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Intervention

The trials and tribulations of enrolling couples in a randomized, controlled trial: A self-management program for hyperlipidemia as a model☆

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ABSTRACT

Objective: Capitalizing on spousal support may enhance the effectiveness of interventions for chronic disease management. However, couples-based interventions present logistical challenges. We describe our experience and lessons learned while recruiting couples into the Couples Partnering for Lipid-Enhancing Strategies (CouPLES) trial.
Methods: This trial seeks to reduce serum low-density lipoprotein cholesterol levels using a couples-based intervention designed to help patients engage in self-management behaviors. We proposed enrolling 250 couples over 13 months.
Results: Due to practical challenges that we encountered, recruitment and enrollment lasted 21 months. Those challenges included: travel to study site; effectively marketing the study; participant burden; and establishing eligibility criteria. By modifying our protocol to address these challenges, the recruitment rate increased from 12 to 33%.
Conclusion: In the absence of trials identifying the most effective recruitment strategies, investigators may need to experiment, amending their protocol intermittently until target enrollment numbers are reached. The lessons we present may help researchers conducting couples-based interventions develop more effective protocols.
Practice implications: To achieve target enrollment numbers, researchers conducting couples-based interventions should consider minimizing travel to the study site; carefully crafting recruitment materials; budgeting more for participant incentives and staff effort; and limiting exclusion criteria. These practices may also enhance retention.

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1. Introduction

A wealth of literature has shown that higher social support is associated with better adherence to health behaviors (e.g., diet, exercise) and emotional well-being, improved clinical outcomes, and lower mortality [1,2]. In patients with chronic disease, social support could be marshaled to enhance self-management and, ultimately, patient outcomes [1,3,4]. To this end, spouses represent a potentially important source of social support [5].

One rationale for including spouses in health interventions is that they are the most common source of influence on people's health behaviors [6,7]. Spouses may positively influence patients' health by providing instrumental assistance (e.g., preparing healthier foods) or emotional support (e.g., empathy, positive reinforcement). Another rationale for couples-based interventions is that they could lead to improvements in several unique domains of quality of life, such as communication or satisfaction with the marital relationship. Finally, couples-based interventions may improve spouses' physical or psychological health (''partner effect'') [8]; spouses with the same condition as patients may accrue direct health benefits, whereas spouses without the same condition may benefit from lifestyle changes (e.g., diet, exercise) or derive psychological benefits (e.g., less worry or stress) from helping their spouses achieve improved health status and outcomes.

Despite the potential benefits of couples-based interventions, conducting trials to evaluate them presents unique operational challenges. Consequently, recruitment rates typically range from

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10 to 60%, with many in the 20 to 30% range (e.g. [9–14]). In studies focusing on individual patients, such recruitment rates would be considered unsatisfactory in general.

In this paper, we describe our experience and lessons learned while recruiting participants into the CouPLES (Couples Partnering for Lipid-Enhancing Strategies) trial, which is evaluating the effectiveness of a couples-based intervention to help patients improve health behaviors, with the goal of lowering their non-fasting serum low-density lipoprotein cholesterol (LDL-C) levels. This ongoing trial is among the largest couples-based trials for chronic disease management to date.

2. Method

2.1. Design

The design and methods of the CouPLES trial have been reported in detail elsewhere [15]. To summarize, eligibility was determined in a three-step process (described in more detail in Section 3.4), then eligible couples were randomized to the control or intervention arm. Patients in the control arm receive usual care from their physician with no contact from study personnel to the patient or spouse except for two subsequent outcome assessment visits. Patients and spouses in the intervention arm receive monthly intervention telephone calls delivered by a single nurse during months 1–5 and 7–10 post-enrollment. Outcomes are assessed at 6 and 11 months.

2.2. Intervention

The intervention is delivered via a custom-designed software application, which provides a standardized script for the nurse to read during the calls and allows information about each couple to be recorded, saved, and viewed during subsequent calls. During each patient call, patients select one of four areas of self-management – diet, exercise, medication adherence, or patient–physician communication – and specify related goals and action plans to pursue over the next month. Each telephone call builds on the previous month's call, with the nurse assessing progress toward the previous month's goals and guiding patients to create new goals for the next month. In separate calls to spouses, the nurse informs spouses about patients' goals and guides them to develop action plans to provide emotional and/or instrumental social support to help patients achieve their goals. Patient calls are typically 15–20 min, with spouse calls 5–10 min. Intervention fidelity is ensured by the intervention software and by review of a random 5% of calls by two investigators (CIV and WSY). This intervention could generalize to other chronic conditions involving self-management behaviors that are susceptible to environmental influences with minor revisions. For example, the dietary materials could be revised to focus on a low-glycemic or low-sodium diet for diabetes or hypertension, respectively. The emphasis on goal setting and achievement is relevant to self-management for a variety of diseases.

