

# Intervention IP-088: A randomized controlled trial of positive-affect intervention and medication adherence in hypertensive African Americans

## Summary

This education intervention in African Americans with hypertension evaluated whether incorporating positive-affect induction and self-affirmation was more effective in improving medication adherence, BP reduction, and controlled BP rates than education alone. Both groups received a hypertension management workbook, telephone calls every 2 months, and developed a post-intervention behavioral contract. The intervention group was also given motivational interviews and small gifts. The intervention improved medication adherence but not BP outcomes.

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## Overview

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### **Purpose of Intervention:**

To assess whether positive-affect induction and self-affirmation (PA) was more effective than patient education (PE) alone in improving medication adherence in hypertensive African Americans

### **Intervention Type:**

Research-Tested — *Interventions with strong methodological rigor that have demonstrated short-term or long-term positive effects on one or more targeted health outcomes to improve minority health and/or health disparities through quantitative measures; Studies have a control or comparison group and are published in a peer-review journal; No pilot, demonstration or feasibility studies.*

## Intervention Details

### **Intervention was Primarily Driven, Led, or Managed by:**

Academic/Clinical Researchers Only

### **Citations:**

- Ogedegbe GO, Boutin-Foster C, Wells MT, Allegrante JP, Isen AM, Jobe JB, Charlson ME. A randomized controlled trial of positive-affect intervention and medication adherence in hypertensive African Americans. *Archives of internal medicine*. 2012 Feb 27;172(4):322-6. Epub 2012 Jan 23.  
Relevance: Main Intervention, Post-Intervention Outcomes
- Boutin-Foster C, Offidani E, Kanna B, Ogedegbe G, Ravenell J, Scott E, Rodriguez A, Ramos R, Michelen W, Gerber LM, Charlson M. Results from the Trial Using Motivational Interviewing, Positive Affect, and Self-Affirmation in African Americans with Hypertension (TRIUMPH). *Ethnicity & disease*. 2016 Jan 21;26(1):51-60.  
Relevance: Post-Intervention Outcomes

### **Adaptation of Another Research-based Intervention:**

No

## Contact Information

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**Primary Contact Name:**

Dr. Gbenga Ogedegbe

**Primary Contact Affiliation:**

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**Intervention URL:**

<https://clinicaltrials.gov/study/NCT00227175>

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**Primary Contact Phone Number:**

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## Results

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**Intentions**

**Improve minority health or the health of other populations with health disparities (e.g. rural populations, populations with low SES)**

**Intervention Primary Outcome:**

The main outcome measures were medication adherence (assessed with electronic pill monitors) and within-patient change in BP from baseline to 12 months.

**Intervention Secondary Outcome:**

The secondary outcome was within-patient change in office BP from baseline to 12 months.

**Key Findings:**

Based on the intention-to-treat principle, medication adherence at 12 months was higher in the PA group than in the PE group (42% vs 36%, respectively;  $P=.049$ ). The difference, the absolute risk reduction, was 6.25%, which yields a number needed to treat of 16. This means that about 1 in every 16 patients will benefit from the treatment. The within-group reduction in systolic BP for both groups was not statistically significant (2.14 mm Hg for the PA group vs 2.18 mm Hg for the PE group;  $P=.98$ ); similarly, the within-group reduction in diastolic BP from baseline to 12 months was  $-1.59$  mm Hg for the PA group and  $-0.78$  mm Hg for the PE group ( $P=.45$ ). Therefore, the PA intervention had a significant impact on medication adherence but not on BP reduction.

**Statistical Method Used:**

Baseline clinical and demographic characteristics compared both groups with t tests or  $\chi^2$  tests, as appropriate. Adherence data were multimodal and highly skewed, we used a nonparametric Wilcoxon rank sum test to compare the mean adherence rate between both groups at 12 months. For secondary outcome, a standard 2-sample t test compared the mean within-patient change in BP from baseline to 12 months. All analyses were based on the intention-to-treat principle and analyzed with Stata version 10

## Evaluations and Assessments

Were Any of the Following Assessments Conducted (Economic Evaluation, Needs Assessment, Process Evaluation)?:

No

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## Demographic and Implementation Description

**Diseases, Disorders, or Conditions:**

Hypertension

**Race/Ethnicity:**

African American or Black

**Populations with Health Disparities:**

Racial and Ethnic Minority Populations

**Age:**

Young Adults (18 - 39 years), Middle-Aged Adults (40 - 64 years), Older Adults (65+ years)

## Socio-demographics / Population Characteristics

**Community Type:**

Urban / Inner City

**Other Populations with Health Disparities:**

Unspecified

**Geographic Location:**

New York

**Socio-Economic Status:**

Unspecified

## Minority Health and Health Disparities Research Framework

		Levels of Influence			
		Individual	Interpersonal	Community	Societal
Determinant Types	Biological				
	Behavioral	✓			
	Physical / Built Environment				
	Sociocultural Environment				
	Health Care System				

