Feasibility and Lessons Learned from the FIRST WIND (Weight loss Interventions after Delivery) Intervention for Urban-based, Postpartum African American Women

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Objective: Rates of overweight, obesity and glucose intolerance of pregnancy are rapidly increasing among pregnant women, and particularly among women of color. We developed and pilot-tested an evidenced-based behavioral weight-loss intervention, tailored for urban-based, postpartum African American women.

Methods: We conducted a feasibility trial among 32 overweight or obese postpartum, urban-based African American women (15 in intervention group; 17 in the usual care group), who had recently delivered at a community-based hospital in Baltimore city. Participants were randomized to the active intervention or the self-directed arm of the study. Both groups received an initial 1-hour session with a behavioral interventionist. The 24-week intervention included five individual sessions and 10 group classes on weight management, mental wellness and exercise. Group sessions consisted of 60 minutes of lessons on behavioral strategies and 30 minutes of organized physical activity (e.g. walking, aerobics). The primary outcome was weight change from enrollment to the end of the intervention.

Results: A total of 64% of those potentially eligible at the in-person screen were enrolled in the study. Participants in the active intervention group were slightly younger with lower income levels, compared to those in the self-directed group. In total, 23 (82%) participants completed the study. Average attendance across all individual sessions was 50% (70% if contact made via email or phone) and 60% for group classes. Average weight loss at 6 months in the active intervention group was 0.49 kgs (4) compared to an average weight gain of 4 kgs (7) in the self-directed group. From a baseline of 80.8 (12.5), mental functioning scores in the active group remained stable at 84 (15) at 6 months. Average scores in the self-directed group decreased from 83 (15) to 68 (17). In post-intervention focus groups, women verbalized the need for group session, but advocated for alternative methods of individual contacts, including phone calls, emails and text messaging.

Conclusion: This pilot study documents the feasibility and preliminary efficacy of a behavioral weight-loss intervention in postpartum, urban-based African American women with perinatal obesity. Study participants favorably received the intervention. The results may have implications for integrating weight-loss interventions into the early postpartum period in other urban-based communities.

Keywords: Postpartum; Weight management; Depression; Behavioral intervention

Introduction

Overweight and obesity have reached epidemic proportions in the United States. Of the 4 million women giving birth annually in the US, an estimated 60% are overweight; 30% are obese [1]. Women who are overweight or obese at the time of conception are at greater risk for developing diabetes of pregnancy (i.e. often referred to as gestational diabetes or GDM) [2,3] excessive gestational weight gain [3-5] and postpartum weight retention [5]. Failure to achieve a healthy weight after delivery increases the risk for type 2 diabetes, chronic obesity and certain cancers (postmenopausal breast, endometria or colon) [6].

Of particular concern is the excessive gestational weight gain and postpartum weight retention among low income or minority women and women living in underserved urban areas. African American women should benefit from postpartum lifestyle interventions, but relatively few RCTs [7,8] have assessed the effect of evidenced-based
lifestyle interventions on postpartum weight loss in this vulnerable group of women. Most postpartum intervention trials [9-11] have been conducted in white women or women from high socioeconomic status. Evidence-based lifestyle components proven effective in general populations have been adapted for use in several high-risk groups [8,12] and various settings,[13,14] but there is little work to describe the effectiveness of these interventions 11 in postpartum African American women.

PREMIER,[15,16] an established NIH-funded lifestyle intervention for adults with Stage 1 hypertension, integrates behavior change strategies into specific techniques for weight loss in adults[16]. These techniques include motivational interviewing, personal goal setting, self-monitoring with food records and physical activity diaries, modifying environmental influences, identifying reinforcements and rewards, modeling healthy behaviors and social skills around eating, identification of barriers, relapse prevention, assertiveness training, making food choices and substitutions, and elicitation of social support. In the current study, our overarching goal was to adapt the PREMIER intervention for use in a community setting among postpartum African American women.

The objectives of this study were to: 1) adapt the PREMIER intervention for use in postpartum African American women living in an urban community in West Baltimore city, 2) test the feasibility and preliminary efficacy of this postpartum-specific behavioral intervention on weight, blood pressure and mental health functioning, and 3) obtain feedback from study participants to refine the intervention through post-intervention focus groups. A postpartum lifestyle intervention takes advantage of an important “teachable moment”14 in the life course of women. We chose a six-month time frame because prior intervention studies in general populations have shown substantial weight loss at six months and represents a reasonable period of time to engage women after delivery.

