Can Compliance with Nonpharmacologic Treatments for Cardiovascular Disease Be Improved?

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Objective: To critically review the literature regarding the effectiveness of interventions aimed at improving cardiovascular patient compliance with nonpharmacologic treatments.

Methods: We searched Medline, Healthplan, and Psychlit from 1985 to 1996; searched the bibliographies of located studies; contacted Australian government departments and nongovernment organizations; and two experts examined the resulting study list. We selected 27 studies, which randomly allocated patients to groups and were published in English, and we evaluated interventions aimed at increasing compliance with nonpharmacologic treatments for cardiovascular disease. These trials were critically appraised against eight methodologic criteria and, subsequently, classified as of good, fair, or poor quality. Information about target groups, samples, trial intervention strategies and their effectiveness were extracted from the 18 good- and fair-quality trials. Interrater reliability was high on the 20% of references that were double-coded. The 18 studies reviewed described the effectiveness of 27 intervention strategies at improving compliance with dietary, smoking-cessation, exercise, weight-loss, stress-reduction, general lifestyle, relaxation, and blood pressure screening programs.

Results: Tentative recommendations were made for or against most trial strategies: partner-focused and structural strategies showed the most consistent benefits, physician-focused strategies were unanimously unsuccessful, and patient-focused strategies were of mixed benefit.

Conclusions: The methodologic quality of many of the located trials was less than optimal. Therefore, further good-quality, randomized trials are necessary to clarify the effectiveness of those strategies identified as potentially useful in this review.

Medical Subject Headings (MeSH): cardiovascular diseases, patient compliance, review literature (Am J Prev Med 2000;18(3):253–261) © 2000 American Journal of Preventive Medicine

Introduction

Many factors have been linked to low compliance with cardiovascular treatments, including various patient, physician, disease, treatment, setting and patient–physician relationship characteristics.[1–3] Consequently, various interventions have been developed and tested to counteract these factors and to maximize patient compliance with recommended treatments.[4–6] Although the results of these trials are somewhat varied, a consensus appears that multiple-strategy interventions are more effective than single-strategy interventions at increasing compliance, especially with long-term treatments.[3,5–9] However, little evidence indicates whether all strategies of these complex interventions are required or which, if any, are the most effective. Similarly, many of the trials conducted, and included in subsequent literature reviews, have not been randomized trials, making it difficult to draw firm conclusions from either the studies or the reviews.[4,6,10] Furthermore, most of the more rigorous reviews of this literature were conducted some time ago, leading to questions about current relevance.[1,5,11]

Therefore, this review aimed to summarize the recent literature regarding the effectiveness of individual intervention strategies, whether trialed alone or as part of complex interventions, at increasing cardiovascular patient compliance with nonpharmacologic treatments.

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Review Methodology

Data Sources

Medline, Healthplan, and Psychlit were searched, from January 1985 to March 1996, for English-language

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papers including the terms "cardiovascular or heart or hypertens*" and "interven* or study or trial*" and "patient-compliance" in Medical Subject Headings (MeSH). The resulting large number of citations (1310) was subsequently searched manually for articles investigating interventions to increase cardiovascular patient compliance with nonpharmacologic treatments or reviews of such studies. The bibliographies of all relevant papers were also searched for additional potentially relevant studies. Health-related government and nongovernment bodies were also contacted, along with any additional organizations and companies suggested, in an attempt to locate unpublished studies. Finally, a list of the studies identified was sent to an expert on compliance literature and an expert on cardiovascular literature with requests for details of potentially relevant omitted studies.

Study Selection

For inclusion in this review, a study must have:

- involved people with diagnosed cardiovascular disease, hypertension, or hypercholesterolemia;
- implemented an intervention aimed at increasing their compliance with a nonpharmacologic treatment;
- reported results on patient compliance; and
- randomly allocated patients to treatment conditions.

