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The Pediatric Autism Research Cohort (PARC) Study: protocol for a patient-oriented prospective study examining trajectories of functioning in children with autism

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ABSTRACT

Introduction The developmentally variable nature of autism poses challenges in providing timely services tailored to a child's needs. Despite a recent focus on longitudinal research, priority-setting initiatives with stakeholders highlighted the importance of studying a child's day-to-day functioning and social determinants of health to inform clinical care. To address this, we are conducting a pragmatic multi-site, patient-oriented longitudinal investigation: the *Pediatric Autism Research Cohort* (*PARC) Study*. In young children (<7 years of age) newly diagnosed with autism, we will: (1) examine variability in trajectories of adaptive functioning from the point of diagnosis into transition to school; and (2) identify factors associated with trajectories of adaptive functioning.

Methods and analysis We aim to recruit 1300 children under 7 years of age with a recent (within 12 months) diagnosis of autism from seven sites: six in Canada; one in Israel. Participants will be followed prospectively from diagnosis to age 8 years, with assessments at 6-month intervals. Parents/caregivers will complete questionnaires administered via a customized online research portal. Following each assessment timepoint, families will receive a research summary report describing their child's progress on adaptive functioning and related domains. Analysis of the longitudinal data will map trajectories and examine child, family and service characteristics associated with chronogeneity (interindividual and intraindividual heterogeneity over time) and possible trajectory turning points around sensitive periods like the transition to school.

Ethics and dissemination Ethics approvals have been received by all sites. All parents/respondents will provide informed consent when enrolling in the study. Using an integrated knowledge translation approach, where stakeholders are directly engaged in the research process, the *PARC Study* will identify factors associated with trajectories of functioning in children with autism. Resulting evidence will be shared with government policy makers to inform provincial and national programs. Findings will be disseminated at conferences and published in peer-reviewed journals.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The current longitudinal study of children with autism has the potential to be one of the largest of its kind in the world; it will examine interindividual and intraindividual growth of clinically meaningful autism outcomes (eg, adaptive functioning) over time and possible trajectory turning points around sensitive periods like the transition to school.
⇒ Findings will help guide collaborative clinical and family decision-making processes and promote personalized early intervention that could be adapted based on a child's progression and changing context.
⇒ Using an integrated knowledge translation approach with ongoing stakeholder engagement, the *Pediatric Autism Research Cohort Study* will inform the design and implementation of provincial autism programs and Canada's National Autism Strategy.
⇒ Families who are not proficient in English (Canada) or Hebrew, Arabic or English (Israel) are excluded from the study, and families without access to adequate technology or the internet will also be excluded.
⇒ Information is collected via caregiver-reported measures and is susceptible to response bias.

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INTRODUCTION

Autism spectrum disorder (ASD), hereafter referred to as 'autism', is a neurodevelopmental condition characterized by impairments in behaviour and social communication. The prevalence of autism in Canadian children is estimated to be 1 in 50.[1] Autism is associated with high costs for children, families and society,[2] including costs related to the needs for medical and intervention services, education and production loss for individuals with autism and their families/caregivers.[3] The day-to-day impacts of autism cut across child and family functioning and overall quality of life.[4] Autism is often diagnosed in early childhood[5] and, in most cases, persists throughout the lifespan.[6] The diverse presentation of autism, *between* children as well as *within* children over time, and further across the lifespan, makes it difficult for clinicians to deliver timely and targeted supports and services to individuals with autism and their families. To this end, assessing functional and other health-related outcomes over multiple timepoints provides an unparalleled opportunity to determine variability in symptoms and functioning over time, and to find if certain points in development present unique opportunities or challenges for different children.[7 8] Such evidence on 'what to expect' as children with autism develop can help clinicians and families coordinate their efforts on care planning.[7 9]

