

# COMPLIANCE WITH CARDIOVASCULAR DISEASE PREVENTION STRATEGIES: A REVIEW OF THE RESEARCH<sup>1,2</sup>

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## ABSTRACT

*The efficacy of cardiovascular risk-reduction programs has been established. However, the extent to which risk-reduction interventions are effective may depend on adherence. Non-compliance, or non-adherence, may occur with any of the recommended or prescribed regimens and may vary across the treatment course. Compliance problems, whether occurring early or late in the treatment course, are clinically significant, as adherence is one mediator of the clinical outcome. This article, which is based on a review of the empirical literature of the past 20 years, addresses compliance across four regimens of cardiovascular risk reduction: pharmacological therapy, exercise, nutrition, and smoking cessation. The criteria for inclusion of a study in this review were: (a) focus on cardiovascular disease risk reduction; (b) report of a quantitative measure of compliance behavior; and (c) use of a randomized controlled design. Forty-six studies meeting these criteria were identified. A variety of self-report, objective, and electronic measurement methods were used across these studies. The interventions employed diverse combinations of cognitive, educational, and behavioral strategies to improve compliance in an array of settings. The strategies demonstrated to be successful in improving compliance included behavioral skill training, self-monitoring, telephone/mail contact, self-efficacy enhancement, and external cognitive aids. A series of tables summarize the intervention strategies, compliance measures, and findings, as well as the interventions demonstrated to be successful. This review reflects the progress made over two decades in compliance measurement and research and, further, advances made in the application of behavioral strategies to the promotion of cardiovascular risk reduction.*

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## INTRODUCTION AND SIGNIFICANCE OF THE PROBLEM

For nearly three decades, we have witnessed substantial reductions in morbidity and mortality associated with myocardial infarction, reductions which have occurred across gender and racial groups (1,2). These favorable findings can be attributed in part to primary and secondary prevention efforts. The preceding articles in this issue have presented the evidence for the efficacy of treatment aimed at preventing initial and recurring cardiovascular events. The purpose of this article is to address compliance (or adherence)<sup>3</sup> as it crosscuts primary and secondary approaches to cardiovascular risk reduction through the life span.

### Significance of Non-Compliance

It is known that risk-reduction programs are efficacious (3-7). However, the extent to which these programs are effective in the individual may depend on adherence. Adherence, or a lack of it, may occur with any of the recommended or prescribed regimens. In fact, non-adherence crosses treatment regimens, age and gender groups, and socioeconomic strata and, moreover, varies across the treatment course (8,9).

Much of the adherence problem occurs early in treatment. It is estimated that 50% of individuals discontinue participation in cardiac rehabilitation programs within the first year (10) and that 16-50% of hypertension patients discontinue their medication within the first year of treatment (11,12). The smoking cessation literature reports a 79% relapse rate in the first six months (13). Not only are early adherence problems likely, but these early adherence rates are predictive of longer-term adherence (14-16).

Over the long term, adherence continues to decline but generally of a less dramatic nature than that seen initially. For example, participants in the Lipid Research Clinic-Coronary Primary Prevention Trial (LRC-CPPT) made substantial improvements in lowering their fat and cholesterol intake initially. However, the participants began to reverse the improvements before the end of the first year and continued to do so in the remaining course

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<sup>3</sup> "The extent to which the patient's behavior (in terms of taking medications, following diets, or executing other life-style changes) coincides with the clinical prescription; the term we have selected to symbolize this behavior is the word: 'compliance' (151)." The previous statement by David L. Sackett constitutes the opening statement of the well-known book reporting the proceedings of the first symposium on compliance held at McMaster's University in 1974. Sackett proposed another thought in this same treatise . . . the term compliance connoted precision and rigor, terms that are highly suitable as research on this concept moved from the era of description to one of analysis and experimentation (151). The controversies surrounding the use of this term, as opposed to "adherence" will not be reiterated here. The terms "compliance" and "adherence" are used interchangeably in this paper.

of the seven-year trial (4,5). Reporting on a cardiovascular risk-reduction program, Leitha and colleagues (17) showed a 43% dropout rate at six months and an additional 43.9% dropout at twelve months, resulting in a cumulative 68% dropout rate. Since the beneficial effects of risk reduction on cardiovascular disease (CVD) are not realized immediately, long-term adherence is essential for preventive strategies to be effective.

Both early and late problems with adherence are clinically significant, as compliance is one mediator of clinical outcome. Non-compliance to prescribed medications has been associated with untoward outcomes in hypertension, coronary heart disease (CHD), heart failure, and heart transplantation. For example, increased morbidity in a study reported by Psaty and colleagues (18) revealed that individuals on beta blocker therapy for hypertension had a transient four-fold increase in relative risk of CHD when they failed to renew their prescriptions at intervals allowing for at least 80% adherence. One study reported that 64% of hospital admissions for decompensated heart failure were precipitated by medication non-compliance (19). Small deviations from immunosuppressive therapy were associated with untoward outcomes, including late rejection, among heart transplant patients (20). These reports highlight the impact non-compliance can exert on cardiovascular morbidity and its associated costs, regardless of where in the disease continuum it occurs.

In the research arena, non-compliance impacts on the evaluation of the therapy prior to its introduction into the clinical arena. Poor adherence to a treatment protocol results in an underestimation of that modality's efficacy. Due to a diminished effect being observed, study power is reduced, requiring additional subjects at increased cost (8). Furthermore, non-compliance to the experimental treatment may mask potential side effects or the true incidence of side effects or result in an overestimation of the optimal dosage for therapeutic efficacy. The trial's internal validity may be threatened by differential compliance across experimental conditions (21). The opposite may be observed in the presence of good adherence, e.g., compliance to what turned out to be a detrimental medication resulted in increased arrhythmic mortality among the active medication group and expedited the termination of two of the active drugs (22). Finally, in the course of a clinical trial, variable adherence to concomitantly prescribed medications may affect the trial outcomes (23).

The following review is organized by categories: (a) adherence rates reported in the compliance literature, (b) a report of the reviewed studies' interventions and findings, (c) the measurement methods used in the studies, and (d) the adherence rates reported by the investigators of these controlled studies utilizing these measures. These categories are applied to each behavior targeted by the interventions, such as medication-taking, exercising, eating, and smoking cessation, as well as those targeting multiple behaviors to achieve CVD risk reduction. This framework is consistent with the literature on risk reduction and will therefore be valuable to the reader in practice as well as research. Tables 1–5 present additional details on each of the reviewed studies.

## REVIEW METHOD

### Procedure for Review of Studies

The ensuing review focuses on compliance as an outcome in studies evaluating risk-factor modification. In conducting the search, the terms "patient compliance," "risk factors," "prevention," "cardiovascular disease," and "coronary heart disease" were used in varying combinations to search the electronic data base, MEDLINE. The search strategy was repeated with "chil-

dren" added as a limiting factor. Further, relevant papers were hand-searched for additional citations. Papers cited in the past 20 years were considered. The major criteria used for inclusion of a study in this review were: (a) focus on cardiovascular risk reduction; (b) report of a quantitative measure of compliance behavior; and (c) use of a randomized controlled design. The populations in the reviewed studies were those either at risk for development of CVD or those with established disease. Few of these studies addressed compliance-enhancing interventions compared to usual care but, rather, reported on compliance to the risk-reduction intervention (e.g. exercise or smoking cessation). Due to the dearth of studies in the former category, this review includes studies reporting levels of adherence to risk-reduction interventions, as well as controlled studies reporting compliance as an outcome. Despite the efforts employed in this search, it is quite possible that trials meeting the described criteria were missed. However, the 49 studies reviewed are representative of the current research in compliance and cardiovascular risk reduction.

While one cannot dismiss the clinical outcomes of these studies, it is not the purpose of this paper to focus on the clinical results. It is imperative that one distinguish between clinical outcomes and behavior change. The former is not a substitute or surrogate for compliance. Changes in biological endpoints (e.g. serum lipid levels or body weight) are indirect measures of compliance and, at best, may serve as a validation of the behavior outcome in some instances, such as in a dietary change or weight reduction program, but may also be influenced by a host of other factors (8,24).

## REVIEW FINDINGS

### Pharmacological Therapy

*Adherence Rates:* It is estimated that 20% to 80% of patients who have medications prescribed fail to adhere to the prescription to the extent that therapeutic benefits can be realized (9). Generally, among patients on chronic disease regimens, the rates are 50% to 90% (25); more specifically, antihypertensive medication compliance approximates 64% (26) and lipid-lowering agents 82% (27). Among children, the rates of compliance to lipid-lowering agents, specifically cholestyramine, are no better, e.g., 21% discontinued the medication within one month and another 60% within 22 months of treatment initiation (28). The method utilized in assessing medication compliance, as well as the point of time in which compliance is measured, influence the reported rates. In a review of hypertensive research, compliance by self-report was deemed 75% and by pill count (PC) 52% (26). Utilizing a microelectronic event monitor (EEM) in a medication bottle cap among patients with epilepsy, Cramer et al. (25) demonstrated the average compliance during the five days prior to a clinic visit was 88%, and 86% during the five days following the visit, but this declined to 67% during a five-day period one month afterward. Comparing the three assessment methods in a group taking lipid-lowering medication, Dunbar-Jacob and colleagues (29) reported rates that display a significant discrepancy, e.g., self-report based on a seven-day recall interview 97%; PC 94%; and EEM 84%. Thus, one needs to consider the method and time of measurement when evaluating medication compliance rates.

*Interventions and Findings:* Trials addressing pharmacological therapies, which appear in Table 1, stand apart from those addressing other intervention modalities, in that eleven of the twelve investigations directly targeted medication compliance (30–40). Seven of the populations were hypertensive patients

(30–32,35,37,38,41) and two of these were newly diagnosed or newly treated patients (30,41). Four studies targeted the elderly (33,34,39,40). There were generally two types of interventions: educational (i.e. teaching patients self-management skills) and providing external cognitive supports (for example, medication charts and pill organizers). These interventions occurred at varying points in the regimen course.

There is limited but promising support in the literature for intervening at the outset of treatment to establish good habits of compliance. Sherbourne and colleagues (14) reported that medication non-compliance at the beginning of treatment was the strongest predictor of medication-taking behavior two years later, while Dubanoski (15) found six-month behavior was strongly predicted by one-month behavior. Further, in the LRC-CPPT, medication compliance behavior at one month predicted compliance in the first and seventh years (42). To date no studies have been published examining the efficacy of early preventive interventions to enhance medication-taking compliance.

Two studies focused on remediating poor adherence. Saunders (30) and Nessman (37) targeted improvement of appointment-keeping as a means to increase medication compliance and blood pressure (BP) control, using appointment reminders and patient involvement in clinical management. Saunders reported a significant improvement in both appointment-keeping (87% versus 29%,  $p < 0.0001$ ) and in medication-taking compliance (68% versus 37%,  $p = 0.009$ ) in the treatment group when compared to usual care (30). Nessman also reported significant improvement in both appointment attendance and medication-taking compliance ( $p < .001$ ) among patients who were taught BP control and encouraged to participate in their management (37).

The remaining studies addressed the full range of adherence and utilized an array of intervention techniques. For example, Morisky (35) used a factorial design to sequentially introduce three educational interventions, while Webb (36) used patient education and psychosocial counseling and Logan (41) used the convenience of a nurse-managed work site clinic. More recently, reported studies based the intervention on cognitive strategies, such as mailed prescription refill reminder and unit-of-use packaging (31,38), medication reminder chart with instructions (33), and chart plus medication organizer (34). A variation of telephone follow-up was tested by Friedman and colleagues (32), which demonstrated a 17.7% improvement in medication adherence among those receiving automated telephone monitoring. Finally, the interventions employed various combinations of cognitive, educational, and behavioral strategies to improve compliance, and only two investigators (34,36) did not report a significant improvement, compared to the untreated group, in the outcome measure of compliance. In summary, these studies were carried out among adults, predominantly hypertensive patients, using combinations of cognitive, educational, and counseling strategies with the duration of intervention ranging from 10 days to 18 months. Posttreatment evaluation occurred as early as immediately postintervention (30,33,34) to five years postintervention (35).

**Measurement Methods:** A variety of measurement methods were used across these studies including self-report, pill counts, prescription refills, bar code, and electronic measures. Bar code technology, used in a study testing external cognitive supports to improve adherence among older adults, indicates time and number of pills taken (34,43). Although the bar code method requires the patient to remember to use a scanner each time the medicine is taken, its particular value is that it allows for an indication of the

number of pills taken (34). None of the studies reviewed utilized an electronic medication event monitoring system (MEMS), which provides unobtrusive monitoring of day and exact time of each medicine bottle cap opening and relies less on active involvement of the patient (44,45). Not unlike the MEMS, the bar code technology has some weaknesses, but is superior to the pill count or self-report medication recall (20,29). Another method used to assess adherence was pharmacy refill records. While this can be utilized only in instances where patients use one consistent pharmacy, this is becoming more commonplace with the growth of managed care and health maintenance organizations which track these data (18,46). The drawback of this method is that patterns of adherence cannot be detected with this method. In summary, the medication compliance measurement methods available currently are an improvement in both accuracy and versatility, and the increased number of methods allows the researcher to use multiple methods concurrently.

