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Identification of neurodevelopmental disabilities in underserved children using telehealth (INvesT): Clinical trial study design

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ABSTRACT

Background: Children living in poverty are at high risk for delays in development of language and behavior and they experience a discrepancy in diagnosis and access to intervention services. This gap is partially caused by barriers in access as well as traits that are specific to each child and family. The Identification of Neurodevelopmental Disabilities in Underserved Children using Telehealth (INvesT) trial is a novel intervention approach that was specifically designed to address these barriers.
Aims: The INvesT trial has three primary aims: 1) to reduce the age of identification of neurodevelopmental disability for high-risk, low-income children. 2) To validate the INvesT protocol as a service delivery model that will decrease age of identifications of neurodevelopmental disability for high-risk, low-income children; and 3) to identify important child-specific factors, family-specific factors, and environmental factors that impact feasibility and success of the INvesT trial for high-risk, low-income children.
Methods: The INvesT trial is an open-label, double-blinded, placebo-controlled multi-level study that includes telehealth risk assessment, telehealth screening, traditional full assessment, and follow through to enrollment in early intervention. The trial is conducted in partnership with an urban community health clinic that largely serves a low-income patient population.
Conclusions: The results of the INvesT trial will provide evidence for the use of a telehealth service delivery model to improve access to care for neurodevelopmental disabilities for high-risk, low-income children.

1. Introduction

The incidence of neurodevelopmental disorders has increased by more than 20% since 2001 [1]. Compared to more economically advantaged peers, children living in or near poverty are at higher risk for neurodevelopmental disability and developmental lag [2]. Environmental risk factors, including lower socioeconomic status (SES), appear to have an accumulating impact with differences in development becoming more pronounced overtime [3]. In fact, environmental factors appear to contribute more significantly to developmental lag for young children than biological factors. Given that nearly half of the children in the US live at or near poverty, with 61% of these children experiencing multiple risk factors for developmental lag [4], programs that specifically target this population are important.

Research has consistently documented disparities in the diagnosis of neurodevelopmental disabilities based on family income level, ethnic background, and parental education level [1,5–8]. Additional factors associated with discrepancy in diagnosis include reduced parental reporting of concern, physical barriers to care, limited referral practices and access to specialty services, family's knowledge/comfort with developmental milestones, and family's ability to navigate health care [9]. Professional barriers exist as well, with increased burden on physicians stemming from limited time and resources [10].

It has been shown that early intervention positively impacts high-risk, low-income children and that the effects carry into adulthood [11–13]. Early intervention has also been shown to increase positive functional outcome for children with diagnosed neurodevelopmental disabilities [14]; however, a novel approach for the initial step of identification prior to accessing early intervention is needed, especially for groups with document disparity in access to care [9].

Telehealth (AKA: Telemedicine, telepractice) is a service delivery method that could improve health care delivery for this population [15]. Telehealth involves the provision of professional services using telecommunications technology (e.g., Internet, videoconferencing), operating with an assortment of approaches, tools, and service delivery

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schedules. Telehealth appears to be an ideal, and highly feasible service delivery framework that directly addresses known barriers to accessing care for high-risk, low-income children [16–18]; therefore, it warrants rigorous clinical trial investigation.

Given the increasing prevalence of neurodevelopmental disabilities in the general population, the disparity that exists in access to early intervention services especially in low-income groups, and positive trends in the literature that support the use of telehealth in the treatment of a variety of developmental conditions [19–25], the Identification of Neurodevelopmental disabilities in underserved children using Telehealth (INvesT) was created. The overall purpose of INvesT is to reduce the age of identification of neurodevelopmental disabilities for high-risk, low-income children using technology, provision of care within their regular medical appointment that is geographically close to home, and the use of non-physician clinicians as service providers. The INvesT model will address some of the most common barriers that appear related to disparate access to care for this population.

