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Rationale, design, and baseline findings from a pilot randomized trial of an IVR-Supported physical activity intervention for cancer prevention in the Deep South: The DIAL study

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ABSTRACT

Telephone-delivered interventions do not require frequent clinic visits, literacy, or costly technology and thus may represent promising approaches to promoting physical activity in the Deep South, a largely rural U.S. region, with generally lower physical activity, income, and education levels. Building on past Interactive Voice Response (IVR) system-based HIV studies and extensive formative research (11 focus groups on physical activity intervention needs/preferences in the Deep South), the resulting IVR-supported physical activity intervention is now being tested in a randomized controlled trial with a waitlist control. The sample (n = 63) includes mostly obese (Mean BMI = 30.1) adults (Mean age = 43 years) in Birmingham, AL. Both genders (55.6% male) and African Americans (58.7%) are well-represented. Most participants reported at least some college (92%), full time employment (63.5%), and household income < $50,000 per year (61.9%). Baseline physical activity (Mean = 39.6 min/week, SD = 56.4), self-efficacy, self-regulation, and social support were low. However, high physical activity enjoyment and outcome expectations bode well. Self-report physical activity was associated with physical activity enjoyment (r = 0.36) and social support (friends r = 0.25, p's < 0.05) at baseline. Consequently, these may be important variables to emphasize in our program. Depression and anxiety were negatively correlated with some early indicators of behavior change (e.g., physical activity self-regulation; r's = -0.43 and −0.46, respectively, p's < 0.01) and thus may require additional attention. Such technology-supported strategies have great potential to reach underserved populations and address physical activity-related health disparities in this region.

1. Introduction

Approximately 20% of cancers diagnosed in the U.S. are linked to physical inactivity, obesity, excess alcohol consumption, and/or poor nutrition, and thus could be prevented [1]. The American Cancer Society recommends at least 150 min/week of moderate-to-vigorous intensity physical activity for primary prevention of cancer; yet, most Americans remain inactive [1,2]. Physical activity levels are particularly low in the Southeast region of the U.S. [3], where many counties are categorized as underserved and rural with income and education levels below the national average [4]. Moreover, cancer incidence and mortality rates are generally higher [5]. African Americans (the largest racial minority in the U.S.) represent a large segment of the population in Southeastern states [4] and report low levels of physical activity along with higher breast and colon cancer death rates [6]. Thus, factors related to culture, literacy, finances, and distance from physical activity facilities may limit access to physical activity information/resources in this region and contribute to existing health disparities.

Telephone-delivered interventions can overcome many of these barriers by not requiring frequent clinic visits, literacy, or access to costly technology and thus represent a promising approach to promoting physical activity for cancer risk reduction in this region. Such interventions have already shown success in increasing physical activity levels, but most rely on calls made by trained staff at least once a week [7]. This requires extensive financial resources and staff time, which seems unnecessary considering the technology now available. Using Interactive Voice Response (IVR) systems to automate can enhance cost-effectiveness, reach, and potential dissemination on a large scale.

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There is a paucity of research on IVR-based physical activity interventions [7,8]. A recent Cochrane review found only three physical activity IVR studies [9–11] and concluded that such interventions may improve several, but not all, measures of physical activity, when compared with usual care or other controls [8]. Several researchers have called for further IVR physical activity studies with underserved populations [9,11–13] and more tailored approaches [10,11,14,15]. Generic physical activity counseling messages are often not perceived as personally relevant or engaging [16]. One such study found no physical activity effects and most participants reported that the untailored IVR messages did not address their personal needs [15].

Thus, for the present study, an existing IVR system, used in previous studies on human immunodeficiency virus (HIV) risk behaviors [17–19] was adapted for physical activity promotion and cancer prevention in the Deep South through extensive literature review and formative research (11 focus groups on physical activity intervention needs/preferences in the Deep South) [20]. Given past research demonstrating that interventions tailored on Social Cognitive Theory (SCT) constructs have produced increases in physical activity [21–25], this model was selected as the theoretical framework for the current study. SCT describes a dynamic ongoing process in which personal factors, environmental factors, and health behavior exert influence upon each other [26]. According to this theory, key determinants of physical activity behavior include self-monitoring (tracking physical activity progress and setting goals), self-efficacy (confidence in one's ability to be physically active, despite barriers), social support from friends and family for physical activity, outcome expectations (anticipated outcomes of physical activity), and perceived enjoyment of physical activity [26]; thus, these constructs will be measured and directly targeted by intervention components in the current study.

Study goals include testing this IVR-supported, individually-tailored physical activity intervention for cancer risk reduction in the Deep South. Moreover, this study will document willingness to call the IVR system, vet new intervention modules addressing physical activity barriers identified in focus groups, and beta-test SCT-based tailoring algorithms in preparation for future efficacy trials and outreach in rural counties. The current paper will describe the rationale, design, and baseline findings of this study.

