Title: Strengthening and Supporting the Diabetes Early Prevention Efforts of Pediatric Primary Healthcare Providers

NCT# NCT05011292

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PROTOCOL TITLE: Well-Child Visit Video Project

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CHOA IRB will be invited to review.

VERSION: Version 3, 03/20/23

FUNDING SOURCE: The Global Center for Diabetes Translation Research, pilot grant program (original funding from NIH).

REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	03/03/21	1. Revised survey instruments for clarity of response options and to add a couple of knowledge and perception questions. Also added a space for the

		last 4 digits of participant phone numbers which will be used as a unique study ID 2. Split the previous "Long-term Follow-Up survey ito two separate surveys, one to be complted at baseline and one at follow-up.. 3. Revised consent form for long-term follow-up sub-study to be read (on IPad) by potential participants and for them to indicate whether or not they wanted to participate. 4. A Handout for sub-study participants was also added. 5. Increased the target number of participants.
2	04/30/21	Slightly revised secondary objective and added exploratory objective. Noted the addition of Dr. Livingston-Burns on the protocol as a collaborator. Adding question to follow-up survey for sub-study participants asking if they'd be willing to be contacted for future studies.
3	03/21/23	Given the higher than expected drop-out rate and the need for stratifying the analyses to account for differences in intervention exposure and response rates between groups, we would like to increase the sample size to a total of 750 in the main study and 100 in the long-term sub-study (page 6) Revision for the payment of a $10 gift card to participants in the main study (page 10 and 11). A correction was made in the listing of the inclusion criteria, clarifying that parents of children from 4 up to and including 15 months are eligible (page 13)

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1. Study Summary

Study Title	Well-Child Visit Video Project
Study Design	Quasi-experimental, controlled before and after study
Primary Objective	Assess the impact of using targeted, age-specific videos during well-child visits on parents' 1) knowledge of fruit juice related recommendations for infants and 2) their compliance with related expert recommendations when feeding their infant.
Secondary Objective(s)	We aim to determine if a short (3-4 minute) educational videos on recommended infant feeding practices played during well-child visits: 1.Can be effectively incorporated into routine practice. 2.Are well-received and informative to parents
Exploratory Objective(s)	We will also explore to determine if a short (3-4 minute) educational videos on recommended infant feeding practices played during well-child visits have an impact on infant feeding practices other than those specific to SCBs.
Research Intervention(s)/ Interactions	For the main study, parents attending a well child visit with their child (4 and 12 months) will be played a ~3 min video while waiting in the exam room and will be asked questions about their perception of the video. When parents return for their next scheduled well-child visits during the study at 6, 9, or 15 months they will be asked to complete a short survey about infant feeding practices. Parents who participate in the study during the first months of the study will be the control group. Those who participate after the sugary

	beverage reduction videos are introduced will comprise the intervention group. A subsample of parents attending their child's 4 or 12-month well-child visit will be invited to participate in a long-term follow-up sub-study. This will include completing a knowledge and practice survey, watching a short video, and completing a video perception survey at baseline. In addition, they will be asked to complete a short survey during their next well-child visit (if they attend Hughes Spalding clinic for this), and by email or text approximately 5 months later. (PHI in the form of first name and email address or phone number for text will be collected). In addition, clinic staff will be interviewed about their perceptions of the usefulness and ease of the videos (no PHI will be collected from staff).
Study Population	Parents of children age 4-15 months at enrollment who attend a well-child visit at the collaborating pediatric primary care clinic during the pilot implementation.
Sample Size	Main parent study: up to 750 total (estimated 375 in each of the two groups). Long-term follow-up: up to 100 parents (30 in each of the two groups). Clinic staff interviews: 6-10 staff
Study Duration for individual participants	Parents in the main study: estimated max total 10 minutes Parents in the long-term follow-up subsample: estimated total 20 minutes. Clinic staff: 5-30 minutes.

Study Specific Abbreviations/ Definitions	SCB: sugar-containing beverages; T2D: Type 2 diabetes; Well-child visit: regularly scheduled preventative healthcare visit for children under the age of 18.
Funding Source (if any)	The Global Center for Diabetes Translation Research, pilot grant program (original funding from NIH).

2. Objectives

The primary objective of the study is to assess the impact of using targeted, age-specific videos during well-child visits on parents' knowledge of SCB recommendations for infants and their compliance with related early SCB feeding recommendations when feeding their infant. The secondary objectives are to determine if educational videos focused on reducing the consumption of SCBs in infancy:

- Can be effectively incorporated into routine practice.
- Increases the frequency and quality of the SCB-related reduction education and counseling provided to parents during well-child visits.

