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Group Recruitment to Improve Clinical Study Enrollment and Retention

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Obtaining informed consent is an essential step in enrolling patients in clinical research studies. Traditionally, informed consent is obtained individually, person by person. Despite this time-consuming, personalized process, studies of informed consent consistently report low levels of comprehension.

A modified process, "group recruitment," offers the potential to improve comprehension, reduce the time required by study personnel, and also increase study participant engagement and retention. The benefits of group recruitment derive from three features: First, because information is presented to a group, it is feasible to present more information than can, as a practical matter, be presented individually. Second, during the group process, individuals share questions and concerns, helping patients feel more confident of a decision to participate. Third, patients bond with the group, so they feel more engaged in the study and are more likely to continue to the end.

Background

The concept and benefits of group recruitment have been previously explored. Menon and colleagues used group meetings to recruit over 200,000 women to participate in a study on ovarian cancer screening. Approximately 25% of women invited to the group meetings believed they were eligible and accepted the invitation; 75% of those attended the appointment they were given. Overall, trial centers recruited 96% of their weekly target of 100 women. Full recruitment was achieved in about four years.[1]

Monson and colleagues used group recruitment meetings for a clinical trial of acupuncture for radiation-induced xerostomia. Approximately 92% of the 149 patients attending a meeting enrolled in the study. Most patients (72%) indicated that the meeting was very helpful in understanding the trial. Very few patients reported that the group setting was uncomfortable; 71% said it was "not at all" uncomfortable. Only three patients reported feeling any pressure to join the trial.[2]

Cox Medical Centers decided to pilot a group process and compare it to a traditional individual process in a clinical trial investigating whether low-dose methotrexate reduces heart attacks, strokes or death in people with Type 2 diabetes or metabolic syndrome that have had a heart attack or multiple coronary blockages.

The Process

Group recruitment is more flexible than it sounds, since it allows patients to communicate privately when they prefer. The group process consists of four phases: feasibility, planning, execution and assessment.

1. Feasibility

A group recruitment process requires a study population large enough to justify group meetings. The patient population, or subgroups of the population, should share common characteristics. For example, Spanish speakers could have their own group. Males and females, or young and old people, might feel more comfortable in their own groups.

Adequate numbers of interested patients must be available at a given time. A group process can be used for some patients and an individual process for others.

A group process will work better if many of the patients in the group are likely to enroll. Otherwise, the group dynamic might discourage those who would otherwise enroll in an individual process. (However, the group dynamic must be watched to ensure that patients do not enroll just because everyone else is enrolling.) Thus, the site must be able to prescreen patients for medical and other factors that make them relatively likely to enroll (without discriminating against, for example, underserved populations).

The site must also have the staff, facilities and medical records systems necessary to screen patients, invite them to participate, host them in a meeting room, present the information, and hold private discussions, as needed.

2. Planning

Planning a group recruitment program requires the following materials:

- A plan that lays out the overall program, the number of group meetings, the expected numbers of invitees and attendees, the time and other costs involved, and the process for assessing and fine-tuning the program, based on interim results
- A description of the logistics of each session, including the date, time and location, which should be convenient for attendees
- A plan for the personnel that will participate in each session
- The agenda and process for each group session
- A slide deck of the educational presentation
- A copy of any letters or call scripts that will be used to invite patients to a group session
- A copy of the acknowledgment-of-rights form that patients must sign to attend the session
- A copy of the informed consent form
- A copy of any other materials that will be distributed before, during or after each session

Given the relative novelty of the group process, it must be explained in detail to the IRB.

3. Execution

Our process for each group recruitment session included the following steps:

Patient invitations. Invite patients with a telephone call, followed up with an introduction letter further explaining the group recruitment process and the study, along with an acknowledgement-of-rights form. Confirm their attendance by phone a week before the event.

Welcome and check-in. Welcome attendees and obtain their signed acknowledgment-of-rights form. This form states that their participation in the meeting and the clinical study is voluntary and they are under no obligations. It also states that their choice to decline participation will not affect their current medical care. The form gives patients confidence that they control what health information they share during the meeting, and that the research site will not disclose information about their health outside the meeting.