2. Materials and methods

2.1. Design

The DIAL (Deep South IVR-supported Active Lifestyle) study is an ongoing pilot randomized controlled trial (N = 63) of a 12-week IVR-supported physical activity intervention for cancer risk reduction compared to a waitlist control condition among individuals living in the Deep South.

Primary aims include examining feasibility, acceptability, safety and preliminary efficacy. We hypothesize that the consumer satisfaction survey and interview data, recruitment, retention, and adherence will demonstrate acceptability and demand for the DIAL intervention among individuals living in the Deep South. The study also aims to assess the magnitude and variability of effect with the DIAL intervention. We anticipate greater increases in physical activity from baseline to 12 weeks in the intervention arm compared to waitlist control arm. Secondary aims include exploring potential intervention effects on functional exercise capacity (6 min walk test), body mass index (BMI), weight, percent body fat, waist circumference, and SCT variables. See Fig. 1 for study schema.

2.2. Setting and sample

Research activities for the DIAL study were conducted at the University of Alabama at Birmingham (UAB) Center for the Study of Community Health. The trial received human subjects research approval from the UAB Institutional Review Board, and is registered with ClinicalTrials.gov (NCT02627235). Participants are adults aged 21 and older from Birmingham, AL. At the time of publication, recruitment of study participants is completed. Refer to Table 1 for demographic characteristics.

2.3. Recruitment and retention

Recruitment activities involved face-to-face recruiting and placing flyers in the greater Birmingham metropolitan area, such as municipal buildings (city hall, county health department), community centers and libraries.

To enhance accessibility and reduce burden associated with study participation (e.g., transportation, childcare), the intervention was delivered free of charge via telephone; however, participants were informed that data charges may occur if calling the IVR system from a personal mobile device. Participants were compensated for their time and received $15 for completing baseline and 12-week assessments and up to $43.25 for calling the IVR system daily over their 12-week intervention period (see intervention section below).

2.4. Screening and eligibility requirements

Interested individuals telephoned the research center and completed an eligibility screening interview, including items from the Physical Activity Readiness Questionnaire (PAR-Q) to assess cardiovascular and musculoskeletal risk factors [27]. A history of heart disease, myocardial infarction, angina, stroke, BMI over 45, orthopedic conditions which limit mobility, or any serious medical condition that would make physical activity unsafe were grounds for ineligibility. Moreover, participants had to be ≥ 21 years old, underactive at time of screening (< 60 min/week moderate physical activity), able to speak and read English, willing to be assigned to either study condition, have access to a telephone, and not plan to move from the area in the next 4 months.

2.5. Protocol

Once initial eligibility was established, participants were invited to attend an orientation session, in which a video detailing the study protocol was shown and staff answered participant questions. Interested individuals then completed the informed consent process, and demographics questionnaire, and received an accelerometer (ActiGraph GT3X, Pensacola, FL), with instructions to wear the device during waking hours for 7 consecutive days and return it at the baseline assessment and randomization visit.

3. Baseline assessment

3.1. Physical activity and performance measures

Minutes of physical activity per week, as assessed by the 7-Day Physical Activity Recall (PAR) [28,29], serves as the main outcome of the DIAL trial. The interview uses several strategies for increasing recall accuracy, including breaking down the week into daily segments (i.e., morning, afternoon, and evening) and asking about a variety of activities such as time spent sleeping and in moderate, hard, and very hard activity. This measure has previously demonstrated reliability, internal consistency, and congruent validity with objective physical activity measures [30–35] and is sensitive to changes in moderate intensity physical activity over time [36,37]. The interviewer underwent rigorous training on the administration of the 7-Day PAR with a research staff member who was professionally trained by the Cooper Institute and has completed over 3000 7-Day PARs. All interviews were audiotaped to promote protocol adherence, and 10% of these recordings will be reviewed for quality control.

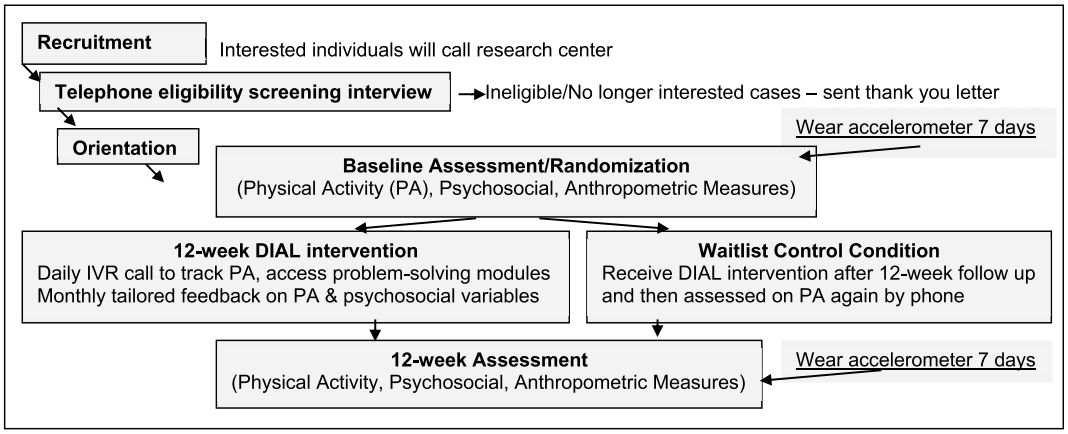

Fig. 1. Study schema.

