

Short Title: Alternate Consent Process

Testing an Alternate Informed Consent Process

Bernice C. Yates^a, RN, PhD, Associate Dean for Research
Diane Dodendorf^b, PhD, Research Psychologist
Judy Lane^a, BSN, RN, Research Assistant
Louise LaFramboise^a, PhD, RN, Associate Professor
Bunny Pozehl^c, PhD, APRN, Associate Professor
Kathleen Duncan^c, PhD, RN, Associate Professor
and Kendra Knodel^a, BSN, RN, Research Assistant

^aUniversity of Nebraska Medical Center, College of Nursing, Omaha NE

^bEglin Air Force Base Hospital, Eglin Air Force Base, FL

^cUniversity of Nebraska Medical Center, College of Nursing, Omaha NE

Email address for corresponding author:

Bernice Yates, RN, PhD, bcyates@unmc.edu

This study was funded in part by grants from the American Heart Association, Heartland Affiliate, and the Dean's Fund, College of Nursing, University of Nebraska Medical Center to the first author

MESH Key words: informed consent, recruitment

Running Head: Alternate informed consent process

The authors gratefully acknowledge Virginia Tilden for her insightful and creative ideas in developing this project and Daniel Brick for his assistance with designing the flip chart.

1 **Abstract**

2 **Background:** One of the main problems in conducting clinical trials is a low participation rate
3 due to potential participants' misunderstanding of the rationale for the clinical trial or
4 perceptions of loss of control over treatment decisions.

5 **Objectives:** The purpose of this study was to test an alternate informed consent process in
6 cardiac rehabilitation participants that involved the use of a multimedia flip chart to describe a
7 future randomized clinical trial and then asked, hypothetically, if they would participate in the
8 future trial.

9 **Method:** An attractive and inviting visual presentation of the study was created in the form of a
10 23-page flip chart that included 24 color photographs displaying information about the purpose
11 of the study, similarities and differences between the two treatment groups, and the data
12 collection process. We tested the flip chart in 35 cardiac rehabilitation participants. Subjects
13 were asked if they would participate in this future study on two occasions: immediately after the
14 description of the flip chart and 24 hours later, after reading through the informed consent
15 document. Subjects were also asked their perceptions of the flip chart and consent process.

16 **Results:** Of the 35 subjects surveyed, 19 (54%) indicated that they would participate in the
17 future study. No subject changed his/her decision 24 hours later after reading the full consent
18 form. The participation rate improved 145% over an earlier feasibility study where the
19 recruitment rate was 22%. Participants overwhelmingly stated that the flip chart was helpful and
20 informative and that the photographs were effective in communicating the purpose of the study.

21 **Discussion:** Participation rates could be enhanced in future clinical trials by using a visual
22 presentation to explain and describe the study as part of the informed consent process. More
23 research is needed to test alternate methods of obtaining informed consent.

1 **Background**

2 Feasibility or pilot studies are often the first study that is done to test a randomized
3 clinical trial to ensure that the intervention and the data collection plans are feasible and
4 achievable. One of the main problems faced in conducting clinical trials is participant
5 recruitment (Prout, Butler, Kinnersley, Robling, Hood, & Tudor-Jones, 2003). In conducting a
6 feasibility study testing an alternate method of delivering cardiac rehabilitation services, we had
7 an enrollment rate of 22%. Given this low enrollment rate, it was critical to generate strategies to
8 increase recruitment for the future larger study.

9 In a previous feasibility study conducted by the first author, the purpose of the study was
10 to generate pilot data for a larger study testing whether home-based cardiac rehabilitation was as
11 effective as traditional cardiac rehabilitation in improving functional capacity, adherence to
12 exercise and diet, quality of life, and self-efficacy for patients after myocardial infarction or
13 coronary artery bypass graft (CABG) surgery. Although 130 potential subjects were eligible over
14 a 20 month time period, only 28 (22%) participants enrolled. Stated reasons given for
15 nonparticipation included: the lack of choice over treatment decisions, perceptions that the
16 home-based program was new and of lesser quality, a lengthy consent form that made the study
17 difficult to understand, and misperceptions about cardiac rehabilitation and research.

