

Enrolling minorities with variable literacy into clinical trials

Lessons learned from behavioral trials of African Americans

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Three small clinical trials in African Americans

Study	Setting	Goals	Design	Outcomes
PREPARED	Dialysis Units in Baltimore, MD	Educational Intervention on End Stage Kidney Disease Treatments	RCT	Pursuit of Kidney Transplant
ACT	Urban Primary Care Clinic in Baltimore, MD	Community Health Worker and Behavioral Interventions for Hypertension	RCT	Blood Pressure Control
TALKS	Transplant Center in Durham, NC	Educational and Behavioral Interventions to Improve Live Donor Kidney Transplant	RCT	Living Donor Inquires, Evaluations, Transplants

Methods

- Patient engagement before, during, and throughout study enrollment
- Iterative revision of recruitment and retention materials
 - Reading level
 - Health literacy
 - Cultural tailoring
- Follow up phone calls– in person contacts, when needed



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Study	Final N	Enrollment Numbers	Enrollment Rate	Retention Rate	Retention Rate by Arm
PREPARED	92	Screened and Eligible: 189 Declined: 54 Consented: 105	66%	80%	Arm 1: 84% Arm 2: 73% Arm 3: 84%
ACT	159	Screened and Eligible: 308 Declined: 93 Consented: 185	60%	83%	Arm 1: 83% Arm 2: 83% Arm 3: 83%
TALKS	300	Screened and eligible: 465 Declined: 106 Excluded for other reason: 147 Consented: 300	65%	87%	Arm 1: 89% Arm 2: 86% Arm 3: 87%

Literacy levels of those enrolled (37-85% limited or inadequate)

Literacy Level	PREPARED (N=92)	ACT (N=159)	TALKS (N=300)	Measure
3 rd grade and below	10 (11)		10 (3)	REALM-SF ¹
4 th -6 th grade	9 (10)		13 (4)	
7 th -8 th grade	27 (29)		89 (30)	
≥ 9 th grade	46 (50)		177 (59)	
Inadequate		77 (48)		Newest Vital Sign ²
Limited		58 (37)		
Adequate		24 (15)		

1 Davis TC, Long SW, Jackson RH, Mayeaux EJ, George RB, Crouch MA. Rapid estimate of adult literacy in medicine: a shortened screening instrument. Fam Med. 1993;25(6):391–395

2 Quick assessment of literacy in primary care: the newest vital sign. Ann Fam Med. 2005;3:514–22.

Consent Form Example: PREPARED

1. What you should know about this study :

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Please ask questions at any time about anything you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to be in the study.
- Ask your study doctor or the study team to explain any words or information in this informed consent that you do not understand.
- For clinical trials: A description of this clinical trial will be available at www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time.
- If you have clinical tests done as part of this research study, a statement will be added to your medical record that you are in this research study. Results from any clinical tests you have will be included in your medical record. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.

Recruitment Letter Example: ACT

Dear <<Title>> <<Last Name>>,

We are inviting you to join the **Achieving Blood Pressure Control Together (ACT) Study**. ACT is a research study conducted by Johns Hopkins and East Baltimore Medical Center (EBMC). In this study, we will learn more about how to help people take care of their high blood pressure.

Everyone who joins this study will get a home blood pressure cuff to keep that is worth \$100 and have a Community Health Worker to help you.

If you say yes to join this study, we will ask you to:

- Answer questions by telephone and in person.
- Meet with research staff at your home for 90 minutes.
- Take your pressure at home.
- Complete blood and urine tests.

You may also be asked to:

- Meet research staff before one visit with your EBMC doctor to learn about things you can do to get ready for your visit.

OR

- Go to a 2-hour group meeting at EBMC once a week for 8 weeks to learn about new ways to solve problems you may have with controlling your high blood pressure.

If you choose to join this study, **we will pay you from \$310 to \$535 for your time**, depending on which group you are assigned to in the study.

If you want to join this study:

- Please fill out the YELLOW form that is inside this envelope and mail it back to us. The envelope already has the address and stamp on it.
- If you do not return the yellow form in 10 days, we will call you to talk about the study.
- You can also call us at 443-287-1814 to find out more about the study.

If you do not want to join this study:

- Please check the box that states, "No I am NOT interested in participating in the study."
- If you do not join this study, your medical care at EBMC will not change in any way.

Thank you for thinking about joining this study. We hope that you will join us in helping people with high blood pressure.

Thank You,

L. Ebony Boulware, MD

About
2 out of 5
African
Americans
have high
blood
pressure*

Why ACT?

- Only about half of people treated for high blood pressure are well controlled.
- More African Americans develop high blood pressure than Whites and Mexican Americans.
- Controlling your blood pressure can lower your chances of a heart attack or stroke.

What is The ACT Study?

The Achieving Blood Pressure Control Together (ACT) Study is a research study to help people work with their doctors, families, and community to take care of their high blood pressure.

Eligible participants will be put into one of three groups by chance:

- 1. ACT Group 1**
Usual care from your doctor, a home blood pressure machine, and help from a Community Health Worker
- 2. ACT Group 2**
Usual care from your doctor, a home blood pressure machine, help from a Community Health Worker, and training to improve your doctor's visits
- 3. ACT Group 3**
Usual care from your doctor, a home blood pressure machine, help from a Community Health Worker, and free group classes to help you solve problems that get in the way of controlling your blood pressure

You have an equal chance of getting any one of the three ACT groups. You will not be able to choose the group.

You will receive a FREE home blood pressure cuff worth \$100 to keep.

You will receive from \$310 to \$535 for participation in this study.

Who Can Participate?

You may be eligible to join if you:

- Are a patient at the East Baltimore Medical Center (EBMC)
- Are at least 18 years old
- Have high blood pressure
- Are African American
- Speak English
- Are willing and able to participate in trainings or group classes
- Are able to complete interviews by phone

Two ways to contact us today:

EMAIL: actstudy@jhmi.edu

CALL: 410-502-8376



*Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, Berry JD, Borden WB, et al. Heart disease and stroke statistics—2012 update: a report from the American Heart Association. *Circulation*. 2012;125(1):e2–220.

Key Points

- Engagement of study population representatives throughout
- ‘Tailored’ recruitment, enrollment, and retention approaches
 - Literacy
 - Straightforward messaging
 - Cultural sensitivity
- Personal follow up with participants as needed