1.1. INvesT outcomes

The outcomes of the INvesT are as follows:

Primary outcome: To reduce the age of identification, and diagnosis, of neurodevelopmental disability for high-risk, low-income children.
Secondary outcome: To validate INvesT as a service delivery model that will decrease age of identifications of neurodevelopmental disability for high-risk, low-income children.
Tertiary outcome: To identify important child-specific factors, family-specific factors, and environmental factors that impact feasibility and success of INvesT as a service delivery model for the identification of neurodevelopmental disability in a high-risk, low-income population.

2. Methods

2.1. Feasibility

To establish the feasibility for the INvesT trial, our group conducted an initial project that focused on speech-language and hearing abilities [17]. Over a two-year period, 411 screenings were completed using standard screening measures. The majority of the screenings conducted were completed via telehealth (n = 358) with a small number (n = 10) completed on-site for comparison.

Results of the study indicated that, on average, telehealth screenings yielded a 14% failure rate on the hearing measures and a 33% failure rate on speech and language measures. These results were above national population data [1], but are consistent with the poverty and multiple risk factors data reported by the National Center for Children in Poverty [4]. Consistency between on-site screening and telehealth screenings was quite good, with reliability of 84% for the hearing measures and 100% for speech-language measures. Of the children who failed the screening protocol in either condition, 72% scheduled follow-up appointments for full assessment with community agencies. Additionally, family satisfaction surveys revealed that participants were highly satisfied with the use of telehealth procedures to conduct the screening and that the telehealth service delivery model was preferred over on-site screening or having to schedule a separate screening appointment at a secondary location.

From this feasibility project, it was determined that telehealth could be used to screen for developmental milestones in very young children (0–6 years of age), that families in underserved communities were very satisfied with telehealth as a service delivery method, and that families felt the ease of service access via telehealth was a contributing factor to participation.

2.2. INvesT study design

INvesT is an open-label, double-blinded, placebo-controlled multi-level study. The trial protocol is as follows (see Fig. 1):

Level I: Web-based telehealth Risk Assessment.
Level II: Screening [on-site condition and telehealth condition] — Randomization.
Level III: Traditional full assessment.
Level IV: Follow through to enrollment to early intervention.

Both the clinician conducting the standard-of-care full assessment [conducted after the screening] and the Co-PI's responsible for the study outcomes assessment are blind to group assignment during the screening phase. The clinicians conducting the screenings cannot be blinded to condition given their role in conducting the intervention. To limit threats to screening validity, screening clinicians will provide screenings in only one modality (telehealth or on-site).

2.3. Subject recruitment and eligibility

2.3.1. Community health clinic characteristics

A large urban health clinic is the partnering community health organization for this study. The clinic provides comprehensive family primary and specialty care that are community-based and serve primarily urban, minority, low-socioeconomic children and families. The neighborhood where the clinic is located has a median household income of $13,967/year, with 40.8% of its residents living below the federal poverty level [26]. Residents are 97% African–American, 2% Hispanic, and less than 1% Caucasian, Asian, or other. The average education level for individuals is a high school degree or equivalent (40%) or non-completion of formal education (30%).

2.3.2. Participant characteristics

2.3.2.1. Inclusion criteria. Pediatric patients between 12 and 84 months of age who receive care at the community clinic are eligible to participate. Standard American English, or any dialect associated with Standard American English including Black English, must be the primary language spoken in the home.

2.3.2.2. Exclusion criteria. Children ages 12–84 months who are already diagnosed with a developmental disability and/or are actively participating in or being monitored by early intervention services would not be able to participate after Level I risk assessment, since the purpose of the project is to increase and improve identification.

The protocol has been approved by the IRB at the Case Western Reserve University.

2.4. Randomization & blinding

Regardless of risk assessment results, all participants move to the screening condition with randomization to either the telehealth or on-site screening condition occurring at the point of screening (Level II). The biostatistician involved in the project creates the randomization sequence and the randomization scheme is implemented using opaque, serially numbered envelopes.