### Exercise Therapy

**Adherence Rates:** Estimates of adherence to rehabilitative as well as preventive exercise programs suggest a rate of 50% (10,47). Furthermore, the dropout rates are high, averaging 50%, which occur during the first six- to twelve-month interval (10). It has been suggested that adherence to exercise may be lower than that for pharmacological therapies due to the increased behavioral requirements of this preventive regimen (9).

**Interventions and Findings:** The interventions in six of the ten studies (see Table 2) consisted of supervised exercise in the context of a cardiac rehabilitation program (CRP) (48–53). Two studies evaluated adherence to independent exercise in primary prevention (54,55), two tested a home program versus the supervised program as a means to increase long-term adherence (56,57), and one utilized a combination (52). The duration of the home programs varied from 24 weeks to 5 years (53,56,57). DeBusk et al. (57) reported 89% and 84% activity compliance during weeks 3–11 post myocardial infarction (MI), which declined to 72% and 71% at 26 weeks, for the home and group exercisers, respectively. Hambrecht (52) reported higher compliance to home exercise (60% at twelve months), which was prescribed for six 10-minute periods per day, as well as a significant difference between treatment groups in weekly energy expenditure (52). The longest follow-up data were for five years, reported by Erdman et al. (56), which showed 11% for those participating in a systematic CRP and 3% for home exercise participants. These three studies demonstrate declining adherence over a prolonged period.

To improve activity adherence over the long-term, adjunctive strategies were employed. The use of self-monitoring yielded positive results when done on a frequent basis (i.e. recorded daily and returned to the staff monthly) (54). One study utilized self-management techniques and asked participants at the time of enrollment to sign an agreement to participate for six months (50). A second study used verbal persuasion with the participant and the spouse (51). Verbal persuasion, also referred to as social or oral persuasion, is a technique used to talk people into believing they are in possession of capabilities that enable them to master given tasks and achieve definite goals (58). Oldridge (50) found self-management techniques made no difference except among those who agreed to sign the contract for attending. When this subgroup was compared with the control group and those in treatment who refused to sign, there was a significant difference in attendance at six months ( $p < .01$ ), such that the attendance rate was 65% for those who signed and 20% for those who refused to sign the

TABLE 1  
Compliance to Pharmacological Therapy

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Logan AG et al. 1979 (41)	RCT	<i>N</i> = 457 employees in Metropolitan Toronto CON 225, Rx 232 SEX: 80% male RACE: 88% White AGE: 46 SITE: work site in Toronto	<b>Target of intervention:</b> improved BP control CON: appt made with S's MD, ref letter to MD Rx: Work site Care (WSC): baseline evaluation by nurse, goal BP established; seen every 2-4 wks until BP at goal Maintenance visits: 2, then 3-mos interval Duration: 6 mos	Objective: pill count  SR: interview	Duration: 12 mos Pill count on 170 of the 177 Ss on prescribed med in Rx, & all 108 CON Ss on prescribed med Compliance by pill count: CON Rx <i>P</i> value 49.1% 67.7% <.005 Med compliance was judged to be high if S claimed to be taking med as Rx & if $\geq 80\%$ of med were consumed. Ss who admitted non-compliance on direct question were classified as non-compliant. Duration: 6 months
Webb PA et al. 1980 (36)	RCT	<i>N</i> = 123 HBP patients, low SES Blacks CON 55, Rx 1: 37, Rx 2: 31, SEX: 26 M, 97 F RACE: Blacks AGE: 56 SITE: university-affiliated rural health clinic, U.S.	<b>Target of intervention:</b> evaluate relative effectiveness of additional patient education & psychosocial counseling to improve compliance Randomly assigned to one of 3 treatment groups: CON: regular MD visits Rx 1: regular MD visits + group patient education Rx 2: regular MD visits + individual psychosocial counseling Duration: 3 months	3 objective measures: 1) appointment-keeping 2) bringing in medication to appt. 3) pill count; 2 & 3 combined into score	Apppt-keeping comp <i>P</i> value CON 10.2 4.8 Rx 1 10.1 4.6 NS Rx 2 11.2 5.0 Neither intervention produced greater compliance or BP control than the control condition
Nessman DG et al. 1980 (37)	RCT	<i>N</i> = 52 previously non-compliant hypertensive patients CON 26, Rx 26 SEX: 51 M, 1 F RACE: 39 White 5 Blacks 8 Mexican-American AGE: 55 SITES: HBP clinic, U.S.	<b>Target of intervention:</b> improve compliance in previously non-compliant patients CON: nurse-operated HBP clinic (usual care) + 6-45 min audiotape sessions, HBP information over 8 wks Rx: nurse-operated HBP clinic (usual care) + additional 45 min at each audiotape session with nurse & psychologist teaching patient control of BP & participation in clinical management Duration: 8 wks	Objective: pill count  Objective: clinic attendance	Duration: 6 mos Pill count: No. of wks compliant during initial 7-wk period CON Rx <i>P</i> value 3.3 wks 4.6 wks <.001 Attendance during 6 mos f/u was significantly better for Rx group than control group ( <i>p</i> < .001, using single unpaired <i>t</i> test).
Morisky DE et al. 1983 (35)	Randomized factorial design	<i>N</i> = 400 HBP patients SEX: 120 M, 280 F RACE: 36 White 364 Blacks AGE: 54 SITES: OP clinic at medical centers, U.S.	<b>Target of intervention:</b> increase compliance with hypertensive regimen Factorial design with rand. every 6 mos to: CON: exit interview to increase understanding of & compliance with prescribed regimen Rx 1: home visit to encourage family support Rx 2: 3 one-hour group sessions to increase patients' confidence & ability to manage problems Rx were sequentially introduced, approx 6 mos apart Duration: 18 mos	Appointment-keeping compliance: No. of appts kept No. of appts scheduled  Medication compliance: Score on 4-item questionnaire	Duration: 5 years Appt-keeping all subjects: Baseline 54% 2-yr f/u 70% 5-yr f/u 86% Highest compliance in group receiving all 3 interventions (statistics not reported). Medication compliance: Baseline 40% 2-yr f/u NR 5-yr f/u: CON Rx 1 Rx 2 40% 53% 53% Statistics not reported. Correlation between variables: Med compliance: appt-keeping <i>r</i> = .14 ( <i>p</i> < .05) Med compliance BP control <i>r</i> = .22 ( <i>p</i> < .01)

TABLE 1  
Continued

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Becker LA et al. 1986 (31)	RCT	N = 180 HBP patients CON 86, Rx 85 SEX: majority female RACE: Black AGE: middle-aged SITES: university-affiliated family practice clinic, U.S.	<b>Target of intervention:</b> test the effects of special packaging of anti-HBP medication on compliance and BP control <b>CON:</b> regular drug packaging <b>Rx:</b> special packaging (all pills to be taken together included in a single blister with time & day of week labeling) Duration: 1 year	SR: interview re: compliance Objective: pill count	Duration: report on 1st 3 months % compliant (took >80% of med): CON Rx P value 50.6 53.6 NS Pre-Enroll: 3-mos f/u: SR 54.1 56.0 NS 3-mos f/u: Pill count 75.30 84.0 NS
Saunders DL et al. 1991 (30)	RCT	N = 224 (109 infrequent attendees & 115 newly treated) HBP patients (1) CON 55, Rx 54 (2) CON 59, Rx 56 SEX: 61 M, 163 F RACE: Black AGE: middle-aged SITE: urban clinic, Soweto, S. Africa	<b>Target of intervention:</b> improve compliance in (1) infrequent clinic attendance, (2) newly treated HBP patient <b>CON:</b> usual care <b>Rx:</b> appt reminder letters, & after missed appts, recall letter. If no response after 2 letters, home visit. Patient-retained BP & medication record to self-monitor compliance, updated at each visit. Duration: 6 mos.	Attendance at clinic appt Objective: pill count	Duration: 6 mos Attendance compliance: Received 80% of Treatment: CON Rx P value Newly Rx 29% 59% <.001 Infreq Attend 42% 87% <.0001 Pill count—80% Medication Compliance: CON Rx P value Newly Rx 15% 31% .09 Infreq Attend 37% 68% .009 Duration: 2 weeks
Park DC et al. 1992 (34)	RCT	N = 61 community-dwelling adults SEX: 21 M, 40 F RACE: not specified AGE: ≥60 yrs of age SITE: gerontology center, southern U.S.	<b>Target of intervention:</b> assess effects of external cognitive supports on adherence Ss assigned to one of 4 conditions: <b>Rx 1:</b> no intervention (CON) <b>Rx 2:</b> organizational chart for med schedule <b>Rx 3:</b> an over the counter med organizer <b>Rx 4:</b> both the chart & the med organizer Duration: 2 weeks	Electronic: Videx Time Ward to record med-taking using the bar-coding technology, (scan the bar-code sticker # of times equal to # of pills taken)	For comparison, Ss split into young-old (≤70 yrs. & old-old >70 yrs.) Overall mean adherence rate in study = 89% Sig effect of age for total errors, F(1,57) = 7.40, MS <sub>e</sub> = .013; for omission errors, F(1,57) = 10.82, MS <sub>e</sub> = .007. Analysis of omission errors: Sig main effect of condition, F(1,57) = 7.73, MS <sub>e</sub> = .007 condition × age interaction, F(1,57) = 5.81, MS <sub>e</sub> = .007 Duration: 360 days Medication Possession Ratio Group MPR P value 1 0.56 2 0.64 3 0.67 4 0.79 ≤.05 MPR in Rx Groups 2, 3, 4 sig diff from Rx 1 (CON) MPR in Rx 4 sig diff from Rx 2 & 3 (p = ≤.05); diff between Rx 2 & 3 NS
Skaer TL et al. 1993 (38)	RCT	N = 304 HTN patients, Medicaid beneficiaries in FL SEX: 118 M, 186 F RACE: not specified AGE: 55 yrs SITE: pharmacies, FL	<b>Target of intervention:</b> establish refill compliance in previously untreated HTN <b>Rx 1:</b> control cohort, standard pharmaceutical care with each dispensing of anti-HTN drug <b>Rx 2:</b> standard care + mailed med-refill reminder 10 days prior to sequential refill date <b>Rx 3:</b> standard care + provided unit-of-use pkg <b>Rx 4:</b> standard care + med-refill reminder + unit-of-use pkg Duration: 1 year	Objective: Medication Possession Ratio (MPR); defined at patient level as # of days supply of med obtained throughout 360-day study period	

TABLE 1  
Continued

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Raynor DK et al. 1993 (33)	RCT	N = 197 patients being discharged from gen wards in hospital taking >2 meds. SEX: 60% male RACE: not specified AGE: 69 SITE: hospital in England	<b>Target of intervention:</b> discern effects of pharmacy-based added utilities on Rx refill <b>Rx 1:</b> an individualized reminder chart listing doses <b>Rx 2:</b> brief counseling from nurse (content varied) <b>Rx 3:</b> structured counseling from pharmacist—with limited instructions about its use <b>Rx 4:</b> structured counseling from pharmacist—name, purpose, timing, doses for each medication <b>Rx 5:</b> structured counseling from pharmacist + reminder chart with detailed instructions on its use 10 days post discharge, home visit with structured interview, replace pill bottles with new supply Duration: 10 days	SR: medication recall  Objective: pill count Compliance score for each med & mean score based on pill count	Duration: 10–12 days Results pooled for Rx 1 & 3 and Rx 2 & 4 Medication recall: 83% in Rx 2 & 4 vs 47% in Rx 1 & 3 answered questions correctly ( $p < .001$ , $\chi^2$ ) Mean compliance scores for each group: Rx 1 Rx 2 Rx 3 Rx 4 P value 86% 91% 86% 95% <.001 Factorial analysis: sig effect of Rx 2, 4 86% of Rx 2 & 4 vs 63% in Rx 1 & 3 had compliance >80% ( $p = .001$ )
Esposito L 1995 (40)	RCT	N = 42 hospitalized patients >65 yrs SEX: 16 M, 27 F RACE: not specified AGE: 76 SITE: 350-bed community hospital, eastern U.S.	<b>Target of intervention:</b> determine if a defined educational intervention will increase medication compliance <b>Rx 1:</b> (usual care) medication fact sheet, discharge sheet <b>Rx 2:</b> medication fact sheet, 30 minutes verbal instruction <b>Rx 3:</b> medication schedule, list of side effects, dosage schedule <b>Rx 4:</b> medication schedule, 30 minutes verbal instruction Duration: day of discharge, 1- & 2-month follow-up <b>Target of intervention:</b> to determine whether a program of self-medication improves compliance by nurse <b>Rx:</b> 3-stage phase in of patients being totally responsible for taking their medications Duration: hospital stay + 10 days post discharge	SR: interview  Objective: pill count SR & pill count were calculated to give a mean adherence score	Duration: 2 months Mean adherence score: Group 2 wks 1 mo 2 mos #1 2.69 2.69 2.67 #2 1.91 1.85 1.90 #3 2.54 2.57 2.57 #4 1.91 1.94 1.94 P values not reported
Lowe CJ et al. 1995 (39)	RCT	N = 88 elderly hospitalized patients CON 43, Rx 45 SEX: 30 M, 58 F RACE: not specified AGE: CON 81 yrs Rx 78 yrs SITES: 2 medical wards, England	<b>Target of intervention:</b> evaluate the effect of automated telephone patient monitoring and counseling on BP medication adherence <b>Rx:</b> usual medical care + Telephone Linked Computer system (TLC)—an interactive communication system that Ss called every week and reported BP, medication regimen, adherence, and symptoms Duration: 6 months	Objective: pill count Mean compliance score = average of pill counts for all medications	Duration: 10 days post discharge Mean compliance scores: CON Rx P value 83% 95% <.02
Friedman RH et al. 1996 (32)	RCT	N = 267 hypertensive patients CON 134, Rx 133 SEX: 61 M, 206 F RACE: 238 Whites 29 Blacks AGE: 76 yrs SITES: senior citizen centers, U.S.	<b>Target of intervention:</b> evaluate the effect of automated telephone patient monitoring and counseling on BP medication adherence <b>Rx:</b> usual medical care + Telephone Linked Computer system (TLC)—an interactive communication system that Ss called every week and reported BP, medication regimen, adherence, and symptoms Duration: 6 months	SR: report of medication taking for HBP meds	Duration: 6 months Changes in medication adherence by study group (baseline—6 months) Total sample (N = 267) CON Rx (TLC) P value +17.7 +11.7 .03 <80% adherent +36.0 +26.0 .03 (n = 26) Adherent Ss +0.6 +3.0 .69 (n = 241)

