Engage, Develop, Learn: a pilot randomized clinical trial to test if a mobile application can enhance home support for early cognitive development among children living in poverty

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Background: Mobile applications (apps) exist to promote early child development; however, few studies have examined use of these apps among low-income families. Our objectives were to measure engagement with the Engage, Develop, Learn (EDL) app and determine if it promoted engagement and behavior change among low-income caregivers.

Methods: We conducted a pilot study among English and Spanish-speaking, low-income families with children ages 12 to 15 months who received either the EDL app or injury prevention text messages. Baseline data were collected and interventions delivered over two home visits. App engagement was measured using messages opened. Caregiver development-promoting behaviors were measured with STIMQ score changes from baseline to follow-up at child age 2 years. We conducted key informant interviews among families randomized to receive the EDL app to identify barriers and facilitators to app use.

Results: A total of 100 caregivers were recruited at their children's preventive care visit with 50 randomized to receive the EDL app and 50 to receive the injury prevention text messages; however, only 25 in the development app and 34 in the injury prevention group completed both home visits. Follow-up data were collected from 14 in the development app group and 30 in the injury prevention group. Over 10 weeks, 24% (6/25) remained engaged with the development app. STIMQ scores did not differ between groups. Barriers included technical difficulties accessing the app, social stressors, and 'forgetting' to use it.

Conclusions: Our pilot randomized trial of a child development app suggests that it may not be effective for promoting behavior change among low-income caregivers due to low engagement.

Trial Registration: This pilot trial was registered with ClinicalTrials.gov (ID NCT02717390).

Keywords: Child development; mobile application (mobile app); parenting intervention

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Introduction

Responsive parenting to promote early childhood development is a key determinant of future academic success and quality of life. Children living in poverty are at increased risk for delayed cognitive, language, and social-emotional development when compared to their higher income peers (1-9). These delays may be mediated by providing supportive, loving relationships with caregivers. We previously suggested that mobile health (m-Health) interventions could promote positive caregiver interactions and improve child development among low-income families (10,11). m-Health interventions, such as text messaging and mobile applications (apps), are now widely available and used. However, parents with less income, lower education, lower health literacy, and those who do not speak English are less likely to engage with m-Health solutions, thus reducing the potential effectiveness of these interventions among populations who could most benefit (12-14).

To study the effect of a m-Health intervention on caregivers' child development promoting behavior, we created an app, Engage, Develop, Learn (EDL), and conducted a pilot randomized clinical trial among low-income caregivers of children ages 12 to 24 months. Our objectives were to measure user engagement with the EDL app, determine if engagement resulted in sustainable behavior change, and determine if certain features of the app successfully incentivized caregivers to talk, read, play with, and praise their young children. We present the following article in accordance with the CONSORT reporting checklist (available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/rc).

Highlight box

Key findings

- A mobile app to increase parental or caregiver behaviors to promote early child development may not be effective among low-income parents or caregivers due to low engagement.

What is known and what is new?

- Mobile apps exist to promote early child development; however, few studies have examined use of these apps among low-income families.
- This pilot study sought to measure engagement with the EDL app and determine if it caused behavior change among low-income parents.

What is the implication, and what should change now?

- If the goal is to reduce disparities in child development among low-income families, we suggest that m-health interventions may not be adequate on their own and should be studied as a way to augment other interventions.

Methods

Study design

This pilot randomized clinic trial of the EDL intervention was conducted from September 2017 through November 2019. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Colorado Multiple Institutional Review Board (Protocol No. 15-2164) and informed consent was taken from all the study subjects.

EDL development

The EDL intervention was guided by the Theory of Planned Behavior and Social Cognitive Theory. The Theory of Planned behavior suggests that intention is a powerful predictor of behavior and is influenced by a person's attitudes toward the behavior, norms, and perceived control to carry out said behavior (15,16). Social Cognitive Theory endorses that self-efficacy is a critical determinant of behavior change, which includes one's skills and self-confidence to perform a behavior, and can be broken into smaller, more manageable steps (16,17). EDL intended to deliver accessible and understandable positive parenting content in the daily environment, thus increasing caregivers' self-efficacy by influencing attitudes and norms. We developed the messaging structure of the EDL app with input from a parent advisory board whose members were from similar sociodemographic background as study participants and a multi-disciplinary team of experts including pediatricians, a speech pathologist, and a child psychologist. A user experience designer helped design the app with feedback from the parent advisory board.

EDL content and features

EDL content delivered short messages aimed for the child's specific age. Messages were written at a 6th grade reading level and were personalized to reflect child's first name, age, and gender. Messages included information about child development and games/activities encouraging caregivers to engage with their children with a focus on four categories of child development-promoting behaviors: talking, reading,

playing, and praise. Messages were sourced from Bright by Text (https://brightbytext.org), Learning Games and Language Power (18,19). Our team also developed new messages and activities based on expert knowledge and experience. All messages were positively framed to maximize effectiveness and impact and sought to use the ecological moment to help caregivers implement change (20-22). Private Facebook groups were established in English and Spanish. Study staff posted daily messages to share content, complement participant activities delivered via the app and stimulate participants to comment, answer questions, or share experiences.

EDL utilized a point system to enhance user experience and subsequent engagement. Features implemented in the EDL app included:

- Goal setting: caregivers were invited to set a shared reading goal;
- Reading log: a timer allowed caregivers to track the duration spent reading with their child. The reading log provided caregivers a screen to report this time. The built-in EDL function used time/log data to track progress toward the caregiver's reading goal and award points;
- Points: caregivers received 1 point for each minute of time spent reading and up to 15 points for indicating that they completed an activity focused on increasing talking, playing, or praise;
- Rewards: caregivers were eligible to receive a prize, a children's book, once obtaining a pre-determined number of points.