Educational talk. The principal investigator describes the study in 30 minutes, plus 15 minutes for Q&A during or after the presentation. Content includes background on the medical condition, previous research on the condition, and information on the current

clinical study. There is minimal overlap with informed consent information, i.e., this presentation covers material that study participants normally do not receive.

First break. Offer attendees three options: (a) If they are interested in the study and are comfortable with the group process, stay for informed consent. (b) If they are interested in the study but prefer an individual process, make an appointment and then leave. (c) If they are not interested in participating, leave the meeting.

Informed consent. Distribute consent forms to remaining attendees. After allowing them time to read the form, explain the material in the form, as in the traditional process, and answer any questions. Allow attendees to hold questions for private consultation later, if preferred.

Second break. Offer attendees three options: (a) If they wish to participate in the study, meet privately with the principal investigator and/or coordinator for any final questions. If they wish, they may then sign the consent form. (b) If they are potentially interested, but would like more time for consideration, leave the meeting, taking the consent form with them. Ask for their permission to follow up via phone in a week or so to assess their interest and schedule an appointment, if appropriate. (c) If they are not interested in participating, leave the meeting.

Baseline activities. If the scope of the event includes collecting any data or performing any assessments or procedures, proceed to this step, provided the study participant agrees and adequate personnel are available. Otherwise, make an appointment for the first visit.

4. Assessment

Following each group session, we asked the following questions about the event:

- Did the hour and duration of the event work well?
- Was attendance sufficient and as expected?
- Was the presentation informative, understandable and at the appropriate level of detail?
- Were attendees engaged and asking appropriate questions?
- Were the group dynamics constructive and balanced?
- Was anyone uncomfortable with the group process?

Results

Over the course of 18 months, we enrolled 14 study participants through four group recruitment events, and 10 through a traditional enrollment process. Table 1 compares the two processes.

Table 1. Results for Group vs. Individual Recruitment and Consent Processes

	Attended/ Approached*	Enrolled	Retained	Hours Required**
Group Process	17	14 (82%)	14 (100%)	9.3
Traditional Process	13*	10 (77%)	6 (60%)	15.0

* Attended a group meeting or was approached in the clinic for the traditional process

** "Hours Required" is the total number of hours required by the principal investigator and study coordinator (30%/70%, respectively), excluding planning and assessment activities.

Although the numbers are too small to measure statistical significance, the pilot project clearly indicates potential advantages for the group process.

The group recruitment process yielded a high rate of enrollment (82%), slightly higher than the percentage of patients who enrolled in the traditional process (77%). Retention with the group process (100%) was significantly higher than retention with the traditional process (60%).

The combined investigator and coordinator time required to enroll all study participants with the group process (9.3 hours) was significantly lower than the time required to enroll all study participants with the traditional process (15.0 hours). While the group process included 30 to 45 additional minutes for the educational talk, that activity and the informed consent explanation was shared by all patients in the meeting.

The combined investigator and coordinator time required to enroll and *retain* a study participant with the group process (40 minutes) was even more significantly lower than the time required to enroll and *retain* a study participant with the traditional process (150 minutes).

Patients attending the group recruitment meetings were likely better educated after the meeting about their illness, previous studies, and the current clinical study than patients in the traditional process. Patients in the group process had the advantage of hearing the educational presentation and also questions from other patients. This additional information likely created more confidence in the decision to enroll and contributed to the higher retention rate.

Study participants in the group process likely bonded with other members of their group, contributing to better engagement and retention.

The group process could have been less comfortable for patients than the traditional process, but it appears to have been *more* comfortable. No one during any of the group meetings asked for private office visits to consent. (Nor did they need additional time to consider enrolling; they all either enrolled or declined at the meeting.)

The group process may have selected for patients who were more likely to be good study participants, since they were willing to invest the time in the group meeting to learn about their disease and the study. However, there was no apparent difference between the processes in adherence.

Since the success of the pilot study, we have been looking for additional studies that would be suitable for the group process. Most do not appear suitable, but we are currently considering one that looks promising and would yield more data for evaluating the group process.

References

1. Menon U, et al. Recruitment to multicentre trials — lessons from UKCTOCS: descriptive study. BMJ 2008;337.
2. Group recruitment sessions enhance patient understanding in a small multi-centre phase III clinical trial. Monson K, Contemp Clin Trials. 2012 Mar;33(2):286-90 Epub 2011 Nov 11.

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