological, quality-of-life, and angina diary scores by subtracting baseline questionnaire scores from the scores at six months. Results are shown in Table 2. All differences in mean scores (whether statistically significant or not) are in the direction of greater improvement in the Angina Plan group patients.

There were no significant changes on any of the other baseline variables measured, including BMI, blood pressure, the use of medication other than nitrates, the mean duration and severity of each episode of angina, or diet or exercise as measured by the DINE questionnaire. At the follow-up clinic, patients were asked if they had changed their diet or had increased their walking since the intervention; 41 (31.5%) of the Angina Plan group reported changing their diet versus 21 (16.2%) in the Educational session group ( $\chi^2 = 13.542, P < 0.001$ ). The number reporting increasing their daily walking in the Angina Plan group were 30 (23.3%) versus 2 (1.6%) in the Educational session group ( $\chi^2 = 33.223, P < 0.001$ ).

## **Discussion**

## Limitations

The Angina Plan is designed to be used in general practice immediately following the diagnosis of angina by whoever is providing the National Service Framework coronary heart disease clinics. In most cases this will be the practice nurse. In this initial study we had to deviate somewhat from this intention; first, by including patients who had been diagnosed for up to 12 months, secondly, because they did not see their own practice nurse; and finally, because they were seen in a room 'borrowed' from the secondary care trust. In each case this was for practical reasons to do with

resources and completing the research in a reasonable time period. The average GP sees approximately four new patients with angina every year. To recruit the numbers required for the study within a reasonable time frame, we recruited from each general practice in succession all of the patients newly diagnosed in the previous year. If this extended 'window' had any effect on the outcome it is most likely that it led to an underestimate of the value of the Angina Plan rather than inflating its apparent efficacy.

The person using the Angina Plan with the patient requires a brief training in the rationale and method of the cognitive behavioural elements of the Angina Plan. Limitations of resources made it impossible to train every practice nurse in the city; also, such a requirement might have biased the recruitment of practices in a systematic manner. The more hard-pressed practices were less willing to allow their practice nurse time to be trained, especially as there was no 'evidence base' to suggest that it would benefit the patients. For the purpose of this trial one nurse from a practice in York, who was already running coronary heart disease clinics, was employed for one day a week, to treat all patients regardless of their practice of origin. Therefore, it is not clear if the Angina Plan would produce the same benefits in the hands of other nurses. On a related issue, it would have been possible to use a separate nurse to administer the Angina Plan and the educational sessions but we did not do this because 'therapist variables' have a strong effect on the efficacy of cognitive-behavioural treatments<sup>21</sup> and using two therapists would have risked biasing the results. In this study, the nurse acted as her own control for therapist variables. The fact that she delivered both treatments; one being her current practice and the other the novel treatment

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Table 2. Change scores for psychological and quality of life measures. Intention-to-treat analysis of covariance.

	Angina Plan: mean change in score (SD)	Educational session: mean change in score (SD)	Significance leve (P-value)
Hospital Anxiety and Depression (HAD) Scale			
Anxiety	-1.03 (2.61)	0.00 (3.07)	0.052
Depression	-0.48 (1.89)	0.41 (2.10)	0.013
Angina diary	, ,	• ,	
Angina attacks per week	-2.98 (5.54)	-0.41 (5.97)	0.016
Number GTN per week	-4.19 (11.48)	0.59 (9.81)	0.018
Mean pain score	-1.69 (14.78)	-3.48 (17.35)	0.56
Mean duration of event	-9.21 (34.87)	-6.78 (22.98)	0.69
Seattle Angina Questionnaire	, ,	, ,	
Physical limitation	8.42 (16.07)	-1.43 (14.24)	< 0.001
Anginal stability	8.73 (31.48)	4.17 (29.93)	0.40
Angina frequency	5.71 (23.54)	4.24 (24.06)	0.72
Treatment satisfaction	0.81 (16.82)	2.75 (13.52)	0.50
Disease perception	7.8 (14.35) <sup>´</sup>	4.29 (16.94)	0.21

(one she had not been involved in developing), provided a test of the hypothesis that the addition of the Angina Plan would improve her usual results.

Finally, it was not possible for all of the patients to be seen in one practice, therefore a clinic room was provided by the local secondary trust and this is where the nurse saw all of the patients for the intervention. It is not clear if these variations from the intended pattern of use had an effect on the outcome. Following the promising results reported here, we are currently running a trial in which the nurses in 50 practices will be trained and will use the Angina Plan in their own practice as intended.