2.3. Outcomes and hypotheses

The primary outcome is patient LDL-C level at 11 months. Secondary outcomes, assessed by blinded staff, are adherence related to diet, exercise, and medication. We are also obtaining secondary outcomes from spouses, who report on their own behavior. Screening and outcome assessments occur in the clinic; we attempt to schedule these visits on the same day the patient has an appointment with a provider.

Our primary hypothesis is that a telephone-based patient–spouse intervention will result in a greater reduction in LDL-C at 11 months as compared to usual care. Our target sample size was 250 couples (125 in each arm), which provides 80% power to detect a 7% difference (9.4 mg/dL) in LDL-C between the two arms. This sample size was calculated based on a *t*-test adjusted for a correlation between repeated measures [16], assuming a significance level of $p = .05$ and a conservative dropout rate of 25% over 11 months.

2.4. Timeline

Our original study timeline proposed 13 months of recruitment, with 20 couples enrolled per month. Enrollment began in November of 2007. During months 1–3, detailed records were not kept due to staffing changes. During months 4–5 of recruitment, we conducted baseline appointments with an average of 14 (range 12–16) couples per month, with an average monthly recruitment rate of 13% of patients contacted. As we amended our protocol over 12 months to improve our recruitment procedures (detailed below), our recruitment rate increased gradually (see Fig. 1). Subsequent to implementing the last protocol change in October of 2008, we recruited an average of 18 (range 8–32) couples per month, with an average monthly recruitment rate of 33% (range 22–53%). After 21 total months of recruitment, enrollment concluded in July of 2009, with 255 enrolled couples (for CONSORT diagram, see Fig. 2). Data collection for this study is ongoing and will conclude in June of 2010. Baseline demographic characteristics of patients and spouses are shown in Table 1.

3. Challenges and solutions

Researchers conducting couples-based interventions may encounter a number of practical challenges related to identifying eligible couples, attempting to enroll them, and retaining both members of each couple in the trial. Below, we summarize the recruitment challenges we encountered, the protocol amendments we made in attempt to improve the recruitment rate, and our impression of which changes positively affected the recruitment rate. Fig. 3 provides a detailed timeline with recruitment numbers, and Table 2 summarizes the issues and solutions.

3.1. Travel to study site

Initially, we conducted all assessments at the Durham Veterans Affairs Medical Center (VAMC). Because the VAMC serves a large area of central and eastern North Carolina and southern Virginia,

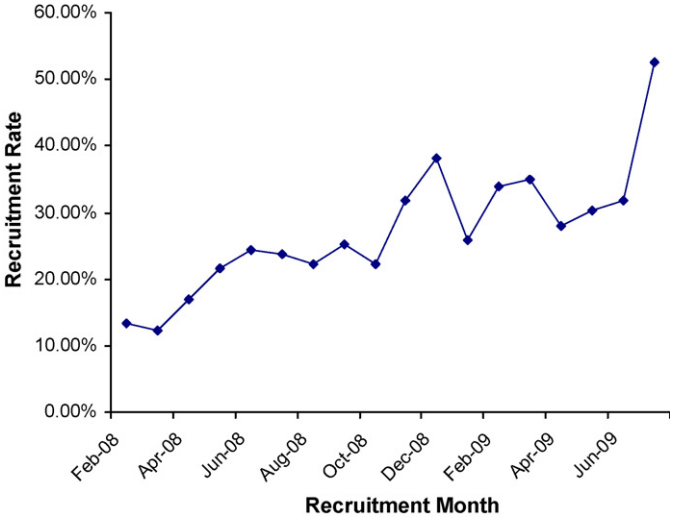

Fig. 1. Recruitment rate by month.