RCT = Randomized Controlled Trial.  
SR = Self-Report.

agreement. Oral persuasive communication coupled with educational counseling of the participant and spouse revealed a significant difference in the resulting attendance after adjusting for baseline covariates in a linear multiple regression model (51). These analyses showed a 12% increase in attendance for the participants whose maximum education was at or below the high school level. Still, at one year, there was a 50% dropout rate. Overall, the duration of intervention and time to follow-up varied widely in these studies, which may be explained by the origin of the program. The U.S. studies were notably briefer in duration.

**Measurement Methods:** Measures of exercise compliance relied heavily on self-report, usually in the form of written exercise logs. While the commonly-used daily record or diary circumvents the bias of recall, it requires training and cooperation of the participant (9). Objective measures for exercise compliance included attendance records and the Vitalog, a microprocessor that measures and sequentially stores heart rates. This was used to monitor the proportion of time the subjects exercised within the prescribed heart rate range, which can be another indicator of adherence. The electronic monitors, while expensive and thereby unavailable on a widespread basis, provide an assessment of the temporal patterns of adherence (9).

### Nutritional Therapy

**Adherence Rates:** Because of the unique set of issues that dietary modification presents to an individual, it is thought that non-adherence with a therapeutic eating plan is higher than with other regimens (e.g. medication-taking) (59). Often therapeutic diets are only one component of a treatment plan that can become burdensome and overwhelming. These issues provide a partial explanation for why adherence with cardiovascular risk-reducing eating plans range from 13% to 76% (59). Long-term participation in weight reducing eating programs is estimated to be less than 50%, with fewer maintaining the weight loss (59).

**Interventions and Findings:** Of the eleven studies targeting eating behavior (Table 3), two tested educational interventions (60,61), which yielded significant reductions in the consumption of total calories, total and saturated fat, and dietary cholesterol among those receiving the treatment. A 24-month follow-up revealed, on the whole, a high level of sustained change in Karvetti's study (61). It is noteworthy that the size of the educational groups in these two studies were very small and there was opportunity for discussion within the group, which may explain the positive effect. Two published meta-analyses of educational papers suggest that attempts to improve compliance and health outcomes through increasing the patient's knowledge alone (i.e. providing information unaccompanied by interpersonal communication) is rarely successful (62,63).

In the second study testing an educational intervention, Mojonner's sample (60) was distinct in its representation of women (60%) and Blacks (33%). Most of the Black participants were inner city residents and the majority were women. Initially the Blacks had a lower nutrition knowledge score, but one month into the program the score differential disappeared. Slightly greater changes in fat consumption were made by the Black participants, suggesting that this specific educational approach may be particularly effective among groups who have not been previously exposed to materials focusing on low-fat diets. A higher proportion of women (59%) than men (45%) were rated "good" adherers. Other researchers have found no gender differences in dietary adherence among post coronary artery bypass graft patients (64),

but reported that women who were older and not working outside of the home demonstrated greater compliance (65).

Wing and colleagues (66) compared weight losses of Black and White participants with non-insulin-dependent diabetes mellitus (NIDDM) in a year-long behavioral intervention program. Results demonstrated significant differences between fat and caloric intake at baseline, six months, and twelve months. There was a trend for Blacks to have lower attendance rates at the weekly sessions during the latter half of the year. Similarly, the adherence data revealed a decline in self-monitoring in the second half of the year, but this was observed in both the Blacks and Whites.

The remaining studies utilized individual counseling with a dietitian (67-70) or group sessions augmented with one-on-one sessions with the dietitian (69,71). It is difficult to compare the findings across the studies since different scoring systems were used, different nutrients were reported, and a wide range in study duration was found. In general, the treatment groups showed a reduction in fat and dietary cholesterol consumption and, if prescribed, an increase in fiber (68-70). In the LRC-CPPT, both groups received dietary intervention and both reduced the median fat intake substantially during the first month (67). However, the initial reductions were reversed during the ensuing seven years but still remained below that reported at baseline.

The two studies utilizing group sessions also included spouse (71) or family participation (69). The former study reported that subjects reduced their percent fat calories from a baseline level of 35% to 24% at the close of the eight-week series of group classes (72). At the eight-week point, 58% of the participants attained their goals; however, this figure declined to 41% at the end of two years. When spouse support was examined, the highest support quartile had the largest proportion of subjects who successfully attained their goals. In summary, three studies reported later follow-up, two studies reported some diminishing effect between 12 and 24 months (61,72), while the third study reported a gradual decrease in adherence during the seven-year trial (67).

Reports in the literature describe compliance to dietary prescriptions in children and adolescents, particularly among those with insulin-dependent diabetes mellitus (IDDM) (73,74) or hyperlipidemia (75,76). Additionally, there are reports of interventions utilizing self-monitoring (77) and child problem-solving competence (78) as means to improve adherence to diet. However, few studies reported changes in eating behavior. Deviations in compliance among children with IDDM were defined as added or deleted prescribed food exchanges in one study (74). Among the reports of randomized controlled trials for eating among children, few specifically addressed adherence. In the trial targeting children at increased risk, Van Horn et al. (75) reported differences in nutrients between baseline and six months in the feasibility cohort of the Dietary Intervention Study in Children (DISC). A report of the three-year data showed these changes persisted through the study (79). A primary prevention field trial, the Children and Adolescent Trial for Cardiovascular Health (CATCH), further demonstrated positive changes in eating behavior among school-aged children (80,81). Two studies, not listed in Table 3, employed educational strategies through home-based (82) and school-based (83) intervention programs. While adherence was not addressed in these papers, the authors reported similar positive changes in risk-reduction behaviors. Collectively, these studies demonstrated that school-aged children are able to make changes in their food selection. However, long-term adherence beyond the study duration has yet to be determined among these groups.

TABLE 2  
Compliance to Exercise Therapy

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Rogers F et al. 1987 (55)	RCT	N = 113 healthy sedentary adults CON 53, Rx 54 SEX: 57 M, 56 F RACE: not specified AGE: M 48, F 47 SITES: university cardiac rehabilitation program (CRP), U.S.	<b>Target of intervention:</b> facilitate independent exercise CON: customary activity <b>Rx:</b> individually prescribed home exercise to elicit 4Kcal/kg per session; biweekly staff initiated phone contact; physical activity logs mailed to investigator for review every 2 wks Duration: 24 weeks	Vitalog—a microprocessor to measure & sequentially store values for average HR. Worn 3 consecutive days at baseline, 12, & 24 wks SR: Physical activity logs reporting duration of activity within prescribed HR range	Duration: 24 wks Vitalog. SR physical activity correspondence—99% for males, 87% for females Physical activity logs: difference between recorded training HR on days with & without Vitalog recording, NS Proportion of time spent above or below the prescribed HR: M 24%, F 16% Dropout at 3 to 6 mos: CON Rx 4 3
King AC et al. 1988 (54)	RCT (2 studies)	N = 103 healthy adults SEX: 52 M, 51 F RACE: not specified AGE: M 49, F 47 SITE: university CRP, U.S.	<b>Target of intervention:</b> facilitate independent exercise Two arms: Adoption & Maintenance—2 levels Adoption: 52 Ss (served as control for study of moderate home based exercise training) received baseline instruction; daily logs to be mailed to staff every mon. → rand to 1 of 2 conditions: (1) phone contacts every 2 wks, or (2) no phone calls. Maintenance: Rec'd instructions identical to Adoption group. Self-monitoring principal strategy for maintaining adherence. Rand to: (1) daily monitoring, sent in every month, or (2) weekly monitoring, sent in every 3 mos Duration: 24 weeks	SR: monthly exercise log	Duration: 24 weeks Adoption SR # of exercise sessions per month: Condition 1 Condition 2 P value 12.4 ± 6 9.8 ± 8 NS SR duration of exercise sessions: Condition 1 Condition 2 P value 32.4 ± 6 28 ± 10 NS Maintenance: SR # of exercise sessions per month: Condition 1 Condition 2 P value 11.4 ± 6 7.5 ± 6 <.01 SR duration of exercise sessions: not reported
Roman O et al. 1983 (49)	RCT	N = 193 MI patients CON 100, Rx 93 SEX: 174 M, 19 F RACE: not specified AGE: CON 59.1, Rx 56.2 SITE: hospital, Santiago, Chile	<b>Target of intervention:</b> risk factor reduction CON: ergometric evaluation every 1–2 yrs <b>Rx:</b> CRP—medically supervised exercise; supervised training on average 42 mos (range 6–108 mos). Med f/u in OP Clinic Duration: 9 years	Retention in exercise training sessions	Duration: 9 years Retention in exercise sessions: Drop rate (DO): CON 3.9% vs Rx 4.1% Overall attendance at training sessions: 76%, difference between groups not reported
Oldridge NB, Jones NL 1983 (50)	RCT	N = 120 coronary heart disease (CHD) patients CON 57, Rx 63 SEX: male RACE: not specified AGE: 50.5 yrs SITE: CRP, Ontario, Canada	<b>Target of intervention:</b> improve attendance compliance CON: standard treatment <b>Rx:</b> self-management techniques—signed agreement to participate for 6 mos, self-monitor exercise HR, daily activity, wt changes, smoking habits Duration: 6 mos	Attendance at exercise sessions DO's def as non-attendance at 8 consecutive sessions Compliance def as >60% attendance	Duration: 6 months Attendance rates (N = 120): CON Rx P value 42% 54% NS Attendance of DO's (n = 62): CON Rx P value 21% 16% not reported Attendance of compliers (n = 58): CON Rx P value 74% 76% not reported Attendance rate by group: CON Rx, signed contract 42% 65% Rx, refused contract 20%, p < .01



