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Effectiveness of an informational video method to improve enrollment and retention of a pediatric cohort

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ABSTRACT

Objective: The Environmental Determinants of Diabetes in the Young (TEDDY), a multinational epidemiological study, is designed to identify environmental exposures triggering autoimmunity and type 1 diabetes (T1D) in children at increased genetic risk. The objective of this analysis was to evaluate the use of an informational video in the enrollment and retention of eligible participants at the Colorado TEDDY clinical center.
Study design and setting: Eligible participants were divided into two groups based on the inclusion of the video in the enrollment materials: the No-Video Group (n = 449) did not receive the video and were contacted between 7/1/07 and 6/30/08. The Video Group (n = 494) received the video and were contacted between 7/1/08 and 6/30/09. Multiple logistic regression compared the enrollment rates (percent of eligible subjects deciding to enroll) of those who received the video compared to those who did not. Kaplan–Meier survival analysis and a multivariate Cox proportional hazards model compared the differences in study retention, as defined by active participation fifteen months after the baseline visit at three months of age.
Results: Both groups were demographically similar. The enrollment rate was significantly higher for the Video Group (56.9%) compared to the No-Video Group (49.9%). Differences remained significant with adjustment for other known factors. A difference in retention between the two groups was not observed.
Conclusion: Methods and materials increasing understanding and more accurately informing participants of what is involved in participation may increase enrollment in a prospective observational study.

1. Introduction

The use of audio-visual technology may increase enrollment in research studies by providing a consistent delivery of information while allowing participants to control the pace of the viewed information [1,2]. Video methods have been shown to increase participant's knowledge and positive attitude toward clinical trial participation [3,4]. Furthermore, video may be beneficial in improving participation while helping potential participants have a better understanding of the studies [5]. Prior studies examining the willingness to consider future trials and the effectiveness of audio-visual interventions on increasing enrollment rates are limited to hypothetical studies using video to educate participants on a particular medical condition instead of including participants with the specific condition being studied [5,6]. Other studies are limited to the measure of the attitudes associated with participation without actually measuring the impact of these methods on the study enrollment decision [3,4].

The recruitment of pediatric participants in long term research studies can be rather challenging due to the protection of children as human participant and ensuring parents are appropriately informed of the protocol since they make a

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decision on behalf of the child [7,8]. It is difficult to determine how well parents comprehend the basic points of a study protocol and how well an informed consent is meeting its intended purpose. Efforts that try to improve the efficacy of this process are important to assess [9]. Interventions such as multimedia technology, enhanced consent forms and discussions with research personnel have been developed to assist in this improvement [10].

The primary aim of this study is to assess the effectiveness of an 8-minute professionally produced video in improving the rate of enrollment and minimizing attrition of pediatric participants recruited at one clinical center of TEDDY conducted through the Barbara Davis Center for Childhood Diabetes at the University of Colorado Denver Anschutz Medical Campus.

2. Materials and methods

The Environmental Determinants of Diabetes in the Young (TEDDY) Study is an observational study designed to identify the environmental exposures that promote or protect against autoimmunity and type 1 diabetes mellitus (T1D) in children with an increased genetic risk [11]. The study is divided into two phases. The first phase is the screening of newborns for known high-risk genes. The second phase is the follow-up of those identified with the high-risk genes that were subsequently invited and decided to enroll in a 15-year observational study. It is conducted in six clinical sites, each with similar but independent methods for enrolling eligible participants into follow-up study.

2.1. Enrollment into the follow-up study

In September 2004, the Colorado site of TEDDY began screening the umbilical cord blood of newborns in Denver metropolitan hospitals for genes associated with a higher risk of developing T1D. The enrollment phase into the follow-up study began when the parents of the children identified with the high-risk genes were contacted by the clinic staff within ten weeks to explain their child's genetic risk and to present the follow-up study for which they were eligible.

A standardized phone script used by eight to ten clinic staff was structured to reflect the points made in the informed consent document signed by parents who agreed to the follow-up study at the first clinic visit. How the child was identified, the results of the genetic screening, and the details of the follow-up study protocol were all covered in the initial call, which took up to 20 min. A packet including information on T1D and the expectations of the study was mailed before subsequent phone calls were made two to three weeks later for a final decision to enroll in the follow-up study.

By the end of the third year of enrollment, rates were lower than originally projected. The staff involved in the enrollment efforts was challenged with an increasing number of eligible participants as a result of greater screening efforts and the amount of time the enrollment protocol required. For these reasons, several strategies were considered to better inform participants in a more efficient manner about the nature of the study in the hopes of increasing enrollment rates. Group information sessions, a strategy successfully employed in at the Finland TEDDY clinical center, were initially tried but were poorly attended. In 2008, the decision was made to produce an informational video based on the information being presented at the group information sessions and in the initial phone calls.

A high-quality DVD was professionally produced by the University of Colorado Denver Anschutz Medical Campus Media Services at a cost of approximately $5000 [12]. With signed consent from the involved parents, the video included participants and their parents interacting with clinic staff during a clinic visit, as well as in their home discussing data collection elements the parents do outside of the clinic visit. An interview with the principal investigator and a professional narrator explained the study purpose and expectations. The main purpose of the video was to enhance the understanding of the study rationale while providing a visual context of the study. The DVD made it possible to standardize the information received by parents about TEDDY, was a more time-efficient method for presenting the follow-up study and provided a basis for eligible participants to ask informed questions of the clinical staff.

In July 2008, the DVD was added to the information packet mailed out to all eligible study participants who had voiced interest in receiving more information about the TEDDY follow-up study. This analysis compares the enrollment rates among eligible participants one year before and one year after the initiation of the DVD distribution to evaluate the effectiveness of the video method on improving enrollment into the follow-up study. It also examined the impact on early retention, or active participation fifteen months after the baseline visit, which occurred at three months of age for all subjects.

2.2. Participants

To examine the enrollment differences based on receipt of the video, we selected two subgroups of the overall TEDDY Colorado population that were eligible for participation in the follow-up study. The No-Video Group ($n = 1059$) was screened, determined to be eligible, and first contacted about enrollment into the follow-up study between 7/1/07 and 6/30/08. The Video Group ($n = 1160$) was screened, determined to be eligible and first contacted between 7/1/08 and 6/30/09. In both groups, participants were excluded if they were deemed ineligible for enrollment due to inability to complete the baseline visit before 4.5 months of age (No-Video Group: 424: Video Group: 508), mothers under age eighteen at time of child's birth (No-Video Group: 14: Video Group: 1), and who preferred Spanish (No-Video Group: 172; Video Group: 157), since the DVD was not produced in Spanish because of budget constraints. The final sample size for this analysis included a No-Video Group of 449 and a Video Group of 494.

For the early withdrawal analysis, retention was defined as active participation in study visits beginning with the baseline visit at three months of age through eighteen months of age. Participants were considered to be disenrolled if they had actively withdrawn from the follow-up study, or had missed four consecutive visits during the 3–18 month period. All participants in this analysis had the opportunity to be enrolled for this length of time.