Recruitment and participants

Study participants were recruited from a large, urban pediatric clinic serving mainly low-income families that participates in the Reach Out and Read and Healthy Steps programs. Caregivers of children between the ages of 12 and 15 months who were low-income [based on insurance status of child being Medicaid or Children's Health Insurance Program (CHIP)], had less than college level education, had a smart phone, and speak English or Spanish were invited to participate. Caregivers whose children were born prior to 36 weeks gestation, had conditions known to affect child development, screened positive on the Children with Special Health Care Needs Screener (23), or were already receiving developmental therapies were excluded. We did not exclude children who received Reach Out and Read books and/or Healthy Steps, because we aimed to conduct a pragmatic trial that reflects the 'real life' context for families. We wanted to understand if the EDL app could augment the care already provided by pediatric primary care clinics.

After consenting to participate in the study, caregivers were randomized using a computerized algorithm in Research Electronic Data Capture (REDCap) to one of two parallel groups: EDL or an attention control which was an injury prevention text messaging program. Participants were randomized with a 1:1 allocation ratio, using a block size of 4. The random allocation sequence (i.e., randomization table) was generated in SAS and uploaded to REDCap by the data analyst. Once the randomization table was uploaded to REDCap, the randomization functionality allowed no access to the random allocation sequence by anyone. The randomization status of each participant was displayed in REDCap once the "Randomize" button was clicked for each consented participant. Caregivers who completed the eligibility survey received a $10 gift card. Since this was a pilot study with the goal of determining feasibility and sample size needed for a future trial, we determined sample size based on available resources.

Data collection

Intervention delivery and data collection visits

After their initial recruitment in the clinic setting, intervention delivery and baseline data collection occurred over two consecutive visits in participants' homes or community locations per recommendations of the parent advisory board. The EDL intervention was delivered by a bilingual 'Infant Development Advocate' who was a community member hired and trained to help caregivers download the app, explain its use, and discuss key concepts for promoting child development. Professional research assistants (PRAs) delivered the control intervention by setting up caregivers' phones to receive injury prevention text messages. Child development measures were collected by PRAs during the first visit and the randomly assigned intervention was delivered and injury prevention measures were collected by PRAs during the second visit. Study participants received $30 and $40 gift cards following the first and second visits, respectively. Participants and those collecting the data were not blinded to group assignments.

Follow-up data collection occurred within 3 months of the child's second birthday and was conducted by PRAs in the study participants' home, community location, or clinic. For participants who were unable to complete a

visit, parent-reported follow up measures were collected by telephone. Study participants received a $50 gift card for completing the follow up visit. Participants who were randomized to receive the EDL app were also invited to participate in key informant interviews by telephone. Participants who completed the key informant interviews received a $20 gift card.

Measures

Caregivers were administered the STIMQ Toddler at baseline and follow up. The STIMQ is a self-reported measure of parent-child activities that promote cognitive stimulation (24,25). The subscales used to quantify parental behaviors were: reading activities (READ) which assesses frequency of shared reading, number and diversity of books and associated activities; parent involvement in developmental activities (PIDA) which assesses parent engagement in teaching activities such as naming body parts, stacking blocks, pointing to and naming items at the grocery store; and parent verbal responsibility (PVR) which assesses parent-child verbal interactions. We hypothesized that use of the EDL app would improve the READ, PIDA, and PVR subscale scores by increasing parental knowledge and self-efficacy and specifically encouraging talking, reading, playing, and praise.

A questionnaire based on the Theory of Planned behavior (15,16) and developed by the study team with pre-testing from the parent advisory board was used to assess parental beliefs, attitudes and norms about target development-promoting behaviors at baseline and follow-up. Caregivers were asked to report their responses on a 6-item scale with the options of 'less than once a month', 'about once a month', 'a few times a month', 'about once a week', 'a few times a week', and 'every day'.

Primary outcome measures included the STIMQ Toddler and the questionnaire developed by the study team described above, as well as results of key informant interviews with caregivers randomized to the EDL group described below. Control group measures were secondary outcome measures and included: (I) a survey regarding prior injury prevention education, current safety practices, knowledge of poison control numbers/clinic numbers/cardiopulmonary resuscitation (CPR)/first aid, report of child injuries during the past year, and attitudes and beliefs about safety practices; and (II) a home observation checklist completed by the PRA. Control results are not reported in this manuscript focused on child development.

Statistical analysis

Chi-square tests and *t*-tests were performed to assess potential differences between the sociodemographic characteristics of the EDL and injury prevention groups at baseline. Descriptive statistics were used to describe technology use among participants and quantitative measurements of engagement with the app. All analyses were conducted as intention-to-treat, meaning that those who were randomized to receive the EDL app were analyzed in the intervention group regardless of their actual use of the app. The nonparametric Wilcoxon Signed rank test was used to assess change in STIMQ scores between baseline and follow up within groups. Difference between groups for change in STIMQ scores from baseline to follow up was assessed using the nonparametric Wilcoxon rank sum test. Fisher's exact test was used to determine whether the change in reading and playing behaviors between baseline and follow up was significantly different between groups.

