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Proof of Concept for the FLEX Intervention: Feasibility of Home Based Coaching to Improve Physical Activity Outcomes and Viral Load Suppression among African American Youth Living with HIV

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Abstract

FLEX is a Motivational Interviewing, home-based coaching program that concurrently targets HIV-related and physical activity goals among African American youth living with HIV in the United States. To create and pilot test FLEX, we leveraged a 2-step exploratory sequential mixed methods design informed by the ORBIT model with initial qualitative work followed by pre-post analysis of quantitative outcomes, concluding with qualitative exit surveys. Data were evaluated pre- and 3-months post-intervention. Recruitment was 90%. Participants reported high program satisfaction and program adherence (76% completion rate). Preliminary findings indicate reductions in participants' viral loads and improvements across 4 measures of physical activity.

Keywords

young adults, youth living with HIV, HIV, intervention, physical activity, African Americans, motivational interviewing, ORBIT model, feasibility, coaching

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Background

African Americans (AfAm) have some of the highest rates of preventable cardiometabolic disorders, such as diabetes and cardiovascular disease,[1,2] and AfAm youth living with human immunodeficiency virus (YLWH) are at even higher risk of developing these conditions.[3,4] Physical activity can prevent cardiometabolic disorders and improve immune function, mental health, and cognition.[5,6] Systematic reviews on the effects of physical activity interventions on the health of adults living with HIV have yielded promising results[7,8]; thus, physical activity interventions that are tailored to the personal circumstances and preferences of AfAm YLWH are warranted. Although there are validated interventions that target improvements in HIV continuum of care outcomes, few of these interventions that are tailored specifically for AfAm YLWH, and to our knowledge, there are no such interventions that successfully target both HIV-related outcomes, such as antiretroviral adherence and viral suppression, in conjunction with physical activity goals among AfAm YLWH. Considering this gap, existing evidence of physical activity intervention benefit for adults living with HIV, and previous successes of Motivational Interviewing (MI) to improve health behaviors among adolescents and YLWH,[9-12] we developed FLEX, a community-based intervention that integrates MI, self-monitoring of physical activity goals, and promotes antiretroviral medication adherence with ongoing physical activity coaching. To develop FLEX, we utilized the ORBIT model for developing behavioral

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What Do We Already Know about This Topic?

Although African Americans (AfAm) have some of the highest rates of preventable cardiometabolic disorders (e.g., cardiovascular disease, diabetes, etc.), and AfAm youth living with human immunodeficiency virus (YLWH) are at even higher risk of developing these conditions—to our knowledge—there are no interventions that successfully target both HIV-related outcomes and physical activity goals among AfAm YLWH.

How Does Your Research Contribute to the Field?

Considering this scientific gap, we leveraged Phases 1 and 2 of the ORBIT model for developing behavioral interventions for chronic diseases, to create and pilot test FLEX, a community-based, Motivational Interviewing intervention that integrates self-monitoring of physical activity goals and antiretroviral medication adherence targets tailored for AfAm YLWH.

What Are Your Research's Implications toward Theory, Practice, or Policy?

We found preliminary evidence that the FLEX intervention was feasibility and acceptability; FLEX was "designed for dissemination," which is a high public health priority, and as such, our proof of concept should be validated in a randomized control trial wherein FLEX is assessed against a counterfactual control condition. Results of such a study could lead to FLEX becoming a validated evidence-based intervention to improve health outcomes among underserved YLWH.

interventions for chronic diseases[13,14] including ORBIT's Phase 1 (Development) and Phase 2 (Preliminary Testing). Phase 2 includes proof-of-concept studies (Phase 2a) and pilot testing (Phase 2b). The purpose of this study is to describe our ORBIT-informed intervention development process (Phase 1) and present results our proof-of-concept (Phase 2a) of FLEX to improve physical activity and viral load among AfAm YLWH.

Methods

Design

We utilized an exploratory sequential mixed methods research design with initial qualitative work (Phase 1) followed by pre-post analysis of quantitative outcomes, concluding with qualitative analysis of exit surveys (Phase 2a).

