

Comparison of Video, App and Standard Consent Processes on Parental Decision Making for Residual Dried Blood Spot Research: A Randomized Controlled Trial

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No Conflict of Interests

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Background

Newborn screening is conducted by every state and territory in the US and represents one of the most successful public health programs of the modern era

Many states save the residual biospecimens for several uses, including biomedical research.

Rothwell E, Johnson E, Riches N, Botkin JR. Secondary research uses of residual newborn screening dried bloodspots: a scoping review. *Genetics in Medicine* 2018

Lawsuits have been filed against several state programs for the lack of informed consent or education for this practice.

The state of Michigan developed the Michigan BioTrust for Health and specimens collected after May 1, 2010, are made available for research with parental permission through an opt-in consent process.

Background

Identifying ways to improve comprehension of biobank-dependent research is a national priority.

Researchers have used interactive, multimedia informed consent platforms to improve comprehension with mixed results.

Lack of guidance from conceptual and theoretical foundations in adult learning and decision-making.

This research developed and evaluated a theory-based, multi-media consent intervention to assist parents in making an informed decision on the retention and use of residual dried blood spots from newborn screening.

Methods

Tools developed by the Genetic Science Learning Center
Video
Interactive App

Conceptual Development based on:
Multimedia Learning Theory and Cognitive Load Theory

Focus Groups were conducted to identify key informational items

The video and app were validated with input from the Michigan Department of Health and Human Services BioTrust Community Advisory Board and employees of the Michigan Department of Health and Human Services.

Leftover blood spots from newborn screening programs across the country are used in research to improve public health in many ways.

POPULATION-BASED RESEARCH

with leftover blood spots can tell us about:

- Birth Defects**
- Diabetes**
- Viral Infections**
- Cancer**



Methods

Institutional Review Board approval was obtained prior to any research activity.

Three hospitals located in Michigan partnered in this study:

Lansing

Ann Arbor

Grand Rapids

Pre-Implementation Assessment

Observations: $n = 30/\text{hospital}$ (90 total)

Methods

Patients provided with brochure-based education material prior to discharge

After newborn screening is complete, a healthcare staff reminds family about brochure for the storage and research use of leftover bloodspots

Ask for a decision and signature to the shortened consent form attached to the filter paper for bloodspot collection.

For this study, after newborn screening was complete, an RA asked if parents were interested in this study.

Eligibility Criteria

Eligible participants were:

Mother or father of the newborn,

English speaking adults

Newborn infant in the post-natal hospital environment but not in the neonatal intensive care unit.

Methods

Left the tablet in the patient room

Watch 6 minute video

Interact with app of nine key points

Read the Brochure only

Provided a \$25 gift card

2-3 weeks later follow up surveys over the telephone or email

An additional \$25 gift card for the follow up surveys.

Surveys

The knowledge survey consisted of two parts.

Part A was composed of 20 knowledge questions

Part B was composed of 14 questions about self-assessed understanding

(Osmond, Quality of informed consent measure; Rothwell et al. 2014)

