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Reasons Related to Adherence in Community-based Field Studies

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Abstract

This study identified participants' reasons for good, marginal or poor adherence, or withdrawing from community-based clinical studies using a dietary and/or drug intervention. Adults aged 48–75 years participated in one of three studies related to decreasing colon polyp recurrence. Qualitative data from progress notes (N = 675) and end-of-study evaluations (N = 87) were coded using constant comparative analysis with 100% content validity panel agreement. Most common reasons for non-adherence were barriers such as side-effects, interference with vacation plans, unrelated illness, forgetting and competing outside stressors. Participation motivators were benefits such as altruism, medical benefits, free service and staff rapport. Findings supported the Health Behavior in Cancer Prevention model-based approach to adherence interventions and provided directions for adherence promotion in future community-based clinical studies.

Key words: Adherence; Colon cancer prevention; Community-based field studies; Study participation motivators

Introduction

Significant attrition rates over time can nullify a study. Thus, difficulty in recruitment and failure to retain participants in clinical studies are major impediments to scientific progress in minimizing the impact of cancer. In addition, selecting participants who will adhere to a recommended regimen is typically an expensive process. Attention to adherence issues is also important because poor health outcomes have been associated with non-adherence in areas such as medication, exercise and diet [1–8]. Good trial adherence has been related to participants being well informed about the nature of the trial from the start [9,10]. Patient characteristics known to be associated with participating in clinical trials (although inconsistently [11]) include perceived susceptibility, e.g. to breast cancer in breast cancer screening trials, or having precursor illness, e.g. positive cervical smear or colon polyps [12,13]. Most of the literature on participant adherence, recruitment for clinical trials and withdrawal considers sick, younger to middle-age adults [12,14]. Health

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care provider's or lay caregiver's views are more prevalent than the participants'. Since age is the single largest risk factor for cancer [15], older study participants' issues of adherence, joining and leaving studies need to be definitively addressed from their perspective. The study reported here provides information from well participants who are 50 years and over.

The initial purpose of this study was to identify participants' reasons for good, marginal or poor adherence, or for withdrawing from three community-based clinical studies with older adults. This paper provides the qualitative reasons that participants identified for adhering, not adhering, joining and discontinuing study participation. For this paper, the term adherence is used throughout, although it is recognized that a distinction exists between adherence, or the negotiated agreement between caregiver and participant on a given intervention [16] and compliance or the accomplishment of treatment goals [17].

Methodology

The data for the study in this paper were generated from the adherence portions of three ongoing colon cancer prevention clinical studies conducted in Sun City and Tucson, Arizona. All of the studies examined different but related questions by focusing on participants eating or taking a product hypothesized to prevent colon cancer. However, the specific product differed. The first study was a randomized clinical trial ($N = 95$) in which a dietary wheat bran fiber and calcium pill supplement intervention was evaluated [18–19]. The second study was a three-month fiber only intervention ($N = 17$) [18] and the third was a four-month dose-finding study ($N = 30$) using the nonsteroidal anti-inflammatory drug piroxicam [20]. A standardized adherence protocol was used in all three studies. In the context of each study, adherence-promoting field staff kept progress notes. End-of-study evaluation forms were filled out by those participants who had completed the intervention by the time this reported analysis was done. The progress notes and evaluation forms provided the data for the analysis described here.

Characteristics of the sample

Participants for all three studies were identified through gastrointestinal endoscopy unit records, pathology reports and physician referrals. Those in the fiber/calcium and piroxicam studies had a history of adenomatous colon polyp resection and were considered at increased risk of developing recurrent adenomatous polyps and/or colon cancer. Those in the fiber-only study had histories of colon resections for cancer. Age of the participants at entry ranged from 48 to 75 years.

Measures of adherence and adherence enhancement

Adherence was measured in each of the three clinical studies in ways consistent with the respective cancer prevention intervention. Adherence rates were measured by a count of unused boxes of cereal, participants' self-reports of the number of boxes of fiber cereal consumed and/or a blister-pack count of piroxicam or calcium pills consumed. Mean adherence rates for the fiber/calcium study were 93.3% (S.D. = 7.8); for the piroxicam study, 97.4% (S.D. = 0.08); and for the fiber only study, 97.6% (S.D. = 7.9).