Study Population and Recruitment

Participants in Phase 1 were AfAm YLWH aged 18-24 years (N = 10). Participants in Phase 2a were 18-24 years, AfAm YLWH, had physician approval to engage in physical activity, and self-reported suboptimal levels of physical activity (N = 9). Exclusion criteria were severe psychiatric illness that would impair study participation; non-English speaking; substance use severe enough to preclude adherence to study requirements, and unable to provide informed consent. All participants were recruited from the primary adolescent HIV-treatment clinic in Detroit, Michigan. When attending a clinical visit, potential participants were informed about this study by the clinic's psychologist. If interested, potential participants were referred to the FLEX study coordinator to confirm eligibility, conduct research intake paperwork, and enroll in this protocol.

Qualitative Data and Analysis

During Phase 1, we utilized rapid content analysis, a process that was derived from classic thematic coding; this method quickly produces actionable information for decision makers.[15] Steps include summarizing transcripts utilizing the focus group guide to yield themes, and then consolidating recurring themes across all transcripts.[16] Since our exploratory Phase 1 included a single focus group, there was no need to merge transcripts. Phase 1 results indicated support for naming the intervention FLEX (abbreviation for "flexing"). There was unanimous enthusiasm for a home-based intervention to improve physical activity using High Intensity Interval Training (HIIT) for those with limited space and resources; home-based coaching was viewed as non-stigmatizing, convenient, and acceptable. Yoga was deemed acceptable in conjunction with other workout modalities, but YLWH were not interested in yoga exclusively. Phase 1 participants believed that an intervention focused holistically on health instead of only on HIV outcomes would be more acceptable to their peers. Phase 1 participants felt that targeting multiple weekly exercise days to meet Centers for Disease Control and Prevention (CDC) goals, with a mix of coaching and independent physical activity, was feasible. We applied these data to refine the FLEX intervention tested in ORBIT Phase 2a, and post-intervention qualitative exit interviews were conducted to ascertain the ways in which the intervention could be improved and was experienced and internalized by Phase 2a participants.

Quantitative Data

Physical activity outcomes, namely strength assessments, number of push-ups, number of curl-ups, chester step (an assessment of aerobic capacity that determines the rate of recovery following intense exercise), and body mass index (BMI), along with viral load (from medical records) were assessed pre-intervention and 3-months post-intervention. Due to the pilot nature of this study, quantitative outcomes are presented, but statistical analyses were not performed.

Ethical Approval and Informed Consent

The Wayne State University (WSU) Institutional Review Board approved this study (Ref:#057313B3E). After a Research Manager explained the protocol, including that the YLWH's participation was voluntary, written informed consent was obtained with physical signature.

Results

FLEX Intervention

We first defined the intervention (ORBIT Phase 1a) to include evidence-based best practices for physical activity and behavior change including HIIT, resistance training, yoga for physical activity, and MI with self-monitoring (e.g., written log of activities, video recording exercise sessions, and wearing devices to monitor biometrics). At the start of the intervention, the YLWH was asked if he/she/they would like FLEX delivered in home or at a community location. Once selected, FLEX began with a MI session to build rapport and collect self-report physical activity and HIV-related data. Thereafter, FLEX included 3-months of HIIT, yoga stretching and breaking, resistance training, all delivered with MI. The Coach physically met with the participant every session. Each session included a warm-up with self-monitoring check followed by 20 minutes of HIIT to maximize cardiovascular fitness; twenty minutes of resistance workout including use of resistance bands and body weight exercises; 10 minutes of cool down with yoga stretching and breathing; and each FLEX session concludes with review of antiretroviral adherence with physical activity self-monitoring and goal setting for additional workouts on their own (called FLEX days). FLEX employed a tapered design to promote sustained and ongoing independent physical activity after the conclusion of the intervention per CDC recommendations. Month 1 included 3 FLEX sessions per week; month 2 included 2 FLEX sessions per week, and month 3 tapered to only one FLEX session per week.