Our hypothesis is that incorporating a ~3 min video for parents about SCB consumption for infants during well-child visits will increase parents' knowledge of SCB recommendations for infants and decrease the prevalence of consumption of SCBs in infancy.

3. Background

The prevalence of Type 2 diabetes and obesity, its leading risk factor, have risen markedly among children in the United States. While previously so rare in children it was referred to as "adult onset diabetes", the prevalence of Type 2 diabetes among 10-19 years olds has increased by 30% since 2001 alone[1]. Infant and young child dietary patterns and practices have been shown to be linked to an increased risk of developing cardiometabolic disease, including diabetes. This highlights the critical need for interventions in early childhood that promote the development and sustainment of risk-reducing lifestyle practices.

High consumption of non-milk sugars, particularly those consumed in beverages, is well-recognized as a risk factor for diabetes, obesity, and related diseases[2,3]. U.S. Dietary Guidelines advise that the consumption of added sugars, those added to foods and

beverages as a part of their processing or preparation, be limited to less than 10% of total energy intake[4]. The World Health Organization (WHO) goes further, including the naturally occurring sugars in fruit juice (which are similar in type and quantity to those in sugar-sweetened beverages) in this limit, and referring to them all together as "free sugars"[5]. Despite concerns related to high consumption of fruit juice among young children, the most common reason cited by parents for giving their children <5 years fruit juice was, "because [fruit juices] are healthy" (56% of respondents)[6].

We've previously shown that, in the United States, excess "free sugar" intake begins in infancy[7] when fruit juice and other sugary foods and beverage are often first introduced, despite recommendations from the American Academy of Pediatrics (AAP) and others against this early introduction [8-11]. Nearly one-half (48%) of infants age 6-11 months consume fruit juice[12]. By age 2 years, mean free sugar consumption exceeds the WHO recommended limit[7]. Our recent analysis of data from over 6,000 children in the U.K. demonstrated that children who consumed (non-milk) sugar-containing beverages (SCBs) in infancy were more likely than non-consumers to be overweight or obese at ages 9 years (27% vs 24%, $p<0.05$) and have more dual x ray absorptiometry (DXA)-measured body fat, (7237g vs. 6962 g, $p=0.05$). These findings support those from earlier studies showing an association between SCB consumption in infancy and higher obesity and diabetes risk later in childhood[13,14,15].

Physicians are parents most trusted source of nutrition and health information[16,17] and nearly all children 0-5 years (88%) attended regular well-child visits[18]. Therefore, pediatric healthcare providers are well-positioned to guide and support parents to adopt health-promoting early feeding practices. Unfortunately, their effectiveness in this role is limited due to a lack of training in nutrition and recommended early feeding practices[19-21]. In addition, the competing demands on the pediatric primary healthcare systems leave providers little time in which to do effective patient education and counseling[22]. Easy-to-use strategies and tools that can be integrated into routine well-child visits are needed to ensure that evidence-based early feeding messages are consistently and effectively communicated to parents and other caregivers.

Videos have previously been shown to be a low-cost and effective way of conveying key educational message to a variety of audiences[23]. Our recent 3-month pilot study in a large pediatric primary care clinic demonstrated that the viewing of a short educational video (on a variety of topics) during each well-child visit, newborn to age 3, was well-received by both parents and healthcare providers. Nearly all (98%) parents who completed a post-video survey (n=67) reported that they liked it, 88% reported that viewing it while waiting to see the doctor was a good use of their time[24], and healthcare team collaborators valued them so much they requested to continue using them after the pilot study was concluded. Building upon this work, the goal of the proposed pilot project is to assess the impact of using targeted, age-specific videos during well-child visits as a tool for increasing parent compliance with feeding practices that promote a reduction in children's SCB

consumption.

The results of this study will be used to inform a randomized control trial to test the impact of a comprehensive program designed to strengthen the early feeding/diabetes prevention related education and counseling provided by pediatric primary care providers. The program to be tested will center around an on-going, evidence-informed program[25,26] which will, dependent on the results of this pilot, be expanded to include the use of videos.

4. Study Endpoints

The primary outcome will be the percentage of parents who a) are aware of infant fruit juice consumption recommendations and b) who report that they do not give their young children fruit juice.

Secondary outcomes will include 1) the percentage of clinic staff who report that the SCB consumption related videos were easy to incorporate into the flow of clinic operations and 2) the percentage of parents who viewed an intervention video report that they enjoyed it or learned something from it

We will also explore to determine if viewing the short (3-4 minute) educational videos on recommended infant feeding practices played during well-child visits have an impact on other (non SCB-related) infant feeding practices .