Materials and Methods

| Core components of PREMIER and First WIND interventions |
|----------------------------------------------------------|
| -Goal: 2.5 kg weight loss in intervention group |
| -Intervention components that include strategies for healthy eating and physical activity |
| -Intervention delivered via trained health educator and behavioral interventionist |
| -Focus on use of self-monitoring tools to promote adherence |
| -Interactive group sessions in which interventionists uses motivational techniques to assist with problem-solving |
| -Culturally tailored for African-American participants |

| Specific Adaptations to PREMIER intervention for Postpartum African-American Women |
|------------------------------|-------------------------|
| PREMIER intervention | Modified First WIND |
| -26 group and 7 individual sessions over 24 weeks with follow-up at 6, 12 and 18 months | -10 group and 5 individual sessions delivered over 24 weeks with follow-up at completion of intervention, with interval calls. |
| -Focus on DASH diet | -Additional individual or family sessions were available upon request |
| | -Primary focus on healthy food choices based on Food Pyramid |

Intervention Development

We based the intervention on the PREMIER Study [17] which incorporates social cognitive theory, behavioral self-management and the stages of change model. While maintaining these core strategies, we made several modifications based on the preferences and preferred components verbalized by pregnant and postpartum African American women in earlier formative work [18]. Our goal was to assist women with improved self-regulation and self-efficacy using structured goal setting, monitoring and feedback and enhanced social support through group discussion and guided cardiovascular physical activities.

The newly developed six-month intervention, termed First WIND (Weight Loss Interventions after Delivery), included three components: weight management, individual counseling sessions, and interactive group sessions with physical activity. The First WIND intervention included five individual face-to-face sessions for individual assessment of progress, targeted feedback, and tailoring of caloric intake and physical activity guidelines based on individual goals and breastfeeding status. There were ten 90-minute group sessions that included educational information based on PREMIER, but modified for postpartum women.

We reduced the number of sessions from 33 to 15 to better accommodate the competing demands of work, family commitments and childcare (Table 1). Other modifications included a focus on healthy food choices and a reduction in fat intake, rather than the DASH diet. We used the MyPyramid (currently known as Myplate) developed by the United States Department of Agriculture[19] to address different food groups and healthy choices within each category. Resource materials included a commercially available fat- and calorie counting book, dietary intake and physical activity diary and an exercise ball and stretch bands. Interactive group sessions were led by a trained interventionist and began with a 45-minute period of education including dietary guidance (nutrition label reading, grocery store shopping tips, and cooking demonstrations). In the mock grocery store sessions, women were instructed on how to choose healthy, cost-conscious food alternatives that met the meal preferences of their families.
muscle toning classes. A group session on postpartum depression was held where participants identify depression as a common issue that they should focus on. The stakeholder group also contributed to the development of recruitment strategies.

symptoms on their ability to adhere to a healthy diet and exercise component to the interactive group sessions and 2) group exercise program that was integrated into the organized group sessions. The educational sessions were followed by a 45-minute period of cardiovascular exercise. Participants began with walking videos and progressed to instructor-led aerobics and muscle toning classes. A group session on postpartum depression was also developed and integrated into the adapted PREMIER intervention in response to our earlier formative work in which African American women expressed concerns about the impact of postpartum depressive symptoms on their ability to adhere to a healthy diet and exercise routine. While group sessions were designed to address these challenges, we developed a targeted group session to review the symptoms of postpartum depression symptoms and to help participants identify depression as a common issue that they should feel comfortable discussing with their provider.

Engagement of Community Health Stakeholders

In the early planning phase, we sought input on the intervention content, research design and recruitment strategies from obstetrical providers within the community. We successfully collaborated with a group of physicians, nurses and health educators (n=10) at St. Agnes Medical Center, a community hospital in West Baltimore County. We presented the components of the intervention in order to gain constructive feedback through a series of collaborative meetings. The stakeholder group also contributed to the development of recruitment brochures and provided suggestions on how to effectively recruit women from January 1, 2007 to June 30, 2008. West Baltimore is largely a blue-collar section of Baltimore city with a median income of $61,000 (compared to median of $70,000 for the state of Maryland) and is estimated to be 61% African American.