Data Extraction: Study Quality

The methodologic quality of located studies was assessed in relation to eight criteria, based largely on those developed by Haynes et al.:[1] selection and description of the study sample, specification of the illness or condition, type of compliance measures, description of the therapeutic regimen, definition of compliance, description of the intervention, consent rate, and loss to follow-up rate. Table 1 summarizes the basic and bonus points achievable within each of these criteria. Compliance measures were rated separately for each target behavior investigated in each study. Where multiple-compliance measures were reported for a single target behavior, the basic score was based on the compliance measure achieving the highest score. Twenty percent of papers were double-coded by independent reviewers.

Studies could achieve up to 35 points. The score obtained was divided by 35 and multiplied by 100 to give a "quality percentage," which classified each study as follows:

- *good quality*—studies with quality percentages of 66.7 or higher;
- *fair quality*—studies with quality percentages between 50 and 66.6; and
- *poor quality*—studies with quality percentages of less than 50.

Only good- and fair-quality studies progressed to the next stage of this review.

Data Extraction: Study Results

Data were extracted from good- and fair-quality studies about the patient groups targeted, samples achieved, and the nature and effectiveness of the strategies trialed. Where control groups received some intervention strategies, the effectiveness of only additional strategies received by the intervention groups was assessed. Similarly, where two or more intervention arms were involved, the effectiveness of only unique components of each arm was assessed.

Data Synthesis

Wide variations in the nature of the interventions, outcome measures, length of follow-up periods, and presentation of study results prohibited the use of meta-analyses. Therefore, results were summarized across all studies having explored each intervention strategy within each target behavior. Each summary resulted in one of five outcomes: strong recommendation for, tentative recommendation for, tentative recommendation against, strong recommendation against, or no recommendation for or against the intervention strategy.

The decision process involved in determining the appropriate recommendation for each intervention strategy is shown in Figure 1. Briefly, strong recommendations were made only where at least three studies, including at least one of good quality, had investigated the strategy; consistent evidence from numerous fair-quality studies resulted in tentative recommendations; and inconsistent evidence resulted in no recommendation for or against the strategy.

Throughout this paper, the number of references cited for any given point may be less than the number of studies being discussed, as some studies involved two or more interventions.[12–23] Due to space restrictions, the tables summarizing the studies exploring each of the target behaviors are available only on the **AJPM Online** website (http://www.elsevier.com/locate/ajpmonline) and only the final summary table of recommendations is included in this article.

Review Results

Coding Quality Assurance

Two independent reviewers assigned identical quality-classification codes for seven of the eight papers double-coded, giving a kappa of 0.82. There was also almost total agreement regarding the sample, intervention, and results information extracted from the included studies.

Table 1. The quality criteria coding schedule and the proportion of the 52 subtrials obtaining each score

Points awarded	Sample*	Definition of illness	Measure of compliance**	Description of intervention	Description of regimen	Definition of compliance	Consent rate	Loss to follow-up
Basic points	—	—	Objective, direct & longitudinal OR Immediate & direct taken 3+ times for ≥80% patients	—	—	—	—	—
4			12%					
3	Adequate demographic description AND Random population sample OR Patients from ≥ 3 clinics OR Patient from regional program/referral center	Replicable diagnostic criteria AND Inclusion and/or exclusion criteria	Immediate & direct	—	—	—	>80%	<10% OR Dropouts counted as non-compliers
	62%	62%	12%				35%	40%
2	As 3 points, but inadequate demographic description	Replicable criteria but no inclusion or exclusion criteria	Object & indirect	Replicable	Replicable	Replicable cut-point OR Continuous	70%–80%	10%–20%
	0%	29%	4%	81%	42%	87%	4%	27%
1	Adequate demographic description AND Nonrandom sample OR Patients from 1 to 2 clinics	Nonreplicable diagnoses only	Subjective	Nonreplicable	Nonreplicable	Nonreplicable cut-point	<70%	>20%
	33%	10%	71%	19%	35%	13%	8%	31%
0	As 1 point, but inadequate demographic description	None/could only be inferred	Not stated	None	None/could only be inferred	None	Not reported OR Volunteers	Not reported
	6%	0%	2%	0%	23%	0%	54%	2%
1	% patients excluded reported	Comorbidity described	(codes 2 & 3 only) Taken at random & patient unaware why	—	Cointer-vention precluded or noted	—	Reported gy group OR Randomized after consent	Reported by group
	19%	12%	25%		0%		29%	60%
1	Consecutive patients OR Random sample with ≥ 80% follow-up	—	(all codes) Follow-up ≥ 6 months	—	—	—	—	—
	73%		81%					
1	Groups' demographics compared at baseline	—	(code 1 only) Measure's validity assessed/referenced	—	—	—	—	—
	79%		35%					
1	Groups' outcomes compared at baseline	—	(all codes) Per extra measure	—	—	—	—	—
	75%		23% (1 extra) 2% (3 extra)					