Author(s)	Study Design	Population	Intervention	Comparison	Outcomes
Oldridge NB, Jones NL 1983 (50) (con't)					
Daltroy LH 1985 (51)	RCT	N = 174 CRP patients 134 spouses CON 90, Rx 84 SEX: >86% male RACE: >92% White AGE: 54 yrs SITES: 6 CRPs, U.S.	<b>Target of intervention:</b> improve adherence to exercise session attendance CON: pamphlet only Rx: oral persuasive communication coupled with educational counseling re: expectations of program participation, oral commitment to participate, spousal support, and pamphlet Duration: 6 wks	Self-monitoring diaries physical activity log 16 Ss (52%) weight loss diary 2 Ss (6%) smoking diary 1 of 10 Ss (10%) Duration: 12 mos Attendance during 1st 3 mos: CON Rx 62.2 ± 28.17 63.8 ± 27.24 statistic t = .38, p = .70, 172 df Adjusting for baseline covariates in a LMR model, Rx 11.7% increase in attendance (t = 2.19, p = .03, 172 df; 95% CI = 1.2%-21.6%) Study site sig associated with time until DO (Lee-Desu's D = 22.9, p ≤ .001, 5 df) Median attendance time = 17.5 wks (range 13.5-31.4 wks)	62.2 ± 28.17 63.8 ± 27.24 statistic t = .38, p = .70, 172 df Adjusting for baseline covariates in a LMR model, Rx 11.7% increase in attendance (t = 2.19, p = .03, 172 df; 95% CI = 1.2%-21.6%) Study site sig associated with time until DO (Lee-Desu's D = 22.9, p ≤ .001, 5 df) Median attendance time = 17.5 wks (range 13.5-31.4 wks)
DeBusk RF et al. 1985 (57)	RCT	N = 127 MI patients CON 61, Rx 66 SEX: males RACE: not specified AGE: 52 ± 9 yrs SITES: university CRP, U.S.	<b>Target of intervention:</b> determine if at-home exercise is safe for post MI patients Exercise testing → pt & spouse counseled by MD, educ/couns by RN for 1st 4 groups Assigned to one of 6 groups: (1) exercise training at home 23 wks; or (2) for 8 wks; (3) group training for 23 wks; or (4) for 8 wks; (5) exercise testing, no training; (6) no exercise testing, no training Duration: 23 wks	Adherence at CRP sessions DO was def as missing 18 consecutive sessions, i.e., 6 wks Adherence: ratio of exercise sessions completed to those prescribed Grp 84% 71% Home 89% 72% NS NS for group diff	Adherence: 3-11 wks 11-26 wks P value Grp 84% 71% <.05 Home 89% 72% <.05 NS NS for group diff
Erdman RAM et al. 1986 (56)	RCT	N = 80 post MI patients SEX: not specified RACE: not specified AGE: 51 yrs SITES: CRP, Rotterdam	<b>Target of intervention:</b> improve psychological & physical function Rx 1: systematic rehabilitation program (Rehab) Rx 2: individual home rehabilitation (Home) Duration: 6 mos	SR: report of continued exercise SR: changes in smoking	Duration: 5 years At 6 mos 20% DO rate, leaving 32 Ss in each group Continued exercise at 5 years: Rx 1 Rx 2 P value 11% 3% <.01 Changes in smoking at 5 years: NS difference between groups Duration: 1 year
Todd I, Ballantyne D 1992 (38)	RCT	N = 40 chronic stable angina patients, no MI SEX: male RACE: not specified AGE: <60 yrs SITE: large general hospital, Glasgow	<b>Target of intervention:</b> to examine effect of exercise training on ischemic burden CON: customary activity pattern Rx: exercise training + 11 minute exercise session daily for 1 year Both had 24 ECG recording at 1 wk & 12 mos Duration: 1 year	Attendance at hospital supervised sessions SR: exercise diaries during recording periods	Attendance at exercise sessions: 1 DO in Rx group; Ss continued to attend, no statistics provided SR exercise during recording period: all Ss reported higher levels of activity, no statistics provided
Engbloom E et al. 1992 (53)	RCT	N = 171 coronary artery bypass graft (CABG) patients SEX: male RACE: not specified AGE: 54 ± 6 yrs SITES: university hospital & CRP, Finland	<b>Target of intervention:</b> evaluate the effects of physical training on exercise capacity post-op CON: reference, hospital-based treatment Rx: comprehensive rehabilitation program begun 2 days pre-op, 3-week exercise course 2 mos post-op, 2-day refresher course at 8 mos post-op Duration: 8 mos	Attendance rate SR: sustained exercise	Duration: 12 mos Attendance: pre-op course 95% 3-wk exercise course 99% 8-mos refresher course 97% Sustained exercise habits at 12 mos: Group CON Rx P value Freq of: ≥3/wk 25% 31% NS No exercise 65% 58% NS

TABLE 2  
Continued

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Hambrecht R et al. 1993 (52)	RCT	N = 62 patients with stable CAD, S/P angiogram CON 33, Rx 29 SEX: male RACE: not specified AGE: 54 yrs SITE: university hospital, Heidelberg, Germany	<b>Target of intervention:</b> define the effect of leisure activity on fitness and disease progression <b>CON:</b> 1-week metabolic ward stay, identical instructions re: necessity of regular exercise & decreasing fat intake <b>Rx:</b> 3-week stay on a metabolic ward, adjust to AHA Step II diet, exercise six 10-min periods/day Duration: 12 mos	Attendance at exercise sessions SR & exercise session records: weekly energy expenditure (based on intensity & duration of physical activity)	Duration: 12 mos Attendance at exercise sessions: mean attendance 62 ± 24% Compliance with home training: 60% Mean weekly energy expenditure in leisure activity (±SEE) in kcal/wk: CON Rx P value 1187 ± 97 1876 ± 163 <.001

RCT = Randomized Controlled Trial.  
SR = Self-Report.

**Measurement Methods:** Measurement of adherence with a prescribed diet entails two steps: (a) assessing what the subject eats; and (b) determining the degree to which the diet approximates the recommended food plan (84). Thus, the method of assessing food intake has significant implications. There are four self-report methods for assessing food intake: 24-hour recall, food records, food frequency questionnaires, and the diet history (84,85). An important consideration in examining any of the methods is that the dietary information collected reflect the long-term, usual intake of the individual (85). The 24-hour recall allows greater accuracy since recent memory may be more precise, but the drawback is that a single day's intake may not be representative of usual nutrient intake (85). The food record avoids the issue of memory for recall and attempts to achieve a more representative eating profile, but the act of recording, in itself, may affect the recorder's eating behavior. There are inherent limitations to validity with the use of the food frequency questionnaire. In particular, the cultural specificity of the food items reflect foods typically consumed by the U.S. population. While the benefits of this method include ease of administration, low cost, and more representative data, it is not recommended for use among minority populations. The food history provides an extensive profile; however, its validity may be threatened by the respondent's ability to recall and possibly fatigue from the extensive interview. Additional issues confront one when the participants are children (e.g. reading level, knowledge of food and methods of preparation, attention span, and ability and willingness to cooperate with an interview or self-monitoring assignment). To summarize, issues of concern common to all self-report measures include validity and sources of respondent error, either non-deliberate errors in recall or deliberate errors or misreporting (84,86,87).

#### Smoking Cessation

**Adherence Rates:** Earlier uncontrolled studies targeting smoking cessation reported one-year quit rates of less than 50% (88). One exception was a report of 62%, a study protocol including involvement by both physician and nurse (89). More recently, models based on relapse prevention have reported higher rates of sustained cessation, for example 69% at six months (90), and studies evaluating different levels of nicotine replacement have reported twelve-month cessation rates of 41%, 35%, and 67% for those who received 11, 22, and 44mg/d during weeks two through four, respectively (91).

**Interventions and Findings:** Three studies meeting the review inclusion criteria were identified in the literature. Two of these provided striking contrasts (92,93). Taylor and colleagues (92) tested a six-month, nurse-managed, telephone-delivered intervention among acute MI patients, a sample of predominantly White middle-aged males in four health maintenance organizations in northern California. Ockene et al. (93) tested a physician-delivered intervention of short duration, delivered in five primary care clinics within the clinic visit context by medical and family practice residents using a sample of young men and women. (Refer to Table 4 for summary.) Both utilized the unequivocal message from the patient's physician regarding the necessity of quitting, which has been shown to influence patients' quit rates (94). Further, counseling and persuasive communication were employed to convince the patient of the benefits of quitting, supplemented by asking subjects to set a quit date and offering the assistance of nicotine gum.

At the twelve-month point, Taylor et al. (92) reported a 71% cessation rate, biochemically verified in 95% of the subjects, which was significantly different from the 45% rate among usual care

patients. Even when those lost to follow-up were included as non-quiters, the difference was significant (61% versus 32%,  $p = .001$ ). Ockene (93) utilized three levels of intervention, advice only (AO), counseling (CI), and counseling plus offering cost-free nicotine gum (C + NCG). Subjects were further assigned to no follow-up or telephone contact at one, two, and three months. Using point prevalence rates, self-reporting no tobacco use in the past week, the cessation rates for AO, CI, and C+NCG were 9.1%, 11.9%, and 17.4%, respectively ( $p < .005$ ). When sustained adherence (i.e. abstinence exceeding three months) was assessed, the rates were lower [AO = 5.9%, CI = 9.2%, C + NCG = 13.2% ( $p < .002$ )]. The effect of telephone follow-up, compared to no follow-up, was not significant. The difference in cessation rates in these studies is likely related to several factors, including the populations studied and the timing of the intervention delivery. Taylor's trial focused on acute MI patients, who may be more receptive to the cessation message, particularly at the point of acute illness. Patients were enrolled while still hospitalized, in a controlled environment, and thus were not able to resume smoking. Further, the intervention was of a higher intensity and longer duration than the Ockene study, which targeted a younger and presumably healthy population with a greater representation of females. These studies demonstrated the feasibility and efficacy of smoking cessation interventions targeting two different populations, which can be implemented in different settings and by different groups of health care professionals without adding excessive costs or personnel time.

A third identified study evaluated three levels of adjuvant smoking cessation counseling among participants treated with two doses of nicotine replacement (95). Self-reported abstinence, biochemically verified, was 63% at 4 weeks when data were collapsed across the nicotine dose and counseling conditions and fell to 28% at 26 weeks. These rates are between those cited in the previous two studies. However, unlike Ockene's findings, the three levels of counseling produced by this latter study produced equivalent effects.

**Measurement Methods:** Measurement of compliance to smoking cessation is assessed primarily through self-report, but may be validated by more objective measures. One of three biochemical measures is used [for example, serum or saliva thiocyanate, cotinine, or expired air carbon monoxide (CO)] (96). Serum or plasma cotinine levels have the highest sensitivity and specificity of the three measures. Additional validation of the individual's self-report may be sought from significant others who may act as informants and provide information about the participant's smoking behavior (97). One of the reported studies (93) chose not to use a validation measure due to concern that the intrusiveness may result in a loss of subjects and thus bias the results; and further, the logistic and financial requirements could not be justified (93).

### Therapies Targeting Multiple Risk Factors

**Adherence Rates:** Generally, the more complex the prescribed regimen is in number of behaviors and frequency of performance required and the longer the duration, the more likely the adherence will decline over time (9). Thus, one might expect poorer adherence in multiple risk factor programs. However, reports of rates for adherence across multiple risk behaviors in multifactor intervention programs have been absent from the literature. A few of the reviewed studies reported on multiple behaviors (e.g. nutrient consumption, smoking cessation, and exercise adherence) but did not apply an adherence rating to each behavior. A composite score was applied by one investigator, but little

information was provided on the method used to derive the score (98). Most studies reported on behavior change or adherence for at least two risk factors.

**Interventions and Findings:** Fourteen studies targeted multiple CHD risk factors, crossing the disease spectrum from primary prevention to post MI. The studies targeted the following populations: high-risk, middle-aged males (99–101); healthy premenopausal females (102); overweight adolescents (24) and overweight adult females (103); hypertensive patients (104,105); patients with angiographically confirmed coronary artery disease (CAD) (3,98,106); post MI patients (107–109); and a Veterans Administration (VA) population with NIDDM (110). Table 5 shows the myriad of approaches employed by the investigators to reach the studies' objectives. These include contracting (104); a series of printed message/phone/self-monitoring/social support (105); face-to-face interventions delivered by specialists (for example, dietitians and behavioral scientists) (100–102); and standardized cardiac rehabilitation (107,111). Further, multicomponent behavioral programs targeted weight reduction through exercise and life-style change (24) and through a varying intensity of exercise prescription (103). Intensive life-style alteration was implemented through an initial residency program (98,106), while several investigators used the mail/phone contact approach among post MI patients (3,108–110). The results of the diverse interventions among the relatively homogenous population groups reveal both failures and successes in achieving behavioral change.

The results of the two interventions implemented among hypertensive patients were mixed. Swain and Steckel (104) reported that compared to education, contingency contracting had a significant impact on patients remaining in treatment ( $p < .0001$ ) and keeping appointments ( $p = .0004$ ). Similar to Swain and Steckel's study (104), the education intervention used by Kirscht and colleagues (105) had a negative impact. However, nurse contact and self-monitoring improved compliance to medication taking/prescription refill and weight control ( $p < .05$ ), respectively (105).

Other studies targeting multiple risk behaviors also focused on weight management. A combination of strategies were used among overweight adolescents (24), while two levels of exercise were evaluated among obese adult females (103). The children were most successful in controlling caloric intake and adhering to the exercise when they maintained complete records ( $r = .61$ ;  $p < .001$ ) and adhered best to the programmed exercise/low-caloric expenditure intervention (24). The two previous studies represent early reports of the salience of self-monitoring in weight control, which has been confirmed more recently by Baker and Kirschenbaum (112). In the study of two exercise levels among overweight women, Jakicic (103) reported exercise adherence was better when prescribed in multiple 10-minute bouts of activity compared to a 20- to 40-minute bout once daily. Interestingly, Hambrecht (52) used six 10-minute exercise periods per day among CHD patients and reported a 60% compliance rate at twelve months. Jakicic, using weekly records and the Tri-Trac accelerometer for verification, reported different findings among this sample (i.e. a decline in exercise in both groups over the 20-week period). Both of these studies targeted important subgroups needing intervention in the primary prevention of CVD.