Qualitative analysis

All study participants who participated in the data collection visits and received the EDL intervention (n=25; see *Figure 1*) were contacted with an invitation to participate in key informant interviews using a standardized protocol (up to 2 phone calls, 2 text messages, and 2 emails to the primary contact and 1 phone call and 1 text to the secondary contact). One bilingual PRA conducted semi-structured interviews of the 13 caregivers who received the EDL intervention and agreed to participate in the interviews. The interview guide was developed by the study team based on existing published literature regarding barriers and facilitators to app use and behavior change. The guide focused on usability of the app itself and factors outside of the app that affected its use, message content, likes and dislikes about the reading log and activities, and perceived effect of the app on development promoting behaviors and child development (see Appendix 1). The interviews were transcribed and translated (Spanish to English). The codebook was developed using an iterative process in which four members of the study team (MC, CG, MA, and CC) reviewed sample transcripts and suggested codes then met to discuss the codes and reach agreement about codes and their definitions. A final codebook was agreed upon after review of three transcripts. All 13 transcripts were coded by two members of the study team (MC and CG) who met regularly to ensure consensus regarding codes. Then the

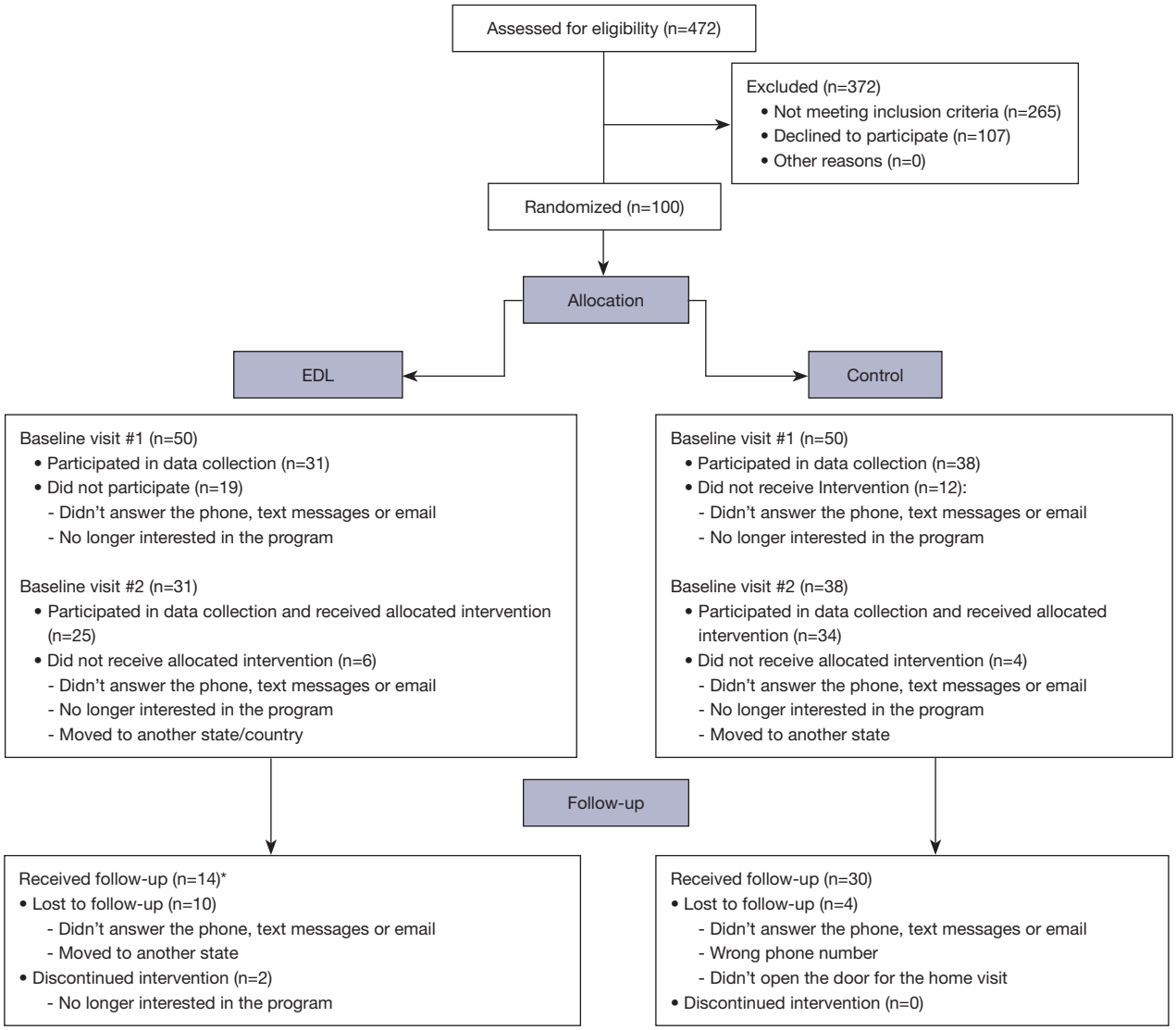

Figure 1 CONSORT flow diagram. *, one caregiver didn't have the baseline visit #2 but received the follow-up home visit. EDL, Engage, Develop, Learn.

study team used a summative content analysis approach where common codes and combinations of codes were grouped, summarized, and placed in context (26).

Results

As shown in *Figure 1*, 50 caregivers initially randomized to receive the EDL app, 31 completed the first and 25 completed the second visit and downloaded the app. Of the 50 caregivers initially randomized to the control group, 38 completed the first and 34 completed the second visit and enrolled in the injury prevention text messaging intervention. Fourteen caregivers in the EDL group and 30 in the control group completed follow up 1 year after enrollment. We conducted intention-to-treat analyses; however, low participation in the data collection visits outside of the clinical setting prevented us from including all 100 of those who initially agreed to participate in the study because we lacked data from those who did not participate in the data collection visits.