* Adequate demographic description required at least age and gender information for recruited patients.

** Direct measures included appointment records (for attendance), biochemical markers, and drug metabolites. Indirect measures included pill counts. Subjective measures included patient self-report.

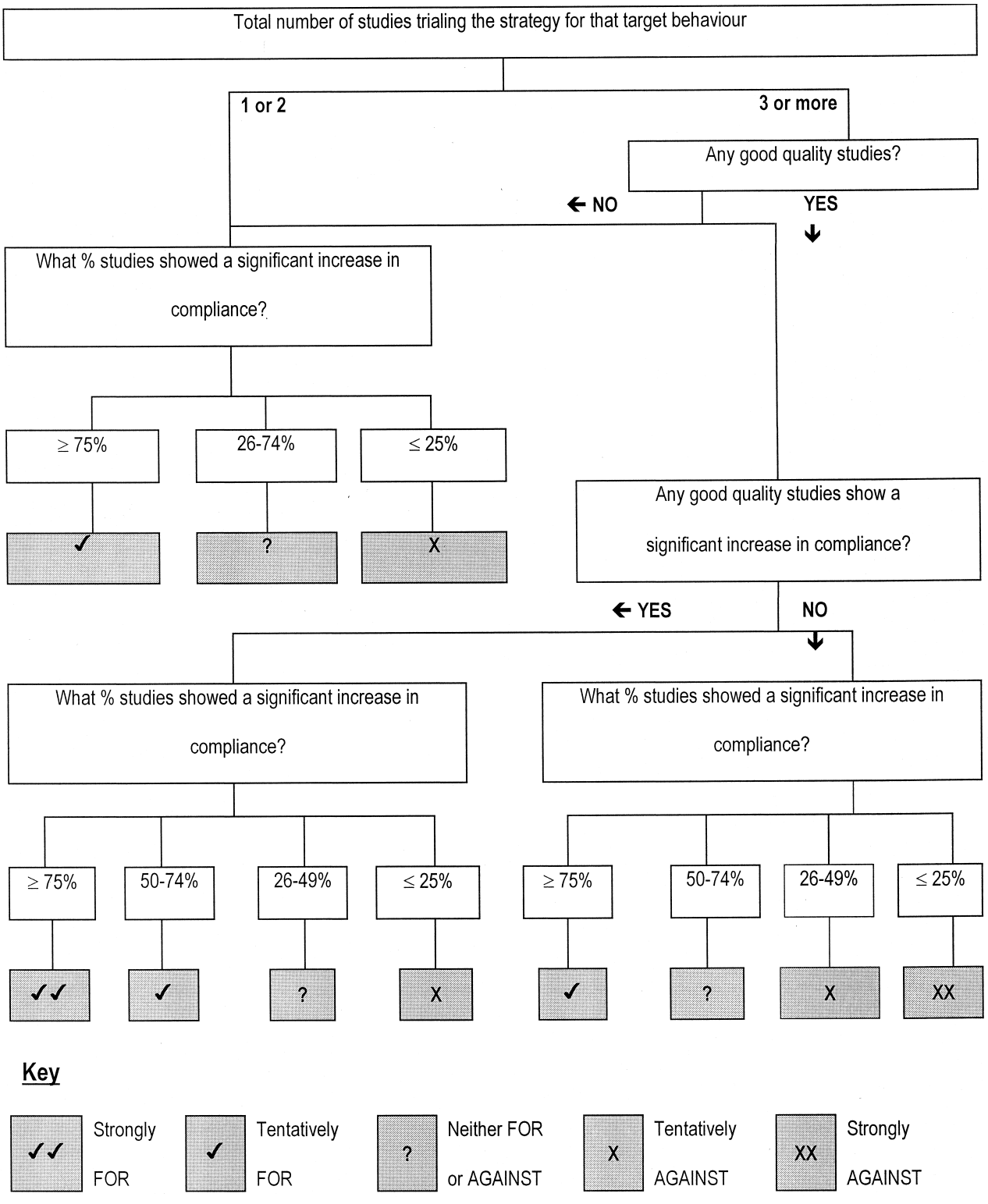

Figure 1. The decision tree used in developing recommendations based on the number, quality, and results of the studies reviewed

Study Quality and Inclusion

A total of 29 potentially relevant intervention studies were located.[12–40] Of these, five (17%) nonrandomized trials were excluded.[20,26,32,39,40] Many studies evaluated more than one outcome measure.[14,15,21,22,24,27,29,30,33,34,36,37] As compliance measures often varied within these studies, methodologic quality was assessed for each of the 52 outcomes across these 24 studies. Table 1 summarizes the proportion of these 52 subtrials scoring

in each of the points categories on each quality criteria. The best performances were seen in the definition of compliance, description of the intervention, definition of illness, and description of sample criteria. However, performance on the remaining criteria was far below optimal.

Subsequently, another 6 (21%) studies were excluded for having quality percentages less than 50%.[19,28,31,34–36] The results of the remaining 18 studies are reviewed in this paper. They explored interventions aimed at increasing rates of compliance with dietary regimes,[13–17,24,29,30,33,37] smoking-cessation regimes,[12,21–25,29,30,37] exercise regimes,[15,21,22,24,29,30,37,38] weight-loss programs,[15,21,22,33] stress-reduction programs,[24,29,30] general lifestyle programs,[14,27] relaxation programs,[18,21] and blood pressure screening.[15]

