AWARD NUMBER: W81XWH-22-1-0452

TITLE: Identifying Sociodemographic, Behavioral, and Genetic Modifiers of a Behavioral Intervention for the Prevention of Overweight/Obesity in Children with ALL

PRINCIPAL INVESTIGATOR: Dr. Elena J. Ladas

CONTRACTING ORGANIZATION: The Trustees of Columbia University in the City of New York

REPORT DATE: OCTOBER 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2023	Annual	1SEPT2022 - 31AUG2023

4. TITLE AND SUBTITLE

Identifying Sociodemographic, Behavioral, and Genetic Modifiers of a Behavioral Intervention for the Prevention of Overweight/Obesity in Children with ALL

5a. CONTRACT NUMBER
W81XWH-22-1-0452

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Dr. Elena J. Ladas

E-Mail: ejd14@cumc.columbia.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Trustees of Columbia
University in the City of NY
Health Sciences Division
630 W 168th Street, floor 4
New York, NY 10032-3725

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The **PE**diatric **D**iet intervention for children, adolescents, and young adults with **ALL** (PEDALL*)* is a 6-month, bilingual (English/Spanish), telemedicine-based intervention aimed at preventing OW/OB in C-AYA with ALL. PEDALL will recruit 708 Hispanic and Non-Hispanic C-AYA to a 6-month lifestyle behavioral counseling program aimed at improving dietary behaviors during treatment for ALL while also promoting healthy lifestyles. We propose to examine personal characteristics to first determine if they promote or hinder the efficacy of PEDALL. We will then synthesize this information to develop a risk prediction model to identify C-AYA at high risk for the development of OW/OB and who may benefit the greatest from the intervention. The study aims are to examine the modifying effect of genetic predisposition to OW/OB, defined by a trans-ethnic GPS for obesity, on the efficacy of PEDALL for the prevention of OW/OB in C-AYA undergoing treatment for ALL; identify if baseline lifestyle factors modify the efficacy of PEDALL for the prevention of OW/OB in C- AYA; examine the modifying effect of sociodemographic factors on the efficacy of PEDALL for the prevention of OW/OB in C-AYA undergoing treatment for ALL; and to develop a multifactorial risk prediction models.

15. SUBJECT TERMS

ALL- Acute lymphoblastic leukemia, C-AYA- Children, adolescents, and young adults, GPS- Global polygenetic risk score, OW/OB- overweight/obesity; WIRB- Western Institutional Review Board

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRDC
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	6	19b. TELEPHONE NUMBER *(include area code)*
U	U	U			

TABLE OF CONTENTS

1.Introduction

This annual report contains the progress for the study entitled, *A bilingual virtually-based intervention (PEDALL) for the prevention of weight gain in childhood ALL patients considering key genetic and sociodemographic risk factors.* Briefly, PEDALL is a 6-month, bilingual (English/Spanish), telemedicine-based intervention aimed at preventing OW/OB in C-AYA with ALL. PEDALL will recruit and randomize 376 Hispanic and Non-Hispanic C-AYA to a 6-month lifestyle behavioral counseling program or standard of care who are undergoing treatment for ALL. Enrollment will be stratified by ethnicity with 30% of participants (approx. n=214) self-reported as Hispanic. Furthermore, support will be provided to ensure digital equity (e.g., access to iPads, hot spots, etc.) among study participants.

This study will examine pre-treatment variables to first determine modifiers of the efficacy of PEDALL and then synthesize this information to develop a multifactorial risk prediction score to identify participants who may benefit the greatest from the intervention. The study aims are: **Aim 1:** To examine the modifying effect of genetic predisposition to OW/OB, defined by a trans-ethnic GPS for obesity, on the efficacy of PEDALL for the prevention of OW/OB in C-AYA undergoing treatment for ALL; **Aim 2:** To identify if baseline lifestyle factors (dietary intake and physical activity) modify the efficacy of PEDALL for the prevention of OW/OB in C- AYA undergoing treatment for ALL; **Aim 3**: To examine the modifying effect of sociodemographic factors (e.g., self-reported race and ethnicity, foreign-born status, food security, and home food environments) on the efficacy of PEDALL for the prevention of OW/OB in C-AYA undergoing treatment for ALL; **Aim 4:** To develop a multifactorial risk prediction model comprised of genetic predisposition, baseline lifestyle variables, and sociodemographic factors to predict OW/OB.

2. Keywords

ALL- Acute lymphoblastic leukemia
C-AYA- Children, adolescents, and young adults
GPS- Global polygenetic risk score
OW/OB- overweight/obesity
PEDALL- The Pediatric Diet Intervention for Children with ALL
WIRB- Western Institutional Review Board

3. Accomplishments

In January of 2022, notification of intent to fund was received by the DOD. Since that time, the following administrative tasks have been performed in preparation for study activation:

a. In February of 2022, The Spa Projects Administrator at Columbia University corresponded with the DOD to initiate the pre-award review process. All documents were submitted except approval from institutional review board, which was pending at the time.
b. In December of 2022, the study committee transferred the study from being administered as part of the Children's Oncology Group's network to that of an institutional network of centers (Refer to participating centers in Section 7) being led by the institution of the principal investigator (E. Ladas), Columbia University. This modification allowed for the study to be expedited through the infrastructure established by Dr. Ladas's clinical research program at Columbia University Irving Medical Center in order to advance study start up. This modification did not change the conduct of the parent clinical trial (nutrition intervention, zoom counseling, and REDCap management) as this aspect of the study was funded by center grants awarded to Dr. Ladas.
c. On February 16, 2023, submission of the study protocol to central institutional board (Western Institutional Review Board) was completed. Approval from Western Institutional Review Board was obtained on May 23, 2023. Subsequent approval from the Institutional Review Board at the lead site (Columbia University) was obtained on August 2, 2023.
d. Submission of approval documents from the Western Institutional Review Board and Columbia University were submitted to Mr. Shadawn Mayer in August of 2023. Currently, we are awaiting final approval from DOD to launch the study.

4. Impact

Not applicable, study is underway

5. Changes/Problems

On January 12, 2023, Dr. Ladas discussed a change in the administrative structure of the grant with Dr. Emilee Senkevitch, Science Officer, CDMRP. The transition from the Children's Oncology Group platform to that of Columbia University Irving Medical Center was discussed and approved. As well, the sample size was reduced from 638 to 376 per revised power calculations.

6. Products

NA

7. Participants and Other Collaborating Organizations

Table 1 provides the list of participating centers, the status of approval by the WIRB and local institutional review boards, and the status of material and data transfer agreements.

Table 1. List of Participating Institutions

Institution	Western Institutional Review Board	Material Transfer Agreement	Data Transfer Agreement
Children's Hospital of Philadelphia (CHOP)	Submission in process	In review	In review
Children's National Medical Center (CNMC)	In preparation	In preparation	In preparation
Rhode Island Hospital (Lifespan)	Submission in process	In review	In review
Roswell Park Comprehensive Cancer Center (RPCI)	Approved by the WIRB on 9/18/23; under review by local IRB	In review	In review
Rutgers Cancer Institute of New Jersey (Rutgers)	Submission in process	In review	In review
University of Texas Health Science Center at San Antonio (San Antonio)	Submission in process	In review	In review
Connecticut Children's Hospital (CT)	Submission in process	In review	In review
The Children's Hospital at Montefiore (Montefiore)	Submission in process	In review	In review
Dana Farber Cancer Institute (DFCI)	Submission in process	In review	In review
Children's Healthcare of Atlanta (Atlanta)	Submission in process	In review	In review

8. Special Reporting Requirements

Not applicable

9.Appendices

Not applicable