Videogames That Encourage Healthy Behavior Did Not Alter Fasting Insulin or Other Diabetes Risks in Children: Randomized Clinical Trial

Tom Baranowski, PhD,¹ Janice Baranowski, MPH, RD,¹ Tzu-An Chen, PhD,² Richard Buday, FAIA,³ Alicia Beltran, MS, RD,¹ Hafza Dadabhoy, MS, RD,¹ Courtney Ryan, MS, RD,¹ and Amy S. Lu, PhD^{4,5}

Abstract

Background: Previous research indicates games for health have substantial promise in promoting change in children's diet and physical activity (PA) behavior for obesity and diabetes prevention, but the research has generally not been rigorous. The study reported here was an efficacy trial of two role-playing videogames played in sequence, "Escape from Diab" (hereinafter called Diab) and "Nanoswarm: Invasion from Inner Space" (hereinafter called Nano), on diabetes and obesity risk factors: fasting insulin and body mass index (BMI), and risk-related behaviors: diet, PA, and sedentary behavior (SB).

Design: A two-group (treatment vs. wait list control) randomized clinical trial was used with baseline, immediate postintervention (\sim 3 months postbaseline), and 2 months postassessments.

Intervention: Diab and Nano were desktop or laptop role-playing videogames with nine sessions (each episode/ session lasting ~ 60 minutes). Two storylines attempted to immerse players and used ethnically diverse characters to model desired behaviors. Tailored goal setting, problem solving, and motivational statements were used.

Methods: A sample of 200 overweight or obese children (ages 10–12 years from 85th to 99th BMI percentile [%ile]) was recruited, primarily using a volunteer list. Fasting insulin was the primary dependent variable. BMI, fruit, vegetable and sweetened beverage intakes, PA, and SBs were secondary outcomes. Generalized linear mixed models were used to test for the treatment effects.

Results: No significant differences were detected in any of the tested outcome variables.

Conclusions: The lack of differences may indicate that games cannot change dietary behaviors and thereby not change-related clinical outcomes. Alternatively, there seem to have been changes in (1) the types of videogames children expect and like to play since a pilot study was conducted, (2) productization challenges, and/or (3) problems in staff management of the trial. All may have contributed to the lack of effect.

Keywords: Videogames, Nutrition, Dietary behavior, Diabetes risk

Introduction

T HE HIGH PREVALENCE of obesity¹ and diabetes² among children have been labeled an epidemic.³ Elevated fasting blood insulin concentration is a common risk factor for diabetes and obesity,⁴ and large body mass index (BMI) is a risk for diabetes.⁵ The most commonly targeted behaviors

to minimize diabetes and obesity risks have included diet, especially fruit, vegetable⁶ and sweetened beverage⁷ intakes, and physical activity (PA).⁸ With many obesity prevention programs not being effective,⁹ innovative programs are needed that capture children's attention and enhance the transmission of behavior change messages. Serious videogames with their immersive stories and incorporation of

¹Department of Pediatrics, USDA/ARS Children's Nutrition Research Center, Baylor College of Medicine, Houston, Texas.

²HEALTH Research Institute, University of Houston, Houston, Texas.

³Archimage, Inc., Houston, Texas.

⁴Health Technology Lab, Department of Communication Studies, College of Arts, Media & Design, Northeastern University, Boston, Massachusetts.

⁵Department of Health Sciences, Bouvé College of Health Sciences, Northeastern University, Boston, Massachusetts.

behavior change procedures offer one promising alternative¹⁰ because of their low-cost approach to intervention dissemination (once developed).

Several reviews have appeared of videogames for diabetes self management with a focus on self monitoring, self injection, other medication taking, appropriate aspects of diet, and PA in relation to medication, among other issues.¹¹⁻¹⁵ Less attention has been accorded to games for diabetes prevention. Diabetes prevention shares many behavioral targets with obesity prevention.¹⁶ A conceptual article encouraged games for diabetes prevention to provide mastery learning experiences, observational learning (through appropriate narrative), and tailoring and achieving a balance between "fun-ness" and seriousness.¹⁷ The videogame "Gustavo in Gnam's Planet," designed to prevent diabesity through dietary change among 14- to 18-year-olds using a narrative and well-regarded behavior change procedures attained some change in consumption of a small subset of foods.¹⁸ This limited success may have been because of the game not enhancing "fun" from playing the game.¹⁹ Most games for obesity prevention have been active video, also called exergames.²⁰ A review of games for diet or PA or weight management change related to obesity reported the games were well received, but attained only small effects, if any.²¹