Intervention Effectiveness

Interventions targeting dietary regimes. Ten papers discussed 15 fair-quality studies exploring interventions aimed at increasing compliance with dietary regimes.[13–17,24,29,30,33,37] Two studies employed single-strategy interventions: regular educational counseling for patients[37] and self-monitoring of urine.[16] The remaining 13 studies trialed multiple-strategy interventions involving 14 different strategies: educational counseling for patients,[13,17,24,29,30,33] behavioral counseling for patients,[17,24,29,30,33] giving patients written health education materials,[15,17] training patients to self-monitor urine samples,[13] sending reminder letters to patients,[14,15] monitoring patient compliance,[17,33] giving patients feedback about monitored compliance,[17,33] encouraging spouse participation in the dietary regime,[13] giving patients diaries to self-monitor diets,[17] behavioral contracting with patients,[17] giving patients prompting devices,[14] giving physicians prompting devices,[14] sending reminder letters to physicians,[14] and sending written education materials to physicians.[14]

Table A on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Only five studies reported in three articles found significant improvements in compliance with the recommended dietary regimes.[13,24,37] These five studies tested six interventions, all included patient educational counseling: one with the addition of patient behavioral counseling,[24] 2 with the addition of spouse participation in the program,[13] and four with the addition of self-monitoring of patients' urine.[13]