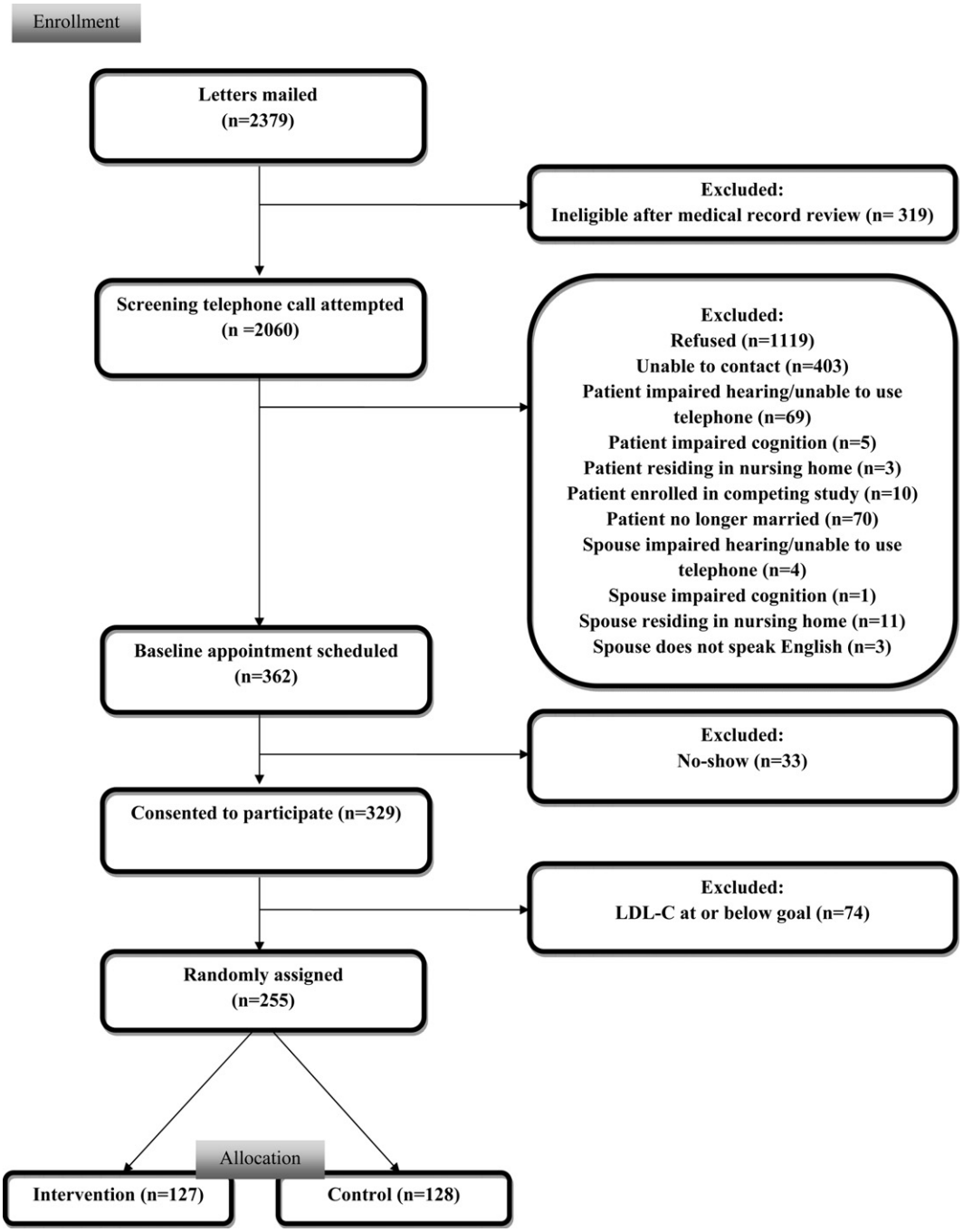

Fig. 2. CONSORT enrollment flow diagram.

many patients must drive a considerable distance. During month 6 of recruitment, we received approval from the Institutional Review Board (IRB) to conduct assessments at the Raleigh Community Based Outpatient Clinic (CBOC), a satellite clinic of the VAMC located 25 miles east. Advantages of using the CBOC are reduced driving distance for some patients and more convenient parking, which are frequently cited barriers. Assessments at both locations were conducted by the same study staff.

Table 1
Demographic information for patients and spouses enrolled in the study.