Two major primary prevention studies, the Multiple Risk Factor Intervention Trial (MRFIT) (99,101,113) and the Women's Healthy Lifestyle Project (102), targeted multiple risk factors among high-risk middle-aged groups. Both studies used individual

TABLE 3  
Compliance to Nutritional Therapy

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Mojonnier ML et al. 1980 (60)	RCT	N = 284 adults with T cholesterol >250 CON 59, Rx 225 SEX: 114 M, 170 F RACE: 215 Whites, 69 Blacks AGE: 49 yrs SITES: 3 study centers, Metropolitan Chicago	<b>Target of intervention:</b> explore ways to modify eating behavior, develop tool to estimate adherence; Ss randomly assigned to one of 5 groups: <b>CON:</b> regular care, referred to MD for follow-up <b>Rx 1:</b> self-teaching <b>Rx 2:</b> group-teaching <b>Rx 3:</b> individual-teaching <b>Rx 4:</b> multi-method (a sequence of Rx 1-3) After completion of teaching sessions, returned for f/u at 1, 2, 4, 6, & 9 mos for blood tests, food records & recalls; food pattern reviewed Duration: 6 weeks	3-day food diary	Duration: 9 mos 3-day food diary report: Variable CON Rx P value % fat cal 36.6 ± 7.5 33.9 ± 7.5 <.01 % sat fat 12.8 ± 4.0 10.5 ± 3.7 <.001 chol 309 ± 157.5 240 ± 143.8 <.01 Diet Achievement Score: Reported to be useful tool for identifying good adherers (score 21) & fair-poor adherers (score 45); results by group or time not reported
Karvetti RL 1981 (61)	RCT	N = 194 MI patients CON 78, Rx 86 SEX: male RACE: not specified AGE: 27-64 yrs SITE: university hospital, Finland	<b>Target of intervention:</b> test a nutrition education program's effect on post MI patients' diet <b>CON:</b> usual care <b>Rx:</b> participated in CRP & nutrition education (3 1:1 & 6 group classes). Randomized <b>Rx 1:</b> lecture—lecture/discussions <b>Rx 2:</b> food-preparation group—6 demonstrations + sample meals Duration: 3 mos	Diet Achievement Score (DAS)—based on the Keys equation, the score indicates each food's potential for elevating serum cholesterol	Duration: 24 mos 24-hour recall nutrition intake at 24 mos: Variable CON Rx P value %fat 36.1 ± 7.1 32.0 ± 7.5 <.001 chol 400 ± 168 290 ± 155 NS Difference between Rx 1 & Rx 2: NS
Glueck CJ et al. 1986 (67)	RCT	N = 3,806 hypercholesterolemia males SEX: male RACE: not specified AGE: 35-59 yrs SITES: 12 centers across U.S.	<b>Target of intervention:</b> test the efficacy of cholesterol lowering to reduce CHD risk <b>CON:</b> moderate cholesterol-lowering diet + placebo; 1:1 diet instruction by RD <b>Rx:</b> moderate cholesterol-lowering diet + bile acid sequestrant cholestyramine resin Clinic visits every 2 mos for medicine packet dispensing, medication & diet counseling Duration: 7 yrs	SR: 24-hr food recall at baseline & semi-annually post randomization	Duration: 7.4 yrs 1 mon: median fat intake: CON RX  27%  28% Gradual ↓ over 7 yrs, but remained substantially < baseline; same pattern in dietary chol; statistics not reported No CON group for diet
McCann BS et al. 1988 (71); 1990 (130)	RCT	N = 531 adult males with elevated LDL-C singly or with elevated triglycerides, not taking lipid lowering drugs, & had a spouse or resident partner to participate SEX: male RACE: 94% White AGE: 48 SITE: industrial work site, U.S.	<b>Target of intervention:</b> determine what is a desirable & achievable reduction in dietary fat to lower serum cholesterol Randomized to one of 4 diet conditions: <b>Rx 1:</b> 30% fat content eating plan <b>Rx 2:</b> 26% fat content eating plan <b>Rx 3:</b> 22% fat content eating plan <b>Rx 4:</b> 18% fat content eating plan Same behavioral management for each group + 8 weekly group & 5 1:1 sessions with RD; participation of spouse/partner required Duration: 60 weeks	SR: 4-day food records Subjective: adherence rating by S, spouse/partner & RD	Duration: 26 mos SR: adherence by 4-day food record not reported Subjective adherence: Preliminary results show adherence was related to change in self-efficacy; self-efficacy was a strong predictor of LDL reduction at 3 mos ( $p = .005$ ) and 6-mos ( $p = .002$ ) f/u visits

Singh RB et al. 1992 (68)	RCT	<p><b>Target of intervention:</b> test the efficacy of adding high fiber &amp; carbohydrate (CHO) as adjunct to prudent diet in reducing serum lipid levels</p> <p>AHA Step I diet for 4 weeks (stabilization period)</p> <p>CON: continue on AHA Step I diet</p> <p>Rx: advised to consume <math>\geq 400</math> g/day of fruits, vegetables, &amp; "plenty of legumes &amp; cereals" in conjunction with prudent diet, used a food to eat approach</p> <p>Duration: 16 weeks</p> <p><b>Target of intervention:</b> test if a diet rich in soluble fiber, antioxidant vitamins &amp; minerals reduces post-MI complications &amp; mortality</p> <p>CON: AHA prudent diet + usual care</p> <p>Rx: diet as described above + advice from RD &amp; regular reinforcement re: risk factor modification</p> <p>Duration: 12 weeks</p>	<p>SR: 24-hour Food Recall</p> <p>Questionnaire to assess effect of dietary advice</p>	<p>Duration: 16 weeks</p> <p>24-hr food recall:</p> <p>Fruit &amp; veg consumption (g/day):</p> <table border="1"> <tr><td>CON</td><td>Rx</td></tr> <tr><td>278.5 <math>\pm</math> 65.6</td><td>592.0 <math>\pm</math> 112.5</td></tr> </table> <p>p value &lt; .01 by Student's t test.</p> <p>Total adherence score:</p> <table border="1"> <tr><td>CON</td><td>Rx</td></tr> <tr><td>71.0 <math>\pm</math> 40</td><td>111.0 <math>\pm</math> 60</td></tr> </table> <p>p &lt; .01 by Student's t test</p>	CON	Rx	278.5 $\pm$ 65.6	592.0 $\pm$ 112.5	CON	Rx	71.0 $\pm$ 40	111.0 $\pm$ 60										
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71.0 $\pm$ 40	111.0 $\pm$ 60																					
Singh RB et al. 1992 (70)	RCT	<p>N = 406 acute MI patients</p> <p>CON 204, Rx 202</p> <p>SEX: 365 M, 41 F</p> <p>RACE: not specified</p> <p>AGE: 50.5 yrs</p> <p>SITES: research center, Moradabad, India</p>	<p>SR: dietary diaries</p>	<p>Duration: 16 weeks</p> <p>SR dietary diaries at 1 year:</p> <p>Fruit &amp; veg consumption (g/day):</p> <table border="1"> <tr><td>CON</td><td>Rx</td></tr> <tr><td>186 <math>\pm</math> 25.4</td><td>575 <math>\pm</math> 91.4</td></tr> </table> <p>p &lt; .001 by Student's t test</p> <p>Saturated fat consumption (%):</p> <table border="1"> <tr><td>CON</td><td>Rx</td></tr> <tr><td>10.8 <math>\pm</math> 0.36</td><td>7.2 <math>\pm</math> 0.24</td></tr> </table> <p>p &lt; .001 by Student's t test</p> <p>Total adherence score:</p> <table border="1"> <tr><td>CON</td><td>Rx</td></tr> <tr><td>71.0 <math>\pm</math> 20.0</td><td>123.0 <math>\pm</math> 30.0</td></tr> </table> <p>p &lt; .001 by Student's t test</p>	CON	Rx	186 $\pm$ 25.4	575 $\pm$ 91.4	CON	Rx	10.8 $\pm$ 0.36	7.2 $\pm$ 0.24	CON	Rx	71.0 $\pm$ 20.0	123.0 $\pm$ 30.0						
CON	Rx																					
186 $\pm$ 25.4	575 $\pm$ 91.4																					
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Barnard ND et al. 1992 (69)	RCT	<p>N = 47 CAD patients</p> <p>CON 20, Rx 27</p> <p>SEX: 42 M, 5 F</p> <p>RACE: not specified</p> <p>AGE: 58</p> <p>SITE: 1 medical center, 1 university hospital in the U.S.</p>	<p>SR: 3-day dietary history</p>	<p>Duration: 8 mos-3.5 yrs</p> <p>3-day dietary diary at 12 mos:</p> <table border="1"> <tr><td>VAR</td><td>CON</td><td>Rx</td><td>P value</td></tr> <tr><td>Fat g/d:</td><td>53.6 <math>\pm</math> 21.7</td><td>14.0 <math>\pm</math> 8.2</td><td>&lt;.0001</td></tr> <tr><td>% fat:</td><td>29.4 <math>\pm</math> 8.4</td><td>7.0 <math>\pm</math> 3.5</td><td>&lt;.0001</td></tr> </table> <p>Total calories: NS difference</p>	VAR	CON	Rx	P value	Fat g/d:	53.6 $\pm$ 21.7	14.0 $\pm$ 8.2	<.0001	% fat:	29.4 $\pm$ 8.4	7.0 $\pm$ 3.5	<.0001						
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Van Horn LV et al. 1993 (75)	RCT	<p>N = 140 children with moderately elevated plasma LDL C (in feasibility cohort)</p> <p>CON 73, Rx 67</p> <p>SEX: 73 M, 67 F</p> <p>RACE: not specified</p> <p>AGE: 8-10 yr</p> <p>SITES: 6 clinical centers, U.S.</p>	<p>SR: 3-24-hour dietary recalls</p>	<p>Duration: 6 month report</p> <p>Mean difference between baseline-6 mos</p> <table border="1"> <tr><td>VAR</td><td>CON</td><td>Rx</td><td>P value</td></tr> <tr><td>kcal/d</td><td>80.0 <math>\pm</math> 583</td><td>63.1 <math>\pm</math> 620</td><td>NS</td></tr> <tr><td>fat (g)</td><td>1.7 <math>\pm</math> 33</td><td>-11.8 <math>\pm</math> 32</td><td>&lt;.05</td></tr> <tr><td>sat fat (g)</td><td>1.2 <math>\pm</math> 13</td><td>-6.0 <math>\pm</math> 13</td><td>&lt;.01</td></tr> </table>	VAR	CON	Rx	P value	kcal/d	80.0 $\pm$ 583	63.1 $\pm$ 620	NS	fat (g)	1.7 $\pm$ 33	-11.8 $\pm$ 32	<.05	sat fat (g)	1.2 $\pm$ 13	-6.0 $\pm$ 13	<.01		
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The Writing Group for the DISC Collaborative Research Group (DISC) 1995 (79)	RCT	<p>N = 663 prepubescent boys &amp; girls with LDL-C <math>\geq 80</math>th percentile for age &amp; sex</p> <p>CON 329, Rx 334</p> <p>SEX: 362 M, 301 F</p> <p>RACE: not specified</p> <p>AGE: 8-10 yrs</p> <p>SITE: 6 clinical centers, U.S.</p>	<p>SR: 24-hour dietary recalls within 2 weeks of clinic visits</p>	<p>Duration: 3 years</p> <p>Adjusted difference Rx-CON group at 3 yrs</p> <table border="1"> <tr><td>VAR</td><td>Difference (95% CI)</td><td>P value</td></tr> <tr><td>kcal/d</td><td>-619 (-923 to -314)</td><td>&lt;.001</td></tr> <tr><td>sat fat</td><td>-2.1 (-2.5 to -1.7)</td><td>&lt;.001</td></tr> <tr><td>mono fat</td><td>-1.6 (-1.9 to -1.2)</td><td>&lt;.001</td></tr> <tr><td>Polyfat</td><td>-0.3 (-0.6 to -0.04)</td><td>&lt;.03</td></tr> <tr><td>chol</td><td>-18.1 (-25.7 to -10.4)</td><td>&lt;.001</td></tr> </table>	VAR	Difference (95% CI)	P value	kcal/d	-619 (-923 to -314)	<.001	sat fat	-2.1 (-2.5 to -1.7)	<.001	mono fat	-1.6 (-1.9 to -1.2)	<.001	Polyfat	-0.3 (-0.6 to -0.04)	<.03	chol	-18.1 (-25.7 to -10.4)	<.001
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TABLE 3  
Continued