A recent review of nutrition education games revealed that, although almost all evaluations of the games revealed some positive effect, it was not clear how much the authors selected their findings from multiple possible outcomes, suggesting statistical type 1 error, and that the quality of the research designs and reporting needed improvement.² "Escape from Diab" (Diab) and "Nanoswarm: Invasion from Inner Space" (Nano) were videogames (not including active videogames also called exergames) that targeted children in a 2003-2008 pilot study with children at relatively low risk of obesity²³ to increase fruit and vegetable (FV) intakes, reduce sedentary behaviors (SBs), increase PA, and to decrease BMI %ile. The games were based on behavioral theory, employed behavior change procedures, a story that modeled desired behavior changes, tailored to child values and deemed to be fun.²³

Analysis revealed a significant treatment versus control difference of 2/3 FV serving, approximately a 50% increase from baseline,²³ but no significant impact on moderate-tovigorous PA (MVPA) or BMI (the primary diabetes risk factor), for which the time interval (2–3 months) may have been too brief to expect such changes. Postgame questionnaires with children and interviews with parents revealed most children (85%-95%) enjoyed playing both Diab and Nano. The average baseline BMI %ile across both groups was 83 %ile, indicating the sample in the average was below the overweight criterion (85 %ile) and, thereby, at lower risk of diabetes and adult obesity. Parents' comments after the pilot study indicated they believed their children were already practicing healthy diet and PA practices before playing the game. Thus, restricting future game play to those at the 85th %ile BMI up to the 99th %ile should reach children who are less likely practicing healthy behaviors and who would benefit most.²⁴ As fasting blood insulin concentration is influenced by some of the same behaviors,²⁵ it is important to test whether these games can help decrease diabetes (i.e., fasting blood insulin concentration) and obesity risks among high risk (85th %tile < BMI <99th %tile) 10- to 12-year-old children.

This article follows the CONSORT guidelines for randomized clinical trials with nonsignificant results²⁶ and for eHealth interventions²⁷ in reporting an efficacy trial of Diab and Nano to assess their impact on the primary outcome and targeted behaviors (hypothesis 1), as registered in Clinical-Trials.gov (NCT01846377). The hypothesis tested was as follows: Children will decrease fasting blood insulin concentration by, at least, $2 \mu U/dL$ (a clinically meaningful change²⁸); increase FV intake by at least 1.0 servings/day (clinically meaningful and reflecting a change we attained in an earlier game intervention²⁹); and increase MVPA by at least 10 min/day from baseline to up to 3 months postbaseline (based on our feasibility study findings).

Methods

Intervention

Development process. The pilot study version of Diab and Nano was funded as a Small Business Initiative Research (SBIR) grant to Archimage, Inc., from the National Institute of Diabetes, Digestive and Kidney Diseases/National Institutes of Health. The two interactive multimedia experiences with games were developed by Archimage, Inc. A large team of professionals with diverse credentials were involved in different stages of development.²³

Theory. Diab and Nano reflected contributions of several theories.³⁰ The games were immersive using deep stories with interesting and likeable characters³¹ (Transportation Theory³²); interactive, with gameplay changing responding to player's input (enhanced central processing from Elaboration Likelihood Model³⁰); adaptive, by being tailored to player behaviors, values, and psychosocial characteristics³³; entertaining, using compelling stories, characters, and settings to make learning fun³⁴ (intrinsic motivation from Self Determination Theory³⁰); and encouraged self-control regulation (Social Cognitive Theory³⁵).

Features/functionalities/components. The videogames targeted FV intakes, PA, and SB changes through the use of interactive minigames interconnected with noninteractive video cutscenes through which the story unfolded. Minigames included challenging, but doable: (1) mastery-learning knowledge games³⁶ that enabled children to learn what constitutes desired behavior (e.g., "Which vegetables count?" to teach children not to increase french fries or fried onion ring intakes, to meet their dietary change goals)³⁷; (2) goal-setting activities (action implementation intentions) tailored to the child player's current behaviors and preferences to make specific lifestyle changes³³; (3) anticipatory problem-solving routines (coping implementation intentions) to enable children to determine strategies most likely to overcome barriers to behavior changes³⁰; (4) motivational statements tailored to a child's values to enhance the child's desire to make the goalrelated lifestyle changes³³; and (5) energy balance games to enable children to select appropriate portions and aerobic or strength-enhancing physical activities.

Each story was designed based on feedback from children in Houston and rural North Carolina.³⁸ The stories evolved over sessions/episodes with increasing complexity and employed "cliffhangers" to entice players to return to gameplay for the next episode. At the end of each session, goals

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were set. Players were allowed to re-play some minigames and related video segments, but could not redo a completed session's goal setting or goal review segments.