Reflecting the importance of heterogeneous presentations of autism over time, the concept of *chronogeneity*[8] has gained significant traction in the autism literature.[10–13] This concept refers to the varying behavioural manifestations over time at group (average trajectory) and intraindividual (child trajectory) levels. It recognises possible deviations from group-level averaged trajectory profiles at key turning points in development and treatment and implies the importance of examining the child and contextual factors that may be associated with these deviations.[8–14] The current body of research has prompted a major shift in the conceptual and methodological approaches to studying autism.[8] Instead of a set of categorical symptoms/deficits that present early and remain relatively static over time, autism might be better understood as a dynamic neurodevelopmental condition, structured on inter-related dimensional constructs (not just symptoms but also functional skills and family/contextual factors) that could vary within the same child but also from one child to another over time.[14 15] This is in line with modern concepts promoted by the World Health Organization with the International Classification of Functioning, Disability and Health, and is often referred to as the 'actual lived experience of health' or 'lived health'.[16]

In a recent scoping review of trajectory research in children with an autism diagnosis, adaptive behaviour functioning and 3 (social functioning, communication and daily living skills) of its 4 subdomains were identified as 4 of the 10 most commonly followed outcome domains.[17] Parent stakeholders and individuals with autism involved in the review highlighted the relevance of adaptive functioning subdomains from their perspectives. Inconsistency among the ages studied and timepoints followed across studies, however, made it challenging to synthesise the evidence. Additionally, numerous other studies included in the scoping review followed symptoms of autism and other outcome domains from a deficit perspective — that is, what a child *cannot* do. This contrasts with adaptive functioning skills, which implies a strengths-based perspective — that is, what a child *can* do in their daily environment.[18 19] Finally, a recommendation from the review was to further consider longitudinal studies that assess outcome domains, such as the adaptive functioning subdomains noted above, that are meaningful to caregivers and families of children with autism.

While there have been recent studies exploring trajectories of adaptive functioning and its subdomains, it remains unknown how contextual factors, such as socioeconomic and service variables, shape developmental trajectories.[14 20 21] Notably, there is currently a lack of evidence on the *time-varying* (ie, dynamic) impacts of child and family factors on child's developmental trajectories, as these factors are conventionally considered static (ie, not changing from baseline).[22] These observed variations and gaps in understanding and addressing child, family and service-related factors, highlight the urgent need for a new generation of longitudinal research to better capture the unique and changing needs of children with autism and their families. To better address these issues, we developed the *Pediatric Autism Research Cohort (PARC) Study*.

The *PARC Study* research team is comprised of numerous academic researchers, clinicians and members with lived experience. Often there is no systematic mechanism that exists to link autism research to clinical practice, resulting in a research-to-practice gap.[23] The *PARC Study* was developed as a pragmatic study to test the integration of a standard research protocol embedded into clinical practice. Protocol development was driven by stakeholder input, with over 150 stakeholders (self-advocates with autism, families, clinicians, researchers, provincial and federal policy makers) invited to a symposium held by our research team. Participants identified major gaps in early intervention services and made three key recommendations for future research: (1) shift the system's emphasis from diagnostic symptoms to adaptive functioning skills; (2) work towards a balanced approach that examines the individual needs of each child within the context of an intervention program monitored in a standardized way across patients; and (3) expand the focus beyond the individual child to include the family in research and clinical care processes. This stakeholder-driven priority-setting activity was formative in the design of the *PARC Study*.

The first phase of this project involved a feasibility study. Although distinctions between feasibility and pilot studies can be vague,[24 25] this phase was considered as the important preliminary work before the main study.[26] The

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primary goal of the feasibility study was to test the protocol both in terms of ability to recruit participants and collect data from families. The secondary goal was to collaborate with a local autism clinic at McMaster Children's Hospital to embed research into operational procedures, develop efficient processes and share data via a 'feedback loop' to inform clinical practice. The feasibility study took place at McMaster Children's Hospital in Hamilton, ON, Canada, from April 2018 to January 2022 and had a 91% recruitment rate (n=99 participants enrolled from 109 participants contacted directly). We considered this a *pragmatic* study, defined as focusing on actual real-world situations,[27] including the variability in age of autism diagnosis in children,[28] and the observations and implications in routine clinical practice.[29] The lessons learnt from the feasibility study informed this protocol for a large-scale multi-site iteration of the study, described herein as the *PARC Study*.