Interventions targeting smoking-cessation regimes. Nine papers discussed 11 fair-quality studies[12,21–24,29,30,37] and one good-quality study[25] that explored interventions aimed at increasing compliance with smoking cessation regimes. One study employed a single-strategy intervention involving regular educational counseling for patients.[37] The remaining 11 studies trialed multiple-strategy interventions involving 16 different strategies: patient educational counseling,[12,21,22,24,25,29,30] patient behavioral counseling,[12,21,22,24,25,29,30] giving patients written health education materials,[12,22,25] telephone reminder calls to patients,[12,25] monitoring patient compliance,[21] giving patients feedback about monitored compliance,[12] encouraging patients to engage in a home exercise program,[23] encouraging patients to attend a supervised exercise program,[23] giving patients fitness assessments,[23] behavioral contracting with patients,[22] giving patients projected coronary heart disease risk assessments,[22] giving patients self-help materials,[12] giving patients audiovisual materials,[22] giving patients nicotine gum,[25] training patients to self-monitor pulse rates,[21] and training patients in relaxation techniques.[21]

Table B on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. One study found significant improvements in compliance with smoking-cessation recommendations[25] but four studies found significantly higher compliance rates among control group patients.[12,24]

Interventions targeting exercise regimes. Eight papers discussed six fair-quality studies[15,22,24,29,30,37] and three good-quality studies[21,38] that explored interventions aimed at increasing compliance with exercise regimes. One study employed a single-strategy intervention involving regular educational counseling for patients.[37] The remaining seven studies trialed multiple-strategy interventions involving 12 different strategies: patient educational counseling,[21,22,24,29,30,38] patient behavioral counseling,[21,22,24,29,30,38] giving patients written health education materials,[15,22] sending reminder letters to patients,[15,38] monitoring patient compliance,[21] giving patients feedback about monitored compliance,[21] behavioral contracting with patients,[22,38] giving patients audiovisual materials,[22] giving patients projected coronary heart disease risk assessments,[22] educational counseling for patients' spouses,[38] training patients to self-monitor pulse rates,[21] and training patients in relaxation techniques.[21]

Table C on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Six studies, including all three of good quality, found significant improvements in compliance with the recommended exercise regimes.[21,22,37,38] These six studies involved the majority of intervention strategies tested in relation to this target behavior.

Interventions targeting weight-loss regimes. Four papers discussed five fair-quality studies[15,22,33] and two good-quality studies[21] that explored interventions aimed at increasing compliance with weight-loss regimes. All

seven studies trialed multiple-strategy interventions involving 11 different strategies: patient educational counseling,[21,22,33] patient behavioral counseling,[21,22,33] giving patients written health education materials,[15,22] sending reminder letters to patients,[15] monitoring patient compliance,[21,33] giving patients feedback about monitored compliance,[21,33] behavioral contracting with patients,[22] giving patients audiovisual materials,[22] giving patients projected coronary heart disease risk assessments,[22] training patients to self-monitor pulse rates,[21] and training patients in relaxation techniques.[21]

Table D on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Three studies found significant improvements in compliance with the weight-loss regimes.[21,33]

Interventions targeting stress-management regimes. Three papers discussed results from three follow-up points for one fair-quality study exploring a multiple-strategy intervention aimed at increasing compliance with stress-management regimes.[24,29,30] This intervention combined educational and behavioral counseling for patients. Table E on the **AJPM Online** website summarizes the results from each follow-up period: no significant improvements in compliance were found at any time.

Interventions targeting general lifestyle regimes. Two papers discussed four fair-quality studies exploring interventions aimed at increasing compliance with general lifestyle regimes.[14,27] All four studies trialed multiple-strategy interventions involving ten different strategies: patient educational counseling,[27] patient behavioral counseling,[27] giving patients written health education materials,[27] giving patients audiovisual materials,[27] telephone reminder calls to patients,[27] sending reminder letters to patients,[14] giving patients prompting devices,[14] giving physicians prompting devices,[14] sending reminder letters to physicians,[14] and sending written education materials to physicians.[14]

Table F on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Only one study found a significant improvement in compliance with general lifestyle regimes.[27]