Revisions and updating. Extensive usability testing and interviews were conducted after the pilot test of the video-games.²³ Qualitative results revealed enhancements to promote effectiveness, such as creating clearer instructions for minigames; including an instruction replay button for children who did not initially read instructions; making peripheral screen cues (e.g., questions) more noticeable; enhancing the challenge of some of minigames; more clearly explaining portion and portion size; explaining why some food selections were not healthy; and more clearly specifying that goals set were for the game player to attain, not the characters in the game. These changes were made as part of the productization of the games from the initial pilot evaluation in 2012–2013.²³

Human involvement. The intervention was completely delivered through the two videogames, although project staff were trained to monitor session completion and prompt completion if 2 days passed after a session should have been completed. Each game had nine sessions with \sim 45–60 minutes of play per session/episode, totaling \sim 6–9 hours of gameplay per video game.

Productization. Diab and Nano were originally designed in 2003, developed using the GarageGames "Torque Game Engine" between 2004 and 2005, and pilot tested in 2007. For economy, the videogames targeted one specific computer platform and operating system, which were loaned to study participants: an Apple iMac computer running Microsoft Windows XP. For the 2012–2017 efficacy trial, Diab and Nano were to be productized to run on a range of typical home computers. However, GarageGames ceased supporting the Torque Game Engine in late 2012 and released the game engine as free open-source software to the game development community. Updates to the Torque Game Engine to accommodate newer computer hardware and operating systems languished, which restricted productization efforts.

Intervention implementation. Children played the videogames at home using their home computers. Each intervention child was provided with a gamepad controller, installation DVD, and user manual. The child could e-mail or call the project office if problems developed. The intervention coordinator was expected to monitor game completion and informed data collection staff when children could be scheduled for immediate postgame data collection. As the project progressed, it became clear that many candidate participants did not have the requisite computers on which to run the games. Game compatible laptops were loaned to interested participants whenever possible. The Control Intervention was a wait list group that received the intervention at the end of the 5-month postbaseline assessment.

Trial design

This efficacy trial employed a two-group (treatment [trt], control [ctl]) design with randomization to group occurring after baseline assessment (to obviate observer bias), and

three assessment periods (baseline, immediate post [~ 3 months postbaseline], and 2 months post [~ 5 months postbaseline]). No assessment occurred between games because our pilot indicated differences emerged only after both games were played. We attempted to advance beyond our feasibility study findings by increasing the sample size, changing the primary outcome to fasting insulin, and avoiding a ceiling effect in behavior change by including a sample of children from the 85th to 99th BMI %ile.

Children were sent home and just informed to play the game. No deadlines were specified. No guidance was provided to parents. We allowed for a 3-month intervention period. Based on the numbers of sessions and minimal time a player was locked out of a game until the time of goal attainment, the briefest possible time to complete one of these games was 3 weeks, or 6 weeks total for both games (1.5 months). The longest it would take a child to complete a game while likely retaining their immersion in the game story would be 45 days per game or 3 months. Project staff were to call a child if they did not complete a session within 2 days after an expected play date, as indicated by e-mail messages automatically sent to researchers at the completion of a session.

Participants

Inclusionary criteria. Children were eligible if they were 10–12 years of age with an 85th %ile to 99th %ile BMI; willing to complete all measures including providing a blood sample; had Internet access (to transmit gameplay information); and a computer with these minimum requirements necessary to playing the game: operating system—Microsoft Windows XP (SP3), Windows Vista (SP2), Windows 7 (SP1), Windows 8 or 8.1; processor—2.13 GHz Intel Core 2 Duo E6400 or 2.8 GHz AMD Athlon 64 x2 5600+; system memory: 2 GB RAM minimum; screen resolution: 1280×800 minimum; hard drive: 10 GB minimum free space; sound: Sound card with speakers or headphone jack; DVD Optical Drive (needed for installation only); DirectX Runtimes: October 2006 version or newer; and Internet: broadband connection.

Exclusionary criteria. Children were excluded if they did not speak and read English (because both games were in English); had a medical condition that influenced diet, PA, or the ability to complete questionnaires (based on pediatrician judgment); or had type 1 or 2 diabetes mellitus (because this would influence the primary outcome).

Recruitment and screening. To conduct primary and secondary analyses using presubmission statistical models, power calculations indicated a need to recruit 444 participants to attain a small effect (0.2) after inflation for anticipated dropout.³⁹ Our primary tool for recruiting children to participate in this project was a participant volunteer list maintained by the Children's Nutrition Research Center (CNRC). This has been presented in detail.³⁹

Outcomes

Settings where data collected. Parents and their child came to the CNRC at each assessment point for measurement. A 2-month follow-up was selected because, in our experience, that is the longest period over which it is likely to detect behavior change maintenance postintervention.^{23,29}

Data collection procedure. Child data were collected using 4 methods: self-reported data collection on preprogrammed tablets; gameplay data collected over the Internet; blood and anthropometric assessments by trained staff; and accelerometers worn on the body. For the tablets, children were logged in, questions appeared on the screen one at a time, and the participant prompted to select an answer. Parent self-reported data were also collected by tablets in English and, where necessary, in Spanish.

