

BCC PROJECT STATUS REPORT SUMMARY — January, 2001

Site Name	(Co-)Principal Investigator(s)	Project Manager(s)/ Coordinator(s)	Sample Size	% Recruited	Intervention Start Date	Intervention Length	Recruitment Challenges To-Date
Cornell University	Dr. Mary Charlson	Candace Young	660	84.00	October, 1999	2 years	<ul style="list-style-type: none"> We have ambitious enrollment (660 patients). <i>Solution:</i> It helped to prorate the total number into weekly goals of 9-10 patients per week so this number did not seem so formidable. The other strategy: persistence, persistence.
Emory University	Ken Resnicow	Dhana Blissett/ Alice Jackson	1,000	30.00	?	1 year	<ul style="list-style-type: none"> Getting our 24-hour recalls completed Blood work
Harvard School of Public Health	Karen Peterson	Rachel Levine	700	0.00	2001	2 years	<ul style="list-style-type: none"> We are recruiting women from 3 different health centers in Boston, but have only one main data collector in that area. We therefore need to structure recruitment so that we can maximize the data collector's time at each of the health centers and prevent her from having to run back and forth between centers. <i>Solution:</i> In response to this concern, the health centers have reserved specific blocks of time for postpartum health center visits, thereby allowing the data collector to spend an entire day at each health center. We have also hired and trained back-up data collectors who can interview women when there are two participants who need to be interviewed simultaneously.

Site Name (cont'd/...)	Intervention Challenges To-Date	Cross-Site Discussion Topics
Cornell University	<ul style="list-style-type: none">• It has been a challenge to ensure standardization of the intervention among the four staff members.• <i>Solution:</i> We addressed this by developing intervention scripts and protocols; conducting group staff training; and holding weekly meetings to share experiences and foster communication between staff members. We also invited Dr. Ken Resnicow to present a 2-day training in philosophy and practice of motivational interviewing.	
Emory University	<ul style="list-style-type: none">• Hard to reach participants with no phone.	<ul style="list-style-type: none">• Review the dietary instrument validation study.
Harvard School of Public Health	N/A	<ul style="list-style-type: none">• In terms of gaining and retaining participants, is it more effective to provide them with tangible incentives, such as gifts and/or money, or is it more effective to develop a strong relationship between participants and the study staff and to convey the idea that their participation is important because it contributes to the development of a health program?

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Illinois Institute of Technology	Tamara Goldman-Sher	Jennifer Tennant	160	10.00	2001	18 sessions	<ul style="list-style-type: none"> We have had a major staff turnover due to job changes and pregnancies. <ul style="list-style-type: none"> <i>Solution:</i> We are adding an additional site to our recruitment strategies and hiring new personnel as a result.
Kansas State University	Davis Dzewaltowski	Jennie Hill	16 (schools)	100.00	August, 2000	2 years	<ul style="list-style-type: none"> Recruiting schools took longer than expected.
The Miriam Hospital/ Brown University	Belinda Borrelli	Susan McNamara (Senior R.A.)	288	0.00	January, 2001	2 months	<ul style="list-style-type: none"> We are having problems recruiting and retaining the nurses who are the intervention providers. We trained the nurses, and then several dropped out of the study (reasons unrelated to study). <ul style="list-style-type: none"> <i>Solution:</i> We are still training new nurses and are testing their skill acquisition by listening to the audio tapes of the nurse conducting the intervention with a pilot subject in the field. Our subject population is low-income and ethnically diverse, and many of them work. We have to schedule appointments in the evening (which broaches safety issues for staff). There is a high rate of no-show (we go to their homes for a scheduled appointment and they are not home).

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Illinois Institute of Technology	<ul style="list-style-type: none">• The actual intervention has been received very well in the pilot study.• We had some minor changes to make in our treatment manual as a result of pilot investigation feedback.<ul style="list-style-type: none">• <i>Solution:</i> These changes have been made and we have received feedback that we have a top-rated manual/intervention.• Full-scale intervention begins next week.	<ul style="list-style-type: none">• Marketing of progress and results; media coverage.• Best way to share results across sites.
Kansas State University	<ul style="list-style-type: none">• Our intervention involves collaboration with middle schools. The challenges are too numerous to list.<ul style="list-style-type: none">• <i>Solution:</i> In general the solution has been to allow the schools to have input in all phases of the project.	
The Miriam Hospital/ Brown University	<ul style="list-style-type: none">• Turn-around time for ETS feedback reports. (We FedEx to Univ. of California at Berkely and they e-mail us the results.)<ul style="list-style-type: none">• <i>Solution:</i> Will be meeting with them shortly to see if they can expedite the process.• We thought there would be a problem with keeping the two treatments distinct, but the nurses seem to have a good grasp of the treatment differences.	<ul style="list-style-type: none">• The statistical speaker is a welcome addition.• Tracking subjects who otherwise would be lost to follow-up. (Are there new and nifty ways to find people?)