This is a double-blinded, placebo-controlled study. Both the clinician conducting the standard-of-care full assessment and the PI responsible for the study outcomes assessment are blind to screening group. The clinicians conducting the screenings cannot be blinded to condition. In order to limit threats to screening validity, the screening clinicians will provide screenings in only one modality — that is the same clinician will conduct all telehealth screenings and a second clinician will conduct the on-site screening.

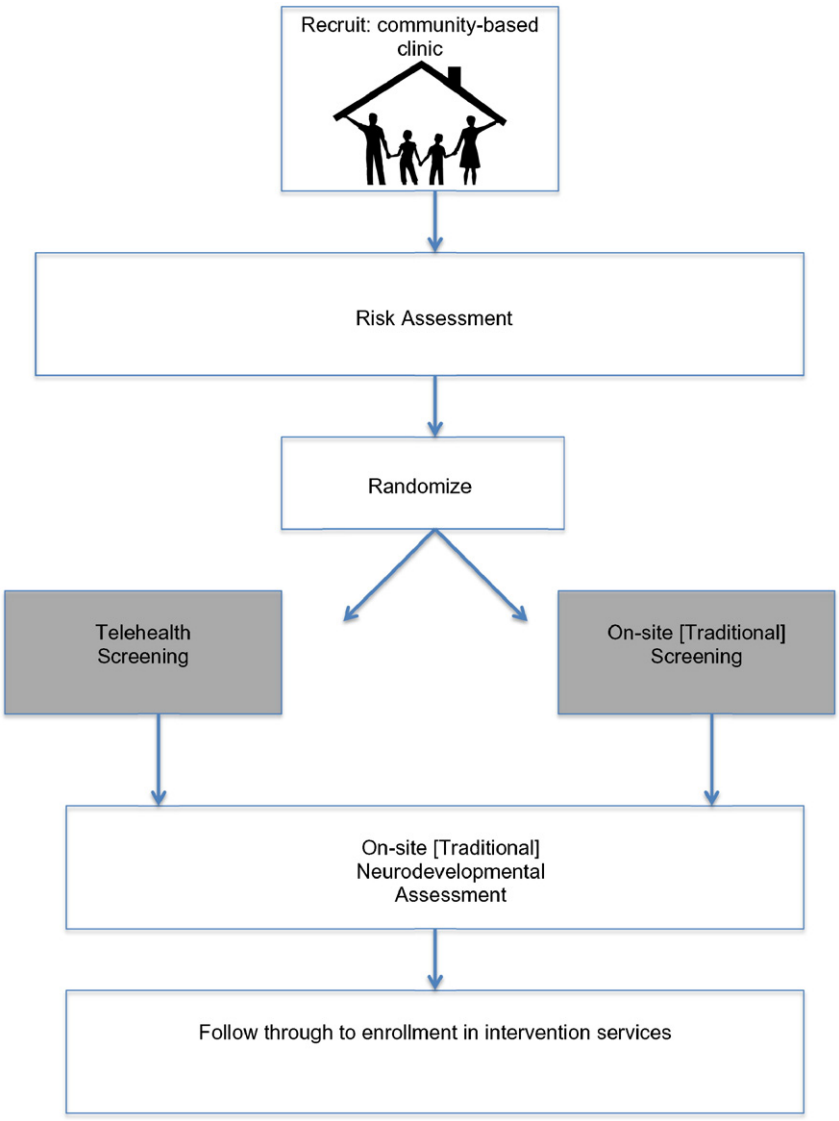

Fig. 1. Study design.

2.5. Fidelity assessment

Given the recommendations of the Treatment Fidelity Working Group of the National Institutes of Health Behavior Change [27–28], treatment fidelity is directly monitored in the areas of study design, training, delivery, and receipt of treatment. Study design is monitored in the following ways: verification of provider credentials, length of the screening session, consistent manual-based training of clinical and research staff, pre- and post-tests to verify staff knowledge of the protocol, role-play to verify skill in protocol administration, and maintenance testing of clinicians to assess skill-drift. Protocol delivery is monitored through interval videotaping which is reviewed for protocol adherence in regular intervals. Receipt of treatment is measured through the monitoring of non-specific effects including clinician behavior, non-verbal indicators, and the family's perceptions of creditworthiness, trustworthiness, and the perceived knowledge of the clinician.