Cohort maintenance and tracking procedures. Data were collected as children were recruited. Because of the required blood draws, child incentives were as follows: \$60 for baseline assessment, \$65 for immediate postassessment, and \$70 for 2-month follow-up. Participants received a healthy snack depending on their need to fast before data collection. Parents/legal guardians also received graduated incentives for participating in interviews: \$20 for the immediate post-intervention questionnaire and \$25 for the 2-month post-intervention questionnaire.

Primary outcome. For child fasting insulin, blood was drawn into EDTA (ethylenediaminetetraacetic acid) tubes by trained pediatric phlebotomists, placed on ice, centrifuged at 4°C, transferred to labeled storage tubes, and frozen at -80°C until analyzed. Plasma insulin was measured using commercially available double sandwich assay on an Elecsys 1010 instrument (Roche Diagnostics Corporation, Indianapolis, IN).

Secondary outcomes. Participant's height was measured to the nearest 0.1 cm twice using a stadiometer (Shorr Height Measuring Board; Olney, MD) and the mean of the two recordings calculated. Body weight was measured to the nearest 0.1 kg twice using a calibrated scale (Seca 770 Model scale; Vogel and Halke, Hamburg, Germany) and the mean of the two recordings calculated. BMI (kg/m²) was computed and the participants' age and gender-specific BMI z-score obtained from the CDC website.

Behaviors. A 32-item previously validated FV food frequency questionnaire (FV-FFQ) (16 fruit, 16 vegetable items) was used, reflecting the most commonly consumed items by children in this age group (grades 3–5).^{40–42} A 22-item previously validated sweetened beverage FFQ was used.⁴³ PA was assessed using the Actigraph GT3X accelerometer, a small device that measures acceleration in three dimensions plus step counts. Participants wore accelerometers for up to 7 days (with a minimum of 360 minutes of recording from 6 am to midnight to count as a valid day). Mean minutes of vigorous PA, moderate PA, and SB were established using published cut points.⁴⁴ Accelerometer counts per minute, an indication of the volume of activity in which the children engaged, was calculated.

Family demographics. Parents were asked to provide marital status, current employment status, race/ethnicity, number of children living in the home, highest educational level in household, and annual household income, as part of the informed consent form. Randomization/sequence generation and blinding. Randomization to group was achieved by sequentially entering names into a list with sequential positions on the list randomly assigned to group from a random number generator in SAS by the study statistician. Each ID had the same probability of being assigned any number within the interval. Group assignment did not occur until after baseline data collection, which blinded participants to group allocation until the start of the intervention. Group assignment could not be blinded beyond that. Data collection staff were blinded to group assignment.

Statistical methods

Standard descriptive statistics including mean values, standard deviations, and frequencies were calculated as appropriate to baseline data. Participants' sleep time based on their sleep logs was excluded from the analyses. Comparisons between treatment group and control groups on baseline characteristics were performed using one-way analysis of variance (ANOVAs) for continuous variables and chisquare tests for discrete variables. The comparison of baseline characteristics between participants having complete data and those having missing data at any time point were conducted using ANOVAs or chi-square tests as appropriate.

Analyses and presentation of data were in accordance with the CONSORT guidelines with the primary comparative analysis being conducted on an intention-to-treat basis. To account for the nested data structure of the two postdata collections within each individual, linear mixed model or generalized linear mixed model analyses were conducted to examine the treatment effect depending on the distributions of variables of interest. The model contained a withinsubjects factor (post 1 and post 2), a between-subjects factor (intervention and control), and the interaction term between within-subjects factor and between-subjects factor. The model also controlled for the corresponding baseline value and potential confounding variables (e.g., age, sex, ethnicity, and BMI %ile). Separate models were conducted for each dependent variable (fasting insulin, dietary intakes, and PA outcomes of interest). A significant group main effect would indicate a difference in the outcome after the intervention. All the analyses were conducted using SAS 9.4.⁴⁵ P < 0.05was considered statistically significant.

Results

Recruitment and follow-up

The differences between people expressing interest and those entering the trial have been reported.³⁹ Despite extensive efforts at recruitment,³⁹ only 200 children were recruited. Of the 200 recruited into the trial, 55 (28%) dropped out. Of these 55, 23 could not be reached after repeated attempts at contact; 12 reported the games did not work on their computer, and they did not want to continue in data collection; in 8 the child lost interest; 5 encountered family conflict issues; 6 ended at post 1 assessment; and 1 was lost to follow-up. Thus, 145 participants remained at 2-month postassessment. Postrecruitment power calculations revealed the initial sample size of 200 had 80% power to detect small effect size *f* of 0.13 between two groups with three repeated measures assuming alpha level of 0.05 and small correlation of 0.1 among three repeated measures.