Fidelity Procedures

Once FLEX was finalized, a Research Assistant (referred to as a Coach) was trained in MI by a member of MI Network of Trainers and in fitness components by a licensed physical therapist, Prior to the start of our study, the Coach submitted video-recorded roleplays that were scored for physical activity coaching accuracy and MI competency using a standard rating scale.[17] Study recruitment began after the Coach attained and sustained high fidelity in both MI and physical activity intervention components; this took about 1 month of time and training.

ORBIT Phase 2 Recruitment

Recruitment rate was high at about 90%, indicating feasibility (N = 9). Participants' mean age was 22 years; participants identified as male, female, and transgender. When given the option to select the site of intervention delivery (home or community location), all participants selected to receive the FLEX intervention at home. Relatedly, a theme that emerged from the exit interviews was "convenience." Study participants said that:

> [I] didn't have to worry about taking the bus to the site since I was already home. I could relax after my workout.

> [The FLEX intervention] was very convenient for me—had sessions at home. I didn't have to leave or when I got off work, I still had time to take a nap and still workout.

ORBIT Phase 2 Satisfaction

Participants reported high program satisfaction; participants completed 76% of FLEX sessions (maximum 24 sessions), indicating that our unique study population (AfAm YLWH) found FLEX acceptable. When participants were asked about what they disliked about the program (in exits interviews), most responded that there was nothing they disliked. One participant requested more sessions with the Coach, stating that FLEX "flew by." Another participant stated that:

> [The only thing that I didn't like about the FLEX program was] that it ended.

ORBIT Phase 2 Physical Activity and HIV Outcomes

Preliminary findings suggested that FLEX may be able to successfully and concurrently influence physical activity and HIV-related outcomes in AfAm YLWH. Results pre- and post-FLEX indicated improvements in physical activity strength assessments and HIV viral load; 89% of study participants had increases in the number of push-ups and curl-ups that they could complete; 78% showed improvements in chester step, an assessment of aerobic capacity. Forty-four percent showed reductions in or maintenance of body mass index (BMI).

Eight of 9 participants had viral load information available in clinical records. Viral suppression is a key HIV outcome and it part of the global Undetectable = Untransmittable campaign. All 8 (100%) of these participants maintained or improved their viral loads at the conclusion of FLEX. Six participants (75%) started FLEX as virally unsuppressed; 4 of these 6 (67%) attained viral suppression at the 3-month conclusion of FLEX. See Table 1 and 2 for blinded, individual participant results.

Results indicated 3 secondary findings. 1) MI may be delivered in community settings by appropriately trained paraprofessionals, which is cost-effective and programmatically efficient. 2) By embedding MI within FLEX, the intervention was able to positively provide external motivation while increasing internal self-efficacy. To quote our exit interviews:

Table 1. Pre- and Post-FLEX Physical Activity and Strength Outcomes.

	Physical activity and strength outcomes											
	# of Push-ups			# of Curl-Ups			Chester Step			BMI		
	Pre-FLEX	Post-FLEX	Δ	Pre-FLEX	Post-FLEX	Δ	Pre-FLEX	Post-FLEX	Δ	Pre-FLEX	Post-FLEX	Δ
Case 1	1	3	Improved	10	17	Improved	1	1	Maintained	40	37	Decreased
Case 2	20	23	Improved	25	28	Improved	1	2	Improved	56	58	Increased
Case 3	12	19	Improved	12	19	Improved	3	4	Improved	27	26	Decreased
Case 4	18	32	Improved	17	23	Improved	3	4	Improved	25	23	Decreased
Case 5	7	9	Improved	24	26	Improved	2	3	Improved	27	27	Maintained
Case 6	4	6	Improved	22	35	Improved	2	3	Improved	52	51	Decreased
Case 7	25	30	Improved	30	33	Improved	4	4	Maintained	22	22	Maintained
Case 8	16	10	Declined	13	27	Improved	3	4	Improved	26	25	Decreased
Case 9	10	20	Improved	29	27	Declined	4	5	Improved	26	28	Improved

Table 2. Pre- and Post-FLEX Viral Load Suppression.