Demographic variable	Patient, *N*	Patient	Spouse, *N*	Spouse
Age, *M* (SD)	255	61.3 (12.3)	251	58.8 (12.0)
Race (% White)	251	64.9%	248	64.1%
Sex (% male)	255	95.3%	251	6.0%
Education (% HS grad or less)	251	23.9%	248	26.6%
Employment (% full-time)	251	41.4%	248	34.3%

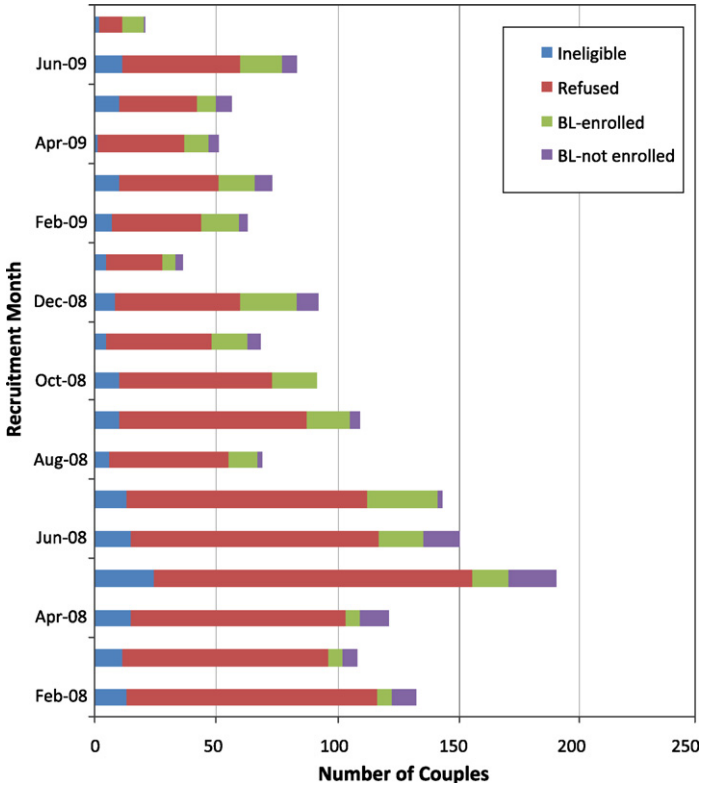

Fig. 3. Recruitment numbers by month. *Note*: Changes to protocol: (1) November 2007: removed fasting requirement for LDL-C test; (2) April 2008: added second site; (3) May 2008: added electronic consult option, posted brochures and flyers, advertised study at the lipid clinic; (4) June 2008: sShortened recruitment letter and phone script, measures by mail, increased incentive; (5) July 2008: lowered LDL-C entry threshold to >76 mg/dL; and (6) October 2008: added physician signatures to recruitment letters.

3.2. *Effectively marketing the study to couples and providers*

Another possible factor in the low recruitment rate is that the targeted recruitment procedure did not identify a sufficient number of potential participants. In month 7 of recruitment, we obtained IRB approval to post-flyers on bulletin boards at both sites and to broadcast an advertisement on the information televisions located throughout the VAMC. We also announced the study to patients attending the VAMC Lipid Clinic, which was instituted to reduce LDL-C among high-risk patients (i.e., with diabetes or established cardiovascular disease). Although 19 patients responded to these advertisement methods, only 2 were enrolled in the study.

Also during month 7 of recruitment, we obtained approval to solicit referrals from providers. We e-mailed all providers a brief description of the study with instructions for referring patients, which included selecting a consult available in the VA Computerized Patient Record System (CPRS) or providing patients with study flyers that were posted in the exam rooms. We also attended one primary care staff meeting at the VAMC and at the CBOC, where we provided information about the goals of the study, the inclusion criteria, and the methods available for referring patients. Although 8 patients were referred to our study from two providers total, only three of these patients were enrolled. In sum, these untargeted procedures yielded few enrolled participants, compelling us to focus on a targeted recruitment procedure.

The targeted recruitment procedure included identifying potentially eligible patients (based on marital status and LDL-C level > 100 mg/dL in past 12 months) using CPRS, mailing an

Table 2
Recruitment issues and solutions.

Recruitment issue	Possible solution
Location of study site inconvenient for some participants	Add a second site Allow completion of measures by mail or telephone
Inadequate patient reach	Post-flyers and brochures at the study site Advertise on closed-circuit television at the study site
Provider buy-in	Advertise at provider staff meetings Provide additional methods for patient referral (e.g., electronic consult)
Recruitment materials	Limit length of recruitment letter to one page Do not include all details of a consent form Obtain feedback from other investigators, study staff Highlight appeal of control group Add provider signature to recruitment letter
Participant burden	Increase compensation, weighing undue influence, to better cover out-of-pocket costs Emphasize or add non-monetary incentives Use direct (non-fasting) LDL-C blood test
Eligibility criteria	Amend patient criteria if too strict Simplify spouse criteria to be as unrestrictive as feasible

introductory letter to these patients, and making recruitment telephones to patients and spouses two weeks later. Our initial inclination was to provide sufficient information in the recruitment letter to patients so that they would be well-informed when we called them. Therefore, the first version of our recruitment letter was two pages long and described many details of the study that would be found on a consent form.