18 Prior research has documented that the main reasons for lack of participation in
19 randomized clinical trials are that potential participants often do not understand the rationale for
20 randomized clinical trials, have poor recall of information provided during the consent process,
21 have concerns about “being a guinea pig,” and perceive loss of control over treatment decisions
22 (Brown, Butow, Ellis, Boyle & Tattersall, 2004; Flory & Emanuel, 2004; Gotay, 1991; Schain,
23 1994). These factors can hinder them from making completely informed decisions. Subject

1 understanding of the informed consent is imperative for conducting research; yet, there are many
2 barriers to obtaining adequate informed consent including: time constraints, complexity of
3 treatment protocols, reading level of the consent form, literacy of subjects, and format of the
4 consent form (Flory & Emanuel, 2004; Elder, Yamokoski, Wittmann, & Kodish, 2007; Raich,
5 Plomer, & Coyne, 2001). In one study on the use of β -blockers to prolong the lives of patients
6 with a history of myocardial infarction, only 44% were aware that they were randomly assigned
7 to either a treatment or control group (Flory & Emanuel, 2004). In another study, parents of
8 children with leukemia provided suggestions for improving informed consents. The most
9 frequent suggestion was to allow more time to make the decision to participate. Other
10 suggestions included: more information about the study, improved communication style with
11 limited jargon and more opportunities to ask questions, and breaking the informed consent
12 meeting into two time periods due to the immense amount of information (Elder et al., 2007). In
13 a systematic review of several interventions (e.g., multimedia, enhanced consent form, extended
14 discussions with subjects, and test/feedback methods) to overcome the barriers to adequate
15 informed consent, extended discussions with the participant had the greatest impact on patient
16 understanding (Flory & Emanuel, 2004).

17 The purpose of the current study, in cardiac rehabilitation participants, was to test an
18 alternate consent process that involved the use of a multimedia flip chart to present a face-to-face
19 extended discussion of the study designed to increase participation rates for a future large scale
20 randomized clinical trial. Cardiac rehabilitation participants were presented with an attractive
21 and inviting visual flip chart of the study, received the written informed consent document to
22 read at home, and 24 hours later, were asked, hypothetically, if they would participate in the
23 large scale trial immediately following the presentation and 24 hours later.

1 **Approach**

2 A non-probability survey design was used in this study. A 23-page powerpoint flip chart
3 was created for the informed consent process and was used to provide the initial description of
4 the study to potential participants (see flip chart in Appendix A). The flip chart was designed to
5 present a clear and appealing description of the purpose of study, to describe the research
6 methods, and delineate the study procedures. The flipchart consisted of 18 side-by-side colored
7 photographs comparing the similarities and differences between the two cardiac rehabilitation
8 programs (traditional [Trad-CR] vs. home-based cardiac rehabilitation [Home-CR]). The two
9 main differences in the programs were the delivery method of the cardiac rehabilitation content
10 and the location where the participant carried out the exercise program. In traditional cardiac
11 rehabilitation, patients participated in a structured program that included exercise and education
12 /counseling 3 times a week for 8 weeks at an outpatient facility. In Home-CR, there were 7
13 interactions with the CR research team staff (two in an outpatient setting and five via telephone)
14 and subjects carried out their exercise program at home. Six additional photos displayed the data
15 collection process which was the same for all participants. An additional 11 pages contained text
16 describing the study purpose and procedures. The study was reviewed and approved by the
17 university's Institutional Review Board (IRB).

18 After obtaining IRB approval, subjects were recruited from an outpatient cardiac
19 rehabilitation program (N = 35). Once individuals provided informed consent to be in this
20 simulation study, a research assistant discussed the flip chart with them in a private area in the
21 outpatient cardiac rehabilitation center. After this presentation, participants were asked their
22 opinions about the study, the flip chart, and their willingness to participate in the future study.
23 Regardless of whether the participant said yes or no to participate in the future study, all were

1 provided with the complete consent form to take home and review over the next 24 hours.
2 Participants were telephoned the next day and asked for the second time if they would
3 participate, hypothetically, in the future study that was described in the flip chart and the written
4 consent form. Subjects were asked to provide accurate and honest opinions about their
5 participation in this future study. Subjects were also asked open-ended questions about the
6 consent process and reasons and concerns about participation in the future study.

7 **Results**

8 Participants were 20 men (57%) and 15 women (43%), with an average age of 61.8 ± 9.9
9 years, Caucasian (97%), married (71%), and had a high school education or greater (94%). Only
10 one-third of the sample was employed and the median annual income was \$40,000. Immediately
11 following the presentation, 19 of the 35 participants surveyed (54%) indicated that they would
12 take part in the future study. The participation rate improved from 22% in the current feasibility
13 study to 54% in the hypothetical study, a 145% increase. In response to the flip chart,
14 participants overwhelmingly stated that it was informative, helpful, explained the study well, and
15 that the photographs were effective in communicating the purpose of the study. After being
16 given 24 hours to read through the entire consent form, no participants changed their earlier
17 decision about study participation. Comments about the consent form indicated that there was
18 too much information in the document and that it was “written in legalese.” All participants were
19 able to clearly and accurately describe the purpose of the larger study. Several participants stated
20 they appreciated hearing about the study from the flip chart first.