2.6. Assessment process

2.6.1. Risk assessment (Level I)

The risk assessment protocol was created for use in the INvesT trial and is based on published developmental norms and neurodevelopmental disabilities screening tools [29]. It can be completed in 10 min and is written at a fifth/sixth grade reading level (Flesh–Kincaid Reading Level = 5.8). The risk assessment was developed to be compatible with multiple device platforms (e.g., touch-screen phones, tablets, and traditional laptop/desktop computers).

The risk assessment is completed by the child's parent/caregiver via a web-based interface and contains three main sections: 1) basic demographic information, including sociodemographic variables; 2) family history of developmental and/or mental health disorders; and 3) developmental milestone questions based on areas known to be important in the early identification of neurodevelopmental disabilities [30], including social communication/joint attention, symbolic play (a proxy for cognitive development), behavioral concerns, emotion/affect, language, and repetitive interests/behavior. Item presentation is specific to the chronological age of the child (12–24 months, 25–36 months, 37–48 months, 49–60 months, 61–72 months, and 73–82 months) with a binary response choice for each item. Low scores on the risk assessment indicate development within normal limits and higher scorer scores indicate developmental concern. Results of the risk assessment are calculated upon survey completion and the project Co-PI's are notified daily for the results. The Co-PI's then share the results with the family and the child's pediatrician.

Data for the risk assessment is collected via Research Electronic Data Capture (REDCap™) [31]. Study data were collected and managed using REDCap at the Case Medical Center, Case Western Reserve University. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trials for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

2.6.1.1. Risk/no risk detection. A child's risk assessment is categorized as "risk" under the following condition/s: 1) risk assessment yields a score of four or higher across all categories; 2) risk assessment yields a score of three or higher within a specific category; and/or 3) the family history section of the risk assessment indicated a first-degree relative has been diagnosed with a neurodevelopmental disability. The risk criteria are purposely designed to be liberal to maximize the likelihood of over-identification in the early risk stage of the project and avoid the danger of under-identification [32]. In addition, this oversampling strategy allows us to identify children who may not otherwise meet full diagnostic criteria, but would benefit from increased developmental monitoring. Given the historic trend for under-identification of neurodevelopmental disabilities in low-SES groups, this strategy appeared reasonable.

2.6.2. Screening (Level II)

Following completion of the risk assessment, all participants move to the screening condition (Level II) regardless of risk assessment results. This is the point of randomized to either the telehealth screening condition [experimental condition] or the on-site traditional screening condition [control condition]. The telehealth screening is conducted using synchronous video-conferencing between the community health clinic and the off-site study staff. The control on-site screening condition takes place in a pediatric exam room at the community health clinic. In both conditions, the screening protocol takes 30–40 min.

2.6.2.1. Screening environment. The telehealth screenings are conducted using a synchronous [real-time] telehealth approach (see Equipment below) between the screening research staff located off-site and the community health clinic site. The screening research staff is seated in front of a large computer monitor that is connected to a computer at the community health clinic. The participant, their family, and a paraprofessional facilitator are seated in a dedicated, quiet, private, and pediatric-friendly clinical room at the clinic site. The child and family are seated in front of a laptop computer.

2.6.2.2. Telehealth screening equipment. A laptop is used for telehealth screening at the community health clinic. The Infocus Mondopad™ is used at the research site. The Mondopad™ is a high performance Intel i5 PC running Windows 7 Pro contained within a 55-in. multi-touch display that includes a high definition 720p camera with 4 integrated microphones and a voice-optimized sound bar. Among it's many features, the native software provides the ability for the Mondopad to be added as a SIP endpoint on standard telepresence servers or services, and to collaborate utilizing its interactive whiteboard, the connection to TPX, and the laptop webcam at the onsite location.