We suspected that this may be unappealing and therefore asked two colleagues, a senior faculty member and a project coordinator, and their spouses to role-play as potential participants. Our colleagues indicated that the recruitment letter was long and detailed; that patients may feel disadvantaged if assigned to the control group and, therefore, that the quality of usual care must be emphasized; that the benefits of participation were not clearly articulated; and that the language describing the importance of involving spouses (i.e., because spouses may shop or prepare meals) may be perceived as sexist. The recruitment telephone script was, by design, lengthy because it included screening questions to determine eligibility. However, like the recruitment letter, it provided too many details, which patients and spouses would be unable to process or recall and which could be communicated subsequently during the consent process.

We edited the recruitment letter and telephone script based on this feedback, resulting in a briefer version of each containing the key information needed for potential participants to decide whether to proceed further. Once these changes were implemented in month 8 of recruitment, for the first time, some patients (numbers unavailable) called us to indicate their interest rather than waiting for us to call them.

Another concern regarding the recruitment materials was that patients may be unreceptive to receiving a recruitment letter from an unfamiliar individual. Many investigators include primary care provider signatures on recruitment letters so that the contact is not perceived as unfamiliar, and some IRBs require this. The VAMC IRB allows provider signatures to be included on recruitment letters, although the letter must communicate an introduction to the study rather than a recommendation to enroll. In month 12 of recruitment, we started including provider signatures on the recruitment letters. However, we did not feel that this affected our recruitment rate substantially.

3.3. Participant burden

Burden refers to the time, monetary costs, and inconveniences associated with participation in the study. An important consideration for our patient population is the monetary cost of participation. When the grant proposal for this trial was submitted in 2004, the price of gas reached $2.00 per gallon for the first time in United States history. We originally budgeted for $10 per patient and spouse, or $20 per couple, for each of the three in-person assessment visits. As gas prices approached nearly $4.50 per gallon at one point during the study, patients increasingly cited transportation costs as a barrier to participation, despite the fact that all but five couples attended baseline appointments together. In month 8 of recruitment, we increased the monetary compensation to $20 per person per assessment, or $40 per couple. This amendment was approved without issue by the IRB. Based on feedback from participants, we felt that increased compensation was a factor that improved recruitment.

Another aspect of burden is inconvenience or discomfort. When we planned our study, we required a fasting blood draw because our primary outcome, LDL-C, was calculated from the Friedewald formula using measured total cholesterol, high-density lipoprotein cholesterol, and triglycerides levels; this formula requires fasting for best accuracy. Further, whenever the triglyceride level exceeds 400 mg/dL, LDL-C is considered too inaccurate to use and therefore is not calculated, which would lead to missing data for some participants [17]. Early in the study, direct measurement of serum LDL-C became available at the VAMC; this method does not require fasting and does not rely on the triglyceride level. We obtained IRB

Table 3
Patient and spouse eligibility criteria.

Method of assessment	Patient criteria	Spouse criteria
Medical record	Inclusion criteria Diagnosis of coronary heart disease (CHD) or risk equivalents according to National Cholesterol Education Program guidelines (i.e., diabetes, peripheral arterial disease) and LDL-C > 100 mg/dL in past 12 months No diagnosis of CHD or risk equivalents with LDL-C > 130 mg/dL Married Exclusion criteria No telephone number Hospitalization in past 3 months Decreased survival prognosis Psychosis or dementia No primary care provider No visit to primary care provider in past 12 months	
Telephone interview	Exclusion criteria 6-item cognitive screener[a] "Part of the study requires speaking with a nurse on the telephone. Will you have a telephone for the next 11 months?" "Is your spouse hard of hearing?" "In order to participate, you would have to have your blood drawn at the lab for a cholesterol test. Do you think you would be okay with that?" "Are you or is your spouse in a nursing home? Is either of you receiving home healthcare?" "Have you been hospitalized for a heart attack, stroke, or any procedure to open an artery in your heart in the past 3 months?"	Exclusion criteria 6-item cognitive screener[a]
Blood test	Exclusion criteria Baseline LDL-C at or below goal according to National Cholesterol Education Program guidelines (through recruitment month 8) LDL-C < 77 mg/dL (recruitment months 9–21)	

LDL-C, low-density lipoprotein cholesterol.
[a] Assessed via 6-item screener [24].

approval and instituted this method in month 1 of recruitment. The benefits include minimization of missing data, more flexible scheduling because patients may be more willing to have appointments later in the day if they do not have to fast, and, possibly, more willingness to enroll in the study.