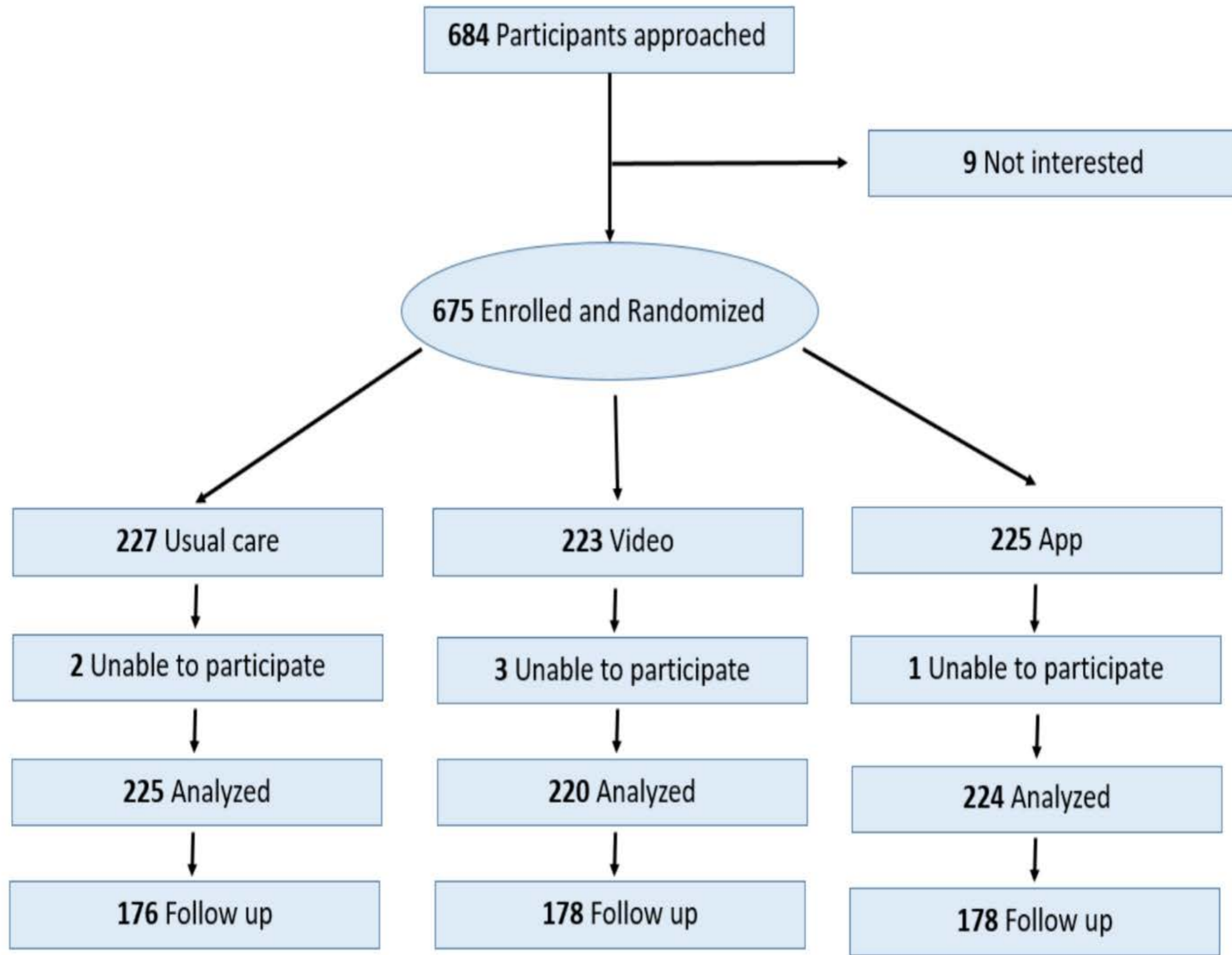
Attitudes toward newborn screening and residual blood spot research

Satisfaction with the content, amount and clarity of the educational information

Self-report to participate in the BioTrust

The Short Form Trust in Medical Research

Decisional regret



Analyses

Univariate analysis of variance with Tukey post hoc adjustment to test the relationship of group assignment (video, app, or brochure) on knowledge, attitudes and behaviors.

A sensitivity analysis was conducted with the following assumptions: sample size of each group = 180, Alpha = 0.05, Power = .80, and two-tailed testing, results showed we will be able to detect a small effect size.

Results

Participants who completed both the post survey and follow-up survey were similar in demographics with respect to ethnicity, race, education, marital status, income, pregnancy history, sex, and language.

Age differed significantly ($p < .05$) and was added to the analyses as a covariate.

The average time between the post survey and follow-up survey was 18.77 days (SD 7.04).

Characteristic	Control n = 225	Video n = 219	App n = 224	Total N = 669
Age at enrollment (years, SD)	30.62 (4.73)	30.08 (4.89)	29.42 (5.02)	30.04 (4.89) *
Gender				
Female	192 (94.1%)	179 (90.4%)	182 (89.7%)	553 (91.4%)
Male	12 (5.9%)	18 (9.1%)	21 (10.3%)	51 (8.4%)
Race				
White	176 (78.9%)	167 (77.0%)	176 (79.6%)	519 (78.5%)
Non-White	47 (21.1%)	50 (23.0%)	45 (20.4%)	142 (21.5%)
Ethnicity				
Hispanic	9 (4.1%)	11 (5.1%)	12 (5.4%)	32 (4.9%)
Non-Hispanic	213 (95.9%)	203 (94.9%)	210 (94.6%)	626 (95.1%)
Income				
Under \$24,999	15 (7.1%)	13 (6.3%)	18 (8.5%)	46 (7.3%)
\$25,000 - \$50,000	27 (12.8%)	39 (18.8%)	32 (15.2%)	98 (15.6%)
\$50,001 - \$100,000	72 (34.1%)	66 (31.7%)	63 (29.9%)	201 (31.9%)
\$100,001 - \$150,000	46 (21.8%)	44 (21.2%)	46 (21.8%)	136 (21.6%)
Over \$150,000	31 (14.7%)	26 (12.5%)	25 (11.8%)	82 (13.0%)
Not sure/did not answer	20 (9.5%)	20 (9.6%)	27 (12.8%)	67 (10.6%)
Education				
Less than college graduate	90 (40.0%)	93 (42.3%)	107 (47.8%)	290 (43.3%)
College graduate and above	135 (60.0%)	127 (57.7%)	117 (52.2%)	379 (56.7%)
Relationship				
Married or living with partner	197 (87.9%)	178 (80.9%)	185 (83.0%)	560 (84.0%)
Significantly involved with partner but not living together	17 (7.6%)	29 (13.2%)	28 (12.6%)	74 (11.1%)
Single / not significantly involved	9 (4.0%)	13 (5.9%)	9 (4.0%)	31 (4.6%)
Other	1 (0.4%)	0 (0.0%)	1 (0.4%)	2 (0.3%)
Given birth before				
Yes	146 (65.2%)	144 (65.5%)	131 (58.7%)	421 (63.1%)
No	78 (34.8%)	76 (34.5%)	92 (41.3%)	246 (36.9%)