The Health Behavior in Cancer Prevention model (HBCP), based on the Health Belief Model [21], guided the adherence promotion. Model variables include participants' knowledge about cancer, social support, perceived health status, perceived barriers and/or benefits for study participation, ability to do what was required in the study (self-efficacy), values about health, attitudes about who is responsible for self health-maintenance (locus of control) and satisfaction with the research team/care providers [22–30]. All participants received the general adherence enhancers such as periodic newsletters. The newsletter topics

and timing were based on Model-predicted concerns or behaviors [31]. For example, early in the studies, participants needed to know the most convenient, pleasant ways to take their supplements, so early newsletter issues contained recipes and strategies for consuming the required volume of fiber. Then, after the novelty of the study had time to wear off, the sixth month issue of the newsletter contained information about how social support helps to maintain motivation and how to get social support. In addition, the Model variables were measured in the Health Behavior Questionnaire (HBQ) [32] which assessed participants' baseline and subsequent levels of the various factors which were in the Model as expected effectors of adherence. Participants' responses to the HBQ were summarized into a Health Behavior Profile which was used to plan interventions when a participant became a marginal or poor adherer [33,34]. For example, once physical toxicity was ruled out, if a participant's adherence was poor for the previous month and his or her Health Behavior Profile indicated a high score on perceived barriers, the intervener initiated discussion of possible barriers. Solutions would be suggested to the participant and once a plan was mutually negotiated, a behavioral contract was signed.

Qualitative data collection procedure

Progress notes were prepared by the on-site study interveners from interviews they conducted with participants at each scheduled monthly or bi-monthly clinic visit. These notes were recorded after each visit and included adherence scores, comments offered by the participant and descriptions of any counseling interventions they did to enhance adherence. From the beginning of the studies, the interveners were asked to document both their interventions and participant comments which were relevant to the study. The interveners were aware that the data would be reviewed later for clues about changes needed in the study protocol. At the end of each participant's involvement in the study, a 10–15-minute telephone project evaluation interview was conducted by a project staff member who was not the participant's intervener and usually was not even in the same research clinic site as the participant. This arrangement for anonymity of responses and candor was explained to the participants at their last visit. The interview was done using semi-structured questions regarding the participant's experiences while on-study, e.g. difficulty the participants may have had with the various study forms, their suggestions for improving forms. These questions were followed by an unstructured question requesting additional comments the participants might have. Qualitative data from both the unstructured question on the end-of-study project evaluation and the on-site monthly progress notes in the participants' charts were used for the analysis reported here.

The primary reasons for obtaining the qualitative data used here were to: (1) validate whether specific variables identified in the HBCP were actually applicable to cancer prevention studies, especially for respondents over 50 years of age; (2) determine if the Health Behavior Questionnaire was measuring the actual reasons that participants gave for adherence, non-adherence or for withdrawing from the study; and (3) evaluate the effectiveness of adherence enhancement strategies early enough in the project to make changes, if necessary.

Data analysis strategies

The eighty-seven available end-of-study evaluations and 675 progress notes were analyzed. Not all of the progress notes or end-of-study evaluations contained qualitative information about the topics of interest; however, all relevant available data were used in the analysis. The comprehensiveness of the content was enhanced by using multiple alternate data sources from among the three levels of good, marginal and poor adherers as well as study dropouts.

Even though adherence rates were high

overall, in anticipation of longer field trials in which adherence problems would be more challenging, attention was focused on non-adherence first. In the initial analysis of data the intent was to find reasons the respondents gave for adhering less than 100% of the time.

A focus group technique with the on-site project interveners was used to initially generate the non-adherence coding categories for the qualitative data on non-adherence [35]. Two of the co-authors then separately coded the data using constant comparative analysis [36]. The coders read each data statement and classified it according to the coding categories. To assess interrater reliability, the percent of agreement on data bits assigned to the same category was calculated. On the first round of review, 95% agreement was achieved; 100% agreement was achieved after discussing category definitions.

Qualitative data analysis emphasizes theoretical data sampling in an unstructured format [36]. The number of times a specific category was identified by participants was noted. However, the purpose was not to obtain statistical distributions of reasons for adherence or non-adherence, but rather to be sure that the spectrum of reasons was actually included in the HBCP model. Usually, a participant needs only one or two reasons to decrease participation or go off study. The reasons differ from person to person and to be useful, the Health Behavior Profile, which was developed to measure factors related to adherence, needs to be sensitive to the spectrum of reasons. Since the unit of data analysis was a document (progress notes or off-study evaluations), more than one reason could have been provided by a single participant and many participants provided no reasons. As the data were being analyzed for non-adherence, some reasons for adherence, joining the study and staying on were also noted as comments in the qualitative data. These comments were grouped into categories which emerged in the coding process. In the last step of data analysis, the inductively generated qualitative categories were compared with the HBCP model variables. The presence of any additional variables was also evaluated.