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Wing RR, Anglen K 1996 (66)	RCT	<i>N</i> = 93 overweight individuals with NIDDM (completers) <i>N</i> = 75 (81% of total) SEX: 24 M, 51 F RACE: 59 W, 16 B AGE: W 52.4, B 49.4 SITE: university affiliated clinic, U.S.	<b>Target of intervention:</b> to compare weight losses of Black & White patients with NIDDM Year-long behavioral weight loss program included weekly sessions of lecture/discussion, review of self-monitoring record of exercise & weight, plus: <b>Rx 1:</b> low caloric diet (LCD) (1,000–1,200 kcal/day) <b>Rx 2:</b> 2–12-week periods of very low calorie diet (VLCD) (500 kcal/day to 1,000–1,200 kcal/day) Duration: 1 year	SR: 3-day food diaries at baseline, 6 & 12 mos	Duration: 12 mos Baseline Kcal/day: W 2200 ± 943 B 1735 ± 729 Fat (g): W 100 ± 52* B 74 ± 44* Fat (% cal): W .40 ± .07* B .38 ± .09* * difference between B & W were significant at baseline ( <i>p</i> < .05), 6 & 12 mos. Values are adjusted for baseline levels: Activity (kcal expended/week) Prestudy W 810 ± 930 B 1644 ± 1178 B 909 ± 791 1666 ± 2441 Number of sessions attended: 1st 6 mos 11.7 2nd 6 mos 8.8 1 year 1364 ± 370 1260 ± 381 NS <.05 <.05
Luepker RV et al. 1996 (80) Lytle LA et al. 1996 (81)	RC Field Trial	<i>N</i> = 5,106 initially 3rd grade students CON 40 schools Rx 56 schools (28 school level Rx, 28 school + family) AGE: 8.76 yrs entry SITE: 4 states (CA, LA, MN, TX) 24-Hr Recall Sample: Baseline <i>n</i> = 1,874 SEX: 50% M RACE: 69% W, 12% B, 15% Hisp F/U <i>n</i> = 1,182 (63%) CON 473 Rx 709 SEX: 52% F RACE: 71% W, 10% B, 15% Hisp	<b>Target of intervention:</b> assess outcome of health behavior intervention focusing on elementary school environmental classroom curricula, home program for primary prevention of CVD <b>CON:</b> usual health curricula, physical education, & food service program <b>Rx 1:</b> school based food service: 30% fat, 10% sat fat, 600–1000 mg sodium meal plan; physical education: moderate to strenuous physical activity 40% of physical ed class; classroom curricula 5, 12, & 8 weeks of bi-weekly classes in 3rd, 4th, & 5th grades, respectively <b>Rx 2:</b> school + family education—home activities requiring adult participation Duration: 3 years	Paffenberger Activity Questionnaire  Attendance at weekly sessions	Interaction of race × time [F(1,89) = 3.14, <i>p</i> = .08] Duration: 3 years 24-hour recall data Change Mean (±SE) CON Rx <i>P</i> value % fat: -0.4 ± 0.5 -2.4 ± .4 <.005 % sat fat -0.3 ± 0.2 -1.2 ± .2 <.005 chol (mg) 7 ± 10 -16 ± 9 <.10 Response similar across gender & ethnic groups No sig difference in dietary intake between Rx 1 & Rx 2 groups

RCT = Randomized Controlled Trial.

SR = Self-Report.

**TABLE 4**  
**Compliance to Smoking Cessation Therapy**

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Taylor CB et al. 1990 (90)	RCT	N = 173 CON 87, Rx 86 SEX: 148 M, 25 F RACE: 80% White AGE: 53 SITES: 4 HMO hospitals, U.S.	<b>Target of intervention:</b> to determine the effect of a nurse-managed intervention for smoking cessation  <b>CON:</b> usual care <b>Rx:</b> initiated in hospital, provided manual emphasizing how to identify & cope with hi-risk situations; baseline assessment of self-efficacy; supplemental audio tapes, printed materials. Post discharge nurse initiated phone contact once/wk x's 2-3 wks, then monthly x's 4. Nurse met with Ss having difficulty; gum Rx if needed. Duration: 6 mos	SR: smoking cessation rates  SR confirmed with biochemical verification	Duration: 12 mos 130 (75%) completed study & f/u, (45 CON, 72 Rx) Of 130, 123 smoking status confirmed biochemically, 7 by a sig other  Smoking cessation rate at 12 mos: CON Rx P value Statistic 45% 71% .003 $\chi^2$ Using total sample, assuming all survivors lost to f/u are smokers, cessation rate: CON Rx P value Statistic 32% 61% .001 $\chi^2$
Ockene JK et al. 1991 (93)	RCT	N = 1,286 Rx 1: 464, Rx 2: 420, Rx 3: 402 SEX: 554 M, 732 F RACE: 91.5% W AGE: 35 yrs SITES: university internal med & family practice residency program, U.S.	<b>Target of intervention:</b> to assess relative impact of 3 MD-delivered smoking interventions + f/u Ss randomly assigned to one of 3 treatment groups: <b>Rx 1:</b> Advise Only (AO)—general advice + personalized message <b>Rx 2:</b> Counseling (CJ)—advice + supportive counseling, written agreement to specify plan, self-help booklet, f/u letter from MD within 1 wk <b>Rx 3:</b> Counseling + Nicotine-containing Gum (C + NCG) info re: gum availability, if willing to set quit date & if interested, given Rx, educate re: use 2  Follow-up conditions: Maximal—phone call at 1, 2, 3 mos, f/u counseling, Minimal—no f/u except at time of monitoring Duration: 1 week to 3 mos	Compliance measured with physicians' delivery of intervention, assessed by exit interview of randomly selected Ss & parallel interview of physician  SR: smoking cessation rates (point prevalence quit rates for 1 week & 6 mos)	Duration: 6 mos Agreement between 249 Ss and parallel physician: 99% agreement topic was discussed, 91% advice given, 85% quit date set, 88% written material provided, & 90% agreed NCG Rx offered or written 1-wk point prevalence SR quit rates differed among 6 treatment groups: AO CI C + NCG P value 9.1% 11.9% 17.4% <.005 Quit rate Minimal vs Maximal: NS difference Abstinence >3 mos, reported at 6 mos: AO CI C + NCG P value 5.9% 9.2% 13.2% <.002 Those with more intensive Rx quit sooner (15.4% C + NCG Ss quit within 1 day of MD contact)
Jorenby DE et al. 1995 (95)	RCT	N = 504 cigarette smokers 22 mg nicotine patch group: n = 252 SEX: 122 M, 130 F RACE: 246 W, 6 B AGE: 44.6 yrs 44 mg nicotine patch group: n = 252 SEX: 112 M, 140 F RACE: 248 W, 4 B AGE: 43.9 yrs	<b>Target of intervention:</b> to compare efficacy and safety of 2 doses of transdermal nicotine therapy when paired with 3 levels of counseling 22 mg vs 44 mg transdermal nicotine therapy for 4 wks, followed by 2 wks of 22 mg & 2 wks of 11 mg, augmented by 3 levels of counseling: <b>Rx 1:</b> self-help pamphlet <b>Rx 2:</b> self-help pamphlet, brief motivational message, & 3 brief f/u visits with a nurse <b>Rx 3:</b> pamphlet, motivational message, & 8 weekly 1-hr group counseling visit Duration: 8 weeks	SR: 8-item questionnaire weekly times 8 wks SR: confirmed by expired CO concentration (<10 ppm)  Abstinence = no smoking previous 7 days	Duration: 26 weeks 4-week abstinence rates: 22 mg nicotine 60% 44 mg nicotine 67% p < .05 Overall abstinence rates by counseling group: minimal 56% individual 66% group 68% p < .05 Overall abstinence rate at 6 mos: 28%

RCT = Randomized Controlled Trial.  
SR = Self-Report.

TABLE 5  
Compliance to Therapies Targeting Multiple Risk Factors

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
Swain MA, Sieckel SB 1981 (104)	3 × 4 repeated measures	N = 115 HBP patients SEX: not specified RACE: not specified AGE: >18 yrs SITES: med center & VA hospital, U.S.	Target of intervention: retention in treatment CON: routine clinic care Rx 1: education Rx 2: contingency contracting Duration: 18 mos	(1) remaining in treatment  (2) appointment-keeping	Follow-up at 18 mos: Lost from treatment: CON Rx 1 Rx 2 P value 7.9% 35.9% 0.0% <.0001 Max L(2) = 25.9 Missed appointments: CON Rx 1 Rx 2 P value 5 11 0 .0004 F(2,49) = 9.24 Duration: 1.5 years Sig effects of the 4 interventions: Rx 1: Message Variable CON Rx P value SR diet .837 .721 ≤.05 Rx 2: Nurse phone contact Variable CON Rx P value Pharmacy .690 .749 ≤.05 SR med .908 .957 ≤.05 Rx 3: Self-monitoring Variable CON Rx P value Wt control .469 .539 ≤.05 Rx 4: Social support All 4 variables: NS
Kirsch JP et al. 1981 (105)	Factorial design with random assign	N = 432 HTN patients SEX: not specified RACE: majority White AGE: majority >50 SITES: community private practice, U.S.	Target of intervention: increase adherence levels Sequential factorial design of 4 interventions, Ss randomly assigned at each time: Rx 1: printed message—a) threatening; b) positive; c) control Rx 2: nurse reminder & reinforcement—a) letter & phone call, or b) control; Rx 3: self-monitoring—a) 2 wk set of daily charts on regimen behaviors, b) take daily BP; c) control Rx 4: social support—a) Rx—nurse visit each S & a selected support person; b) control Duration: 1.5 years	Objective: pharmacy score SR: medication SR: diet  SR: weight control	Duration: 6-7 years SR: cessation at 72 mos CON Rx 28.8% 48.9% Using SR smoking rates & SCN ≥100 µmol/liter Cessation rate: CON Rx 23.6% 36.4% Food Record Rating Score Rating of adherence by category & mean total chole change for Rx at final visit: FRR ≤3 4-9 ≥10 P value n 323 1,576 2,855 Δ 10.5 +7.5 -6.1 <.01 F tests for equality & linear trend of adherence category Subjective rating showed same pattern & trend as FRR/lipid change At 72 mos, 70.7% of Rx group at or below BP goal
Hughes GH et al. 1981 (99) Ockene JK 1991 (100) Caggiula AW et al. 1981 (101) Dolock TA et al. 1986 (114) Grimm RH et al. 1985 (113)	RCT	N = 12,866 CON 6,438, Rx 6,428 SEX: male RACE: 92.8% White AGE: 46.2 yrs SITES: 22 centers across the U.S. Smokers at baseline: CON 4,091, Rx 4,103 HBP at baseline: CON 3,922, Rx 4,018	Target of intervention: test the effect of a multifactor intervention on CHD mortality CON: referred to own physicians Rx: "special intervention" aimed at cessation of cigarette smoking, serum cholesterol & BP reduction (a) 10-wk group intervention (b) maintenance (c) secondary or extender Rx for risk reduction Rx 1: smoking cessation—individual & group sessions feedback, self-management, behavioral skill training Rx 2: cholesterol reduction—2 fat-modified food patterns: dietitian (RD) lead group sessions × 10 weeks, thereafter, 1:1; RD's assessed dietary adherence at 4 & 8-mo intervals between annual visits Rx 3: BP reduction—stepped care protocol, dietary advice (wt. reduction, dietary sodium restriction) Duration: 10 wks, maintenance 6 years	SR: smoking rates Objective: expired CO, thiocyanate (SCN)  SR: 3-day food record used for Semi-objective method [Food Record Rating (FRR)] of evaluating 3 food records; designated # of points assigned to foods Score of <3 = adequate adherence to progressive eating plan, 4-9 = adherence to basic MRFT, score ≥10 = need for additional change Subjective: RD checklist of Ss lifestyle, current adherence	Duration of intervention: 6 mos SR: cessation at 72 mos CON Rx 28.8% 48.9% Using SR smoking rates & SCN ≥100 µmol/liter Cessation rate: CON Rx 23.6% 36.4% Food Record Rating Score Rating of adherence by category & mean total chole change for Rx at final visit: FRR ≤3 4-9 ≥10 P value n 323 1,576 2,855 Δ 10.5 +7.5 -6.1 <.01 F tests for equality & linear trend of adherence category Subjective rating showed same pattern & trend as FRR/lipid change At 72 mos, 70.7% of Rx group at or below BP goal
Sivarajan ES et al. 1993 (107)	RCT	N = 258 post MI patients SEX: 219 M, 39 F RACE: White AGE: ≤70 yrs SITES: 7 university & community hospitals in the U.S.	Target of intervention: risk factor reduction CON: usual care Rx 1: exercise, group B1—usual care + low level exercise in-hospital & 12 wks post at weekly clinic visit Rx 2: exercise, teaching-counseling, group B2—same as group B1, plus eight 1-hour group classes Duration: 14 wks	Attendance exercise sessions SR: cigarette smoking  SR: food intake	Duration of intervention: 6 mos Attendance for 8 classes: range 64%—76% Cigarette smoking: NS difference among 3 groups at 3 & 6 mos Food intake: NS difference among groups from baseline to 6 mos, median change scores were in right direction