Study participants

A total of 100 caregivers were recruited for the study

from September 2017 through January 2018 during a pediatric clinic visit. *Table 1* describes the sociodemographic characteristics of the study population. There were no significant sociodemographic differences between the caregivers randomized to the EDL *vs.* control group. Most caregivers were mothers with 2 grandmothers and 1 grandfather participating. *Table 2* shows the baseline reported technology access and use among study participants.

EDL engagement

Six caregivers in the EDL intervention group (24%) remained engaged with the app throughout the 10-week period opening most messages delivered most weeks. One caregiver opened messages the first 3 weeks and then ceased engagement and six opened messages for the first 2 weeks then ceased engagement. Six caregivers only opened messages the first week (likely during the study visit) and never engaged with the app again. Three caregivers engaged with the app more sporadically, but total weeks of engagement throughout the 10-week period remained low with caregivers opening messages only 2 to 3 of the 10 weeks. Eight caregivers (32%) earned enough points to receive a reward. Two caregivers earned one reward (50 points), two earned two (100 points), one earned four (300 points) and three earned five (500 points). Only 12 English-speaking and 3 Spanish-speaking caregivers joined the private Facebook group with two English-speaking and no Spanish-speaking caregivers engaging on Facebook.

Behavior change

Table 3 shows the STIMQ data collected at baseline and follow up. Among those for whom we had both baseline and follow up STIMQ subscale scores, we found that the PIDA and READ scores increased from baseline to follow up for both groups (READ P=0.001 EDL, P=0.004 injury prevention; PIDA P=0.004 EDL, P<0.0001 injury prevention). There were no statistically significant differences between participants assigned to EDL *vs.* the control group. There was no significant change in PVR scores between baseline and follow up for either group.

Parental beliefs, attitudes, and norms were not statistically different between the EDL and control groups at baseline or follow-up. At baseline, 19% (6/31) of caregivers in the EDL group and 39% (15/38) in the control group reported reading to their children daily, and 77% (24/31) in the EDL group and 95% (36/38) in the control group reported playing with their children daily. At follow up, the reported frequency of reading increased for 57% (8/14) of caregivers in the EDL group and 38% (11/29) in the control group and the reported frequency of playing increased for 7% (1/14) in the EDL group and 4% (1/29) in the control group. These changes from baseline to follow-up were not statistically different between groups.

Barriers and facilitators to EDL app use

Among the 13 study participants who received the EDL app and agreed to participate in semi-structured interviews, all 13 set a reading goal (they were prompted to do this when they first downloaded and opened the app) but only 5 used the app enough to earn one or more rewards. Among the 5 who earned rewards, 4 received 4 or more rewards (300 or more points) indicating regular engagement with the app, and 1 received only 1 reward (50 points) indicating limited engagement with the app. The remaining 8 of those interviewed did not receive any rewards (<50 points) indicating minimal engagement with the app. Content analysis from the semi-structured interviews among 10 English-speaking and 3 Spanish-speaking participants focused on 4 themes: "positive app features", "behavior change", "barriers to use", and "incentives and rewards". Illustrative quotes are provided in *Table 4*.

Positive app features

Most caregivers interviewed found the app easy to use. Most caregivers also reported that they liked the content of the messages and activities. A few caregivers specifically mentioned that they liked receiving messages that explained why specific behaviors or activities were helpful to their child's development. Many caregivers also appreciated having a reading log and timer so they could track weekly reading minutes. A few caregivers specifically mentioned that they liked being able to set a goal and track their progress toward that goal.

Behavior change

Caregivers reported that the app encouraged changes in the way they read with their children and talked to them throughout the day. The most common behavioral changes endorsed were increased talking and engagement in dialogic reading. One caregiver gave a specific example of how she had increased her talking to her child. Another gave an

Table 1 Characteristics of participants randomized to EDL app *vs.* control

Characteristics	EDL app	Control	P value
Language usually spoken to child[a], % [n]			
English	74 [37]	70 [35]	0.656
Spanish	44 [22]	50 [25]	0.548
Language preferred for reading, % [n]			0.528
English	76 [38]	70 [35]	
Spanish	24 [12]	28 [14]	
Other	0 [0]	2 [1]	
Ethnicity, % [n]			0.300
Latinx	68 [34]	58 [29]	
Race[b], % [n]			0.587
Caucasian	71 [35]	67 [33]	
African American	18 [9]	27 [13]	
Other	8 [4]	6 [3]	
Multi-racial	2 [1]	0 [0]	
Education level, % [n]			0.325
Less than high school grad	32 [16]	22 [11]	
High school grad or GED	34 [17]	48 [24]	
Vocational school/some college	34 [17]	30 [15]	
Relationship to child, % [n]			0.390
Mother	94 [47]	96 [48]	
Father	4 [2]	0 [0]	
Grandmother	2 [1]	2 [1]	
Grandfather	0 [0]	2 [1]	
Marital status[c], % [n]			0.470
Single/divorced/widowed	32 [16]	43 [21]	
Married	32 [16]	33 [16]	
Partner or other	36 [18]	25 [12]	
Number of children in home, mean, median (IQR)	2.42, 2.00 (1.00–3.00)	2.26, 2.00 (1.00–3.00)	0.569
PSI score, mean (SD)	69.81 (3.98)	60.45 (2.34)	0.048
PSI total (%), mean (SD)	38.58 (5.06)	27.29 (3.47)	0.062
PHQ-9 total score, mean (SD)	4.32 (5.32)	2.74 (0.62)	0.155
Health insurance of child, % [n]			1.000
Medicaid	98 [49]	98 [49]	
CHIP	2 [1]	2 [1]	
Age of child in months at baseline, mean (SD)	13.13 (1.72)	13.02 (1.84)	0.747
Age in of child in months at follow up, mean (SD)	26.80 (0.54)	25.89 (0.30)	0.087