Table 1
Demographic characteristics of DIAL study participants.

	Intervention (N = 32) (M and SD or %)	Control (N = 31) (M and SD or %)	Overall (n = 63) (M and SD or %)
Age	43.6 (11.7)	42.4 (12.2)	43.0 (11.8)
Male	53.1%	58.1%	55.6%
Non-Hispanic (N = 60)	100%	96.7%	98.3%
Race			
Asian	3.1%	9.7%	6.3%
Black or African American	65.6%	51.6%	58.7%
White	28.1%	38.7%	33.3%
Other	3.1%	0.0%	1.6%
Education			
< High school graduate	3.1%	3.2%	3.2%
High school graduate	3.1%	6.5%	4.8%
Some college	28.1%	35.5%	31.7%
College graduate	43.8%	22.6%	33.3%
Post-graduate work	21.9%	32.3%	27.0%
Employment			
Full-time	59.4%	67.7%	63.5%
Part-time	21.9%	3.2%	12.7%
Unemployed	15.6%	22.6%	19.0%
Retired	3.1%	6.5%	4.8%
Household Annual Income			
< 10,000	3.1%	16.1%	9.5%
10,000–19,999	12.5%	12.9%	12.7%
20,000–29,999	6.3%	9.7%	7.9%
30,000–39,999	6.3%	12.9%	9.5%
40,000–49,999	28.1%	16.1%	22.2%
≥50,000	43.8%	32.3%	38.1%
Marital Status (N = 62)			
Single	41.9%	32.3%	37.1%
Married	41.9%	29.0%	35.5%
Divorced	12.9%	29.0%	21.0%
Widowed	3.2%	6.5%	4.8%
Separated	0.0%	3.2%	1.6%
No children living at home*	84.4%	54.8%	69.8%
BMI*	33.2 (6.9)	29.0 (6.4)	31.1 (6.9)
% Body fat* (N = 59)	42.8 (7.9)	36.3 (11.5)	39.5 (10.4)
Waist circumference cm	104.9 (16.2)	100.5 (13.7)	102.7 (15.1)

*p < 0.05 between groups.

To corroborate self-report data from the 7-Day PAR, participants wore ActiGraph GT3X accelerometers for seven consecutive days prior to the baseline assessment (overlapping the 7-Day PAR time points). These devices are small, lightweight, and worn on the waist. Accelerometers measure both movement and intensity of activity and have been validated with heart rate telemetry [38] and total energy expenditure [39].

ActiLife software version 6.1 was used to validate and analyze bouts of activity, with 1952 counts/minute as the cut point for moderate-intensity activity [40]. The GT3X accelerometers were set to 60-s epochs during initialization. Moreover, a minimum valid wear time was 5 days of at least 600 min of wear or 3000 min of wear over 4 days. Accelerometer data were analyzed in bouts of 10 min or greater, with the allowance of one to 2 min below these thresholds during the 10-min period. A 6 Minute Walk Test measured the distance that can be quickly walked on a hard, flat surface in 6 min [41–43].

3.2. Psychosocial measures

Participants were administered a brief demographics questionnaire regarding age, gender, education, income, race, and ethnicity.

Social Cognitive Theory constructs also were measured at baseline and via the IVR system to generate the automated physical activity counseling messages for intervention participants. Self-regulation for physical activity was measured using a 10-item scale with a reliability estimate (Cronbach's alpha) of 0.78 for this study [44]. The 13-item Social Support for Exercise Scale was used to measure support from family and friends for physical activity and has demonstrated internal consistency (alphas = 0.61-0.91) and criterion validity in past studies [45]. Outcome expectations or the perceived consequences of engaging in physical activity were measured by 9 items with internal consistency (alpha = 0.89) and validity [46]. Perceived enjoyment of physical activity was assessed using an 18-item scale with high internal consistency (alpha = 0.96) and test-retest reliability [47]. Self-efficacy or confidence about participation in physical activity in various situations (e.g., inclement weather) was measured with 5 items (alpha = 0.82) [48].

Short form (7–8 item), hard copy versions of the PROMIS subscales on anxiety, depression, fatigue, and sleep disturbance were also included and have previously demonstrated validity and reliability (alphas = 0.95, 0.98, 0.84, and 0.83, respectively) [49]. All items used a 5-point Likert scale and sums were converted to T scores for the analysis according to conversion tables published on the PROMIS web site (http://www.nihpromis.org/default.aspx).