Findings

Reasons for Adherence, Recruitment and Retention

In terms of reasons for adherence (Table 1), benefits to future generations were indicated with comments such as: 'By helping with research, I might help my grandchildren,' and, 'It probably won't help me but it may benefit my children.' Medical benefits to self included receiving information about self, possible detection of other problems, improved bowel regularity, early harvesting of potentially lethal polyps, improved mobility and decreased risk of cancer. Examples of participants' comments indicating perceived medical benefits were: 'With all these blood tests, it gives me a lot of information on what might be wrong.'; 'This fiber really cleared up my nodular bowel movements...I am really happy about that.' All of the study participants had had either adenomatous polyps or colon cancer surgically removed and having a precursor illness is related to study participation [12]. The data reported here corroborate Stacy's [37] finding that perceived susceptibility among older participants was related to adherence, smoking cessation in their case. Monetary benefits, such as free cereal, lab work and compensation upon completion, were indicated by comments such as: 'It is really nice to get this cereal because cereal is so expensive.'; 'The few dollars would help with my social security check.'; and, 'I'm drawing unemployment anyway...this will help.' Consistent with the HBCP model, perceived benefits were the major reason for adherence.

Also of interest were the spontaneously offered reasons for willingness to start and continue study participation. Comparing the reasons given with the HBCP Model showed

Table 1. Practical Implications: Reasons related to willingness to start, willingness to continue in study and reasons for adherence

Reasons for willingness to start study	**Model variable**
Opportunity to socialize	Social support
Altruism	Benefit
Alternative to colonoscopy	Benefit
Interested in CA research	Benefit
Monetary compensation	Benefit
Thought it would be fun	Benefit
Benefit to health	Benefit
Physician recommended/suggested	Health locus of control
Reasons for willingness to continue in study	**Model variable**
Staff rapport	Satisfaction with c/p relationship
Social support aspect of visits	Social support
Knowing patient as individual	Satisfaction with c/p relationship
Individualized care re: protocol	Satisfaction with c/p relationship
Personal Commitment	None
Reasons for Adherence	**Model variable**
Benefit to society	Benefits
Medical benefits to self: information regarding self; detection of other medical problems; improved bowel regularity; early harvesting of polyps; fewer polyps; improved mobility; decrease risk of cancer	Benefits
Monetary benefits to self: free cereal; free lab work; compensation upon completion	Benefits

that the reasons for participating given by the participants supported the importance of existing variables in the Model, e.g. benefits to self and others, health locus of control, social support from staff and satisfaction with the client/provider relationship. Similar to the well participants here, ill people say they join studies to contribute to medical knowledge and to benefit others [12]. In a community study polling people's willingness to start studies (n = 576), those most likely to say they would tended to be younger adults, better educated with higher incomes, taking vitamins regularly, more enthusiastic about participating in a cancer prevention dietary trial, had a better idea of the link between diet and cancer risk and believed in the efficacy of diet to decrease cancer risk [13]. Participants in the current study were well educated with relatively high incomes, as well. The findings of Myers et al. [38] with 50–74 year olds in a fecal occult blood test trial validated the treatment efficacy prediction of Mettlin et al. [13]. One additional reason the participants in the current study cited for remaining was having made a personal commitment to stay. Commitment as a motivator for participants [39–40], including older people [41] is one basis for the goal contracting used with poor adherers in the current study.

Reasons for non-adherence

The most frequently occurring reason for non-adherence (Table 2) in the team-generated categories was perceived side effects of treatment related to the number (too many or

Table 2. Practical Implications: Reasons Related to Non-Adherence

Reason	Frequency	Model variable
A. Side Effects of Treatment	26	Barrier
1. Stools		Barrier
a. Number of stools		
Too many or too few		
b. Consistency of stools		
Too hard or too soft		
2. Intestinal Gas		Barrier
B. Vacation	10	Barrier
1. Length		Barrier
2. Inaccessibility to restrooms		Barrier
3. Paid Meals		Barrier
4. Inconvenience		Barrier
C. Change in schedule	2	Barrier
1. Major (family death/illness)		
2. Minor (house guests)		
D. Unrelated illness	10	Health status
E. Trouble remembering (forgetting)	7	Barrier
F. Various characteristics of protocol	7	Barrier
1. Completing the Health Behavior Questionnaire		
Repeated measures and/or redundant questions		
2. Painful procedures		
3. Protocol letter for marginal/ low compliers		
4. Stool collection and/or storage		
5. Treatment		
Cereal characteristics		
bulk (so much to eat);		
form; taste; texture		
6. Too much trouble (in general)		
G. Needing 'time off' (e.g. weekends & holidays)	4	Barrier
H. Other medical procedures interfering with protocol	2	Health status
I. Feelings of 'being exploited'	1	Satisfaction with client/ provider relationship

too few) and consistency (too hard or too soft) of stools or flatus. The difficulty of adhering when side effects are present can, perhaps, be best understood by the following comments from participants: 'I was working full time in a facility with no restroom...'; 'The gas was pretty embarrassing when I visited my friends.'; and, 'I cut down on my calcium because I got so constipated.'