[a], EDL app: 9 families reported speaking primarily English AND Spanish to child at home, control: 10 families reported speaking primarily English AND Spanish to child at home; [b], EDL app: 1 missing response; control: 1 missing response; [c], control: 1 missing response. EDL, Engage, Develop, Learn; GED, General Education Development; IQR, interquartile range; PSI, Parenting Stress Index; SD, standard deviation; PHQ-9, Patient Health Questionnaire-9; CHIP, Children's Health Insurance Program.

Table 2 Description of technology access and use among study participants by group—EDL app *vs.* control

Reported technology access/use	EDL app (n=31)		Control (n=38)	
	No	Yes	No	Yes
Own a tablet	13	18	21	17
Have internet access at home	0	31	0	38
Have WiFi access at home	11	20	9	29
Have an unlimited data plan on mobile phone[a]	2	27	10	27
Mobile Phone disconnected in the last 12 months	18	13	29	9
Mobile phone used to send and receive text messages	1	30	3	35
Mobile phone used to look up information	0	31	3	35
Mobile phone used to read/post comments[b]	5	25	7	31
Mobile phone used to post photo/video	6	25	6	32
Mobile phone used to watch videos[c]	0	31	4	33
Mobile phone used for apps	4	27	3	35
Mobile phone used to play games	16	15	12	26
Facebook used on mobile phone	6	25	7	31

[a], EDL app: 1 don't know and 1 missing response, control: 1 don't know response; [b], EDL app: 1 missing response; [c], control: 1 missing response. EDL, Engage, Develop, Learn.

Table 3 STIMQ scores in EDL app *vs.* control at baseline and follow up

Characteristics	EDL app			Control			Difference in change EDL *vs.* IP
	Baseline (n=31)	Follow up (n=14)	Change	Baseline (n=38)	Follow up (n=29)	Change	
STIMQ-READ, mean (SD)	8.48 (4.47)	11.07 (3.52)	3.57 (3.06)	9.82 (3.81)	11.90 (3.66)	1.90 (3.64)	P=0.152
STIMQ-PIDA, mean (SD)	7.29 (2.16)	9.43 (1.09)	1.93 (0.67)	7.71 (2.00)	9.34 (1.11)	1.66 (1.95)	P=0.617
STIMQ-PVR, mean (SD)	3.35 (0.75)	3.29 (0.61)	−0.21 (0.58)	3.63 (0.59)	3.41 (0.78)	−0.17 (0.80)	P=0.643

EDL, Engage, Develop, Learn; IP, injury prevention; READ, reading activities; SD, standard deviation; PIDA, parent involvement in developmental activities; PVR, parent verbal responsibility.

example that showed she had learned to engage in dialogic reading. Another reported playing more with her child after using the app. Finally, a few caregivers indicated that they had changed how they praised their children based on what they learned from the app. For example, one mother described how she was more vocal about when she was proud of her child.

Barriers to use

Engagement with the app was low for the majority of 13 caregivers we interviewed. Upon further questioning the most common barrier to use, reported by 8 caregivers, was inability to access or download the app without assistance due to forgotten passwords, phone change, phone reset, or phone not functioning properly. Two caregivers reported that they often forgot to use the app. One mother reported that the app did not allow her to engage with others.

Incentives and rewards

Most of the caregivers we interviewed reported knowing that they could earn points for completing activities and logging reading minutes. The majority reported that points were "easy" to earn, but most did not earn any rewards or could not remember if they had earned rewards. One caregiver reported that she was earning points but did not know about rewards. A few caregivers explained that they