Epstein LH et al. 1984 (24)	RCTs	<p><i>N</i> = 46, 49, 42, 42 children                      SEX: not specified                      RACE: not specified                      AGE: 8-12 yrs                      SITES: university childhood obesity research program, U.S.</p>	<p><b>Target of intervention:</b> behavioral control of eating &amp; exercise  <b>Study 1:</b> diet + lifestyle, exercise; diet, programmed exercise; lifestyle, exercise; programmed exercise  <b>Study 2:</b> diet + lifestyle, exercise; diet; no treatment  <b>Study 3:</b> thin parent/parent control; obese parent/parent control; thin parent/child self-control; obese parent/child self-control  <b>Study 4:</b> diet + programmed exercise; diet + life style, exercise; diet + stretching/calisthenics                      Duration: 6 mos  <b>Target of intervention:</b> risk factor modification                      CON: usual care, invited back for check-ups at 1, 2, 3, 6 mos, 10 yrs                      Rx: supervised exercise 1st 3 yrs, risk factor modification counseling. MD visits monthly <math>\times</math> 6, then quarterly.                      Years 4-10: maintenance                      Duration: 3 years  <b>Target of intervention:</b> risk factor modification                      CON: usual care                      Rx: 1-week residential retreat to teach life-style intervention, 4-hr twice weekly support group mtg (strategies for maintaining adherence); low-fat vegetarian diet for at least 1 yr. Stress mgmt techniques 1 hr/day, individually prescribed exercise levels                      Duration: at least 1 year  <b>Target of intervention:</b> test effects of intensive diet &amp; exercise program                      CON: 1-week metabolic ward stay                      Rx: 3-week metabolic ward stay, instruction of 20% fat diet; group exercise + daily home exercise, info mtg 5<math>\times</math>/yr                      Seen at 3, 6, 9 mos following 3-wk ward stay                      Duration: 3 mos  <b>Target of intervention:</b> risk factor modification                      CON: usual care                      Rx: mail-out program designed to help pts reduce dietary fat, exercise regularly, &amp; quit smoking, supplemented by phone contacts                      Duration: 2 mos, 4 mos maintenance contact</p>	<p>Duration: Study 1: 18 mos                      Studies 2-4: 12 mos                      Weeks of complete record keeping, NS difference                      Sig group difference in exercise adherence [F = 2.45], <i>p</i> &lt; .05.                      Post hoc analyses: greater adherence to programmed exercise/low cal expenditure (Study 4)                      Exercise adherence was related to complete record keeping (<i>r</i> = .61, <i>p</i> &lt; .001); &amp; remaining below calorie limit (<i>r</i> = .60, <i>p</i> &lt; .001)</p>
Hamalainen OJ et al. 1989 (111)	RCT	<p><i>N</i> = 375 MI patients                      CON 187, Rx 188                      SEX: males                      AGE: &lt;65 yrs                      RACE: White                      SITES: 2 university hospitals, Finland</p>	<p>SR: smoking cessation rates                      41.5% CON                      50% Rx                      NS                      # of cigarettes smoked: at 0-3 yrs, change was greater in the Rx group (<i>p</i> = .002); at 6 &amp; at 10 yrs, NS</p>	<p>Duration: 10 years                      Smoking cessation rate:                      CON Rx <i>P</i> value                      41.5% 50% NS                      # of cigarettes smoked: at 0-3 yrs, change was greater in the Rx group (<i>p</i> = .002); at 6 &amp; at 10 yrs, NS</p>
Omish D et al. 1990 (98)	RCT	<p><i>N</i> = 41 angiographically documented CAD patients                      CON 19, Rx 22                      SEX: 36 M, 5 F                      AGE: 48-69 yrs                      RACE: not specified                      SITES: 1 medical center, 1 university hospital, U.S.</p>	<p>SR: change in the # of cigarettes smoked</p>	<p>Duration: 1 year                      Food intake: Sig differences between baseline &amp; 12 mos &amp; between Rx &amp; CON groups, <i>p</i> &lt; .0001                      Total adherence score:                      CON Rx <i>P</i> value                      .62 1.22 &lt;.0001</p>
Schuler G et al. 1992 (106)	RCT	<p><i>N</i> = 113 dx CAD patients                      CON 57, Rx 56                      SEX: males                      RACE: not specified                      AGE: 53.5                      SITES: university hospital, Germany</p>	<p>Attendance at exercise sessions                      SR: 24-hr recall (total cal, fat, CHO, chol)</p>	<p>Duration: 12 mos                      Attendance: 68% (range 39-92%)                      Study Period                      Variable Rx                      fat g/day 62 <math>\pm</math> 28 45 <math>\pm</math> 13                      ANOVA, <i>p</i> &lt; .05                      chol mg/d 232 <math>\pm</math> 139 135 <math>\pm</math> 52                      ANOVA, <i>p</i> &lt; .05                      Difference between CON &amp; Rx groups for total cal and CHO, NS</p>
Heller RF et al. 1993 (109)	RCT	<p><i>N</i> = 450 MI patients                      CON 237, Rx 213                      SEX: 71% male                      RACE: not specified                      AGE: 25-69 yrs                      SITES: 5 major hospitals Newcastle, Australia</p>	<p>SR: food intake, yielded fat intake score                      SR: exercise                      SR: cigarette smoking</p>	<p>Duration: 6 mos                      SR: food intake/fat intake score:                      CON Rx <i>P</i> value                      15.3 13.1 .002                      SR exercise: NS                      SR cigarette smoking: NS</p>

TABLE 5  
Continued

Authors/Year	Design	Sample	Intervention	Compliance Measures	Findings
DeBusk RF et al. 1994 (108)	RCT	N = 586 MI patients CON 292, Rx 293 SEX: ~79% male RACE: ~76% White AGE: 58 yrs SITES: 5 HMO Med Ctrs, U.S.	<b>Target of intervention:</b> risk factor modification <b>CON:</b> usual care <b>Rx:</b> specially trained nurses initiated Rx in hospital, post discharge implemented primarily via telephone & mail contact, counseling behaviorally based, computer generated progress report guidelines provided in response to FFQ at 3 intervals; smoking cessation intervention Duration: 12 mos	SR: food frequency questionnaire (FFQ) FFQ score: Baseline Rx 322 ± 206 121 ± 90 FFQ scores at 52 wks: CON Rx 140 ± 83 124 ± 84 Statistics not reported Biochemical determination of smoking status: CON Rx P value 6 mos 55% 69% 12 mos 53% 70% .03 Duration: 4 years On Study measures: Variable CON Rx P value total fat 32.7 ± 7.2 23.8 ± 7.0 p = .0001 sat fat 10.6 ± 3.3 9.8 ± 2.8 p = .0001 chol 270.7 ± 135.5 43.7 ± 74.3 p = .0001 smoking 18.1 10.1 NS exercise 70 ± 34 90 ± 23 p = .02 (%)	Durations: 52 weeks f/u 6-wks P value <.001
Haskell WL et al. 1994 (3)	RCT	N = 300 angiographically defined CAD patients CON 166, Rx 145 SEX: 259 M, 41 F RACE: not specified AGE: 56 ± 7.4 yrs SITES: 4 hospitals (1 VA, 1 university, 2 community), U.S.	<b>Target of intervention:</b> individualized risk reduction based on S's profile, motivation, & resources <b>CON:</b> usual care <b>Rx:</b> individualized nurse counseling for behavior change, progress tracked via phone, mail, quarterly clinic visits Duration: 4 years	SR: total fat (% cal) SR: sat fat (% cal) SR: dietary chol (mg/d) SR: smoking status (%) Participation in exercise training	Behavior CON Rx P value # smokers 14 42 attend clinic 21 21 >.9 % quit (SR) 0 26 .033 % quit (CO ver) 0 9.5 .231
Kirkman MS et al. 1994 (110)	RCT	N = 275 NIDDM patients CON 71, Rx 204 SEX: 99% male RACE: 59% White AGE: 63 yrs SITES: VA Med Ctr, U.S.	<b>Target of intervention:</b> improve glycemic control & coronary risk factors in NIDDM patients <b>CON:</b> usual care <b>Rx:</b> monthly phone contacts initiated by nurse for behavioral counseling & information provision, ref. to smoking cessation & nutrition counseling Duration: 12 mos	SR: smoking status (reported cessation verified by exhaled CO measurement)	Duration: 20 weeks Weekly exercise logs: No. days ex. (days/wk) SB LB P value 87.3 ± 205 69.1 ± 28.9 <.05 Total duration (min/wk): SB LB P value 223.8 ± 69.5 188.2 ± 58.4 .08
Jakicic JM et al. 1995 (103)	RCT	N = 56 obese sedentary women (BMI 33.9) SEX: female RACE: not specified AGE: 40 yrs SITE: university clinic, U.S.	<b>Target of intervention:</b> weight control Randomized to 1 of 2 comparison groups: <b>Rx 1:</b> short-bout exercise program (SB) n = 28, exercise 5 d/wk 3-4 times per day <b>Rx 2:</b> long-bout exercise program (LB) n = 28 exercise once daily Behavioral wt control program + dietary instructions Duration: 20 wks	SR: weekly exercise records: type of activity, duration	The Tri-Trac corroborated the decline in exercise in both groups over time FFQ Dietary intake (kcal): Baseline 20 wk P value LB: 1,728 1,203 SB: 1,981 1,316 NS

<p>Simkin-Silverman L et al. 1995 (102)</p> <p>RCT</p> <p><i>N</i> = 535 healthy premenopausal women</p> <p>CON 267, Rx 253</p> <p>SEX: female</p> <p>RACE: 92% White</p> <p>AGE: 47</p> <p>SITE: recruited by mail from random sample, U.S.</p>	<p>Target of intervention: prevent elevations of CHD risk factors occurring with menopause</p> <p>CON: customary life-style</p> <p>Rx: intensive dietary &amp; behavioral Rx group program, weekly × 10, then biweekly for 10 wks</p> <p>Maintenance: 3 monthly, then 3 bimonthly group, mail, or phone contact every 2-3 mos, &amp; if needed for adherence difficulties</p> <p>Duration: Rx 20 wks, maintenance 4.6 yrs</p>	<p>Attendance at sessions</p> <p>SR: physical activity (Paffenbarger Activity Questionnaire)</p> <p>SR: food intake (Block FFOQ)</p>	<p>Duration: 5 years</p> <p>Ss attended average of 11.4 of 15 sessions; no. of sessions attended sig correlated with change in risk factors (<math>p &lt; .001 - .05</math>)</p> <p>SR activity &amp; food intake at 6-mos:</p> <table border="1"> <thead> <tr> <th>Variable</th> <th>CON</th> <th>Rx</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>act kcal</td> <td>1,295</td> <td>1,632</td> <td>0.001</td> </tr> <tr> <td>Block FFOQ kcal/d</td> <td>1,503</td> <td>1,369</td> <td>0.001</td> </tr> <tr> <td>% fat</td> <td>34.5</td> <td>25</td> <td>0.001</td> </tr> <tr> <td>% sat fat</td> <td>11.4</td> <td>8.0</td> <td>0.001</td> </tr> </tbody> </table>	Variable	CON	Rx	P value	act kcal	1,295	1,632	0.001	Block FFOQ kcal/d	1,503	1,369	0.001	% fat	34.5	25	0.001	% sat fat	11.4	8.0	0.001
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% fat	34.5	25	0.001																				
% sat fat	11.4	8.0	0.001																				
	<p>SR: cig smoking</p> <p>SR: alcohol intake</p> <p>Caltrac physical activity monitor</p>	<p>SR smoking: NS difference</p> <p>SR alcohol intake: NS difference</p> <p>2-way repeated measures ANOVA</p> <p>Caltrac activity monitor: increases compared to baseline: (<math>p &lt; .001</math>)</p> <p>Rx 3.2 vs CON .08 motion counts/hr</p>																					

RCT = Randomized Controlled Trial.  
SR = Self-Report.

and group strategies, including behavioral skill training and self-management techniques, in their risk-reduction program targeting middle-aged males and premenopausal females, respectively. The MRFIT resulted in significant changes in smoking cessation and eating behavior (99,101,114). Ockene et al. (100) reported the smoking cessation rate at 72 months, utilizing data from self-reported smokers and the serum thiocyanate levels of self-reported quitters, to be 36.4% in the special intervention group compared to 23.6% in the usual care group. Of the 4,754 special intervention subjects whose dietary adherence was reported at 72 months, 7% were in the high-adherence category, 33% were adequate, and 60% needed to make additional change (114). Since these early reports, four centers re-examined their participants and provided data on long-term maintenance of the initial behavior changes (115). Approximately 2 to 3.5 years post-MRFIT completion, 989 subjects demonstrated that the group difference persisted for eating behavior and diastolic BP control. The food frequency record represented 70% of the value at the completion of the intervention, which would be consistent with maintaining the group difference. Self-report smoking rates and serum thiocyanate levels indicated that a difference no longer existed between the groups, attributable to recidivism in the treatment group and cessation among the control group participants (115). Simkin-Silverman's study (102) focusing on the prevention of risk factor elevations in healthy premenopausal women is ongoing. However, results at six months reveal significant differences between groups in energy expenditure and caloric intake ( $p = .001$ ). The maintenance of these behavioral changes has yet to be determined.

Programs that are substantially different from the primary prevention approach are residential programs, used in both the U.S. and Europe (98,106). Results reported by Ornish et al. (98) at the one-year mark showed significant differences between the groups in food intake, and the mean adherence score (122%) indicated participants were complying over and above what was recommended. Schuler (106) showed significant differences in fat and dietary cholesterol intake at one year, while attendance at exercise was, on average, 68%. It is not possible to directly compare compliance rates across all studies because of the differences in measurement of behavior (for example, exercise compliance may be reported as a score on a questionnaire, the percent of the group that achieves a certain level of participation, or the percent of attendance for a series of classes or sessions). However, despite this dilemma, when the initial intensity of the intervention was considered in one resident program (106), the exercise compliance (68%) was not higher than that reported by a program using extended phone contact (3) or among those considered compliers in a rehabilitation program (50).