No risks to study participation are anticipated.

5. Study Intervention / Design

The main study will involve:

1) parents viewing a ~3-minute video during routine 4-month or 12-month well-child visits and completing a survey about their perception of the video afterwards. The control group will view an educational video about a topic other than infant SCB consumption. This will be done in the first months of the study. The intervention group will include those parents who participate in the study after the control data has been collected and two SCB reduction-related videos have been introduced (one for showing at the 4-month visit and one for the 12-month visit).

2) parents attending a 6-month or 15-month well- child visit will be asked to complete a survey to assess infant feeding practices.

A sub-sample of parents who consent to participate in a long-term follow-up component of the study will complete a child feeding knowledge and behavior survey at the enrollment clinic visit (4-month or 12-month well-child visit). In addition, they will view a short video (~ 3 minutes) and answer a few questions about their perception of the videos. They will be asked to complete another knowledge and behavior survey at their child's next well-child visit at 6 and 15-months, and by e-mail 4-5 months after enrollment. The control group will be comprised of parents enrolled prior to the introduction of the intervention videos.

In addition, clinic staff involved in providing well-child care will be invited to participate in key informant interviews to learn from them how they how they perceived the process of integrating the videos into practice, the parent response to the videos, and whether or not they perceive them to be a valuable tool.

6. Procedures Involved

The intervention centers around the use of short educational videos to 1) improve and increase the SCB reduction related education and counseling provided by healthcare providers as part of infant well-child visits, 2) reduce the feeding practices of parents of infants and young children that promote SCB consumption, and 3) reduce the proportion of infants and young children that consume SCBs. As no suitable existing videos have been identified, two videos will be developed, one to be viewed by parents attending their child's 4 month well child visits and one for those attending their 12-month visit. These visits are prioritized given that most parents begin to introduce complementary foods, including fruit juices and other SCB, around age 4-6 months[27], and the intake of juice and other sugary drinks and foods is known to rise sharply during a child's second year[7].

After escorting parents/children to the patient exam room the parent will be asked if they would like to participate in the study which involves:

Main study

1. For parents attending a 4-month or 12-month well child visit: viewing a video and answering a few short questions about it. These parents will be offered a $10 gift card for their participation.

2. For parent attending a 6-month, 9-month or 15-month well-child visit: completing a survey on child feeding and related knowledge and practices. These parents will be offered a $10 gift card for their participation.

Sub-study
In addition, a subsample of the above parents will be invited to participate in a long-term follow-up study which will include completion of a knowledge and practice survey, watching a video and completing a short survey about the video upon enrollment, completing a knowledge and practices survey at their child's subsequent well-child visit, and another survey four to 5 months later by emal or text.. A $20 gift card will be offered (electronically) to those who successful completion of the final follow-up (e-mail) survey.

Parents will be asked to view the video on an available computer or using a dedicated electronic tablet, while they await the physician. After viewing the video, a digital prompt will ask parents to complete the *Perceptions of the Video* survey. When the physician enters the room, the physician will then, as part of their interview and assessment, reinforce the video's key messages and inquire as to any questions. Face-to-face interaction such as this has been shown to increase the effectiveness of videos as a health education tool[23].

The video content will be developed in collaboration with a registered dietitian with extensive experience developing early feeding related education materials. Content development will be guided by the Health Belief Model of behavior change which predicts that individuals are more likely to perform a health-related behavior if they believe that (1) a negative health condition can be avoided, (2) a recommended action is available to avoid a negative health condition, and (3) they have the ability to take a recommended health action[28].

The *Knowledge and Behavior* survey will ask parents (mostly) close-ended questions about their child feeding practices and their knowledge of SCB recommendations for infants and the feeding practices of their child. The *Perceptions of the Video* survey will ask parents about how informative they thought the video was and their enjoyment with the video (close-ended questions on a 5 item Likert-type scale from "strongly disagree" to "strongly agree"). Responses to both surveys will be gathered through RedCap and results in electronic database of responses.

At the completion of the pilot project, key Informant Interviews will be done with participating clinic staff as part of a group de-briefing or through one-on-one interviews, as needed. These will range from 5-30 minutes in length and will be used to collect feedback on the impact of the video on patient flow and on staff perception of the impact on parents.

Anticipated risks include loss of confidentiality and loss of time for the subsample of participants in the long-term follow-up. To minimize the risk of loss of confidentiality, we will not collect identifying information from the main study participants or from clinic staff. For the long-term follow-up subsample, contact information (name and phone number) will be collected, but study IDs will be assigned to participants and identifying information will be saved on a password protected computer that is only accessible to the research team. RedCap secure data management system maintained by Emory will be used to collect and store study data, will be password protected and will only be accessible to the study team.