Having the protocol as simple as possible [14] and specifically tailored for the participant is recommended for prevention studies, e.g. the cholesterol-lowering intervention among men in the Multiple Risk Factor Intervention Trial (MRFIT) who were at high cardiovascular risk [39,42,43]. A specific vacation protocol was used in the current study, e.g. to facilitate receiving the fiber supplement or returning the study forms in a timely fashion. Nevertheless, vacations and unrelated illnesses were the second most com-

mon reasons for non-adherence. Adherence to the protocol was viewed by some as costly, inconvenient, or simply not a priority to remember during a trip. Comments on this issue included: 'I paid all this money to go on a cruise and decided not to eat my fiber (since all meals were prepaid),' 'We were traveling by car, 3000 miles across country and I couldn't find a bathroom often enough (with having 4 bowel movements a day),' and, 'I forgot to pack capsules for my fishing trip out of the country.' Unrelated illness as a reason for non-adherence was noted when, for example, one participant decided to stop taking the piroxicam when his physician prescribed prednisone to alleviate arthritis symptoms. Similarly, having another chronic disease was associated with withdrawal from studies targeted at primary prevention of coronary artery disease [12].

A major change in schedule also contributed to non-adherence. For example, one participant had difficulty remembering to take the pills during a stressful time involving finding a nursing home for her parent. Other participants decided they needed some 'time off' from following the protocol as indicated by the following comment: 'I decided to have a good breakfast on weekends so I didn't eat my fiber.' Others occasionally simply forgot to take the pills or fiber.

Additional reasons for non-adherence had to do with the protocol itself; e.g. characteristics of the cereal in the fiber studies including form, texture, bulk and taste. As stated by one participant, 'The stuff tastes like cardboard and I am not going to eat it.' Other barriers to participation included inconvenience of stool collection and storage, uncomfortable colon examination procedures, completing similar questionnaires several times during the trial, receiving a letter encouraging them to eat more fiber, or too much trouble in general. A feeling of being exploited was indicated by one participant.

When comparing the reasons for non-adherence with the HBCP model, barriers were the most frequently occurring variable of non-adherence. Other variables represented by the reason for non-adherence were issues of satisfaction with the client/provider relationship and health status.

Summary and Recommendations

The qualitative findings reported here identify reasons cited by older participants for poor adherence and going on and off community-based chemoprevention field studies. Key reasons for non-adherence were predominately physical side-effects, but also interruption in lifestyle while on vacation, unrelated illness, forgetting, competing outside stressors and the need for a break. Motivators for adherence were predominately psychosocial. In terms of benefits, the motivators included the altruistic helping of future generations, medical benefits to self and monetary support (e.g. free fiber food and lab tests). Motivators for initial study participation included many of the same reasons provided for staying on study. In addition, satisfaction with relationships with the staff in terms of rapport and receiving individualized attention were important. The need for psychosocial motivators to balance physical inconveniences is clear. For the most part, the 'reasons' given by study participants are part of the HBCP Model and its adherence strategy.

Based on the adherence procedures used and the findings of the three studies, the following recommendations are offered to enhance adherence in short or long term chemoprevention clinical studies:

1. Develop materials that are clear, interesting, easily used in field settings and adaptable to similar projects. All participant support materials should be developed in relation to the theoretical model. Also, all information elicited from the participants and interveners should be considered.

2. Prior to initiating the study, develop and pilot test all protocols. This should be done to assess potential barriers to participation so strategies to combat any barriers can be developed. Such barriers include side effects, vacations, participants' inconsistent motivation and adherence criteria for remaining on study.
3. Plan adherence enhancement strategies, such as newsletters, recipes (where appropriate), follow-up phone calls, appointment reminders and information which highlight the benefits of participation in that particular study.
4. Train personnel in the implementation of these adherence enhancement strategies, so each study participant has the professional support needed to complete the study.
5. As a cross-check, obtain both qualitative and quantitative data to monitor reliability and validity.

Prevention of cancer is a major challenge to cancer scientists. Careful attention to recruitment, adherence and attrition is vital to maximize investigators' efforts in conducting sound clinical trials.

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