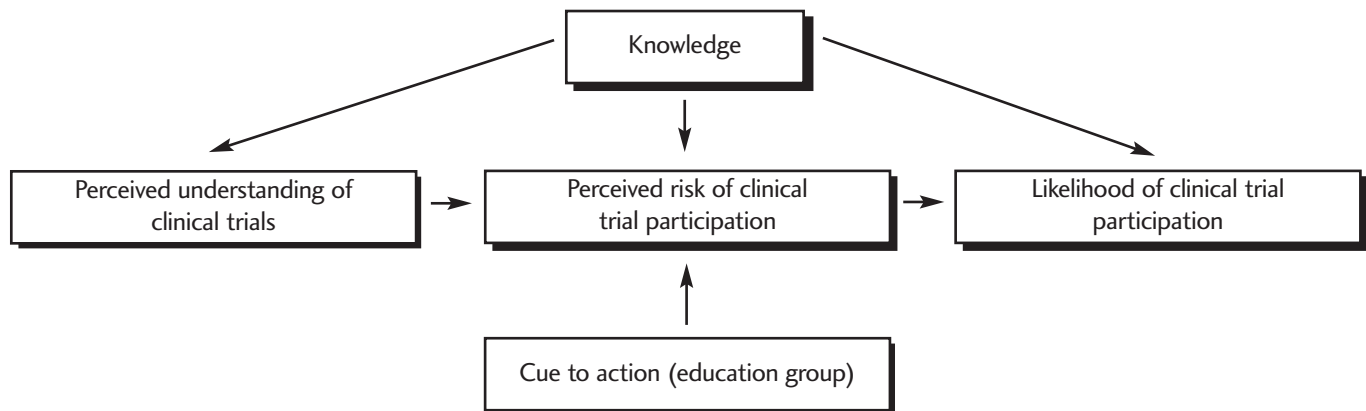# Impact of a Clinical Trials Information Handbook on Patient Knowledge, Perceptions, and Likelihood of Participation
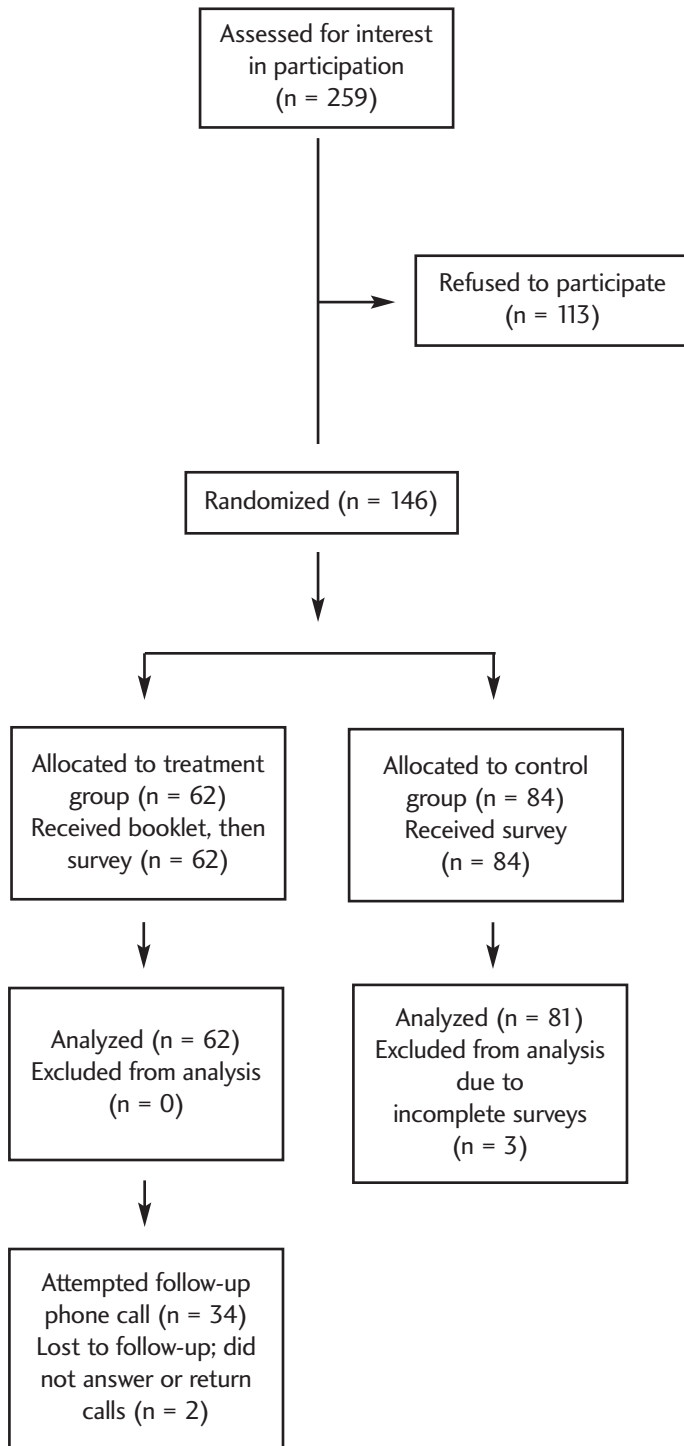
BY HEATHER M. CAMPBELL, DENNIS W. RAISCH, MIKE R. SATHER, ALISSA R. SEGAL, STUART R. WARREN, AND RUPALI NAIK