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Baseline data

Table 1 presents descriptive statistics and baseline values for the sample by groups completing the intervention and those not. Compared with completers, those who did not complete the intervention were significantly more likely to be from the treatment group (80.00% vs. 35.86%), older (11.54 vs. 11.18), with higher BMI (27.07 vs. 25.23), and reported more light physical activity minutes per day (238.14 vs. 208.38). In addition, the

participating parent of all children not completing the intervention was the mother, who was more likely to have some college education (44.44%).

Outcomes

The values in Table 2 showed no statistically significant differences for any of the outcomes. No adverse events were reported to us by participants.

TABLE 1. DIFFERENCES AT BASELINE BETWEEN PARTICIPAN	NTS COMPLETING THE STUDY AND THOSE NOT
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LPA % of minutes/day 25.11 (9.68) 22.23 (8.79) 0.05)523
MPA minutes/day 10.54 (9.34) 9.84 (7.55) 0.59	591
MPA % of minutes/day 1.11 (0.97) 1.06 (0.83) 0.70	066
VPA minutes/day 2.48 (4.06) 1.89 (2.53) 0.23	23
VPA % of minutes/day $0.25(0.41)$ $0.2(0.28)$ 0.31	\$18
PA minutes/day 932.25 (104.13) 931.57 (100.36) 0.96	675
Sedentary minutes/day 681.08 (115.84) 711.47 (124.42) 0.12	288
Sedentary % of minutes/day 73.53 (10.38) 76.51 (9.42) 0.06)604
Parent (interview) (interview) (interview)	
Age (years) 41.78 (12.86) 40.04 (11.28) 0.35	3511
Sex 0.03)346
Male 0 [0.00] 11 [7.8]	0.0
Female 54 [100,00] 130 [92,2]	
Educational attainment 0.00)098
HS or less 2 [3,70] 15 [10,64]	
Some college 24 [44,44] 30 [21,28]	
Undergraduate 17 [3].48] 56 [39.72]	
Graduate 11 [20,37] 40 [28,37]	
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\geq \$40,000 10 [18.52] 37 [26.43]	

Completer: participants had complete PA data across three time points.

BMI, body mass index; HS, high school; LPA, light physical activity; M, mean; MPA, moderate physical activity; P, probability; PA, physical activity; SD, standard deviation; VPA, vigorous physical activity.

	Post 1					Post 2				
	Control		Treatment			Control		Treatment		
	Estimate	SE	Estimate	SE	Р	Estimate	SE	Estimate	SE	Р
Primary outcome										
Fasting insulin	24.373	1.712	21.747	2.01	0.307	22.381	1.707	21.268	2.207	0.681
Activity-related outcomes										
Sedentary min/day	747.02	15.187	736.663	18.004	0.652	762.204	15.106	815.784	20.057	0.03
Sedentary % of min/day	79.505	1.054	78.619	1.249	0.576	79.486	1.049	81.454	1.385	0.244
LPA min/day	185.186	10.929	189.27	12.96	0.804	182.475	10.877	176.653	14.38	0.739
LPA % of min/day	19.397	0.989	20.187	1.173	0.596	19.315	0.984	17.38	1.301	0.223
MPA min/day	8.448	0.909	9.565	1.076	0.415	8.878	0.905	9.527	1.196	0.656
MPA % of min/day	0.887	0.093	0.998	0.111	0.434	0.94	0.093	0.934	0.123	0.968
VPA min/day	2.087	0.477	2.095	0.564	0.991	2.453	0.475	3.005	0.627	0.47
VPA % of min/day	0.221	0.045	0.222	0.054	0.992	0.26	0.045	0.272	0.059	0.87
MVPA min/day	10.545	1.246	11.657	1.475	0.553	11.324	1.24	12.544	1.638	0.541
MVPA % of min/day	1.108	0.127	1.22	0.15	0.56	1.199	0.126	1.207	0.166	0.969
PA minutes/day	942.915	13.157	938.331	15.585	0.818	956.357	13.09	1005.935	17.367	0.02
Dietary outcomes										
Fruit	-0.191	0.082	-0.127	0.096	0.599	-0.351	0.082	-0.303	0.108	0.716
Vegetable	-0.422	0.088	-0.303	0.104	0.367	-0.495	0.089	-0.254	0.116	0.093
Sweetened beverage	-0.107	0.058	-0.222	0.068	0.191	-0.143	0.058	-0.131	0.076	0.900

TABLE 2. ADJUSTED MEANS OF OUTCOME VARIABLES OF INTEREST EXCLUDING SLEEP TIME

Controlling for corresponding baseline value, age, gender, ethnicity, and BMI percentile in generalized linear mixed model. MVPA, moderate-to-vigorous physical activity; SE, standard error.