21 **Discussion**

22 We were able to greatly increase the participation rate for a future randomized clinical
23 trial using an attractive and engaging flip chart as a springboard for initiating the informed

1 consent process. The participation rate improved from 22% in the previously conducted study to
2 54% in the hypothetical study, a 145% increase. Participation rates did not change following a 24
3 hour delay period. Potential participants appeared to have gained a better understanding of what
4 the study was about because it presented visual images of various rehabilitation activities and
5 data collection processes. Photographs of subjects exercising, having blood drawn, or wearing a
6 nose clip and mouthpiece during cardiac stress testing, for example, allowed potential
7 participants to view others engaged in the expected activities and provided them with clearer
8 expectations of what the study entailed.

9 Incorporation of the flip chart method into the recruitment procedure is planned for a
10 future study as an initial approach to help potential subjects with the enrollment decision. Flory
11 and Emanuel (2004), in their systematic review of interventions to overcome the barriers to
12 adequate informed consent, found that spending extra time with the participant, initially, to
13 describe and discuss the study, had the largest impact on patient understanding. The flip chart
14 allowed the researchers to spend extra time with the subject to review each facet of the study, to
15 be consistent in what was presented to each potential participant, and to accurately portray the
16 similarities and differences between the two treatment groups. It also allowed the researchers to
17 provide rationale for the random assignment to groups, and to clarify misperceptions that the
18 home-based program was of lesser quality than traditional cardiac rehabilitation which was a
19 reason identified for nonparticipation in the earlier study.

20 Cardiac patients often do not understand the rationale for cardiac rehabilitation let alone
21 participation in a randomized clinical trial testing two methods of delivering cardiac
22 rehabilitation. In a qualitative study of myocardial infarction patients' beliefs about cardiac
23 rehabilitation, Cooper et al. (2005) found that 85% of patients were uncertain as to what cardiac

1 rehabilitation involved. Further, patients who did not go on to participate in cardiac rehabilitation
2 were those who did not understand the content of cardiac rehabilitation, the nature of coronary
3 heart disease, and the role of aerobic exercise in helping them regain functioning. They also
4 expressed several reasons why they thought CR was unnecessary (e.g., too unfit or embarrassed
5 to exercise with others, know what to do on my own, can use home weights, etc.). In addition,
6 potential subjects often do not understand the rationale for randomized clinical trials and have
7 poor recall of information provided during the consent process that hinders them from making
8 completely informed decisions (Brown et al., 2004). Cardiac patients often assume that the
9 surgery or coronary intervention has corrected the underlying problem and no additional
10 treatment is needed, including cardiac rehabilitation, which contrasts with cancer patients where
11 at times the new program or experimental option is the best chance for an improved quality of
12 life or survival. It is likely that participation rates would be improved in the proposed future
13 study and in other randomized clinical trials with the use of multimedia interventions as part of
14 the informed consent process to complement and enhance the informed consent document.

15 In summary, given the low participation rate (22%) in an earlier feasibility study, it was
16 critical to generate strategies to increase recruitment for the future randomized clinical trial.
17 Using an attractive and engaging flip chart to initiate the informed consent process, we found a
18 145% increase in the participation rate over the earlier feasibility study. There were limitations in
19 this study, however, including the small sample size (n=35) and primarily Caucasian sample. In
20 addition, although subjects were asked for their honest opinions, the future study was still a
21 hypothetical study for them, which made it easier to say yes. Future studies are needed to
22 examine the informed consent process including time constraints and complexity of treatment
23 protocols, potential participants' understanding of the rationale for the study concerns about

- 1 “being a guinea pig” and loss of control over treatment decisions, and format and complexity of
- 2 the informed consent document. Future studies are also needed to test alternate methods of
- 3 obtaining informed consent.