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Oregon Health Sciences University	Diane Elliot	Rosemary Johnson	700 fire-fighters; 36 stations	100.00 (recruited) 29.00 (tested)	October, 2000	2 years	<ul style="list-style-type: none"> • Fire fighters opting not to participate in the study. Some possible reasons include concerns about testing and confidentiality. • <i>Solution:</i> We have developed flyers and videos to increase program awareness and participation. We also visit individual fire stations to promote the PHLAME program and answer any questions.
Oregon Research Institute	Deborah Toobert	Deborah Toobert; Lisa Strycker; Katie Geiser	250	100.00	July, 2000	2 years for each wave	<ul style="list-style-type: none"> • It was difficult to get physicians on the telephone in order to sign their practice up to refer participants to the study. This has been resolved but it was very time consuming and difficult.
Stanford University	Abby King	Cynthia Castro	225	30.00	June, 2000	18 months	<ul style="list-style-type: none"> • No major recruitment problems — we are ahead of schedule! Main reasons for exclusion are: <ol style="list-style-type: none"> 1. persons too physically active already; 2. have medical problems/complications that prohibit unsupervised exercise. • One problematic issue: People come to our study really interested in an active exercise program; the idea of an attention-control condition that doesn't focus on exercise is not appealing to some.

Site Name (cont'd/...)	Intervention Challenges To-Date	Cross-Site Discussion Topics
Oregon Health Sciences University	<ul style="list-style-type: none"> • Due to the work structure of fire departments, there have been transfers of firefighters between stations and study groups. <ul style="list-style-type: none"> • <i>Solution:</i> We have been working closely with the fire bureau to track transfers. • Firefighters work schedule has been a challenge to work around because they are only on every third day. Their busy work schedule also makes it a challenge to hold intervention sessions. <ul style="list-style-type: none"> • <i>Solution:</i> We have been flexible in our ability to work around their schedules. 	<ul style="list-style-type: none"> • Data management • Show and tell of instruments • Presentation of ongoing funding opportunities (esp. involving MI) • What is planned for the BCC two years into the future when interventions have wrapped up • Demonstrations of methods (i.e., computer feedback, MI, etc.)
Oregon Research Institute	<ul style="list-style-type: none"> • Attrition not resolved. 	<ul style="list-style-type: none"> • Subject retention. • Minority recruitment (not relevant to this project any more, but is of interest to us in general coming from the Pacific Northwest where there are few minorities).
Stanford University	<ul style="list-style-type: none"> • Problem #1: Not-so-smooth operation of computer-based exercise counseling system <ul style="list-style-type: none"> • <i>Solution:</i> Ongoing, bi-weekly status reports between sites & staff; daily communication between sites to troubleshoot. • Problem #2: Participants not responding; hard-to-reach. • <i>Solution:</i> Tracking system to log attempts; different callers and methods of contact; persistence! 	<ul style="list-style-type: none"> • What is the best way to pitch a control condition to prospective participants? Try to dress it up as it's own special program, or be up-front and honest about the scientific need for a control condition?

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University of Maryland	Barbara Resnick	Denise Orwig	240	8.00	July, 2000	12 months	<ul style="list-style-type: none"> We have had some challenges in working with a variety of hospital IRB boards with a current fear of breaking patient confidentiality. <i>Solution:</i> We have been able to negotiate some systems in some facilities that meet everyone's needs. In one facility we had to pull out because we could not adhere to our protocol and do what they wanted us to do to recruit participants.
University of Michigan	Vic Strecher	Holly Derry	2,700	0.00	March, 2001	4 months plus 12-month follow-up	N/A
University of Minnesota	Bob Jeffery; Alex Rothman	Christie King	600	100.00	October, 1999	1 year	<ul style="list-style-type: none"> We had difficulty getting enough smokers to enroll. <i>Solution:</i> We reached our goals by advertising longer and more widely for additional waves of treatment.

Site Name (cont'd/...)	Intervention Challenges To-Date	Cross-Site Discussion Topics
University of Maryland	<ul style="list-style-type: none"> • We continue to have challenges in recruitment. The eligibility criteria are rigorous and then the individuals, many of whom have no interest in exercising and feel they are too frail or too busy to do so, have to consent to a year-long program. <ul style="list-style-type: none"> • <i>Solution:</i> Our research nurses are actively involved in 4 hospitals and we are going into a 5th to continue to recruit eligible women post hip fracture. • We have had some challenges in hiring and keeping exercise trainers. We taught several interested individuals the program and then life situations occurred such that they were no longer able to work with us. <ul style="list-style-type: none"> • <i>Solution:</i> We have met some challenges in that we must bring supplies for the exercise intervention into a variety of places and some are less geared to having a stairstepper (which we give to each participant) in their homes or facilities. We have worked with facilities in some cases to store the stairstepper. We are planning to begin a series of observational sessions with the trainers to make sure that the intervention is being implemented as devised (both the exercise and the motivational component). 	<ul style="list-style-type: none"> • Motivating individuals to consent to an exercise intervention study — the pre-intervention intervention. • Treatment fidelity will continue to be of interest to all groups. • Retention of participants might be appropriate as we get further along in the studies. • Data management and analysis.
University of Michigan	N/A	
University of Minnesota	<ul style="list-style-type: none"> • We had difficulty getting smokers to complete their diary homework. <ul style="list-style-type: none"> • <i>Solution:</i> This was improved by emphasizing in treatment how important the homework was to success. 	