Discussion

Interpretation

The combination of *Escape from Diab* and *Nanoswarm: Invasion from Inner Space* did not impact the diabetes or obesity risk factors or risk-related behaviors of the participating overweight or obese children. This is different from reviews indicating that evaluation of such games revealed some small changes.^{21,22} The problems in not recruiting an ample sample size have been presented and discussed at length elsewhere.³⁹ It is possible that these games did not include the right combination of elements to impact risk factors or behaviors. However, since an earlier pilot study indicated this combination of videogames had an immediate substantial impact on FV intake,²³ the lack of effect in this study may have other explanations.

First are players' changing video gameplay expectations. At the time of the Diab and Nano pilot study (2003–2008), the market for videogames was defined by genres approximating Diab and Nano's use of passive video cutscenes connected by active minigames. The intervening 10 years between pilot and efficacy trials saw the rise of multiplayer videogames (Diab and Nano were single-player games), as well as social, casual, and mobile videogames, many of which replaced passive storytelling with interactive story development (e.g., use of free-roam three-dimensional environments that allow players to discover on their own what happens next). As well, game computers evolved from a bifurcated platform comprised of dedicated videogame consoles made by Nintendo, Sony, and Microsoft on the one hand, and desktop PCs on the other, to games also played on smartphones and tablets. Children's expectations for gameplay in 2016 likely moved well beyond what was considered entertaining in 2006, particularly, a desire for social interaction and mobile games.

Second were the technical difficulties adapting Diab and Nano games from 2003-era computers to 2013 platforms. Without support from GarageGames, the game engine publisher used to develop Diab and Nano, developing for newer operating systems and video graphics standards was hindered. This caused even some high-end home computers to repeatedly malfunction, leading to participant frustration, with some discontinuing participation. Others may have lost the immersiveness/transportation designed into the game, as demonstrated in the pilot study.⁴⁶

Lessons learnt appear to be that games should be developed in as short a period as possible to capitalize on current popular gameplay modalities and minimize the rapid obsolescence of hardware and software. This may not be a problem for large entertainment game developers with hundreds of millions of dollars to bring games to the market, but it is for health games developed on more modest budgets.

Another aspect is that videogames for health are complex interventions from which it may be impossible to have confidence delineating which aspect of gameplay has desirable or undesirable effects on outcomes. If videogames have short shelf-lives because of technology obsolescence or market changes, no one game can be used repeatedly over time to impact desired behaviors and health outcomes unless considerable resources are available to continually port the game. Thus, ensuing systematic reviews and meta-analyses will be challenged to delineate the effective/ineffective components. This implies that more games for health research should be devoted to varying and experimentally testing component game mechanics and/or behavior change techniques to clearly identify, titrate, or gauge effectiveness to enhance likely effectiveness of future games for health that use the same procedures.

A third problem in this project was project management. About two thirds of the way through the project, almost half

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the participants did not initiate gameplay; follow-up phone calls with participants were not conducted (allowing some to discontinue participation without follow-up); events were not documented; incentive payments were not provided; accelerometer wear was not documented; and data were not correctly filed. To the best of our ability, we corrected these at the end of the trial.

It is not clear from the published research how often research staff task completion problems occur or under what circumstances. Our findings indicate there should be a tightening of project management practices, with multiple staff knowing how to accomplish all tasks, permit checking of task accomplishment with some chance of early identification of task non- or inadequate completion, and establishment of a sufficient sense of responsibility for successful completion of all tasks, including encouragement to communicate concerns about inadequate or non-completion of tasks to the principal investigator.

Limitations

Other limitations existed beyond changing culture of games, productization, and staff performance. The sample was likely not representative (most coming from a volunteer registry) and had a high dropout rate. Measures of dietary intake involved self-reported data, which are subject to memory error and reliability concerns. Unfortunately, there is no readily available reasonably priced alternative to self-reported dietary intake perceptions at the present time. Children and parent/guardians in both games were exposed to the same measurement procedures, thereby equating the possibility of measurement reactivity. There was some possibility of contamination of intervention and comparison groups. Exchange of intervention materials between children or parents across families in a large metropolitan area (>6.5 million residents) does not appear likely to have occurred with any regularity.