Interventions targeting relaxation-practice regimes. Two papers discussed five fair-quality studies exploring interventions aimed at increasing compliance with relaxation-practice regimes.[18,21] All five studies trialed multiple-strategy interventions involving nine different strategies: patient educational counseling,[21] patient behavioral counseling,[21] monitoring patients' compliance,[21] giving patients feedback about monitored compliance,[21] behavioral contracting with patients,[18] training patients to self-monitor pulse rates,[21] training patients in relaxation techniques,[18,21] training patients individually,[18] and training patients in group sessions.[18]

Table G on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Four studies found significant improvements in compliance with the recommended relaxation-practice regimes.[18,21]

Interventions targeting blood pressure screening. One paper discussed two fair-quality studies exploring interventions aimed at increasing compliance with blood pressure screening.[15] Both studies involved sending patients written education materials and reminder letters; in one study, this happened only once, whereas in the other study patients received six sets of these materials.

Table H on the **AJPM Online** website summarizes the effectiveness of these interventions and gives brief descriptions of each study's target population and sample characteristics. Surprisingly, the once-only intervention resulted in significant improvement in compliance with blood pressure screening but the multiple mail-out intervention did not.[15]

Review Recommendations

Twenty-seven different intervention strategies were trialed in the 18 studies reviewed. Sometimes they were trialed as single-strategy interventions, but more often they formed part of multiple-strategy interventions. For ease of discussion, the types of strategies trialed have been divided into four types: patient-focused interventions (70%), partner-focused interventions (8%), physician-focused interventions (11%), and structural interventions (11%).

Table 2 summarizes the recommendations for or against each tested intervention strategy within each of these intervention types across the eight target behaviors. Strong recommendations were made for only three intervention strategies within two target behaviors: giving audiovisual materials for smoking cessation, and compliance monitoring and feedback for weight loss. This signifies the lack of good-quality studies from which to make recommendations. The patient-focused strategies showed mixed results. Involving patients' partners in treatment programs showed some promise but physician-focused strategies were consistently unsuccessful. The structural strategies also showed promise, especially when targeting weight-loss, relaxation, and exercise regimes.

Discussion

This review aimed to critically summarize the evidence and make recommendations regarding the effectiveness of intervention strategies aimed at increasing

Table 2. Summary recommendations for and against each trialed intervention strategy by target behavior

Intervention strategies	Target Behavior: Dietary regimes		Smoking cessation		Exercise regimes		Weight-loss regimes		Stress-control regimes		General lifestyle regimes		Relaxation programs		Blood pressure screening	
	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$	Recommend	N studies $p < 0.05$
Patient-focused																
Behavioral counseling	×	1/6	?	3/10	✓	5/8	✓	3/5	×	0/3	✓	1/1	✓	2/2		
Educational counseling	?	6/11	?	3/11	✓	6/9	✓	3/5	×	0/3	✓	1/1	✓	2/2		
Sending reminding letters	×	0/4			?	1/3	×	0/2			×	0/2			?	1/2
Behavioral contracting	×	0/1	✓	1/1	✓	2/2	×	0/1					×	0/1		
Written education materials	×	0/4	✓	3/6	?	2/4	×	0/4			✓	1/1			?	1/2
Telephone reminders			?	1/2							✓	1/1				
Self-monitoring of urine	✓	4/5														
Self-monitoring of pulse rate			×	0/2	✓	2/2	✓	2/2					✓	2/2		
Giving self-monitoring diaries	×	0/1														
Giving self-help materials			×	1/4												
Giving audiovisual materials			✓✓	3/3	✓	2/2	×	0/2			✓	1/1				
Relaxation training			×	0/2	✓	2/2	✓	2/2					✓	4/5		
Individual relaxation training													✓	1/1		
Group relaxation training													?	1/2		
Giving a projected coronary heart disease risk assessment			✓	2/2	✓	2/2										
Home exercise program			×	0/1												
Supervised exercise program			×	0/1												
Giving a fitness assessment			×	0/2												
Giving prompting devices	×	0/2									×	0/2				
Partner-focused																
Spouse participation in regime	✓	2/2														
Educational counseling					✓	1/1										
Physician-focused																
Sending prompt letters	×	0/2									×	0/2				
Sending written education materials	×	0/2									×	0/2				
Sending prompting devices	×	0/2									×	0/2				
Structural																
Giving nicotine gum			✓	1/1												
Monitoring compliance	×	0/2	×	0/2	✓	2/2	✓✓	3/3					✓	2/2		
Giving feedback about monitored compliance	×	0/2	×	0/2	✓	2/2	✓✓	3/3					✓	2/2		