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University of Rhode Island	Phil Clark	Claudio Nigg	1,300	50.00	July, 2000	12 months	<ul style="list-style-type: none"> • How to get the unmotivated to join. <ul style="list-style-type: none"> • <i>Solution:</i> We are now using a second wave of advertising along with proactive recruitment, i.e., direct mailings coinciding with an ad campaign which will be followed by direct recruitment calls if needed.
University of Tennessee	Robert Garrison	Mace Coday	360	66.00	February, 2000	24 months	<ul style="list-style-type: none"> • Interfacing study staff and community agencies staff (e.g., three general medical clinics and Hope and Healing Center). <ul style="list-style-type: none"> • <i>Solution:</i> to keep study staff as visible as possible at all 4 locations; share information that we are collecting with agency staff to keep them in the loop; hold periodic lunches at their office to keep staff informed and to keep referral awareness up for the doctors. • Keeping pace up during down times such as holiday months (e.g., Nov/Dec). <ul style="list-style-type: none"> • <i>Solution:</i> Increase volume in Jan/Feb to compensate. • Getting high enough volume of interested screeners. <ul style="list-style-type: none"> • <i>Solution:</i> to do direct mailings to Hope and Healing members every 3-4 months.

Site Name (cont'd/...)	Intervention Challenges To-Date	Cross-Site Discussion Topics
University of Rhode Island	<ul style="list-style-type: none">• A few individuals have asked to receive materials not from their assigned group.• <i>Solution:</i> We told them that we would supply them with the information at the conclusion of the study.	<ul style="list-style-type: none">• Maximizing retention• Longitudinal data analysis techniques• Workgroup publications
University of Tennessee	<ul style="list-style-type: none">• Staff from study interfacing with staff from H&H.<ul style="list-style-type: none">• <i>Solution:</i> To maintain consistency and friendly demeanor no matter what changes going on at H&H.• Participants feeling guilty if not doing physical activity and therefore not wanting to show their face for follow up visits.<ul style="list-style-type: none">• <i>Solution:</i> To role-play with staff how to talk to participants to break down these barriers; to initiate an incentive program in 2001.• Maintaining level of desired intervention contacts using paper only. In process of planning an intervention tracking system that is electronic.	<ul style="list-style-type: none">• Maintaining "the blind" issues.• Use of computerized tracking systems both for measurement data and for intervention contacts/retention information on participants.

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University of Rochester	Geoffrey Williams	Chantal Levesque	1,000	36.00	December, 1999	6 months	<ul style="list-style-type: none"> The major challenge we face is to be able to bring participants into the study, i.e, come for their first visit. On average, only about 40% of participants who schedule a first appointment actually show up and get randomized into the study. <ul style="list-style-type: none"> <i>Solution:</i> In order to reduce the barriers that potential participants face to get into the study, we required less (sometimes none) preliminary blood tests; we modified our script in several ways in order to make potential participants realize the importance of the first visit and hence motivate them to show up for their first appointment. We are still looking for ways to increase the number of potential participants that call our office, given the available financial resources. <ul style="list-style-type: none"> <i>Solution:</i> We are now advertising in smaller newspapers, where ads are less costly. This strategy helped us get more calls of interested participants, but only about 25-30% of those scheduled for their first appointment actually came. We have just started a more aggressive advertising campaign in the newspaper consistent with other large smoking studies in the area that have successfully recruited participants.

Site Name (cont'd/...)	Intervention Challenges To-Date	Cross-Site Discussion Topics
University of Rochester	<ul style="list-style-type: none">• The major challenge here is to make sure that the intervention is delivered in a consistent manner that is uniform across all of our health counselors (4).<ul style="list-style-type: none">• <i>Solution:</i> In order to assure a high level of uniformity across our health counselors, weekly supervision sessions are conducted with the clinical supervisor of the Study. During this meeting, role-play is conducted that mimic situations that are likely to be encountered in the intervention sessions. In addition, health counselors bring tapes of their own intervention sessions for discussion with the group of counselors.• The current national guidelines for tobacco dependence have been changed, and we are expecting the NCEP to release new guidelines for cholesterol. Each of these changes affects the recruitment, randomization, and treatment recommendations for our participants.<ul style="list-style-type: none">• <i>Solution:</i> We adapted to the new guidelines for smoking and will need to assess the new cholesterol recommendations to determine how it will influence our study, before making any changes.	<ul style="list-style-type: none">• Additional ideas about recruitment and retention are always of interest.