3.3. Anthropometric measures

Participant height, weight, and waist circumference was measured in a private room while wearing light indoor clothing and no shoes. Height was measured using a portable stadiometer (Seca 213, Chino, CA). Weight was measured on a EatSmart Precision Plus digital bathroom scale (Taylor Precision Products Incorporation, Oak Brook, IL). Waist circumference was measured using a Gulick II measuring tape (County Technology, Gary Mills, WI) that was calibrated for accurate

body measurements to ensure repeatable measurements by applying a constant tension. The tape was placed around the waist and just above the iliac crest. Measurements were recorded to the nearest 0.1 cm at the end of the participant's normal expiration.

Percent body fat was assessed using a Quantum II bioelectrical composition analyzer (RJL Systems, Inc., Detroit, MI), a four-electron system that determines resistance and reactance. The Lukaski equation [50] was used to calculate percent body fat because of its diverse and accurate use in men and women, especially African Americans [51].

3.4. Randomization

After completing baseline assessments, participants were randomly assigned by research staff to either the DIAL intervention or waitlist control condition. Group assignment was determined using a list of random numbers. Allocation information was kept in sealed, opaque envelopes and assigned in the order of baseline assessment completion.

3.5. DIAL intervention

The DIAL intervention is based on Social Cognitive Theory [52] and emphasizes behavioral strategies for increasing physical activity. Participants were given pedometers (AccuSplit AE120XL, Pleasanton, CA) and trained to make brief daily calls to the IVR system to report pedometer steps and minutes of moderate intensity or greater physical activity within the past 24 h. Feedback on physical activity progress will be provided via IVR system and monthly graphic-based feedback letters delivered in the mail. Messages will encourage incremental increases until national physical activity guidelines are reached (e.g., for a participant reporting 100 min/week of moderate intensity physical activity, “You are on your way to meeting the national guidelines. Keep up the good work. Consider leaving yourself reminders and finding a walking partner to help you reach that goal.”).

To promote self-monitoring, reporting of daily physical activity via the IVR system is incentivized, as in our team's past studies [17–19]. Participants receive $.25 each day they call in to record their physical activity data until 7 consecutive days are reached, then each subsequent day is worth $.50. If a day is missed, the amount resets to $0.25 until another continuous week of reporting is established. Participants may receive up to $43.25 for perfect call compliance.

Self-efficacy, social support, outcome expectations, and perceived enjoyment are assessed via the IVR system at 4 weeks, 8 weeks, and 12 weeks. Participant responses are used to select appropriate tailored physical activity counseling messages and progress feedback is provided using earlier data points. For example, for low self-efficacy scores that represent a decrease since the last call, participants receive the following message: “You sound unsure about your ability to exercise, even more so than last time we spoke. Try squeezing-in a 10-min walk 1 or 2 days this week. Meeting this small goal will help you feel more sure that you can fit physical activity into your life.”

Finally, participants receive access to problem solving modules, addressing physical activity barriers identified by the community during formative research [53] (e.g., lack of time, negative outcome expectations, enjoyment, social support). As past researchers [14] noted that physical activity information provided via IVR systems (often using digitized human speech) [9,12] does not evoke strong emotion and suggested adding engaging first person testimonials, this format was used for the problem solving modules. Moreover, the IVR system messages were narrated by a familiar community voice (project director and former local YMCA exercise instructor).

The IVR system assures that daily call length cannot be shortened by reporting no physical activity. In the case of no reported activity, the system directs the caller to questions about potential physical activity barriers to equalize call length (< 2 min for streamlined daily survey). The system also allows participants to correct responses during the call and includes an option for inputting missing data if the previous day was missed. In the case of 2 or more missed calls, staff will contact the participant to determine the reason why and retrieve missing data. If unable to reach by telephone, a letter will be sent.

Prior to starting their 12-week trial of the DIAL intervention, participants receive training in assessing moderate intensity activity using a number of strategies (e.g., Rating of Perceived Exertion) and instructions to perform activity in the moderate range of exertion and make gradual increases in activity from week to week (i.e., 20% per week) until reaching the CDC/ACSM guidelines of 150 min per week. Participants receive injury prevention education and handouts from the staff, encouraging warm-ups, cool-downs, and flexibility training. Moreover, participants are asked whether they have experienced any physical symptoms or complaints that could interfere with their physical activity program each time they call the study line. If they respond ‘yes’ to this question, they are told to stop exercising and contact their personal physician to discuss the health issues further. The IVR system will then prompt the research staff to follow up with a telephone call to the participant within 48 h and discontinue physical activity intervention until physician clearance is provided.

3.6. Intervention fidelity

Research staff performed regular IVR system audits to ensure that the system is functioning optimally, monitor the helpline used by participants to report problems with the system, and manually inspect feedback letters for accuracy before mailing to participants.

3.7. Waitlist control condition

Control participants are assigned to a waiting list and encouraged to continue with their daily routine for the next 12 weeks. Then, at the follow-up assessment, participants are offered the same 12-week trial of the DIAL intervention.