Risks to the clinic staff participating in the study include loss of productivity while they are working. To minimize this risk, staff will have the option to participate or not based on their schedule and can spend much less than the 45 minutes participating if they wish to do so.

Describe:

- Project data will be collected using self-administered surveys (parents) and interviews (clinic staff). Data to be collected include information on child feeding related knowledge and practices and perceptions of the videos (parents) and perceptions of the videos and their impact on clinic practice (clinic staff)
- A small subsample will be followed until the end of the study period to longitudinally assess their experience with and perception of the videos and the possible impact of the videos on their knowledge and practices.

7. Data and Specimen Banking

At the conclusion of the study, all data will be destroyed. Study data will not be related to anyone outside of the research group.

8. Sharing of Results with Participants

Results will not be shared with participant.

9. Study Timelines

A detailed description of activities for the 12 months study can be found in Appendix A.

10. Subject Population

Inclusion criteria for participants includes
1) Being over 18 years of age, AND
2) Being a parent/caregiver of a child age 4-15 months, AND
2) Attending a well-child visit at the collaborating pediatric primary care clinic and planning to continue during the pilot implementation.

Exclusion criteria includes
1) Parents/caregivers with cognitive or behavioral limitations that preclude completion of the survey
2) Parents/caregivers of children with conditions that require special feeding protocols, e.g. tube feedings, high calorie supplements
3) Parent/caregivers who are not able to communicate in English

We will not be targeting a specific community or racial/ethnic group in this study.

11. Local Number of Participants

The total number of participants for the study will be 50-54 participants. For the main part of the study with parents, we will have at least 44 parents (22 parents in each of the two groups). The long-term follow-up participants are a subsample of the 44 parents and will include 20 parents (10 from each of the two groups). For the clinic staff interviews, 6-10 staff participants will be included.

12. Recruitment Methods

Participants for the main study will be recruited while attending a well-child visit at the Hughes Spalding clinic during the study period. The clinic staff that escorts parents and their children from the main waiting room to the exam room will ask parents if they are willing to participate in the study. All parents over the age of 18 years with the cognitive and language ability to respond to the survey question in English will be invited to participate. As this activity will be integrated into and offered to parents of all children attending the selected well-child visit, no payment will be provided

Parents participating in the sub-sample will be recruited by clinic staff who will inform them about the study. Name and contact information will be collected then. This will be conveyed to the research team who will follow up to do an informed consent. The

parents will be provided a $10 Amazon gift card for each follow-up interview completed. These will be sent electronically following the completion of the final survey.

13. Withdrawal of Participants

We do not anticipate withdrawing any participants from the study without their consent.

14. Risks to Participants

Potential risks to the long-term follow-up subsample of participants are the loss of confidentiality and the time spent for the follow-up survey phone call. The risk of loss of confidentiality will be minimized by using study IDs and saving identifying information on password protected computers, to which only select study staff will have access.

A potential risk for clinic staff in participating in the study is loss of productivity while working at the clinic. Loss of productivity will by minimized by giving staff the choice to not participate and if they decide to participate, they will decide how much time they would like to be engaged (from 5 to 45 minutes).

We do not anticipate any unforeseeable risks to study participants.

15. Potential Benefits to Participants

There will be no direct benefits to parent participants other than the possibility of increased knowledge regarding healthy child feeding which could result in improved practices with their child. The benefit to clinic staff will be in knowing that they contributed to efforts to improve patient care and clinic work flow and the food we provide to them at the clinic to thank them for their time.

The parents in the long-term follow-up subsample will be compensated for their time via a $10 Amazon gift card for completion of the final survey. These will be sent electronically following the completion of the surveys.

16. Data Analysis, Management and Confidentiality

Study IDs will be used to identify parents enrolled in the long-term follow-up study and only the PI will be able to link the ID to the personally identifying data. Data will be stored on a password protected computer.

Sample size. Previous studies estimate that 47.7% (SD=3.2) of children age 6-11 months drink 100% fruit juice. Fewer, 13.6% (SD=2.0) drink sugar-sweetened beverages[12]. We determined that a sample size of 44 per group will provide 80% power to detect a significant difference ($p<0.05$) if the prevalence of SCB consumption is 48% among infants in the control group and 20% among those in the post-intervention group. Participation of 49 parents in the intervention group will allow for a final sample of 44 assuming a 10% drop-out.