We conducted a pilot trial among 30 postpartum African American women who were overweight or obese in the first trimester (BMI 25-40 kg/m²) or a diagnosis of GDM during this pregnancy, Women with a BMI of 40 kg/m² or more were excluded due to the possible need for medically directed weight loss. Also, we excluded women with a history of pre-existing diabetes, a cardiac or stroke event in the last 6 months, special nutritional needs (e.g. HIV, malignancy) or currently taking weight loss medications, or planning to leave the area within six months. Participants were primarily recruited through physician referrals and face-to-face contact at the time of their prenatal appointments. Participants were also recruited through brochures and fliers that were placed at the St. Agnes hospital labor and delivery unit and at the West Baltimore Women’s and Infant’s (WIC) Office, which is located within the geographical region.

Study population, eligibility and recruitment

Women were eligible to participate in the trial if they were: 1) African-American, 2) age 21 to 35 years, and 3) were overweight or obese. Women were recruited during pregnancy and the early postpartum period and were asked to complete study eligibility forms, including their expected delivery date and best contact information. Women were recruited during pregnancy and re-contacted by research staff two weeks prior to their delivery date to confirm their interest in participating in the study. If there was continued interest, an in-person screening and enrollment visit was scheduled at six weeks postpartum. Participants returned at 10 weeks postpartum for a randomization visit. Randomization occurred through a computer-generated sequence. Participants randomized to the First WIND intervention received 15 group sessions and 5 individual sessions, led by a trained interventionist. Women randomized to the self-directed arm had a single post-randomization visit with an interventionist who provided support.
educational materials on dietary intake and exercise based on national recommendations. Each of the study visits and individual and group sessions for participants in the intervention arm of the study occurred at Johns Hopkins ProHealth research facility, a behavioral intervention unit located in West Baltimore community. Johns Hopkins ProHealth is the home of several NIH-funded behavioral intervention trials, including PREMIER20 and Look-AHEAD [20].

Measures

Physical measures

Measures were collected at baseline and at six months post randomization. Trained and certified data collectors using standardized protocols at the ProHealth intervention site obtained weight, height and blood pressure measures. Weight was measured using a calibrated scale and the average of two measurements with participants in indoor clothes without shoes. Height was measured using a calibrated, wall-mounted stadiometer. Blood pressure measurements were determined by the OMRON 907 device (Omrton Healthcare, Kyoto, Japan), which records blood pressure using an oscillometric technique [21]. Three blood pressure measurements at each visit were obtained on the right arm of participants after they rested quietly in the seated position for at least 5 minutes.

Questionnaires

Interviewers administered each of the study instruments at baseline and at six months post randomization. Socio-demographic characteristics and medical history were assessed using a participant history questionnaire. Mental health functioning was assessed by the Medical Outcomes Study (SF-36) Short Form 36 Survey [23]. The SF-36 is comprised of 36 items measuring 8 aspects of health and well-being: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. Scores vary from 0-100, with higher scores indicating better health status. Leisure time physical activity was measured using the Baecke leisure time physical activity survey [24]. This questionnaire is commonly used in epidemiologic studies, is designed to measure habitual physical activity, and has reported test-retest reliability of the leisure time index as 0.74. A leisure activity index was derived at baseline that ranged from 1 (low activity) to 5 (high activity). A modified version of the Block Rapid Food Screener [25-28] was used to assess dietary intake at the baseline interview and at the 6-month follow-up visit.

Outcomes

The primary outcome was weight expressed in kilograms (kg) and BMI. Other outcomes included systolic and diastolic blood pressure, leisure time physical activity, and mental health function.

Process measures

We collected data on attendance at individual and group sessions. In order to be counted as participating in individual sessions, participants had to meet with the interventionist in a face-to-face encounter. For group sessions, in-person attendance was required for a least half of the 90-minute sessions. We also collected data on compliance with weekly entries in the food and activity diary for women in the active lifestyle arm of the study.