3.8. Twelve-week assessment

Twelve-week follow-up assessments are ongoing. Prior to the visit, accelerometers are mailed to participants with instructions to wear the device for 7 days. At the visit, participants return the accelerometer and complete anthropometric and psychosocial measures, 7-Day Physical Activity Recall interview, and 6-Minute Walk Test again. A consumer satisfaction survey is administered to intervention participants to explore overall satisfaction and perceptions of the intervention. Moreover, a semi-structured qualitative interview will be conducted to discuss intervention features found to be helpful or needing improvement and potential m-Health future directions. Waitlist control participants receive access to the DIAL intervention at this time point and complete 7-Day PARs and consumer satisfaction surveys by phone 12 weeks later.

3.9. Data analyses and sample size considerations

Baseline data are compared across treatment arms (using t-tests for continuous variables and chi square analyses for categorical measures). Correlational analyses were conducted amongst baseline physical activity and related psychosocial variables.

Once 12-week assessment data are available, we will investigate acceptability and preliminary efficacy. Using mixed methods, we will evaluate the acceptability of the DIAL intervention in the Deep South using participant satisfaction questionnaire data and qualitative exit interview data. Moreover, recruitment, retention, and adherence will be examined. Achieving recruitment goals and maintaining 80% retention at 12 weeks will be viewed as indicators of feasibility and acceptability. Regarding adherence, we will analyze data on completed calls to the IVR system within the specified timelines. We anticipate that participants, on average, will complete at least 75% of the daily IVR calls.

For the current study, preliminary efficacy will be assessed by

exploring group differences in changes in physical activity. The analyses will include assessing the normality of the self-report physical activity and, if necessary, making a normalizing transformation of this variable. A longitudinal regression model will be implemented using Generalized Estimating Equations (GEE) to model the effect of treatment assignment on mean minutes of physical activity at 12 weeks, while controlling for baseline covariates. Data will be analyzed by intent-to-treat, and missing data points will be imputed by carrying the baseline value forward. We will also consider conducting sensitivity analyses by applying other imputation approaches (multiple imputations). To corroborate these self-report findings, similar analyses will be conducted using accelerometer data.

Considering sample size, the power analysis was designed to test the hypothesis that the intent-to-treat effect was 0 versus the 2-sided alternative that the effect was different for those randomized to DIAL Intervention vs. Waitlist Control. In a similar past IVR study [9], participants randomized to the intervention reported a mean of 180 weekly minutes (SD = 230.6) of moderate-intensity physical activity at 6 months compared to 100.6 weekly minutes (SD = 113.8) for those randomized to control arm. With 30 participants randomized to each arm at baseline and a significance level of $\alpha = 0.05$, we have 45% power to detect a similar difference in minutes of physical activity at 12 weeks. That said, these calculations are provided as a formality, since this is a pilot study and analyses are exploratory. The sample size will allow us to explore the extent to which this new program shows promise of being successful with the intended population and estimate effect sizes for future power analyses.

Secondary aims include exploring potential intervention effects on functional exercise capacity, weight, BMI, % body fat, waist circumference, and psychosocial variables using repeated measures multivariate analyses of covariance.

4. Results

4.1. Sample characteristics

A total of 157 individuals expressed interest in participation. Of these, 94 were not included in the study: 41 did not meet inclusion criteria (e.g., too active, BMI ≥ 45, no phone, health issues), 15 declined to participate (e.g., too busy, not interested), and 38 were unable to be scheduled for an appointment. The remaining 63 participants were randomized: 32 to the DIAL intervention and 31 to the Waitlist Control arm. Fig. 2 illustrates the CONSORT diagram. The sample was comprised of mostly obese adults (mean BMI = 30.1, SD = 6.9), with correspondingly high percent body fat (M = 39.51%, SD = 10.36) and waist circumferences (M = 102.7 cm, SD = 15.1). The average age was 43 years old. Both genders (55.6% male) and African Americans (58.7%) were well-represented. Most participants reported at least some college level education (92%), full time employment (63.5%), and household incomes under $50,000 per year (61.9%). The intervention arm had significantly higher BMIs and % body fats and were less likely to have children living at home than the control arm, but no other significant group differences in demographic, physical activity, or psychosocial variables were found at baseline. See Table 1 for demographic characteristics.

4.2. Physical activity, physical performance, and related psychosocial variables

As noted in Table 2, participants reported little moderate intensity or greater physical activity (M = 39.6 min/week, SD = 56.4) at baseline. Self report was similar to, yet not significantly correlated with, accelerometer-measured physical activity (M = 32.1 min/week, SD = 47.1; Spearman's rho = 0.19, p = 0.17). Six minute walk distances were also low at baseline (M = 351.4 m, SD = 65.6).