Figure 1. Theoretical Impact of a Clinical Trials Information Handbook[a]

a. We controlled for age, sex, and ethnicity in this model.

Figure 2. Study Enrollment Summary

Assessed for interest in participation (n = 259)

Refused to participate (n = 113)

Randomized (n = 146)

Allocated to treatment group (n = 62)
Received booklet, then survey (n = 62)

Allocated to control group (n = 84)
Received survey (n = 84)

Analyzed (n = 62)
Excluded from analysis (n = 0)

Analyzed (n = 81)
Excluded from analysis due to incomplete surveys (n = 3)

Attempted follow-up phone call (n = 34)
Lost to follow-up; did not answer or return calls (n = 2)

Table 3. Likelihood of Participation in Hypothetical Trials (Mean ± Standard Deviation, Median)

Question [a]	Control Group (n = 81)	Intervention Group (n = 62)	P-value [b]
If you had high blood pressure, would you participate in a clinical trial if all patients received the new drug (scenario 1)?	0.8 ± 1.4, 1.0	1.0 ± 1.3, 2.0	0.216
If you had high blood pressure, would you participate in a trial in which you would be randomly assigned to receive either the usual treatment or a new kind of drug (scenario 2)?	0.7 ± 1.4, 1.0	1.0 ± 1.3, 1.0	0.134
If you had cancer, would you participate in a trial in which the doctors gave all patients a new kind of chemotherapy (scenario 3)?	0.8 ± 1.5, 1.0	0.7 ± 1.5, 1.0	0.742
If you had cancer, would you participate in a trial if you would be assigned by chance to either the usual chemotherapy or a new kind of chemotherapy (scenario 4)?	1.0 ± 1.3, 2.0	0.6 ± 1.5, 1.0	0.215
If you had a heart disease, would you participate in a trial if you would be randomly assigned to either the usual drug or a new drug AND neither you nor the doctor would know which medication you were receiving until the study ends (scenario 5)?	0.7 ± 1.4, 1.0	0.7 ± 1.4, 1.0	0.710
If you had a chronic disease for which there was no usual treatment, such as Alzheimer's disease, would you participate in a trial in which you were randomly assigned to receive a new drug or ineffective tablets (placebo) (scenario 6)?	0.9 ± 1.4, 1.0	1.1 ± 1.3, 2.0	0.383
Overall likelihood to participate (mean of scores)	0.8 ± 1.2, 1.0	0.9 ± 1.1, 1.0	0.716

a. Probability of enrollment assessed on an ordinal scale whereby probably = +2, maybe = +1, undecided = 0, not likely = -1, highly unlikely = -2.
b. Analyzed using Mann-Whitney U tests except for overall likelihood to participate which used a Student's t-test.