Significance

There were no statistically significant outcomes from playing Diab and Nano, indicating games for health may not have desired physiological, anthropometric, or behavioral effects. Alternatively, it may not have been possible to adequately assess if playing Diab and Nano influenced diabetes risks or risk-related behaviors because of the likely nonrepresentative sample and problems in productization. More attention needs to be devoted to duration of game development and project management.

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References

- Ogden CL, Fryar CD, Hales CM, et al. Differences in obesity prevalence by demographics and urbanization in US children and adolescents, 2013–2016. JAMA 2018; 319:2410–2418.
- Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017: Estimates of Diabetes and Its Burden in the United States. 2017. www.cdc.gov/ diabetes/pdfs/data/statistics/national-diabetes-statisticsreport.pdf (Accessed June 26, 2018).
- 3. Dietz WH. The response of the US Centers for Disease Control and Prevention to the obesity epidemic. Annu Rev Public Health 2015; 36:575–596.
- 4. Varvel SA, Voros S, Thiselton DL, et al. Comprehensive biomarker testing of glycemia, insulin resistance, and beta cell function has greater sensitivity to detect diabetes risk than fasting glucose and HbA1c and is associated with improved glycemic control in clinical practice. J Cardiovasc Transl Res 2014; 7:597–606.
- Scott LK. Presence of type 2 diabetes risk factors in children. Pediatr Nurs 2013; 39:190–196, 80.
- 6. Boeing H, Bechthold A, Bub A, et al. Critical review: Vegetables and fruit in the prevention of chronic diseases. Eur J Nutr 2012; 51:637–663.
- Schwingshackl L, Hoffmann G, Lampousi AM, et al. Food groups and risk of type 2 diabetes mellitus: A systematic review and meta-analysis of prospective studies. Eur J Epidemiol 2017; 32:363–375.
- Elmesmari R, Martin A, Reilly JJ, et al. Comparison of accelerometer measured levels of physical activity and sedentary time between obese and non-obese children and adolescents: A systematic review. BMC Pediatr 2018; 18:106.
- 9. Waters E, de Silva-Sanigorski A, Hall BJ, et al. Interventions for preventing obesity in children. Cochrane Database Syst Rev 2011;3:CD001871.
- Baranowski T, Blumberg F, Buday R, et al. Games for health for children—Current status and needed research. Games Health J 2016; 5:1–12.
- 11. DeShazo J, Harris L, Pratt W. Effective intervention or child's play? A review of video games for diabetes education. Diabetes Technol Ther 2010; 12:815–822.
- 12. Klingensmith GJ, Aisenberg J, Kaufman F, et al. Evaluation of a combined blood glucose monitoring and gaming system (Didget[®]) for motivation in children, adolescents, and young adults with type 1 diabetes. Pediatr Diabetes 2013; 14:350–357.
- Theng YL, Lee JW, Patinadan PV, et al. The use of videogames, gamification, and virtual environments in the self-management of diabetes: A systematic review of evidence. Games Health J 2015; 4:352–361.
- Charlier N, Zupancic N, Fieuws S, et al. Serious games for improving knowledge and self-management in young people with chronic conditions: A systematic review and meta-analysis. J Am Med Inform Assoc 2016; 23:230– 239.
- Lazem S, Webster M, Holmes W, et al. Games and diabetes: A review investigating theoretical frameworks, evaluation methodologies, and opportunities for design grounded in learning theories. J Diabetes Sci Technol 2015; 10:447–452.