As for psychosocial variables at baseline, most participants reported low physical activity self-efficacy (M = 2.4, SD = 0.8, range = 1–5), self-regulation (M = 2.3, SD = 0.7, range = 1–5), and social support from family (M = 32.0, SD = 11.8, range = 13–65) and friends (M = 30.6, SD = 11.2, range = 13–65). The relatively high perceived physical activity enjoyment (M = 91.9, SD = 19.9, range = 18–126), and positive outcome expectations (M = 4.0, SD = 0.7, range = 1–5) bode well for potential engagement in the intervention. Moreover, mean PROMIS instrument t-scores showed no substantial (≥1 standard deviation) elevations in anxiety (M = 50.9, SD = 10.3), depression (M = 46.6, SD = 10.2), fatigue (M = 51.6, SD = 7.8), and/or sleep disturbance (M = 51.1. SD = 6.9).

4.3. Correlations amongst physical activity and related psychosocial variables at baseline

There were several significant associations found between psychosocial variables and self-reported physical activity at baseline, but not accelerometer-recorded physical activity. Self-reported physical activity was positively correlated with physical activity enjoyment (Pearson correlation = 0.36, $p < 0.01$) and social support from friends ($r = 0.25$, $p < 0.05$) at baseline. Moreover, there were significant associations amongst most of the SCT variables at baseline. For example physical activity enjoyment was positively correlated with physical activity self-regulation ($r = 0.47$), social support (family $r = 0.32$; friends $r = 0.37$), outcome expectations ($r = 0.33$), and self-efficacy ($r = 0.37$), all p's < 0.05. Self-regulation of physical activity was positively correlated with social support (family $r = 0.48$; friends $r = 0.43$), outcome expectations ($r = 0.38$), and self-efficacy ($r = 0.32$), all p's < 0.05. Outcome expectations for physical activity were positively correlated with social support from family ($r = 0.31$, $p < 0.05$), but not friends.

There were also significant associations amongst all of the PROMIS variables, as well as between the PROMIS subscales and the SCT variables, at baseline. Depression was positively correlated with sleep disturbance ($r = 0.26$), fatigue ($r = 0.43$), and anxiety ($r = 0.79$); anxiety with fatigue ($r = 0.49$) and sleep disturbance ($r = 0.39$); and fatigue with sleep disturbance ($r = 0.37$, all p's < 0.01). Depression was negatively correlated with physical activity self-regulation (Pearson correlation = −0.43, $p < 0.01$) and outcome expectations ($r = -0.30$, $p < 0.05$). Anxiety was also significantly negatively correlated with physical activity self-regulation ($r = -0.458$) and enjoyment ($r = -0.373$, p's < 0.01). See Table 3 for correlation matrix.

5. Discussion

The DIAL study tests an IVR-supported physical activity intervention for cancer risk reduction in the Deep South, a region with generally high rates of physical inactivity and related cancer incidence and mortality. Baseline data from the DIAL study indicate that most participants were sedentary and obese and would greatly benefit from physical activity intervention. The average 6 Minute Walk Distance was low (351.4 m), even compared to a recent study with older African American women (382 m) [54]. The mean BMI was high at baseline (30.1 kg/m2), which is concerning given past research indicating that a BMI ≥30 led to a 50% increased risk (95% CI: 0.92–2.5) of colon cancer among middle-aged adults and a 2.4-fold increased risk (95% CI: 1.5–3.9) among older adults [55]. Similarly, waist sizes [≥/ = 99.1 cm and 101.6 cm for women and men, respectively] comparable to those found at baseline in the current study (M = 102.7 cm) were associated with a two-fold increased risk of colon cancer in the previously mentioned study [55].

As for psychosocial variables at baseline, participants reported little exercise goal-setting or planning (self-regulation), social support from friends and family for physical activity and/or confidence in their ability to stay active when barriers arise. However, responses also indicated that this sample generally enjoyed physical activity and