Table 4 Illustrative quotes regarding barriers and facilitators to EDL app use

Theme	Summary	Quote
Positive app features	Easy to use	It was not difficult at all. It's, like, very simple. You read the little—it asks you a question, like very knowledgeable questions, like really good. It gives you good tips on the child's, like, learning development and all of that
	Content of the messages and activities	I like, like, the little messages that I receive. So it's, like, if I use the app more, the more messages I get to read about different developments, you know, that I should be recognizing in my child…So I try to make sure I use it as much as I can to try to get some of those messages
		I have to say like all the things like it didn't just tell you like the suggestions, but it tells you, you know, why this is a good idea, why pointing everything in the store teaches him names and how all the words before three. I just I mean, I tend to see myself as a know it all, so it just helps me know it all
	Reading log and timer	I definitely used the timer. The timer saved me because I'm really, really—I don't know why. But I'm still kind of bad at reading clocks. So if it's not digital, I don't, you know, I don't kind of mess with those… But if I set the timer for a certain time, I can just set the timer, close my phone, and start reading to my daughter. And I'll read to her until I here that timer goes off. So I know that I've read to my daughter the full time that the timer is going
	Goal setting	So it lets me read more and it keep me—like, it reminds me, 'Oh, we have to try to reach our goal'. So I have to keep on trying to read. And it's fun for the child
Behavior change	Talking	When I'm dressing him, putting on a sock, to say, 'Okay, Martin. Give me your foot. This is called a sock'
	Reading	A good length of how to read to him, just not reading but to show him the features so that we could look at the features. Like I said, not just reading the book but when I read show him the pictures and point out the pictures in the book like the stars
	Playing	In the sense that before, I almost never played with my daughter and now I played with her. I bought her things like dice, so she can understand, with letters, with numbers
	Praising	Before I was like oh, I would watch him and myself I was like oh my God, he just did that, that's awesome. I pointed it out to him. Like I'll say oh, good job, high five
Barriers to use	Inability to access or download the app	I use apps for everything to check the app and I can do it and I stopped because I couldn't open it. My phone is not working right
		But every time I tried to recover the password, it'll tell me that the server is down and for me to try again later. So I kind of haven't messed with it in a while. So I'm just trying to sort of—I'm actually—I was like, "I wonder when they're going to call", because I forgot when I was going to get a phone call
	Forgot to use the app	I did at the beginning and I have not after messing up my phone. I stopped logging in because I didn't have access to it until I just, I had spoken to you not to long ago and got the password. And so I haven't logged on yet, but because I really forget. Yeah, I was really terrible. I forget to login
	Lack of engagement with others	I don't know. I feel disconnected from other people. It doesn't really give you the option to go to anybody for help. I guess that's what frustrates me right now, but that's it
Incentives and rewards	'Easy' to earn	I mean, it was pretty easy in the beginning. But like I said, like, now since I have other stuff going on, sometimes it makes me forget to put in the points or anything like that
		It was actually pretty easy. I didn't even really, maybe five points here, ten points, it adds up. You know it was just fun achieving them
	Did not earn rewards	Not yet. Because like I said, I ended up logging out of the app. So I haven't been in the app in a while. So I haven't won any rewards yet
	Confused about rewards	I didn't know at first. But recently, I seen that it gives me rewards. And I didn't know what the rewards were for
		I would say the only thing that I really didn't understand was, and I can't remember if this was explained or not actually, what happens once you complete activities or you log in or you meet your goals and you earn prizes. Like how do you go about you know, receiving those prizes

learned about points and rewards at the home visit but were still confused about how to earn or receive rewards.

Discussion

We conducted a pilot randomized trial to determine if the EDL app could successfully promote behavior change among low-income caregivers of young children. Our objective was to determine if certain features of the EDL app could enhance engagement with the app and incentivize caregivers to talk, read, play with, and praise their children. We experienced challenges with completing visits to deliver intervention and collect data among our study population. Only half of the caregivers who were initially randomized to receive the EDL intervention actually completed the data collection visits and, among the 25 caregivers who downloaded the app, only 6 (24%) engaged with it for the entire 10-week study period.

We did not find statistically significant changes in self-reported behaviors and STIMQ scores between caregivers who were randomized to receive the EDL intervention *vs.* the control intervention using an intention to treat analysis. While not statistically significant, we did find that more caregivers who were randomized to receive the EDL intervention increased the target behaviors based on self-report compared to the control group, and our qualitative data suggest that those who engaged with the EDL app changed their behavior based on what they learned from the app.

Previous studies of m-Health interventions to promote positive parenting behaviors have often relied on a convenience sample without a control group (27,28). A strength of our pilot study is that participants were randomized to receive either the EDL or attention control (injury prevention) intervention. The control group and the intervention group received a similar volume of content reducing the likelihood that the changes we observed in the intervention group were a result of the Hawthorne effect. Our selection of only caregivers who had not graduated from college and whose children had public health insurance was also unique, enabling us to focus on a subset of the population that has been traditionally harder to engage with m-Health solutions. A cohort study of the Text4Baby program where women were randomly selected to be offered the text messaging program found similar results to ours in terms of engagement. About half of those who were randomly selected attempted to enroll to receive text messages, and those who successfully enrolled were more likely to have at least some college education (12). Similarly, a recent systematic review of digital health interventions to increase physical activity found that these interventions were not effective among participants with low socio-economic status (14). Another strength of our study was that usage data collected through the app gave us objective data to measure app usage while semi-structured interviews allowed for the interpretation of our quantitative findings in an explanatory sequential manner.

Despite using strategies known to promote app engagement to develop the EDL intervention, only 24% of users demonstrated sustained engagement with the app at 10 weeks in our study (29,30). This is consistent with previous studies of digital self-help interventions that have shown rates of completion or sustained engagement beyond 6 weeks that range from 0.5–28.6% (31). Specifically, 3 therapeutic persuasiveness items—rewards, adaptive design, and on-going feedback—have been shown to significantly correlate with user retention (29). While we did not employ an adaptive design for this pilot, the EDL app utilized rewards and on-going feedback. While a total of 32% of users were able to earn at least 1 reward, incentives did not seem to promote app use among the caregivers we interviewed. Most of these users did not earn rewards despite reporting that points were easy to earn. This may be because rewards were not emphasized within the app, and some caregivers were unaware of the potential to earn rewards or how to receive rewards once they were earned. Some caregivers did not earn rewards despite reporting that they were aware of the gamification features that allowed them to earn rewards. This suggests that rewards might be less persuasive in encouraging app use and retention among our target population, or that the rewards selected (children's books) were not persuasive.

We found that few caregivers engaged with Facebook though one caregiver reported that connecting with other mothers was important to her and she did not feel like the app provided sufficient contact with other caregivers. This suggests that perhaps social media is not an effective platform to facilitate these connections and face to face or real time contact via an on-line video platform may be more successful in establishing connections and promoting engagement.

