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.

Overview

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

Primary Contact Name:

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Intervention URL:

https://clinicaltrials.gov/study/NCT00227175

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Results

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

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

Characteristics and Implementation

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

Impact, Lessons, Components

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

Products, Materials, and Funding

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

Expertise, Partnerships, and Funding Sources

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

Product/Material/Tools

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

Implementation Materials and Products

	Material
Implementation/Delivery Materials	
Guidebooks/Workbooks/Participant Manual	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4669680/
Gifts	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/
Implementation/Output Materials	
Best Practice Guidelines	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958599/

Articles Related to Submitted Intervention

	Article
Reports/Monographs	
No Reports/Monographs provided.	
Additional Articles	
No Additional Articles provided.	