Study aims and objectives

Given the intent of the *PARC Study* to be pragmatic, overarching aims include ensuring the feasibility of the study and that results are integrated into clinical practice. The key objective of the *PARC Study* is to understand and document the early trajectories of adaptive functioning (based on three subdomains: communication, socialization and daily living skills) in children with autism. These trajectories might be characterized by no change, steady improvement, steady decline or discontinuity in the rate of change marked by turning point(s) across developmental stages (eg, initiation of intervention/service, transition to school). Individual variability in trajectories of adaptive functioning will be examined and tested for associations with risk and protective factors that are time-invariant (eg, demographic characteristics) and time-varying (eg, clinical or diagnostic characteristics, service-related factors).

METHODS AND ANALYSIS

Study design

The *PARC Study* is a multi-site longitudinal cohort study of preschool-aged and early school-aged children with autism. Data are systematically being collected over multiple timepoints (depending on age at enrolment; must be <7 years of age), 6 months apart, until completion of the study when the child turns 8 years of age. Onboarding of sites occurred in a staggered manner, with some sites beginning recruitment in 2021 and other sites later on, into 2024. We expect to complete recruitment at all sites by the end of 2025; due to the variable age at enrolment, data collection for subsequent assessment points will continue until all participants reach 8 years of age. Information is provided by caregivers of children with a recent diagnosis of autism. Via a series of repeated online questionnaires, caregivers will provide information (via self-report) on their family (demographics and family context and experiences) and their child (symptom frequency and impacts, functioning and abilities, participation and services received).

Participants: selection and recruitment

Participants will be recruited from two countries: Canada and Israel. In Canada, participants will be recruited from six sites across three Canadian provinces (Hamilton, Ottawa, Kingston, Sudbury (Ontario), Edmonton (Alberta) and Winnipeg (Manitoba)), in conjunction with local autism clinics/service providers. In Israel, participants will be recruited through a diagnostic service at Hebrew University. Inclusion criteria were an age under 7 years and having received a formal clinical diagnosis of autism by a licensed health professional within the prior 12 months. Those without working proficiency in the language of the questionnaires would have difficulty completing project measures, and thus a lack of English proficiency is an exclusion criterion for Canadian sites. In Israel, questionnaires and data collection materials will be available in Hebrew, English and Arabic; thus lack of proficiency in any of these languages is an exclusion criterion at the Israel site. Finally, as there are technological requirements (including access to internet) to complete the study materials and questionnaires, participants without access to adequate technology or the internet will be excluded from the study.

Each site has a collaborative relationship with a local diagnostic clinic. While our pragmatic approach allows for unique recruitment methods based on local contexts, most sites use a 'Consent to Contact' process, where families receiving clinical services are asked if they would be interested in learning more about the research study from a staff person in their circle of clinical care and at a specific point in their diagnostic journey. Contact information of interested families is passed to the local research study coordinator, who will recruit participants, engage them in an informed consent process, and enrol them in the study.

Data collection procedures

The study team has programmed the materials and questionnaires into an electronic research platform — Lumedi.[30] This online platform — and a custom-made participant-facing web portal called the Autism Electronic Research Platform (AERP) — allows for direct and real-time data collection from participants at each site, reducing time delays in receiving individual data via mailed pen-and-paper format, as well as eliminating the need for manual data entry and thus reducing the potential for errors. The system also sends out automatic reminders to participants, prompting them to complete questionnaires within the completion window (automatically enforced, wherein after 3 months a questionnaire will no longer be accessible).