✓✓ = Strongly FOR; ✓ = Tentative FOR; × = Tentatively AGAINST; ? = Neither FOR nor AGAINST.

patient compliance with nonpharmacologic treatments for cardiovascular disease. Unfortunately, the ability to make strong recommendations was hampered by a number of limitations within the studies located.

Limitations of the Studies Located

First, the overall methodologic quality of the studies located was poor: more than one third were excluded because they were not randomized trials[20,26,32,39,40] or because they failed to reach the 50% methodologic quality cut-off.[19,28,31,34–36] Furthermore, only three studies attained quality percentages considered to indicate "good" quality studies.[21,25,38]

Second, the reviewed studies relied heavily on subjective outcome measures, such as patients' self-reported compliance.[12,14,15,21–24,26–32,34–37] Because, for at least 20 years, numerous studies and reviews have outlined problems with the sensitivity and specificity of self-report,[1,9,41] it is disappointing to see these measures still so widely used.

Third, the reviewed studies tended to employ small samples: more than half had less than 50 patients per experimental group, increasing the likelihood of Type II errors.[13,14,16–18,21–24,27,29,33]

Fourth, the reviewed studies tended to employ rather short follow-up periods: only half followed patients for 12 months or longer.[12,14,15,21,22,24,25,29,37] Although it is difficult to obtain funding for and conduct long-term follow-ups, their absence prohibits recommendations about an intervention's longer-term effectiveness.

The generally low quality of studies in this area was particularly disappointing because similar criticisms have been raised in previous reviews of this literature.[5,6,10]

Limitations of this Review

First, we included all studies stating random allocation of patients to experimental groups although little information was provided about the randomization processes employed. Therefore, some of the included studies may have had inadequate concealment of allocation.

Second, as with all reviews, some relevant studies may not have been located. However, the multifaceted search strategy employed should have minimized the number of such omissions.

Third, the methodologic quality scale has not been validated and arbitrary cut-points were used to classify the studies as of poor, fair, or good quality. However, given the wide variation in study quality, it was considered necessary to introduce some weighting element when interpreting the results. All criteria and cut-points were specified a priori and 20% of references were double-coded by independent reviewers to ensure objectivity and reliability in classifications.

Overview of Review Findings

Despite the above limitations, we believe this review represents one of the most rigorous conducted of the recent literature. However, only tentative recommendations could be made for or against most of the intervention strategies. Of all the strategies trialed, structural and partner-focused strategies showed the most consistently positive results. On the other hand, physician-focused strategies showed a consistent lack of improvement in compliance rates. Patient-focused strategies, which comprised the majority of those trialed, showed varying results within and among target behaviors.

Recommendations for Future Research

The major finding of this review was that, despite literature spanning more than 20 years, it remains difficult to make firm recommendations about the effectiveness of intervention strategies aimed at increasing patient compliance with nonpharmacologic treatments for cardiovascular disease. This inability is largely due to the relatively poor methodologic quality of such studies. Therefore, although this review makes some recommendations for or against the use of a number of strategies, further rigorous trials are recommended to confirm or refute these.

It is important that, wherever possible, future trials should attempt to overcome the methodologic flaws of the existing studies by:

- being randomized, controlled trials, with explicit randomization protocols; having follow-up periods of at least 6 months;
- involving no-intervention, or usual care, control groups;
- employing adequate sample sizes to detect feasible and meaningfully significant increases in compliance;
- employing direct, objective measures wherever possible; and
- if objective measures are unavailable or impractical, employing multiple-outcome measures or assessing the validity of the measures used in a subgroup of patients.

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