	HIV-related outcome		
	Viral load (VL) suppression		
	Pre-FLEX	Post-FLEX	Δ
Case 1	Unsuppressed VL = 14,317	Unsuppressed VL = 5,262	Improved
Case 2	Unsuppressed VL = 8,671	Suppressed VL < 50	Improved to Suppression
Case 3	Suppressed VL < 50	Suppressed VL < 50	Maintained
Case 4	Suppressed VL < 50	Suppressed VL < 50	Maintained
Case 5	Unsuppressed VL = 79,517	Unsuppressed VL = 276	Improved
Case 6	Unsuppressed VL = 334	Suppressed VL < 50	Improved to Suppression
Case 7	Missing	Missing	Missing
Case 8	Unsuppressed VL = 123	Suppressed VL < 50	Improved to Suppression
Case 9	Unsuppressed VL = 453	Suppressed VL < 50	Improved to Suppression

> [FLEX] helped in a different way. Getting active again and bettering myself; it was like a relationship, a bond. I needed to help me. Needed somebody to help until I was able to get there by myself (external motivation)
>
> That's the good thing about [the Coach]—he knows where you're at and what you can handle; made it challenging but doable, I felt like I could do it (self-efficacy).

Lastly, 3) participants express interest in receiving more health information, such as on diet and nutrition, and asked for continued FLEX sessions with the Coach. With the positive signal attained during this proof-of-concept, there is support for combining behavior change targets, rather that developing interventions that only target either HIV-related goals or physical activity goals.

Discussion

In addition to the FLEX intervention showing feasibility, acceptability and proof-of-concept, FLEX was "designed for dissemination," which is a high public health priority.[18] Paraprofessionals are situated in most if not all Ryan White-funded HIV adolescent clinics, but are inconsistently engaged in intervention delivery. Public health researchers often develop interventions for delivery by clinicians in clinical settings,[16,19] but our proof-of-concept indicates that trained paraprofessionals can extend their influence by applying MI to support YLWH to attain their physical activity and HIV-related goals outside of clinical settings, indicating that FLEX may be extensible and adaptable for YLWH in other resource-constrained settings where YLWH are unable to access gyms and clinics may lack private, dedicated space for multi-component intervention delivery. Although outside of the immediate scope of this project, evaluating barriers and facilitators for paraprofessionals to learn and sustain MI with fidelity is also a dissemination and implementation research topic that merits further evaluation,[20] particularly if there is interest to move behavioral and lifestyle interventions out of the clinic and into more accessible real world settings. Because this FLEX intervention proof-of-concept was successfully delivered in real world settings where YLWH live, meaning that even with all the distractions that exist in YLWHs' homes—such as barking pets, street noise, and televisions on in multiple rooms during the delivery of the intervention—we were still able to capture a signal of potential effectiveness, providing support to warrant evaluating FLEX in a randomized controlled trial against a counterfactual time attention control.[21]

Limitations

We did not collect biological measurement of cardiometabolic markers such as cholesterol, blood pressure, and glucose.

Sample size was small; thus, we did not conduct statistical analyses to not overextend our findings, and we only recruited from a single adolescent HIV clinic.

Conclusion

By developing FLEX as a tailored intervention that emphasized holistic lifestyle changes rather than focusing exclusively on HIV-related outcomes or only targeting physical activity goals, outcomes from this study indicate the FLEX intervention is acceptable to YLWH, while also being relatively straightforward to embed within existing HIV healthcare infrastructure and real world settings. Our promising proof-of-concept study suggests that our next step is to test FLEX in an more extensive trial, concurrently enrolling YLWH participants from multiple settings and evaluating FLEX against a counterfactual control condition.

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Authors' Note

SN was the senior author and originally conceptualized this study. HB formulated and drafted this manuscript, and MB was the primary interventionist and data collector. Data is available by request to the senior author, Dr. Sylvie Naar, Distinguished Endowed Professor at Florida State College of Medicine. The Wayne State University Institutional Review Board provided ethical approval (#057313B3E).

Declaration of Conflicting Interests

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