## Community Involvement

The community's role in different areas of the Intervention (Choices are "No Role", "Participation", and "Leadership"):

**Design:**

No Role

**Dissemination:**

No Role

**Evaluation:**

No Role

**Implementation:**

No Role

**Outreach:**

No Role

**Planning :**

No Role

**Recruitment:**

No Role

**Sustainability:**

No Role

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## Characteristics and Implementation

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**Intervention Focus Area:**

Behavior Change

**Disease Continuum:**

Secondary Prevention

**Delivery Setting:**

Clinic / Health Care Facility, Home

**Mode of Delivery:**

Telephone calls and mailed gifts

**Who delivered the Intervention?:**

N/A

## **Conceptual Framework**

### **Intervention Theory:**

Social Cognitive / Social Learning Theory

### **Intervention Framework:**

None

## **Implementation**

### **Intervention Study Design:**

Individual Randomized Controlled Trial/Comparative (requires random assignment, a control/comparison group, and pre and post intervention outcome assessments)

### **Targeted Intervention Sample Size:**

256

### **Actual Intervention Sample Size:**

256

### **Start Year:**

2003

### **End Year:**

2008

## **Intervention Exposures**

### **Duration of Intervention/How Long it Lasted:**

10-12 months

### **Frequency of Intervention Delivery:**

Monthly

### **Number of Sessions/Meetings/Visits/Interactions:**

More than 10 Sessions

### **Average Length of Each Session/Meeting/Visit/Interaction:**

Less than 1 Hour

### **Format of Delivery:**

Individual

### **Highest Reading Level of Intervention Materials Provided to Participants:**

Grade 6-7

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# Impact, Lessons, Components

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## Produced an impact or change beyond the primary or secondary outcome:

Not Tested

## Essential Aspects for Success:

A significant component of the intervention that we found successful was the signing of behavioral contract by the patients at the beginning of the study. The idea of the behavioral contract was to obtain patient commitment to engaging with the study staff.

## Intervention Impact:

Not available

## Lessons Learned

### Key Lessons Learned and/or Things That Could be Changed or Done Differently:

Addressing stereotype threats has a major impact on medication adherence. We found that patients know their limitations and having researchers understand those and their values is crucial for addressing medication adherence.

## Insights Gained During Implementation

Insight Category	Insight Description
Logistics	Most of the intervention components were developed by research staff outside of the primary care practices where patients received their care. The insight gained is that integration of the intervention components within practices would have led to sustainability of intervention effects
Recruitment	Key factor that drove improvement of recruitment and retention was collaboration with the patients' providers - this is important for all practice-based studies

## Intervention Components

### Intervention Has Multiple Components:

No

### Assessed Each Unique Contribution:

N/A

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# Products, Materials, and Funding

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Please contact the researcher for additional guidance or information on materials.

## Expertise, Partnerships, and Funding Sources

	Used for Implementation	Needed for Sustainability
<b>Expertise</b>		
Health Education / Health Literacy	Yes	Yes
<b>Partnerships</b>		
Health care facilities (local clinics)	Yes	Yes
<b>Funding Sources</b>		
Public funding (e.g., federal, state or local government)	Yes	Unknown

## Product/Material/Tools

	Tailored For Language	Language(s) if other than English	Material
<b>Outreach/Recruitment Tools</b>			
Baseline assessment tool	No		<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669680/#R15">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669680/#R15</a>
<b>Participant Educational Tools</b>			
hypertension workbook	No		<a href="https://pubmed.ncbi.nlm.nih.gov/9174398/">https://pubmed.ncbi.nlm.nih.gov/9174398/</a>
<b>Measurement Tools</b>			
Standardized Instrument/Measures	No		<a href="https://pubmed.ncbi.nlm.nih.gov/6668417/">https://pubmed.ncbi.nlm.nih.gov/6668417/</a>
Non-Standardized Instruments/Surveys/Questionnaires	No		<a href="https://pubmed.ncbi.nlm.nih.gov/12873646/">https://pubmed.ncbi.nlm.nih.gov/12873646/</a>
Standardized Instrument/Measures	No		<a href="https://pubmed.ncbi.nlm.nih.gov/3397865/">https://pubmed.ncbi.nlm.nih.gov/3397865/</a>
Standardized Instrument/Measures	No		<a href="https://pubmed.ncbi.nlm.nih.gov/2035047/">https://pubmed.ncbi.nlm.nih.gov/2035047/</a>

## Implementation Materials and Products

	<b>Material</b>
<b>Implementation/Delivery Materials</b>	
Guidebooks/Workbooks/Participant Manual	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669680/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669680/</a>
Gifts	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/</a>
<b>Implementation/Output Materials</b>	
Best Practice Guidelines	<a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/</a>

## **Articles Related to Submitted Intervention**

<b>Article</b>
<b>Reports/Monographs</b>
No Reports/Monographs provided.
<b>Additional Articles</b>
No Additional Articles provided.