A series of studies utilized phone and/or mail contact with varied results (3,108-110). Heller's program (109) was initiated following discharge from the hospital for acute MI and lasted two months, in contrast to DeBusk's (108), which enrolled MI patients while still in the hospital and continued contacts for twelve months thereafter. Heller (109) reported significant differences in food intake. DeBusk (108) reported that both intervention and usual care participants made significant changes in their eating habits the first year, so that food frequency scores were similar at twelve months. No differences in cigarette smoking or exercise were reported in the shorter duration study (109), while there was a significantly higher smoking cessation rate in the treatment group of the one-year study (70% versus 53%,  $p = .03$ ). In a similar intervention, Haskell (3) evaluated a four-year individualized risk-reduction program among patients who had angiographically-

defined CAD. At the four-year mark, subjects in the intervention group had favorable changes from baseline when compared to the usual care group [e.g. subjects in the risk-reduction group reported significantly lower fat and dietary cholesterol consumption ( $p = .0001$ ) and greater participation in exercise training ( $p = .02$ ), but no significant difference in smoking rates] (3). Kirkman (110) reported that 26% of the treatment group reported having stopped smoking; however, only 9.5% could be verified biochemically ( $p = .0231$ ); the control group reported no change (110). The discrepancy found in this study between self-report and biochemical verification was reported previously by Taylor and colleagues (90).

*Measurement Methods:* With the exception of two investigators who utilized newer technology to monitor the prescribed physical activity, most of the measurement methods used in these studies have been previously described. There are two types of accelerometers: the Caltrac, which uses one plane of body motion, and the Tri-Trac, which uses three planes—vertical, horizontal, and lateral body movement. The accelerometer measures movement produced by skeletal muscles and resulting in energy expenditure, which provides an objective and direct measure of frequency and intensity of physical activity (116). Jakicic (103) used the Tri-Trac accelerometer to corroborate the exercise log data on randomly selected days, while Simkin-Silverman (102) utilized the Caltrac accelerometer. As noted previously, the use of electronic devices provides a validation for self-report measures and additional data on the patterns of adherence.

#### GENERAL OBSERVATIONS AND DISCUSSION

The 49 studies reviewed in this paper represent 27,321 adult and 2,164 child participants. The combined sample of children has an 84% representation of Whites and is balanced by gender. However, the aggregate adult sample is comprised of 85% males, 90% Whites, and 90% U.S. residents (i.e. the average subject in a CVD risk-reduction trial is a 52-year-old White American male). The homogeneity of the sample is striking. However, when the individual samples had a more diverse or balanced composition, it was rare that gender or race were considered in the analyses (60,66,81). Among children, the CATCH study provided evidence that children respond similarly to health promotion efforts, regardless of gender or ethnic background (81). For adults, Connett and Stamler (117) reported that the 931 Black participants (7.2%) in MRFIT demonstrated overall attendance rates similar to Whites, and the changes in smoking cessation and diet were comparable to White participants. These findings are not dissimilar to those reported by Mojonner (60). However, Wing and Anglin (66) reported smaller weight losses among Blacks when compared to Whites and a trend for Blacks to have poorer attendance and report smaller changes in calorie intake in the second half of a twelve-month program.

While the sample composition of the exercise studies reflected the aforementioned figures, 60% of the exercise trials were conducted outside of the U.S. Exercise studies elsewhere typically have prolonged intervention and maintenance phases. Thus, the generalizability of these findings to the overall U.S. population is limited and, for females, nearly irrelevant.

Women were included in 32 of the 45 studies of adults. Examination of differences by gender were reported in one study, and this indicated women achieved better dietary adherence (60). Cross-sectional data indicate women who participate in structured programs self-report better diet and exercise adherence at two weeks and six months post coronary artery bypass graft surgery

(118). Only 20% of those who enroll in cardiac rehabilitation programs are women, and to date, a lower proportion participate in related trials. Thus, much remains unknown about women and their adherence to exercise or other risk-reducing behaviors. The studies reported by Jakicic and Simkin-Silverman are needed additions to the empirical literature.

When compliance is viewed across the life span, the groups at the opposing ends of the spectrum, children and the elderly, received the least attention. Even though there are few controlled trials among children targeting CVD risk-reduction, the literature reflects the emphasis on the very important risks associated with, or aggravated by, poor eating habits (e.g. obesity, familial hyperlipidemia, and IDDM) (73–76, 79–83, 119). Considering that one-third of the prescriptions written are for individuals over age 65 (120), it is not surprising that studies among the elderly segment of the population focused on medication-taking behavior, testing strategies to reduce the forgetting of doses or making fewer errors (34,39,40). As the safety and efficacy of pharmacological therapy among children is being reported and prescribed (28,121) and the elderly segment of the population is pursuing participation in non-pharmacological approaches to risk-reduction, we need to learn which strategies are most effective in enhancing compliance to additional behaviors in these subgroups of the population.

In the past two decades, progress has been made in the measurement of compliance behavior, as illustrated by several researchers. Technology has provided the tools to go beyond pill counts and to use the bar code scanner or the electronic event monitoring system (29,34,43,44,122). However, none of the studies reviewed used the electronic event monitor to assess medication compliance. Adherence to the prescribed heart rate can be monitored by devices such as the Vitalog (55) and energy expenditure by the Tri-Trac (103,116) or the Caltrac accelerometers (102,123). The use of hand-held computers for self-monitoring offers great promise, particularly when an accurate assessment of compliance to the recording process is required or when accuracy of the recording schedule is important (124). Moreover, the hand-held computer offers an attractive alternative to paper-and-pencil diaries.

Progress has also occurred in the development of psychometrically sound instruments to measure adherence or factors related to it. Morisky et al. (125) reported on a four-item self-report adherence measure which addresses barriers to medication-taking, and Hill and Berk (126) reported on self-administered scales to assess selected psychological barriers to regimen compliance as perceived by the adult hypertensive patient. The literature also contains reports of psychometrically established instruments assessing one's self-efficacy for exercising (127,128), adhering to a cholesterol-lowering diet (129,130), reducing weight (131), quitting smoking (132), and taking medication (133). These assessment instruments represent several behavioral domains which are the target of risk-reduction interventions.

An earlier review by Godin (134), published in 1989, noted that interventions for cardiovascular risk-reduction often were educational in format, infrequently involved family members, and typically were delivered in the hospital or rehabilitation center. This review suggests progress has been made, particularly in the broad array of interventions available and the flexibility of timing and access to patients, allowing for longer follow-up periods. Overall, the intervention programs reviewed called upon the behavioral sciences and utilized strategies that were robust across varied risk behaviors and groups [e.g. social or spousal support was utilized in attempts to increase adherence to exercise programs

(51) and dietary changes (72,130); self-monitoring was applied to the establishment and maintenance of exercise (24,54,55,103) and weight control (66,103); contingency contracting was applied to appointment-keeping (104); and persuasive communication was utilized to improve adherence to exercise session attendance (51)]. Written agreement was employed by Oldridge (50) to prevent attrition during the first six months of an exercise program; and behavioral skill training was utilized by investigators in the MRFIT (99–101, 114), in the LRC–CPPT (67), in the Women's Healthy Lifestyle Project (102), in weight control (66), and in cardiac rehabilitation programs (50).

Compliance-improving strategies being employed more recently are self-efficacy enhancement, follow-up via telephone contacts, and nurse-managed interventions. Self-efficacy based strategies appear to be particularly robust across several behavior domains [for example, smoking cessation (92,97), exercise (135,136), and eating behaviors (71,137,138)]. Telephone contacts, utilized nearly as often as self-monitoring in the reviewed studies, have been shown to be a cost-effective means of increasing contact with patients (139,140) and improving adherence in most instances (3,92,108,109). Similarly, nurse-managed interventions have been shown to be effective in improving smoking cessation rates (92), blood pressure control (41), and reducing risk behavior in multicomponent intervention trials (3,108).

A list of the strategies shown to make a difference in outcome appears in Table 6. The studies in which these strategies were successful are indicated by the accompanied citations, directing the reader to the papers describing the populations and settings in which the interventions were applied successfully. For additional background information, the reader is referred to a host of excellent review papers pertaining to adherence [e.g. compliance among children and adolescents (141), as well as compliance with hypertension treatment (26), medication-taking (142), appointment-keeping (143), dietary regimens (144,145), exercise (146,147), and exercise in the treatment of obesity among children and adolescents (119)].

### SUMMARY

The previous paragraphs have identified the progress or gains made in compliance research. However, much remains to be learned. Table 6 lists strategies deemed to be successful in enhancing compliance, but the majority of these have not been tested in controlled studies for comparative efficacy. Further, the majority of studies have not included diverse populations, and very few focused on those identified as non-adherent. Thus, little is known about the efficacy or acceptability of interventions to ensure compliance across gender, age, race, or cultural groups, or to improve or remediate adherence problems in the subgroup of poor adherers. Advances have been made in the measurement of compliance behavior, yet the more accurate methods are relatively costly and infrequently used in the research setting and nearly non-existent in the clinical setting. Improved methods of self-report, as well as more available objective measures, could facilitate the direct measurement of compliance behavior and allow non-compliance to be evaluated separately from clinical outcomes and, further, disentangled from therapeutic failure (9). Improvement in the accuracy of assessment methods would permit better identification of non-compliance and parallel the development and systematic testing of interventions.

In spite of the identified advances made, compliance rates have remained nearly unchanged during the time covered by this review. Compliance in clinical trials, as noted, is not ideal; and

**TABLE 6**  
**Strategies Demonstrated to be Successful in Improving Compliance to CVD Prevention Strategies**

Successful Strategies	Investigators/Studies in Which Improved Compliance Was Demonstrated
Signed agreements	Oldridge NB, Jones NL 1983 (50) Ockene JK et al. 1991 (93) DeBusk RF et al. 1994 (108)
Behavioral skill training	Doloncek TA et al. 1986 (114) Glueck CJ et al. 1986 (67) Van Horn LV et al. 1993 (75) Simkin-Silverman L et al. 1995 (102) Oldridge NB, Jones NL 1983 (50) Nessman DG et al. 1980 (37) Wing RR, Anglin K (66)
Self-monitoring	King AC et al. 1988 (54) Rogers F et al. 1987 (55) Epstein LH et al. 1984 (24) Kirscht JP et al. 1981 (105)
Telephone/mail contact	Friedman RH et al. 1996 (32) DeBusk RF et al. 1994 (108) Haskell WL et al. 1994 (3) Heller RF et al. 1993 (109)
Spouse support	Bovbjerg VE et al. 1995 (72) Barnard ND et al. 1992 (69) Ornish D et al. 1990 (98)
Self-efficacy enhancement	Taylor CB et al. 1990 (92) DeBusk RF et al. 1994 (108) Haskell WL et al. 1994 (3) McCann BS et al. 1988 (71)
Contingency contracting	Swain MA, Steckel SB 1981 (104)
Exercise prescription: frequent short periods	Jakicic JM et al. 1995 (103) Hambrecht R et al. 1993 (52)
External cognitive aids: appt reminder letter, f/u letter for missed appt, med refill reminder, unit-of-use packaging, med reminder chart	Saunders LD et al. 1991 (30) Skaer TL et al. 1993 (38) Raynor DK et al. 1993 (33) Park DC et al. 1992 (34)
Persuasive communication (successful for participants with education $\leq$ HS)	Ockene JK et al. 1991 (93) Daltroy LH 1985 (51)
Convenience: work site clinic (nurse-managed)	Logan AG et al. 1979 (41) Taylor CB et al. 1990 (92)
Nurse-managed intervention	DeBusk RF et al. 1994 (108) Haskell WI et al. 1994 (3)
School-based food service program plus education	Luepker RV et al. 1996 (80, 81)

further, there remain important discrepancies between compliance reported in clinical trial settings and that in clinical practice settings (46,148,149). In the practice arena, treatment modalities for cardiovascular risk reduction exist (150). However, non-compliance is a formidable problem impacting on the failure of risk-reduction therapies, on patient morbidity, and on health care costs. One of the challenges facing the compliance researcher and the clinician is to reduce this gap between the clinical trial setting and clinical practice through improved dissemination, translation, and application of what has been demonstrated empirically to improve compliance behavior. Attention to the deficits in knowledge of compliance behavior, measurement methods, and implementation of successful strategies into practice may contribute to a successful reduction in non-compliance behavior. Further, several

of the studies tested innovative approaches in the current health care delivery system while others tested the application of skills that go beyond the traditional concept of particular professionals, and by so doing, they promoted interdisciplinary collaboration in clinical investigations and clinical management. These offer promising paths to pursue in the quest for improved patient compliance in the clinical trial setting, as well as in the rapidly changing health care environment.

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