2.6.2.3. Screening protocol. The measures used in the screening protocol were selected to reflect all areas of the risk assessment and important areas of assessment for neurodevelopmental disabilities. Table 1 (appendix) outlines the screening measures by age category.

2.6.2.3.1. Autism screening

2.6.2.3.1.1. Infant-Toddler Checklist for autism (ITC) [33]. The ITC is a component of the Communication and Symbolic Behavior Scales Developmental Profile (CBCSDP) and is meant to be used as a screening tool for the early identification of ASD. The ITC was developed for use with children ages 6–24 months, with optimal positive predictive value beginning at 9 months of age. In the INvesT trial, the ITC is used for participants 12–18 months of age. The ITC generates three composite scores: Social Composite, Speech Composite, and Symbolic Composite. As indicated by Wetherby et al. [25], children that were diagnosed with ASD after a positive screen on the ITC were most likely to perform in the bottom 10th percentile on the Social Composite; therefore the Social Composite cut-off score was selected for use for the designation of a "failed" performance.

Table 1
Telehealth screening measures by age category.

	12–18 months	18–24 months	24–36 months	3–4 years	4–5 years	5–6 years	6–7 years
ITC	X						
M-CHAT		X	X				
CARS-2			X	X	X	X	X
PLS-5	X	X	X	X	X	X	X
ABLE-II				X	X	X	X
Play	X	X	X	X	X	X	X
Parent interview	X	X	X	X	X	X	X

2.6.2.3.1.2. Modified Checklist for Autism in Toddlers (M-CHAT) [34]. The M-CHAT is a validated screening tool for ASD for use with toddlers between 16 and 30 months. For the INvesT trial, it will be used with children ages 19–30 months of age. The published pass/fail scores will be used in this protocol.

2.6.2.3.1.3. Childhood Autism Rating Scale-2 (CARS2) [35]. The CARS-2 is a 15-item clinical tool designed to identify children with ASD and differentiate them from children that are present with other developmental disabilities. The revisions included in the CARS-2 allow for identification for less severe forms of ASD. In the INvesT trial, the Standard version is used for participants between 31 and 72 months of age and the High Functioning Individuals rating is used for children between 73 and 84 months of age. The published cut-off scores will be used in this protocol.

2.6.2.3.2. Language screening

2.6.2.3.2.1. Pre-school Language Scale — 5 Screening Test (PLS-5) [36]. The PLS-5 is a clinical tool designed to screen children from birth to 7; 11 for speech and language disorders. It is a broad-based speech and language screener that considers multiple domains of impairment, including language, articulation, feeding, connected speech, social/interpersonal communication, fluency, and voice. Administration time is approximately 10 min. Its' precursor, the PLS-4 Screening Test, was used by this research group in the feasibility project [17]. The PLS-5 allows for dialectical variations in scoring which is critical for this study population. The published pass/fail scores will be used in this protocol.

2.6.2.3.3. Mental health screening

2.6.2.3.3.1. Attention, Behavior, Language, & Emotion screener (ABLE) [32]. The ABLE is a global screening measure for attention, behavior, language, and emotion for children living in a high-risk environment. The goal of the ABLE screener is not the assignment of a clinical diagnosis, but rather the *identification* of children who might benefit from intervention services designed to address early onset mental health symptoms that place the children at risk for a diagnostic disorder. The ABLE II will be used in the INvesT trial. This is a 40-item questionnaire that screens for oppositional behavior, aggression, language, and the dysregulation of attention and emotional behavior [37]. The published cut-off scores will be used in this protocol.

2.6.2.3.4. Performance-based measure

2.6.2.3.4.1. Affect in play task — play task [38]. A 5-min play screener is included in the screener. The play screening includes three components: pre-instructional, instructional, and play. The pre-instructional and instructional components of the task focus on the set up of the toys and the introduction of a play script to the participant. In the play component, the child is encouraged to briefly play independently with the toys without involvement of research staff or family members.