* p < 0.05

Knowledge Outcomes

Knowledge – 20 items (% correct)	Usual care N = 176	Video N = 178	App N = 178
	64.8 (0.009)a	70.9 (0.009)a	68.5 (0.009)b
Self Assessment of Understanding – 14 items			
1 - I didn't understand this at all 5 - I understood this very well	4.04 (0.045)a	4.23 (0.046)a	4.12 (0.045)a

a = p<.001; b=p=.013

Satisfaction

How satisfied were you with the information you just received about the Michigan BioTrust?	Usual care N = 176	Video N = 178	App N = 178
1 – Highly dissatisfied, 5 - Highly satisfied	3.98 (0.054)a	4.23 (0.053)a	4.18 (0.053)a

a = p=.002

Amount of Information

How would you rate the amount of information you just received about the Michigan BioTrust?	Usual care N = 176	Video N = 178	App N = 178
1 - A lot less than I needed, 3 – About right, 5 - Much more than I needed	2.92 (0.058)	3.07 (0.057)	3.13 (0.057)

Clarity of Information

How clearly was that information presented about the Michigan BioTrust?	Usual care N = 176	Video N = 178	App N = 178
1 - Many things were unclear, 4 - Everything was clear	2.88 (0.054)a	3.15 (0.054)a	3.14 (0.054)a

a = p=.002

Supportive of Newborn Screening

From your experience, and what you understand about newborn screening, how supportive are you of this program?	Usual care N = 176	Video N = 178	App N = 178
Not supportive at all	3 (1.8%)	0 (0.0%)	3 (1.8%)
A little supportive	5 (3.0%)	3 (1.8%)	12 (7.1%)
Moderately supportive	39 (23.2%)	36 (21.3%)	34 (20.0%)
Very supportive	121 (72.0%)	130 (76.9%)	121 (71.2%)

Support for BioTrust

From your experience, and what you understand about the Michigan BioTrust, how supportive are you of this program?	Usual care N = 176	Video N = 178	App N = 178
Not supportive at all	4 (2.4%)	0 (0.0%)	3 (1.8%)
A little supportive	4 (2.4%)	7 (4.1%)	10 (6.0%)
Moderately supportive	51 (30.5%)	42 (24.7%)	45 (26.8%)
Very supportive	108 (64.7%)	121 (71.2%)	110 (65.5%)

Partner's Role in Decision

Please tell us about your partner's role in your decision.	Usual care N = 176	Video N = 178	App N = 178
1 – Me alone, 3 – My partner and me equally, 5 – My partner alone	2.59 (0.057)	2.55 (0.056)	2.68 (0.056)

Comparison to Past Rates for BioTrust

	2017 for state of Michigan	Usual Care	Video	App	
Yes	67.5%	84.9%	85.0%	78.9%	P<.001
No	21.6%	5.8%	8.2%	9.0%	P<.001
No Signature	10.9%	9.3%	6.8%	12.1%	P<.001

Discussion

Clinic Flow

Clinical duties inhibit capturing decision making

App/Video improved knowledge even with brochure

Significantly higher satisfaction, clarity, amount

Higher participation rates

Unknown if it was the survey or the intervention or just

increased attention

Video versus App

App too much information

Lowest participation in self report but highest potential.

Video effective for this population because of the context

Limitations

Unsure if the intervention was delivered before or after their decision to participate in the BioTrust

Relied on Self-report for participation on BioTrust

Limited diversity and did not assess health literacy

Future Research to address health disparities

Educational Resources

App with the Video will be available for free download and use by May 2019

Spanish Version will be available

QR codes will be available

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