3.4. Eligibility criteria for patients and spouses

Recruitment rates in couples-based interventions are likely to be lower than in patient-only interventions because both members of the couple must meet eligibility criteria and be willing to participate. Eligibility criteria are shown in Table 3. In Step 2, we excluded patients if they had any conditions that would make it difficult to participate in a telephone-delivered intervention (shown in Fig. 2).

In Step 3, final patient eligibility was determined via blood draw to assess baseline LDL-C. During the first nine months of recruitment, baseline LDL-C had to exceed goal LDL-C, as determined by National Cholesterol Education Program (NCEP) Guidelines. For patients at low risk for CHD, goal is $<$160 mg/dL; for patients at medium risk, goal is $<$130 mg/dL; and for high risk, goal is $<$100 mg/dL. Of the 99 patients who completed baseline interviews while this criterion was in place, only 42% (42/99) were eligible and thus enrolled. The number of patients whose LDL-C exceeded goal was minimized significantly due to an effective provider-level co-intervention that was instituted at the VAMC [18] and, possibly, the Lipid Clinic. Because the Lipid Clinic is part of usual care, co-enrollment, which occurred among 10 control and 11 intervention patients, was not an exclusion criterion. To help meet our target enrollment numbers, we introduced a less conservative inclusion criterion of baseline LDL-C $>$ 76 mg/dL, a value 2 standard deviations above the optional goal of $<$70 mg/dL for high-risk patients in NCEP's updated guidelines [19]. Thereafter, 81% (213/263) of couples scheduled for baseline appointments were eligible and thus randomized.

Couples also may be excluded due to spouse ineligibility. The more spouse eligibility criteria that are introduced, the higher the ineligibility rate will be. We simplified our spouse exclusion criteria to the minimum necessary for participating in a telephone-delivered intervention. Consequently, of the 176 patients who became ineligible during phone screening, only 19 were in eligible because of their spouses (shown in Fig. 2).

3.5. Recruitment summary

Of the patients we identified as potentially eligible via medical records, only 15% (362/2379) were scheduled for baseline appointments. Although many individuals ended up being ineligible after additional information was obtained, it is noteworthy that over 1100 patients refused participation. Of the 362 dyads that were screened as eligible and had baseline appointments, 329 (91%) consented to participate, and of those 329, 255 (77.5%) were enrolled in the study.

4. Discussion and conclusion

4.1. Discussion

Given the wealth of literature showing the potential beneficial effect of the social context on health behaviors, and given our lack of understanding about the best way to intervene in spousal support interventions [1,4], more couples-based studies are needed. These studies present significant logistical challenges, underscoring the need to identify effective recruitment and retention strategies. We were unable to determine the distinct impact of each amendment because several amendments were implemented simultaneously. Nonetheless, we could draw some conclusions about which strategies were effective based on interactions between the study staff and participants.

One consideration for conducting couples-based studies is how to solicit participation. Recent trends in research have been to provide more rather than less information about a research study during recruitment and enrollment. However, we were more successful when we used brief recruitment materials to spark interest and then explained study procedures during the consent process.

It was also our experience that advertising to providers did not yield a great number of participants. This was not surprising given the increasing time pressures that providers face and, more importantly for this particular project, the competing quality improvement initiatives taking place at the VAMC. During the study period, three separate lipid management clinics were available for patients who needed more intensive counseling and therapy than the provider could provide. Two of these clinics did not require a referral from the provider; the clinics actually contacted patients whose recent LDL-C level was above goal and offered them an appointment. These quality improvement initiatives likely made referring patients to our research study a lower priority to providers. Of the few patients who were referred, 38% (3/8) enrolled, which is consistent with our average rate resulting from other recruitment procedures.

Another factor in recruitment is monetary compensation. Participation 'incentives' are not inherently coercive but may exert undue influence on members of vulnerable populations, and their potential to be coercive increases as the ratio of dollar amount to participation requirements increases [20–22]. Yet it is clear that monetary incentives must be offered to offset out-of-pocket costs associated with participation in trials (e.g., transportation costs, meals, child care, lost hours of productivity). The amount we offered in the early stages of the trial was insufficient for offsetting travel costs, compelling us to increase the incentive. In our opinion, the increased incentive, $40 per couple per assessment, did not exert undue incentive because, for many patients, it just covered the cost of gas and meals.