Play is scored in the areas of imagination, organization, elaboration and comfort, as well as frequency of symbolic and functional play [38]. Scores are also generated in the areas of cognitive (i.e. language, joint attention, organization, turn-taking), behavior (i.e., defiance, impulsivity, out of seat) and affect (i.e., enthusiasm, eye contact, imitation) as evidenced in play. A score of 4 or lower on any one of the three domains would indicate a "failed" play screen.

2.6.2.3.4.2. Caregiver interview. The caregiver interview is conducted in an open-ended format to gain additional information in the areas of 1) medical history; 2) any noticeable regression or lack of development, and 3) an inquiry about specific areas that may be concerning to the parents including social relatedness, behavioral disturbance, emotional regulation disturbances, or intellectual concerns. Any one or more item that is endorsed by the family during the interview as being an area of concern will be given a score of 1 and will be considered in conjunction with the comprehensive formal screening measures for the determination of pass or fail.

2.6.2.3.4.3. Pass/fail decision screening. A child's total screening (regardless of screening condition) is categorized as "fail" if any of the formal screening measures meet failure criteria (i.e., ITC/M-CHAT/CARS2, PLS-5 screener, Play task) or if the interview indicates 2 or more areas of concern and any of the formal screening measures (i.e., ITC/M-CHAT/CARS2, PLS-5 screener, Play task) *approach* "failed" performance (within 1 point). Children that meet the criteria for a "fail" on the telehealth screening are referred for full developmental assessment with an outside community agency that is convenient to the family and accepts the families insurance and/or that has specific federally-funded early intervention programs.

2.7. Full assessment

Community organizations complete the full developmental assessment. The clinicians conducting the full assessment are blinded to screening condition but are aware of the screening results that triggered the referral. The assessment clinician's are notified about the child's participation in the INvesT trial and that the results of the full assessment will be shared with the research team. Because full assessment is conducted by community organization, several factors (i.e., insurance, waiting list, time, location) will determine the location of the assessment.

2.7.1. Follow through to early intervention

Children receiving a diagnosis of neurodevelopmental disability after full assessment are monitored through enrollment into special education. Data is collected regarding the appearance of new concern, amount of developmental progression (marked progress, progress, limited progress, no progress, or regression), satisfaction with the clinical trial protocol, and barriers experienced in the full assessment process or with intervention service access. Monitoring occurs using the families' preferred modality of contact (i.e., phone, paper, email, text). Additionally, all participants are offered the opportunity to report the development of new concerns and satisfaction with the INvesT trial.

2.8. Data analysis plan

2.8.1. Primary outcome: to reduce the age of identification, and diagnosis, of neurodevelopmental disability for high-risk, low-income children

To address this outcome, two analyses are planned. First, the total number of participants at each stage of INvesT will be compared to the total number of participants identified as having potential developmental concerns (i.e., binary categories "risk/no risk", "failed screening/passed screening", "final diagnosis yes/final diagnosis no") using chi-square analysis with $p \leq .05$. Second, to identify which variables predict completion of INvesT, a logistic regression analysis will be conducted with full completion of INvesT (binary Yes/No) used as the dependent variable and the factors identified through EFA (tertiary outcome) as independent variables. $p \leq .05$ and a 95% confidence interval for Odds Ratio will be used.

2.8.2. Secondary outcome: to validate INvesT as a service delivery model that will decrease age of identifications of neurodevelopmental disability for high-risk, low-income children

To determine the validity of INvesT as a service delivery model, two analyses will be conducted. First, (and expressly related to the screening condition) estimates of sensitivity, specificity, and accuracy for each of the screening tests will be constructed and compared for the telehealth screening and separately for the on-site screening. Results will be considered comparable (equivalent) if the respective confidence intervals overlap between the two screening conditions.

Second, factors identified through exploratory factor analysis (EFA, tertiary outcome) will be entered into multiple linear regressions to determine child-specific factors, family-specific factors, and environmental factors that impact identification of neurodevelopmental disabilities using INvesT. $p \leq .05$ will be used to determine significance.