Post-intervention interviews

We conducted post-intervention interviews with a subset of participants (n=10). Post-intervention interviews centered on the usefulness of the intervention, barriers to participation and recommendations for the conduct of a larger study. Each of the ten participants was asked five questions: 1) what was the most useful components of the intervention? 2) Did the group sessions provide you with the amount of social support needed? 3) What were your greatest barriers to adhering to the group sessions or the individual sessions? 4) Which component of the intervention was the most useful to you? 5) What is the main thing you would change about the intervention for the next group of participants?

Table 2: Characteristics of First WIND participants at enrollment (N=32)

| Demographic factors | Intervention Groups |
|---------------------|---------------------|
| Active Lifestyle    | Self-Directed       |
| n=15                | n=17                |
| Age, years, (mean ± SD) | 33 ± 5              | 35 ± 6 |
| Married             | 7(46)               | 8(47)  |
| Technical college or postgraduate education | 13(85) | 16(93) |
| Employed at enrollment | 12(77)              | 11(64) |
| Income, < $50K      | 11(71)              | 8(46)  |
| Parity, 1 live birth | 2(15)               | 2(11)  |
| 2 or more live births | 13(85)             | 15(89) |
| GDM in most recent pregnancy | 5(30) | 3(20) |
| Chronic Hypertension | 5(31)               | 4(21)  |
| Lactation status, enrollment | 13(85) | 16(94) |
| Pre-pregnancy BMI, kg/m2, (mean ± SD) | 38±6 | 37±7 |
| Gestational weight gain (lbs.), (mean ± SD) | 13.6±2.7 | 14.5±1.8 |

Data is presented as numbers and proportions unless other indicated. Unless indicated, P-values are > 0.05; GDM = gestational diabetes; BMI = body mass index

Statistical Analysis

Descriptive statistics were used to present and compare baseline demographic and clinical characteristics of participants in the active intervention and the self-directed groups. The primary outcome, weight from baseline to 6-months post randomization, was assessed using the intent-to-treat analysis- all participants were considered part of the group to which they were randomized regardless of their level of participation. If a follow-up measurement was not available, the baseline value for that participant was assumed to be unchanged. Paired t-tests were used to compare weight change between groups. Changes in weight were expressed in absolute terms (kg) as well as percent change from baseline. Average systolic blood pressure, mental
health score and leisure time physical activity scores were compared between groups using paired t-tests.

Figure 1: Participant flow in weight loss intervention

Results

Study Population

Of the 140 women who initially expressed interest in the study (postcards, phone inquiries, direct physician referrals), 50 women were thought to be eligible for the study based on direct in-person screening or telephone follow-up and discussion with program staff (Figure 1). Of these, 40 women showed continued interest in the study at 6-12 weeks postpartum and presented for an in-person screening visit. Of these 32 returned to provide informed consent and randomization to one of two treatment arms. Fifteen women were randomized to the active lifestyle arm and 17 were randomized to the self-directed arm of the trial. Women in the intervention arm were slightly younger than those in the self-directed arm (33± 5 vs. 36 ±6, respectively). The majority of participants were employed and had more than a high school education (Table 2). There was no difference in pre-pregnancy BMI (38± 6.2 in the intervention arm; 37± 7 in the self-directed arm) or gestational weight gain. There was no difference in breastfeeding status between the two groups at the time of randomization.

Retention

Of the 32 participants, we obtained six-month follow-up measures on 29 individuals, or 90% of our sample. One participant in the intervention group left the area for new employment. Two participants in the self-directed group were lost to follow-up.

Weight change

Anticipated trends in weight and other outcomes were observed (Table 3). Among participants in the intervention group with a baseline and 6-month follow-up weight, mean weight loss was 0.49 kgs (4). Participants in the self-directed group experienced an average increase in weight of 4 kgs (7). The net difference in weight between the two groups at six months was -4 kgs. Analysis, including all enrolled participants assuming those not completing follow-up measurements remained at their baseline weight showed a difference in weight of 4 kgs.