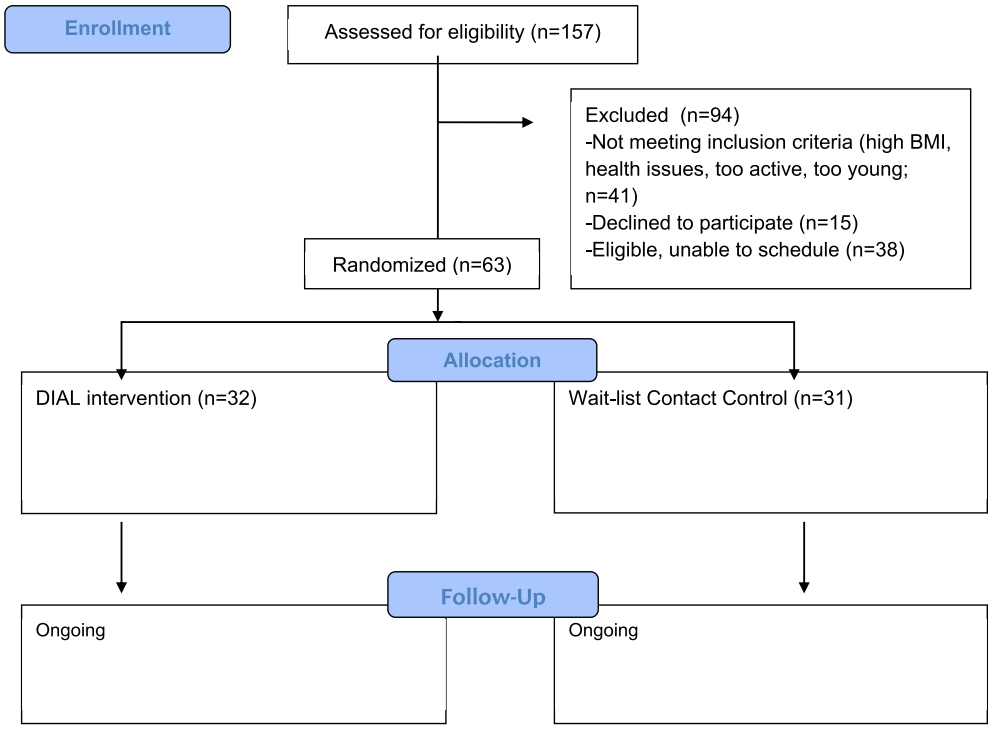

Fig. 2. Study flow diagram.

expected more good than bad to come from participating in physical activity, which suggests that such interventions will be warmly received by this sample. Indeed, several baseline psychosocial measure scores (social support from family and friends, self-regulation, enjoyment) were higher in the current study than in past physical activity studies conducted among sedentary Latinas [56] and/or African American women [57]. Outcome expectations were similar to those found in a past physical activity intervention study with a mostly White sample, yet baseline self efficacy was lower in this sample vs. the mostly White sample [58] and comparable to findings from the previously mentioned study with Latinas [56]. Mean PROMIS instrument t-scores on fatigue, depression, anxiety and sleep disturbance in the current study were similar to those found at baseline in a past physical activity study for breast cancer survivors [59].

Correlational analyses indicated that self-reported physical activity was associated with physical activity enjoyment and social support from friends at baseline. Consequently, these may be important variables to emphasize in our program. Significant correlations amongst SCT constructs support the internal consistency of the theoretical model, as it applies to physical activity behavior. However, findings indicating an inverse relationship between depression and anxiety and key SCT constructs are worrisome, given that more depressed/anxious participants may struggle with physical activity goal setting and planning and/or expect less good to come from physical activity than less depressed/anxious participants. Moreover, associations among the baseline PROMIS subscales indicated that depressed and/or anxious participants are likely experiencing additional barriers (sleep disturbance, fatigue) to participation in the DIAL study that will need to be addressed.

While the project is still ongoing, we have already learned a great deal regarding acceptability and feasibility of the DIAL intervention. Participants were easy to recruit for the study. They did not seem

Table 2
Baseline physical activity levels and psychosocial variables.

	Intervention (N = 32) (M and SD)	Control (N = 31) (M and SD)	Overall (N = 63) (M and SD)
Self-reported ≥ moderate intensity physical activity (minutes/week, 7-day Physical Activity Recall)	27.4 (33.1)	52.2 (71.6)	39.6 (56.4)
Accelerometer-measured ≥ moderate intensity physical activity (minutes/week, N = 56)	27.2 (41.3)	37.8 (53.2)	32.1 (47.1)
6-min walk test (meters, N = 62)	341.4 (68.9)	362.1 (61.1)	351.4 (65.6)
Physical activity self-efficacy (range = 1–5)	2.5 (0.9)	2.3 (0.7)	2.4 (0.8)
Physical activity enjoyment (range = 18–126)	92.2 (18.9)	91.6 (21.3)	91.9 (19.9)
Physical activity self-regulation (range = 1–5)	2.4 (0.6)	2.3 (0.7)	2.3 (0.7)
Social support for physical activity			
Family (range = 13–65)	33.2 (11.4)	30.8 (12.2)	32.0 (11.8)
Friends (range = 13–65)	31.8 (10.4)	29.4 (12.1)	30.6 (11.2)
Outcome expectations for physical activity (range = 1–5)	4.0 (0.7)	4.0 (0.6)	4.0 (0.7)
Anxiety (range = 36.3–82.7)	51.4 (10.9)	50.4 (9.7)	50.9 (10.3)
Depression (range = 37.1–81.1)	46.6 (10.6)	46.6 (9.9)	46.6 (10.2)
Fatigue (range = 29.4–83.2)	52.3 (7.2)	50.9 (8.5)	51.6 (7.8)
Sleep (range = 28.9–76.5)	52.5 (6.9)	49.5 (6.7)	51.1 (6.9)

*There were no significant group differences.

Table 3
Baseline correlations amongst physical activity and related psychosocial variables.