Data analysis. Descriptive statistics will be used to describe the sample and to compare the SCB-related knowledge, perceptions and practices of parents who received the intervention compared to those who did not. Chi-squared tests will be used to compare the prevalence of SCB-related practices between the control group and the intervention group. Any demographic differences between the pre and post cohorts will be assessed and controlled for using stratified analyses or multivariate models. A p-value of 0.05 will be used to determine statistical significance. All statistical analysis will be conducted using SAS 9.4 (Cary, NC). Key themes arising from the discussions with key informants will be summarized.

To minimize any risk of misuse of personal data, a participant ID will be assigned upon enrollment. No names, addresses or other potentially identifying information will be collected and used for any purpose with the exception of the first names and email addresses that will be used to do the follow-up survey of those who volunteer to participate in the subsample among whom a long-term follow-up survey will be done. Only the PI will have the information to link a participant to their study ID. This information will be stored on the Emory Pediatrics file server protected with encrypted passwords and kept printed in a locked office.

17. Provisions to Monitor the Data to Ensure the Safety of Participants

Given the low-risk involved in this study, a provision for safety monitoring will not be established.

18. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

No personal information will be collected from the majority of study participants. PHI will be collected only from those who consent to participating in the long-term follow-up study and that will include only first name and email address. A study ID will be used to refer to these participants and only the PI will have the ability to match the study ID with a participant's name.

Electronic data collected at the clinic will be transmitted via secure email to the research team. Data will be stored on the RedCap secure data storage system.

19. Economic Burden to Participants

There is no expected economic burden of this study to participants.

20. Consent Process

For the three different components, the plan for consenting is as follows:

1. Main study: a waiver of written consent is being requested. Participants will be provided a one-page handout outlining the purpose of the study, what it entails, and who to contact if they have questions. This information will also be available as part of the introduction to the study survey.

2. Long-term follow-up subsample. A waiver of written consent is being requested. Participants will be provided the opportunity to read the consent information electronically before deciding (and indicating) whether or not they will participate. In addition, a one-page handout outlining the purpose of the study, what it entails, and who to contact if they have questions will be provided.

3. Clinic team/key informant interviews. Informed consent will be obtained by research team members who will be conducting the interviews on site at Hughes Spalding clinic. A waiver of written consent is requested.

21. Setting

This study will take place at the Hughes Spalding primary care clinic. Participants will be recruited as part of regular well-child visit care.

22. Resources Available

As the all components of the main study are designed to be integrated into usual care, clinic staff will introduce the videos and requested parents to complete the survey questions. The research team will oversee the data collection from those participating in the long-term follow-up by email. All members of the research team will have a current CITI certification.

23. References

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Appendix A

Activity	1 Month	2 Month	3 Month	4 Month	5 Month	6 Month	7 Month	8 Month	9 Month	10 Month	11 Month	12 Month
Project Management												
IRB approval												
Video development												
Data analysis												
Manuscript preparation												
Draft grant proposal												
Pre-intervention (control) group												
At all 4-month visits			Control video 1 (4 mo); Video perception survey	Control video 1 (4 mo); Video perception survey								
At all 6-month visits					(6 mo) KAP survey	(6 mo) KAP survey	(6 mo) KAP survey					
At all 9-month visits								(9 mo) KAP survey	(9 mo) KAP survey	(9 mo) KAP survey		
At all 12-month visits			Control video 2 (12 mon); Video perception survey	Control video 2 (12 mon); Video perception survey								
At all 15-month visits						(15 mo) KAP survey	(15 mo) KAP survey	(15 mo) KAP survey				
Intervention group												
At all 4-month visits						Intervent video (4 mon); Video perception survey	Intervent video (4 mon); Video perception survey					
At all 6-month visits								(6 mo) KAP survey	(6 mo) KAP survey	(6 mo) KAP survey		
At all 9-month visits											(9 mo) KAP survey	(9 mo) KAP survey
At all 12-month visits						Intervent video (12 mon); Video perception survey	Intervent video (12 mon); Video perception survey					
At all 15-month visits									(15 mo) KAP survey	(15 mo) KAP survey	(15 mo) KAP survey	
Prospective Sub-sample												
Control		(All 4 mo and 12 mo visits) Enroll, KAP survey, control video and video perception questions					Follow-up email or text KAP survey	Follow-up email or text KAP survey				
Intervention					(All 4 mo and 12 mo visits) Enroll, KAP survey, intervention video and video perception questions					Follow-up email or text KAP survey	Follow-up email or text KAP survey	
Key Informants												
Clinic team										Interviews		

KAP= knowledge, attitude, practice