Our pilot study had limitations. Though we initially recruited 100 study participants as planned for this pilot, many of those initially recruited in a clinic setting did not continue with the study outside of the clinic setting resulting in a smaller sample size than originally planned. In

addition, we experienced high attrition with more attrition among the group randomized to receive the EDL app. Despite our use of methods known to encourage study retention, the 1-year follow up visit was only completed for 14 in the EDL group and 29 in the attention control group. For future studies, we would consider routinely conducting data collection directly before or after well child care visits in the clinic setting, when possible, given the difficulty we experienced with collecting data outside of the clinic setting. This difficulty resulted in small sample sizes, baseline differences for the outcome of interest between the EDL intervention and control groups, and differential attrition. To address these issues, we would also consider emphasizing the need for long term participation at the time of recruitment, decreasing the monetary incentive for completing the recruitment process, and increasing the monetary incentive for completing follow up data collection. An additional limitation was that our measures of talking, reading, playing, and praise were based on parent/caregiver-reported measures rather than direct observation.

The findings from our pilot randomized trial suggest that the EDL app may increase caregivers' child development promoting behaviors if they are able to actively engage with the app. However, we also found that the majority of low-income caregivers with less than college education whom we recruited for the study did not engage with the app. The most common barrier to engagement was difficulty accessing the app. Some of the features that caregivers who did access the app found to be most be useful could be delivered via text messaging. Therefore, focusing on text messaging may be a solution to overcome the access barriers to using an app. We considered providing phones and/or data plans to study participants to decrease m-health access barriers, but chose not to because of our desire to conduct a pragmatic trial that reflected the 'real life' context of the families we thought were most likely to benefit from the intervention.

Our findings imply that, while m-health interventions may be one way to promote positive parenting, they are not a panacea for reducing disparities in early child development as they may not effectively reach caregivers of the children most in need of an intervention to promote child development. If the goal is to reduce disparities in child development among low-income families, we suggest that m-health interventions may not be adequate on their own and should be studied as a way to augment other interventions, such as Reach Out and Read, the Video Interaction Project, and home-visiting programs that have been shown to successfully increase child-development promoting behaviors among caregivers. Most m-Health that is commercially available is designed as a stand-alone intervention. Little has been done to explore how mHealth in pediatric intervention can be designed to supplement, enhance, and intensify effects of in-person interventions. We have seen evidence that mHealth interventions when linked to *in vivo* interventions can achieve this (32). Researchers have emphasized that the benefit of mHealth is likely in generating small effects through intervention that can reach exponentially greater audiences than in person intervention (33). A key could be to find a way to build on the success of a strong in-person intervention with booster or enhanced content delivered digitally.

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Footnote

Reporting Checklist: The authors have completed the CONSORT reporting checklist. Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/rc

Trial Protocol: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/tp

Data Sharing Statement: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/dss

Peer Review File: Available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://mhealth.amegroups.com/article/view/10.21037/mhealth-22-13/coif). CAD received payments from Walton Family Foundation, Daniel's Fund, made to her institution to conduct the BB3 project which supported a small portion of her FTE to work on this project; received payments

from Children's Hospital Foundation, which were made to her institution to support part of her FTE to conduct other research; and she also reports that owning stock in the Amgen company. The other authors report that Development of the Engage, Develop, Learn mobile application and its evaluation were funded by Walton Family Foundation [Nonprofit 501(c)(3)], Daniel's Fund [Nonprofit 501(c)(3)], Frankenburg-Camp Fund [Nonprofit 501(c)(3)], and the Gantz Family [Nonprofit 501(c)(3)]; there are no conflicts of interest with any of the above organizations. SB also reports that was on the board of Bright by Three/Bright by Text and the Gantz Family Foundation at the time of this study.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Colorado Multiple Institutional Review Board (Protocol No. 15-2164) and informed consent was taken from all the study subjects.

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Appendix 1

Key informant interviews

The purpose of this interview is to find out what you think about the BB3 app and understand your thoughts on the infant development advocate and how they worked with you to understand the BB3 app. Since we cannot take notes while conducting the interview by phone we will be recording today's phone discussion. I know that sometimes people are uncomfortable with the idea of being recorded, but I want you to know that we take your privacy very seriously and we will not be sharing any of your personal information.

Your participation is voluntary and there are not right or wrong answers, we just want to know your opinion. Do you have any questions before we start?

Great, let's begin.

1. What was your experience when you met with the infant development advocate?
   (If needed, the infant development advocate was the lady that helped you download the BB3 app and explained the resources the day of your second visit.)
   (If they say it was a good experience, ask "what made it a good experience", or the opposite if it was a bad experience. Probe for elaboration on vague responses, e.g., "It was ok".)
2. How was the communication with the infant development advocate?
3. How well did the infant development advocate explain things that may be hard to understand?
   (For example: your child's brain development, how the app will help your child, the purpose of Bright by Three, how to input numbers into the app.)

Next, I am going to ask you some questions about the assistance provided by the IDA in understanding the BB3 app.

4. How did the infant development advocate help you understand how to use the app?
   A few days after the visit, do you feel you were able to use the app on your own?
   (If they state that they were good at communicating, ask how? Probe for examples.) Alternative ways at asking this question include:
   - ❖ Were there things that the IDA did to help you understand the app that you wouldn't have had without the IDA? What specifically about the IDA made the experience of learning about the app easier or harder?
   - ❖ How did the cultural background of the infant development advocate affect your understanding of how to use the app?
     (Other words for cultural background: ethnicity, country of origin, etc.)
5. What else could the infant development advocate have done to improve your experience with Bright by Three?
6. What suggestions do you have for making this experience with the infant development advocate better?