	Self-Report Physical Activity	Enjoyment	Self-Efficacy	Self-Regulation	Social Support Family	Social Support Friend	Outcome Expectations	Anxiety	Depression	Fatigue	Sleep
Self-Report Physical Activity		0.357**	0.050	0.227	0.172	0.248*	0.171	−0.181	−0.167	0.029	0.046
Enjoyment	0.357**		0.367**	0.473**	0.323**	0.367**	0.332**	−0.373**	−0.273*	−0.117	0.074
Self-Efficacy	0.050	0.367**		0.322**	0.070	0.158	−0.054	−0.195	−0.087	0.079	−0.030
Self-Regulation	0.227	0.473**	0.322**		0.484**	0.430**	0.375**	−0.458**	−0.432**	-−0.169	0.026
Social Support Family	0.172	0.323**	0.070	0.484**		0.754**	0.309*	−0.193	−0.104	−0.043	0.019
Social Support Friend	0.248*	0.367**	0.158	0.430**	0.754**		0.179	−0.154	−0.154	−0.116	0.076
Outcome Expectations	0.171	0.332**	−0.054	0.375**	0.309*	0.179		−0.223	−0.304*	−0.088	0.098
Anxiety	−0.181	−0.373**	−0.195	−0.458**	−0.193	−0.154	−0.223		0.786**	0.493**	0.391**
Depression	−0.167	−0.273*	−0.087	−0.432**	−0.104	−0.154	−0.304*	0.786**		0.434**	0.260*
Fatigue	0.029	−0.117	0.079	−0.169	−0.043	−0.116	−0.088	0.493**	0.434**		0.374**
Sleep	0.046	0.074	−0.030	0.026	0.019	0.076	0.098	0.391**	0.260*	0.374**	

*p ≤ 0.05.
**p ≤ 0.01.

deterred by the description of the study design and protocols at orientation and were generally willing to participate in either group. Those who were assigned to the waitlist control arm vs. intervention did not express disappointment (several even stated that such a schedule was more convenient for them) and thus differential dropout is not anticipated. Participants randomized to the intervention arm appeared remarkably open to following the demanding protocol (i.e., call the DIAL study line every day for 90 days). While payment for the IVR calls likely played a role in this willingness, incentive schedules are based on behavioral economics tactics and not all participants who have completed their 12-week trial thus far received the full $43.25 for call adherence. In fact, study staff have already contacted several participants regarding missed daily calls (due to lost PIN, etc.) and most were re-engaged. Moreover, participants were reminded at orientation that data charges could occur if calling the IVR system from a personal mobile device (vs. landline) and there have been no complaints or comments thus far on that issue.

The actual set-up of the IVR system has been a surprisingly arduous, ongoing task. Drafting and frequent editing, recording, (and re-recording) the intervention messages, daily/monthly call scripts, and algorithms for generating counseling messages (based on the survey responses) proved time consuming yet necessary to ensure that the call flow felt natural and relevant feedback was delivered. Providing progress feedback can be a particularly complicated process and effort was required to avoid conflicting messages (i.e., “You are reporting low physical activity this week. Congrats for increasing your physical activity”). Moreover, numerous message options had to be developed for each SCT construct and time point to minimize the likelihood of participants receiving the same feedback at 30, 60, and/or 90 days. Past studies indicated that participants might prefer IVR system feedback provided in a human voice (vs. computer-generated) and our initial qualitative impressions confirm this hypothesis. The project director served as “the voice” of the IVR system for the current study by narrating the IVR daily/monthly call scripts and intervention messages and thus far participants appear to appreciate this personal touch. Most participants quickly recognized her voice when oriented to the IVR system and often smiled and made positive comments in response. Moreover, IVR training (especially conducting the first IVR call with research staff) appears critical as it allows participants to ask questions in the moment and receive clarification on the intervention protocol early on. Finally, dedicating multiple phone lines for study purposes is helpful in accommodating periods of high call volume and avoiding missed calls. In fact, technical issues have already arisen; however, when the IVR system was down, participants quickly alerted study staff and the IT team was able to resolve this matter in a timely manner (less than 24 h).

Strengths of the study include the randomized design with a waitlist control arm, which will allow for replication of results. Moreover, the diverse sample, including African Americans and males, will improve the generalizability of our study findings. Limitations include the short duration of the trial (12 weeks) and small convenience sample of community volunteers. Moreover the enrolled population may not be representative of the target population given the higher rates of obesity, African Americans and education in this sample compared to the general Alabama population [60,61]. However, the pilot study process has already helped generate ideas on how to improve the DIAL intervention before rolling-out this program on larger scale. For example, with a bit more coding, monthly graphic-based feedback letters can be automatically generated based on IVR system data and thereby minimize related research staff time devoted to such tasks and improve cost-effectiveness. Moreover, new problem solving modules will be developed based on participants' feedback in the current trial, as rotating new modules and content in regularly may be key to keeping participants calling back in to IVR system over the long term and maintaining active lifestyles.

Given that the DIAL intervention provides automated phone counseling via land lines (or cell) at the participants' convenience, is available 24 h a day, 7 days a week and makes minimal demands from participants in terms of literacy, travel, and technology access, such approaches may be particularly appropriate for addressing barriers to physical activity participation in this region related to income, education, distance, and culture. Moreover, intervention messages were guided by formative research with the target population and Social Cognitive Theory and thus will likely improve the health behaviors of the participants.

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