2.8.3. Tertiary outcome: to identify important child-specific factors, family-specific factors, and environmental factors that impact feasibility and success of INvesT as a service delivery model for the identification of neurodevelopmental disability in a high-risk, low-income population

Given the data that is generated for child-specific factors, family-specific factors, and environmental factors across all aspects of INvesT, an exploratory factor analysis (EFA) will be conducted. The maximum likelihood approach will be used for factor extraction and oblique rotation (direct oblimin) coupled with screen plots with multiple test runs will be used to identify meaningful factors. Additionally, factor scores obtained through EFA will be used as predictors for regression analysis (secondary outcome).

3. Discussion

Evidence suggests that working within the community is the best way to access medically-underserved communities [39]. The INvesT clinical trial was created around this central tenant by providing access to multi-level developmental monitoring and screening within the community practice setting using technology. The telehealth approach addresses many of the barriers that have been identified that contribute to the disparity in early access of care for neurodevelopmental disabilities and provides a resource efficient method to reduce the initial age of identification of neurodevelopmental disabilities and for high-risk, low income children.

Telehealth gives a single clinician, potentially a specialty non-physician provider, the ability to serve multiple community-based/family practice clinics simultaneously negating the requirement for an on-site physical presence. In this way, telehealth reduces the demand for qualified professionals in any given geographic region, the demands placed on physician's time within any given clinic day by transferring the load of developmental monitoring to an allied health professional, and the transportation dilemma faced by families with limited economic resources. Telehealth also specifically addresses time limit demands placed on families with low resources by providing the opportunity to express developmental concerns within an already scheduled medical appointment. Additionally, initiating the process of identification in an environment that is comfortable for the family decreases the demand for navigating the unfamiliar specialty health care system and the caregiver stress associated with the unfamiliar diagnostic process. Finally, the design of the INvesT trial allows for coordination of services by capitalizing on interactions with the researchers and both the families and the medical staff. This type of ongoing interactions supports relationships between provider and family that increase the likelihood of family support of the process [40]. Addressing the barriers to access critical developmental, medical and diagnostic services for all children and their families is essential for optimizing our most important economic

resource — our children [41]. If successful, the INvesT trial will demonstrate that the use of telehealth to conduct risk assessment and screening for neurodevelopmental disabilities during pediatric well-check visits allows providers to directly address barriers by helping children and families living in poverty or near poverty access early identification and intervention services.

Data analysis in the INvesT trial will not only allow for direct testing of the trial aims, but will also allow for exploration of variables that would be useful for prediction of risk including child specific variables (i.e., temperament, overall health status, family medical and behavioral history, sleep and eating patterns, developmental competencies across domains), family specific variables (i.e., socioeconomic status, primary caretaker, family structure) and environmental variables (i.e., neighborhood, school system, availability of early intervention services). Understanding the broader picture of neurodevelopmental disabilities in this population will allow for a more refined, scalable approach as the INvesT group moves toward broad implementation.

Upon completion of this phase of the INvesT trial, additional analysis will be completed to consider scalability, cost-effectiveness, and testing other populations including other types of medical clinics and primary points of contact with children and families.

3.1. Limitations

The INvesT trial is currently being conducted at a single clinical site with a homogenous population (race/ethnicity/socioeconomic status). Additionally the process of working the INvesT trial into the regular clinical workflow requires ongoing monitoring and adjustment. The trial does have the potential for attrition because of multiple steps in the study design as well as keeping a typically developing cohort engaged for direct comparison. Additionally, it is possible that there could be unusually low performance on screening measures because of the high-risk nature of the testing population as a whole. This requires ongoing monitoring and potentially adjustment on pass/fail criteria as data is analyzed.

4. Conclusion

The INvesT clinical trial is innovative in its application of telehealth, its multi-level approach to identification, and its' collaboration with an urban community health clinic to improve the identification of neurodevelopmental disabilities in underserved, low-income young children. The benefits of conducting a clinical trial is that the results could have immediate impact on practice options for screening in community-based clinics, as well as providing a more comprehensive picture of the characteristics of neurodevelopmental disabilities in young children living at or near poverty.

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