Now we will ask you questions related to apps, in general, and later about the BB3 app.

7. How often do you use apps in your phone?
8. How do you normally learn to use apps on your phone?
9. How easy or difficult is it for you to understand new technology, such as new smartphones, new apps like the BB3 app?
10. Tell us what people, including friends and family, you ask for help with understanding, downloading, and setting up new apps?
    If you do not ask friends for help, what are other strategies or resources that you use?
    (If they ask for suggestions: family members, friends, kids, YouTube, Google, in-app help).
11. After meeting with the infant development advocate, how likely are you to still ask other people for help or use resources to understand how to use the BB3 app?
    If likely, which other resources did you or will you use? Can you tell me more about that?
12. Have you changed your phone number or phone since you were enrolled?
    If yes, phone number, why?

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If yes, phone, why?
- ❖ Were you able to use the app after those changes?

13. Do you know how to contact us for help with the app if you need it?
    If yes, how can you contact us?
    If no, give them the email for contact.

Now we will ask you questions specifically related to the BB3 app.

14. How easy or difficult was to log on to the BB3 app? Were you able to open the app without trouble?
    If easy, what made it easy to use?
    If difficult, what made it difficult?
15. How easy or difficult was it to use the app?
    If easy, what made it easy to use?
    If difficult, what made it difficult?
16. Tell me about reading to your child and logging your reading minutes.
    - ❖ If the mom read and log the minutes, how easy or difficult was logging the reading minutes?
    - ❖ If the mom is reading but not logging minutes, why you are not logging the minutes?
    - ❖ Did you set a reading goal? Why or why not?
    - ❖ Did setting a goal help you to read more consistently with your child?
17. What did you like most about the BB3 app? Parents might need help reminding them the features of the app if they don't know what to say.
    (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction.)
    - ❖ Which features of the app did you find helpful? Why?
    - ❖ Which features of the app did you use the most?
    - ❖ Which features of the app were the easiest to use? How?
18. What did you dislike most about the BB3 app?
    (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction.)
    - ❖ Which features of the app did you find least helpful? Why?
    - ❖ Which features of the app were the most difficult to use? How?
    - ❖ Were there features that you didn't use or know about?
19. Where did you use the app most often?
    - ❖ Did you use the app mostly at home or outside of your home? If outside your home, where did you use the app most often?
    - ❖ How did your access to WiFi (wireless internet) determine the location in which you used the app?
20. When did you usually use the BB3 app?
21. What motivated, reminded, prompted you to use the BB3 app?
22. Why didn't you use the BB3 app?
23. What would make you more likely to use the BB3 app or a similar app to promote child development?

Next, I am going to ask you some questions about the messages that you received in the app.

24. How did the messages help you learn more about your child's development?
25. Which messages did you like or find most helpful? Can you give some examples?
    - ❖ Did you feel these activities were easy for you to fit into your lifestyle, or your daily routine?
26. Which messages didn't you like or find least helpful? Can you give some examples?
27. Have you joined the BB3 facebook page? How often have you logged into the Facebook page?
    - ❖ Have you been looking at the Facebook messages?

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If not, go to question 28.

- ❖ What did you think of the Facebook messages?
  Probe: Describe what you liked or didn't like about the Facebook messages.
  Probe: Describe how you used the BB3 Facebook page.

Now I am going to ask you some questions about how the app may have changed some ways that you interact with your child.

28. How did the app affect how you play with your child, if at all?
29. Did using the app change how often you play with your child?
    If yes, which features help you play more often? How helpful were that features you use?
    (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction.)
30. Did using the app change the activities that you do with your child?
31. How did the app affect how you read with your child, if at all?
    - ❖ Did using the app change how often you look at books with your child?
      If yes, which features help you read more often? How helpful were that features you use?
      (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction.)
    - ❖ Did using the app change what you do or say while looking at books with your child?
32. How did the app affect how you talk with your child, if at all?
    - ❖ Did using the app change how often you talk with your child?
      If yes, which features help you talk more often? How helpful were that features you use?
      (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction.)
    - ❖ Did using the app change what you say or how your talk to your child?
33. How did the app affect how your praise or encourage your child, if at all?
    - ❖ Did using the app change how often you encourage or praise your child?
      If yes, which features help you talk more often? How helpful were that features you use?
      (Features: logging reading minutes, messages, setting up goals, rewards, seeing how you are doing in comparison to other parents, Facebook interaction).
34. Did using the app change what you say or do to encourage or praise your child?
35. What would you tell a friend about the BB3 app?
    - ❖ Probe: Would you recommend it to a friend? Why or why not?
36. Is there anything else you would tell us that could improve the BB3 app?
37. Is there anything that you can think of that would make the app easier to use?
38. Are there any features that you would recommend adding to this app?
39. Is there anything that you would recommend removing from the app?

Reward/reminder questions.

40. Did you know that you could earn points and rewards for logging reading minutes and completing activities?
41. How difficult was it to earn points and rewards?
42. Did you earn any of the rewards? If yes, did you receive your rewards?
43. What rewards/prizes would you want to earn for logging reading minutes or completing activities? (Books, toys, puzzles, other items?)
44. Did you receive notifications on your phone when you had a new activity? If yes, were these notifications helpful reminders? What would be a good reminder to log reading minutes or complete activities? (Give examples like text messages, emails, other reminders?)

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