Other health outcomes

Average mental health functioning scores at baseline were 80.8 (12.5) and 83.2 (15.3) in the intervention and self-directed groups, respectively (Table 3). At the end of the intervention, there was a net 13-point difference in mental health scores between participants in the active lifestyle and the self-directed groups.

| Outcomes                  | Baseline (M, SD) | Post Intervention (M, SD) | Change (M, SD) |
|---------------------------|------------------|---------------------------|----------------|
| Weight (kg)               |                  |                           |                |
| First WIND                | 104 (23)         | 104 (22)                  | -0.49 (4)      |
| Control                   | 98 (19)          | 103 (19)                  | 4 (7)          |
| Mental health functioning*|                  |                           |                |
| First WIND                | 80.8 (12.5)      | 83.2 (14.8)               | 2.4 (20)       |
| Control                   | 83.2 (15.3)      | 67.6 (17)                 | -11.1 (24)     |
| Systolic BP               |                  |                           |                |
| First WIND                | 133 (23)         | 129 (26)                  | 3.3 (10.3)     |
| Control                   | 118 (19)         | 116 (16)                  | 1.25 (5.5)     |
| Diastolic BP              |                  |                           |                |
| First WIND                | 72 (8)           | 70 (9)                    | -2 (8.2)       |
Process outcomes

Attendance at in-person group sessions was 75%. Attendance at individual sessions was 50%. When a telephone call and/or email correspondence was substituted for a face-to-face individual session, adherence increased to 70%. Compliance with weekly completion of the food and activity diary was 60%. Average leisure time physical activity scores increased slightly in the active lifestyle group from 2.89 ± 0.24 to 2.93 ± 0.37. Participants in the self-directed group had a lower average score over the same six-month period ranging from 2.93 ± 0.62 to 2.87 ± 0.43.

Results of post-intervention interviews

We categorized participant responses into 4 broad domains which include 1) usefulness of intervention content; 2) perceived barriers to and facilitators of adherence to the intervention; 3) attitudes toward group sessions and 4) preferences for specific components of the weight loss program.

Usefulness of intervention content Most participants verbalized that the content of the intervention was useful and increased their knowledge of how to live a healthier lifestyle. However, participants also verbalized disappointment that the information had not been provided prior to conception or during the course of pregnancy. Several participants strongly expressed the need to provide such information to women during routine gynecologic and prenatal visits rather than waiting until a designated time after delivery.

Barriers to and facilitators of adherence to intervention

While the commitment to postpartum weight loss was high, participants verbalized multiple logistical barriers (time restraints, sick children, family commitments) to attending individual face-to-face and group sessions. The ability to bring their infants and children to the group sessions was a key factor in compliance. Women suggested that the enrollment period be extended from 6-10 weeks postpartum to up to 16 weeks (4 months) postpartum. The additional enrollment period would provide women with sufficient time to arrange childcare and likely increase participation in the group sessions. Participants also believed that the individual face-to-face sessions were too difficult to attend. They strongly recommended that these sessions be replaced with social media tools, such email, or text messaging.

Most useful intervention aspects of intervention

Participants stated that the 30-minute exercise program incorporated into group sessions was one of the most useful aspects of the intervention. Attending these group exercise activities helped to promote and maintain their commitment to exercise. Also, the opportunity to exercise with other new mothers with similar weight challenges made the experience more enjoyable. Participants also expressed the importance of social networking during group sessions. Peer relationships formed during these group sessions extended outside of scheduled intervention activities. Participants verbalized that peer support provided during and outside of the group sessions helped to improve their adherence to dietary and physical activity recommendations.

Discussion and Lessons Learned

To our knowledge, this is the first study to adapt and deliver the PREMIER intervention to postpartum women with perinatal obesity or gestational diabetes. We incorporated important components identified from our earlier formative work in pregnant and postpartum African American women with the core components of the PREMIER intervention to deliver a patient-informed, postpartum intervention, tailored to the needs of urban-based African American women. Our six-month pilot trial demonstrates the feasibility of conducting a postpartum behavioral intervention among African American women in an urban-based setting and the preliminary effects of the intervention on weight and mental health scores.

Our findings suggest that postpartum African American women can benefit from behavioral interventions. At 6 months post-randomization, there was a net difference in weight of -4 kgs between the two study arms (-0.49 kgs in the intervention group; +4 kgs in the self-directed group). Weight loss for participants in the First WIND intervention was similar to that reported in an earlier RCT among 450 postpartum African American women. Ostybe et.al reported weight loss of 0.9 (4 kgs) in women who received a 12-month intervention (18 in-person classes; 6 telephone counseling sessions) compared 0.81lbs in those in the usual care group. We chose to deliver a 6-month intensive intervention (15 in-person group sessions; 5 individual sessions) based on feedback we received from African American women and local perinatal providers in preparation for the trial. It may be that a short-term (6 month) high-intensity intervention is a more acceptable time frame for postpartum African American women.