References

- Brown, R. F., Butow, P. N., Ellis, P., Boyle, F., & Tattersall, M. H. N. (2004). Seeking informed consent to cancer clinical trials: Describing current practice. *Social Science & Medicine*, *58*, 2445-2457.
- Cooper, A. F., Jackson, G., Weinman, J., & Horne, R. (2005). A qualitative study investigating patients' beliefs about cardiac rehabilitation. *Clinical Rehabilitation*, *19*, 87-96.
- Elder, M., Yamokoski, A., Wittmann, P., & Kodish, E. (2007). Improving informed consent: Suggestions from parents of children with leukemia. *Pediatrics*, *119*(4), 3849-e859.
- Flory, J. & Emanuel, E. (2004). Interventions to improve research participants' understanding in informed consent for research: A systematic review. *Journal of the American Medical Association*, *292*, 1593-1601.
- Gotay, C. C. (1991). Accrual to cancer clinical trials: directions from the research literature. *Social Science & Medicine*, *33*(5), 569-577.
- Prout, H., Butler, C., Kinnersley, P., Robling, M., Hood, K., & Tudor-Jones, R. (2003). A qualitative evaluation of implementing a randomized controlled trial in general practice. *Family Practice*, *20*, 675-681.
- Raich, P., Plomer, K., & Coyne, C. (2001). Literacy, comprehension, and informed consent in clinical research. *Cancer Investigations*, *19*(4), 437-445.
- Schain, W. S. (1994). Barriers to clinical trials. Part II: Knowledge and attitudes of potential participants. *Cancer*, *74*(9 Suppl.), 2666-2671.

Figure 1.

Selected Excerpts from the Flip Chart

<h3>CARDIAC REHABILITATION STUDY</h3> <ul style="list-style-type: none">• The purpose of the study is to compare two different methods of delivering cardiac rehabilitation through:<ul style="list-style-type: none">■ traditional outpatient program■ home-based program including two outpatient visits and five follow-up phone calls   <p>1</p>	<h3>WHAT DO BOTH GROUPS GET?</h3> <p><u>The full 8-week cardiac rehab program will be provided to participants in both groups</u></p> <p>The difference is the delivery method and where the participant carries out the exercise program (traditional vs. home setting)</p> <p>2</p>								
<h3>RISK FACTOR, DIET AND EXERCISE COUNSELING</h3> <table border="0"><tr><td data-bbox="217 852 358 873"><h4>TRADITIONAL</h4></td><td data-bbox="496 852 630 873"><h4>HOME-BASED</h4></td></tr><tr><td></td><td></td></tr></table> <p>Participants in both groups will engage in counseling about risk factors, dietary, and exercise changes needed in lifestyle.</p> <p>3</p>	<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>			<h3>HEART RATE MONITORING</h3> <table border="0"><tr><td data-bbox="773 852 924 873"><h4>TRADITIONAL</h4></td><td data-bbox="1045 852 1195 873"><h4>HOME-BASED</h4></td></tr><tr><td></td><td></td></tr></table> <p>Regardless of which group you are in, you will monitor your heart rate to know if you are exercising at the right pace.</p> <p>4</p>	<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>	 	 
<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>								
									
<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>								
 	 								
<h3>EXERCISE ENVIRONMENT</h3> <table border="0"><tr><td data-bbox="220 1304 358 1325"><h4>TRADITIONAL</h4></td><td data-bbox="496 1304 630 1325"><h4>HOME-BASED</h4></td></tr><tr><td></td><td></td></tr></table> <p>Participants in traditional rehab will exercise at a cardiac rehab center near where you live.</p> <p>Participants in home-based rehab will exercise at the location of their choice.</p> <p>5</p>	<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>							
<h4>TRADITIONAL</h4>	<h4>HOME-BASED</h4>								
									

EXERCISE ROUTINE

TRADITIONAL

HOME-BASED

- ◉ **Fixed Schedule**
 - Exercise 3 times a week at rehab center for 8 weeks and 2 times a week on your own
 - Exercise at the same time every week
 - Cardiac Rehab hours are: Monday - Friday, 6:30 AM to 2:15 PM
- ◉ **Flexible Schedule**
 - Exercise 5 times a week for 8 weeks on your own
 - Exercise when it's convenient for you, your family, and your work schedule

6

DATA COLLECTION

- ◉ For both groups, testing is done before and after the cardiac rehab program and at 6 and 12 months. Testing includes:
 - Questionnaires about diet, physical activity, smoking, confidence to change behaviors, and quality of life
 - Blood tests
 - Cardiopulmonary exercise test
 - Activity monitor

7

QUESTIONNAIRES AND BLOOD TESTS



Completion of questionnaires can be done at home and brought in at the time of the exercise test. A lab tech will take a blood sample. We are testing for blood fats, liver enzymes, and cotinine.

8

EXERCISE TESTING



The exercise test measures functional status; that is, how much work you can do.

9

NOW IT IS YOUR CHOICE

- ◉ We encourage you to join our study but before you do that:
 - Read the consent form and review it with your family
 - Discuss any questions you might have about the study with the researchers

10