Our follow-up point was six months, therefore our study was not capable of determining if the observed benefits continue beyond that time. However, unlike rehabilitation programmes provided in secondary care, the Angina Plan could be 'topped-up' by the practice nurse during follow-up heart disease clinics. Finally, this trial was powered to establish if the Angina Plan could improve psychological outcomes; it may have other benefits that the study did not have the power to demonstrate.

## Strength of the results

We chose a reduction in anxiety and depression as the main outcome because we had previous experience and data from a similar study with post-MI patients on which to base a power calculation. The mean reduction in anxiety and depression is slight, although for some patients it was profound. The low change in means is most probably owing to the fact that a large number of patients had little in the way of distress, masking a more significant improvement in the more distressed patients; a similar pattern has been shown in our previous work.<sup>12</sup> Unfortunately, in this trial there were insufficient numbers to allow an analysis of a subset of 'distressed' patients. We also included a disease-specific quality-of-life measure, the Seattle Angina Questionnaire and this, with the angina diary, showed a pattern of reduced angina and GTN use, accompanied by an increase in activity levels - a picture similar to that shown by our hospital-based programmes.4,8

# Psychological effects

Psychological outcomes are often treated as less important

than 'hard' measures, such as blood pressure; but, in addition to causing the patient unnecessary suffering, anxiety and depression can have a major effect on the use of health services. For example, Allison showed that anxious or depressed cardiac patients accrued four times the hospitalisation costs of non-distressed patients<sup>22</sup> and Frasure Smith showed medical costs to be 41% higher in depressed versus non-depressed cardiac patients.<sup>23</sup> Psychological factors are also powerful predictors of symptom report and of the success of medical and surgical treatment<sup>4</sup>.

## Effect on the frequency of angina

Most of the patients who received the Angina Plan also reported a reduction of three episodes of angina per week. This is a clinically worthwhile reduction of nearly 50% from the baseline mean of seven episodes per week. It could be suggested that it was merely the result of a social desirability effect, the patients trying to please the nurse. If so, then this desire did not extend to the other measures recorded on the same diary form, that of the severity and duration of each episode. Also, patients were blinded as to which was the control procedure and there was no significant difference in 'satisfaction with treatment'.

How could this reduction have been produced? BMI, blood pressure, medication use, diet or smoking did not change significantly between groups and it seems unlikely that the reduction in angina reflects a change in disease status. Increased activity levels and daily walking may have raised the Angina Plan patients' threshold for exercise-induced cardiac ischaemia. Relaxation training, a component of the Angina Plan, has been shown to be capable of reducing the report of angina, and anxiety is known to be positively related to angina frequency.<sup>4</sup>

## Effect on secondary prevention

The results of trials of secondary prevention interventions in primary care have been equivocal; some have demonstrated relatively little benefit while others have produced quite marked improvement. For example, in Belfast, Cupples *et al* demonstrated that health education delivered by health visitors improved activity levels, compliance with medication, lifestyle, and quality of life.<sup>24</sup> In Aberdeenshire, Campbell *et al* showed that an intervention by practice nurses could pro-

duce improvement in blood pressure, lipids and aspirin use, and a 28% reduction in hospital admissions.<sup>25</sup> Both interventions were mainly educational; neither demonstrated an impact on anxiety or depression.

In the study reported here, nearly twice as many Angina Plan patients said that they had changed their diet and increased their walking. However, if patients had really made these changes then they were not sufficient to be revealed by the DINE questionnaire. Nor, at six months, had they led to any improvement in BMI or other medical variables, such as blood pressure. In this study we were not comparing the Angina Plan with a 'no intervention' group, but with an educational session plus adjunctive written materials about secondary prevention, which can be successful in improving secondary prevention. Furthermore, most of the patients had (presumably) already been advised about secondary prevention and those who were going to had most likely already changed their behaviour. Therefore it is important that these results are not taken as evidence either for or against the efficacy of either the Angina Plan or the educational sessions in changing health behaviour.

#### Conclusions

There are 1.8 million angina patients in the UK, many of whom are known to have a poor quality of life, including suffering problems with anxiety and depression. These patients are increasingly being asked to attend nurse-run secondary prevention clinics in primary care. This study demonstrated that a brief, cognitive-behavioural, nurse-facilitated, self-help intervention, added to a routine secondary prevention clinic, can reduce anxiety and depression and the self-report of angina and physical disability. A larger, multi-centred trial would be required to ascertain if the treatment remains effective in wider use, if there are other quality of life benefits, if the additional lifestyle changes reported are worth-while, and if the benefits last for more than six months.

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