We also found that a healthy lifestyle intervention that includes strategies for mental wellness is beneficial. Prior studies have reported a decrease in women's perceptions of postpartum mental health functioning across different racial/ethnic groups. The relationship between postpartum perceptions of mental health functioning, weight retention and social support has not been fully investigated. The different in mental health scores found in the current study should be confirmed in a larger trial. There were changes in leisure physical activity, dietary fat consumption and daily servings of fruit and vegetable servings between the two groups.

This feasibility study contributes to the growing body of literature on evidence-based lifestyle interventions in several important ways. First, we focus on African American women who bear a disproportionate burden of postpartum weight retention and chronic obesity after childbearing. Despite this racial disparity in weight retention, postpartum weight loss intervention studies have largely been conducted in Caucasian women. Second, we adapted and implemented PREMIER, a state-of-the art behavioral intervention, in postpartum African American women and incorporated feedback.

Table 3: Preliminary Effects of Intervention on Weight, Blood Pressure and Mental Health Functioning

| Intervention | Weight Change (kg) | Blood Pressure (mmHg) | Mental Health Functioning |
|--------------|--------------------|-----------------------|--------------------------|
| Control      | 0                  | 0                     | 0                        |
| Intervention | 0.81               | 73                    | 8                        |

BP= blood pressure; BMI= body mass index; *Mental health functioning based on scores from Medical Outcomes Survey (SF)-36
from community-based perinatal providers to develop successful recruitment strategies and participant retention.

Conducting a postpartum intervention in urban-based, African American women is challenging. The majority of participants in the intervention arm of the study encountered multiple logistical barriers to attending individual and in-person group sessions. Work deadlines, sick children, and family commitments were frequent barriers to attendance at individual or group sessions and adherence to recommended dietary intake and physical activity. Participants applauded our efforts to provide on-site child supervision and breastfeeding accommodations within the ProHealth facility, but reported that in many instances, it was still difficult to balance the pick-up of children/infants from day care with coming to meetings after a long work day. While women professed a strong commitment to weight loss, they admittedly were unable to comply with many of the strategies necessary for successful weight loss. These challenges notwithstanding, our intervention was successful in helping women to lose weight. However, these barriers suggest that alternative methods of delivering the components of First WIND are necessary to ensure future compliance. Such methods include web-based tools. Webinars might be an alternative for some in-person group sessions for mothers who are balancing work and family life. Facebook is an alternative venue for social support and participant interaction.

Our study has several strengths. This is one of the first studies to integrate postpartum-specific content with the behavioral strategies of PREMIER. We engaged urban-based, postpartum African American, an understudied and underserved population of women. We were able to effectively adapt the PREMIER materials for postpartum women. We successfully expanded in-person group sessions to include an organized exercise component that was well received by participants. Attendance at in-person group sessions was moderate and we were able to obtain high rates of follow-up data collection. The sample size was small, but appropriate for a pilot study and provided important information on effect sizes for primary and secondary outcomes. The results of this study will need to be confirmed in a larger trial.

There are limitations to the study that deserve further attention. First, the small sample limits the generalizability of study results. Second, the follow-up of participants ended with completion of the intervention and data collection at six months. We are unable to provide information on the sustainability of behavioral changes or longer-term weight management. We did not formally assess knowledge and attitudes about weight management before and after completion of the study. Also, we did not compare changes in metabolic measures, such as insulin resistance or lipid profiles, which have important clinical implications in overweight or obese individuals. Finally, additional study is needed to assess the relation of depression symptoms on postpartum weight management.

Limitations notwithstanding, our study demonstrates the feasibility of a patient-centered, postpartum lifestyle intervention for urban-based, African American. We show that evidence-based interventions proven effective in general populations can be effectively adapted for specific target patient groups based on patient feedback and provider input. Further collaborations between patients, community providers and clinical researchers can inform the planning and conduct of pragmatic RCTs in postpartum women. Our preliminary results in weight loss, blood pressure and mental health functioning are promising. A larger randomized trial comparing the effects of First WIND to usual care should be conducted to confirm the efficacy of the intervention.

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