Couples may also perceive or receive non-monetary incentives for participation. In this trial, all couples received written educational materials that exceed the standard of care. In the intervention arm, patients received education and self-management strategies from the study nurse, which are likely to improve patients' health. Other possible benefits are health benefits for spouses if they adopt the same health behaviors, better communication and provision of support, and increased relationship satisfaction. These possible benefits may be communicated during the consent process.

Another issue affecting recruitment is the inconvenience or discomfort caused by study procedures. Fasting for a blood draw may be inconvenient because patients have to remember to fast and to do so according to instructions. Also, patients may experience discomfort resulting from hunger, and patients with diabetes can suffer complications from fasting and may need to adjust their medications preventatively. Although we cannot quantify the extent to which removing the fasting requirement affected our recruitment rate, we assume it was more appealing, and it improved our ability to schedule study appointments at various times of the day.

Finally, the strictness of eligibility criteria can be critical to achieving target recruitment goals. Investigators carefully choose eligibility criteria to maximize the internal validity of an intervention, and ascertaining the feasibility of implementing such criteria in the planning stages can be difficult. We conducted two pilot interventions prior to starting recruitment and still did

not foresee the difficulty we would have with recruitment. For example, we did not foresee that a facility-level intervention would make it difficult to identify patients above goal. Additionally, inferring the effectiveness of recruitment procedures can be difficult when the small sample size is small, as with pilot studies. Because patient eligibility criteria alone can impact recruitment rates significantly, spouse eligibility criteria should be minimized to the conditions that would preclude participation in a couples-based intervention.

4.2. Conclusion

As illustrated by our experience, conducting couples-based interventions for chronic disease management poses unique challenges. Ultimately, trials of recruitment strategies nested within larger trials may provide the best evidence about the effectiveness of various recruitment strategies. In the absence of such trials, investigators may need to experiment with different strategies, amending their protocol intermittently until target enrollment numbers are reached. The lessons we present may help researchers conducting couples-based interventions develop more effective protocols.

4.3. Practice implications

Consideration of these factors has many implications for the planning, design, and conduct of couples-based interventions. More staff time may be needed to accommodate the lower yield of recruitment efforts relative to patient-only studies and to accommodate assessments or study procedures that occur separately for patients and spouses [23]. Monetary incentives should account for possible increases in transportation costs as well as the possibility of patients and spouses attending appointments separately. Finally, although the non-fasting (direct) LDL-C test has the advantages of reducing patient burden and missing data due to high triglyceride levels, it is significantly costlier.

The practices that we felt enhanced recruitment – minimizing travel, increasing compensation, using non-fasting tests, and carefully crafting recruitment materials – may also enhance retention of couples. To enhance retention further, we allow patients to remain in the study and, for patients in the intervention arm, to continue to receive telephone calls even if spouses withdraw; we will analyze data according to intent-to-treat principles. Flexible scheduling is also important because study staff must accommodate two individuals' schedules. Our interventionist schedules intervention calls for weekday evenings, and our staff schedule weekend, early morning, and late evening appointments, to maximize recruitment. Also to enhance retention, in May of 2009, we amended our protocol to reduce travel burden because the average distance from patient homes to the Raleigh site, using zip codes, is 56 miles and to the Durham site is 66 miles. If scheduling patients and/or spouses for follow-up visits is difficult, we allow patients to have blood drawn for the primary outcome at a CBOC closer to their home and allow patients and spouses to return self-report measures for secondary outcomes by mail. Three patients have had blood drawn at a CBOC. Three times as many spouses as patients have returned self-report measures by mail (14 spouses vs. 5 patients for 6-month follow-up). Although this method adds a source of measurement error, the cost may be offset by the benefit of fewer missing data, particularly for spouse outcomes. When outcomes are collected from patients and spouses, multiple modes of administration may be needed, and sensitivity analyses can determine whether responses differ by mode.

The majority of clinical trials do not achieve target enrollment goals. Formal courses and other training methods often focus on design and methodology, with an emphasis on maximizing internal validity. Rarely is attention given to the logistical challenges involved in conducting trials, such as failing to meet recruitment goals, and possible solutions. We hope that the lessons learned while conducting the CouPLES trial will aid other investigators in the planning and conduct of couples-based studies.

I confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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References

[1] Martire L, Lustig A, Schulz R, Miller G, Helgeson V. Is it beneficial to involve a family member? A meta-analysis of psychosocial interventions for chronic illness. Health Psychol 2004;23(6):599–611.
[2] Tower RB, Kasl SV, Darefsky AS. Types of marital closeness and mortality risk in older couples. Psychosom Med 2002;64:644–59.
[3] Berg CA, Upchurch R. A developmental-contextual model of couples coping with chronic illness across the adult life span. Psychol Bull 2007;133:920–54.
[4] Martire L, Schulz R. Involving family in psychosocial interventions for chronic illness. Curr Dir Psychol Sci 2007;16:90–4.
[5] Kiecolt-Glaser JK, Newton TL. Marriage and health: his and hers. Psychol Bull 2001;127:472–503.
[6] Rook, Thuras, Lewis M. Social control, health risk taking, and psychological distress among the elderly. Psychol Aging 1990;5:327–34.
[7] Tucker JS, Mueller JS. Spouses' social control of health behaviors: use and effectiveness of specific strategies. Pers Soc Psychol Bull 2000;26:1120–30.
[8] Kenny D. Models of non-independence in dyadic research. J Soc Pers Relat 1996;13:279–94.
[9] Martire LM, Schulz R, Keefe FJ, Rudy TE, Starz TW. Couple-oriented education and support intervention: effects on individuals with osteoarthritis and their spouses. Rehabil Psychol 2007;52:121–32.
[10] Burke V, Giangiulio N, Gillam HF, Beilin LJ, Houghton S. Physical activity and nutrition programs for couples: a randomized controlled trial. J Clin Epidemiol 2003;56:421–32.
[11] Manne SL, Ostroff JS, Winkel G, Fox K, Grana G, Miller E, et al. Couple-focused group intervention for women with early stage breast cancer. J Consult Clin Psychol 2005;73:634–46.
[12] Northouse LL, Mood DW, Schafenacker A, Montie JE, Sandler HM, Forman JD, et al. Randomized clinical trial of a family intervention for prostate cancer patients and their spouses. Cancer 2007;110:2809–18.
[13] van Lankveld W, van Helmond T, Naring G, de Rooij DJ, van den Hoogen F. Partner participation in cognitive-behavioral self-management group treatment for patients with rheumatoid arthritis. J Rheumatol 2004;31:1738–45.
[14] Wallace JP, Raglin JS, Jastremski CA. Twelve month adherence of adults who joined a fitness program with a spouse vs without a spouse. J Sports Med Phys Fitness 1995;35:206–13.
[15] Voils CI, Yancy Jr WS, Kovac S, Coffman CJ, Weinberger M, Oddone EZ, et al. Study protocol: Couples Partnering for Lipid Enhancing Strategies (CouPLES)—a randomized, controlled trial. Trials 2009;10:10.
[16] Cohen J. Statistical power analysis for the behavioral sciences, 2nd ed., Hillsdale, NJ: Erlbaum; 1988.
[17] Friedewald WT, Levy RI, Fredrickson DS. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. Clin Chem 1972;18:499–502.
[18] Goldberg KC, Melnyk SD, Simel DL. Overcoming inertia: improvement in achieving target low-density lipoprotein cholesterol. Am J Manag Care 2007;13:530–4.

[19] Grundy SM, Cleeman JI, Merz CN, Brewer Jr HB, Clark LT, Hunninghake DB, et al. Implications of recent clinical trials for the national cholesterol education program adult treatment panel III guidelines. Circulation 2004 Jul;110(2):227–39.
[20] Dunn LB, Gordon NE. Improving informed consent and enhancing recruitment for research by understanding economic behavior. J Am Med Assoc 2005;293:609–12.
[21] Singer E, Bossarte RM. Incentives for survey participation: when are they "coercive?" Am J Prev Med 2006;31:411–8.
[22] Faden R, Beauchamp T. A history and theory of informed consent. New York: Oxford; 1986.
[23] Sadler GR, Ko CM, Malcarne VL, Banthia R, Gutierrez I, Varni JW. Costs of recruiting couples to a clinical trial. Contemp Clin Trials 2007;28: 423–32.
[24] Callahan CM, Unverzagt FW, Hui SL, et al. Six-item screener to identify cognitive impairment among potential subjects for clinical research. Med Care 2002;40:771–81.