- Ruggiero L. Diabetes prevention and management: What does a serious game have to do with it? Games Health J 2015; 4:333–334.
- Thompson D. Designing serious video games for health behavior change: Current status and future directions. J Diabetes Sci Technol 2012; 6:807–811.
- Marchetti D, Fraticelli F, Polcini F, et al. Preventing adolescents' diabesity: Design, development, and first evaluation of "Gustavo in Gnam's Planet". Games Health J 2015; 4:344–351.
- Fraticelli F, Marchetti D, Polcini F, et al. Technology-based intervention for healthy lifestyle promotion in Italian adolescents. Ann Ist Super Sanita 2016; 52:123–127.
- Gao Z, Chen S. Are field-based exergames useful in preventing childhood obesity? A systematic review. Obes Rev 2014; 15:676–691.
- Mack I, Bayer C, Schaffeler N, et al. Chances and limitations of video games in the fight against childhood obesity - A systematic review. Eur Eat Disord Rev 2017; 25:237–267.
- 22. Baranowski T, Ryan C, Hoyos-Cespedes A, Lu AS. Nutrition education and dietary behavior change games: A scoping review. Games Health J 2018; doi: 10.1089/g4h .2018.0070. [Epub ahead of print] [in press].
- 23. Baranowski T, Baranowski J, Thompson D, et al. Video game play, child diet, and physical activity behavior change: A randomized clinical trial. Am J Prev Med 2011; 40:33–38.
- Foster GD, Linder B, Baranowski T, et al. A school-based intervention for diabetes risk reduction. N Engl J Med 2010; 363:443–453.
- 25. Donin AS, Dent JE, Nightingale CM, et al. Fruit, vegetable and vitamin C intakes and plasma vitamin C: Crosssectional associations with insulin resistance and glycaemia in 9–10 year-old children. Diabet Med 2016; 33:307–315.
- Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: Explanation and elaboration. Ann Intern Med 2008; 148:295–309.
- Baker TB, Gustafson DH, Shaw B, et al. Relevance of CONSORT reporting criteria for research on eHealth interventions. Patient Educ Couns 2010; 81 Suppl:S77–S86.
- Sacks FM, Bray GA, Carey VJ, et al. Comparison of weight-loss diets with different compositions of fat, protein, and carbohydrates. N Engl J Med 2009; 360:859–873.
- 29. Baranowski T, Baranowski J, Cullen KW, et al. Squire's Quest! Dietary outcome evaluation of a multimedia game. Am J Prev Med 2003; 24:52–61.
- Thompson D, Baranowski T, Buday R, et al. Serious video games for health: How behavioral science guided the development of a serious video game. Simul Gaming 2010; 41:587–606.
- Baranowski T, Buday R, Thompson DI, et al. Playing for real: Video games and stories for health-related behavior change. Am J Prev Med 2008; 34:74–82.
- 32. Lu AS, Baranowski T, Thompson D, et al. Story immersion of videogames for youth health promotion: A review of literature. Games Health J 2012; 1:199–204.
- Simons M, Baranowski J, Thompson D, et al. Child goal setting of dietary and physical activity in a serious videogame. Games Health J 2013; 2:150–157.

- Mellecker R, Lyons EJ, Baranowski T. Disentangling fun and enjoyment in exergames using a expanded design, play, experience framework: A narrative review. Games Health J 2013; 2:142–149.
- 35. Baranowski T. Interpersonal models for health behavior intervention with minority populations: Theoretical, methodologic and pragmatic issues. In: Becker D, Hill DR, Jackson JS, Levine DM, Stillman FA, Weiss SM, editors. *Health Behavior Research in Minority Populations: Access, Design, and Implementation.* Bethesda, MD: National Institutes of Health; 1992. pp. 112–121.
- Bloom BS. Learning for mastery. Evaluation Comment 1968; 1:1–11.
- Ledoux T, Griffith M, Thompson D, et al. An educational video game for nutrition of young people: Theory and design. Simul Gaming 2016; 47:490–516.
- Thompson V, Thompson D, Baranowski T. Understanding "serious video game" storyline and genre preferences related to game immersion among low-income ethnically diverse urban and rural adolescents In: Evans CM, editor. *Internet Issues: Blogging, the Digital Divide and Digital Libraries.* Hauppauge, NY: Nova Science Publishers, Inc.; 2010. pp. 177–188.
- Ryan C, Dadabhoy H, Baranowski T. Participant outcomes from methods of recruitment for videogame research. Games Health J 2018; 7:16–23.
- 40. Warneke CL, Davis M, De Moor C, et al. A 7-item versus 31-item food frequency questionnaire for measuring fruit, juice, and vegetable intake among a predominantly African-American population. J Am Diet Assoc 2001; 101:774–779.
- 41. Resnicow K, Odom E, Wang T, et al. Validation of three food frequency questionnaires and 24-hour recalls with serum carotenoid levels in a sample of African-American adults. Am J Epidemiol 2000; 152:1072–1080.
- 42. Cullen KW, Baranowski T, Baranowski J, et al. Validity and reliability of brief fruit, juice, and vegetable screeners among inner city African-American boys and 17–20 year old adults. J Am Coll Nutr 1999; 18:442–450.
- 43. Cullen KW, Ash DM, Warneke C, et al. Intake of soft drinks, fruit-flavored beverages, and fruits and vegetables by children in grades 4 through 6. Am J Public Health 2002; 92:1475–1478.
- Evenson KR, Catellier DJ, Gill K, et al. Calibration of two objective measures of physical activity for children. J Sports Sci 2008; 26:1557–1565.
- 45. SAS Institute, Inc. SAS (Version 9.4) [Computer Software]. Cary, NC: SAS Institute, Inc.; 2014
- 46. Lu AS, Thompson D, Baranowski J, et al. Story immersion in a health videogame for childhood obesity prevention. Games Health J 2012; 1:37–44.

Address correspondence to: *Tom Baranowski, PhD Department of Pediatrics USDA/ARS Children's Nutrition Research Center Baylor College of Medicine 1100 Bates Street Houston, TX 77030*

E-mail: tbaranow@bcm.edu