Patient-reported outcome measures (PROMs)[31] will be deployed as parent self-completed questionnaires about their child and family, at 6-month intervals. On enrolment, the first questionnaire package is emailed to the

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participant from the AERP. They have a 3-month window to complete the questionnaires, with automatic reminder emails sent out at 1, 2 and 2½ months. New questionnaire packages are sent out every subsequent 6 months after the enrolment date, until the child turns 8 years old (study exit point). As such, the number of timepoints will vary depending on the child's age at enrolment. For example, a child who enrols at 2 years old will have an opportunity to complete 13 timepoints (until age 8), while a child who enrols at 7 years old will have an opportunity to complete three timepoints (see online supplemental material 1). For each completed questionnaire package, respondents receive a CAD$20 thank-you gift card of their choice as a token of appreciation for their time.

Measures

Given the pragmatic nature of the *PARC Study*, we accept a formal clinical diagnosis of autism from participating sites. Although this approach does not allow for standardization of diagnostic measures at study entry, all sites are run by trained, licensed diagnosticians who use clinical best practices for assigning an autism diagnosis using the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) criteria.[32] The Vineland Adaptive Behavior Scale, third edition (VABS-3) is a validated tool with strong psychometric properties that was selected for administration to assess adaptive functioning as the primary trajectory indicator.[33] Participants will complete the self-administered parent/caregiver domain level version of the VABS-3 approximately every 6 months over the study period. A battery of theoretically driven correlates of adaptive functioning trajectories were selected following a review of the literature,[20 34–36] consultations between the research and clinical teams, input from a family advisory group and findings from our team's *Pathways in ASD* study,[21 37–40] including: core autism symptoms and their functional impacts (Autism Impact Measure (AIM)),[41 42] social communication capacity (Autism Classification System of Functioning: Social Communication (ACSF:SC)),[43 44] daily activity participation (Young Children's Participation and Environment Measure (YC-PEM) or Participation and Environment Measure—Children and Youth (PEM-CY)),[45 46] behavioural and sensory needs (Behavioral Inflexibility Scale (BIS),[47] Sensory Experiences Questionnaire-short form (SEQ)),[48] socioeconomic status (Sociodemographic Questionnaire), service characteristics (Autism Services Questionnaire), diagnosis path (Canadian Health Survey on Children and Youth[49] questions pertaining to pathways to diagnosis) and family experience (Autism Family Experience Questionnaire (AFEQ)).[50] Since this is a pragmatic study, consideration was given to ensure the completion time of questionnaires was kept brief, to minimise participant burden. An overview of the instruments and the timepoints at which they are collected is provided in table 1.

Feedback research summary reports to families

After each completed data collection timepoint, participants will electronically receive a synopsis of their responses in the form of a research summary report. This report outlines their responses on a variety of measures, including the AIM, ACSF:SC, VABS-3, YC-PEM/PEM-CY, BIS, AFEQ and SEQ, accumulated across all completed timepoints, allowing a family to see (in text, tables, and figures) the documented changes in their child's and family's functioning over time. This research summary report was developed in collaboration with our clinical administrators, supervisors and front-line clinicians, as well as family representatives/partners, to ensure information is shared in a standardized format that does not require clinical oversight and is accessible to a lay audience who do not require any specialized knowledge nor clinical expertise for interpretation. Participants will be encouraged to share the report with their clinicians, service providers or school support teams as a resource to help guide discussions on the focus of their child's interventions; families themselves have told us that such a research summary report makes participation in research more beneficial. This return of research results to participants is not only increasingly seen as an ethical and moral obligation of researchers[51–53] but is also endorsed by autism research participants themselves.[54]

The research summary reports are uploaded to families via the AERP, facilitating enhanced communication between families, researchers and clinicians with an opportunity to evaluate how the report could impact *how* clinicians and service providers support families, affect service planning and empower family decision-making. Understanding a child's strengths and limitations via research summary reports could better focus and adapt further interventions to what is relevant to the child and their family. This innovative research summary report and link to clinical care is not traditionally provided in clinical encounters and offers participating families an evidence-based way to track their children's progress and development and increase their own awareness and knowledge about autism care and management.[55] Repeated research summary reports serve as a promising monitoring strategy to close the 'feedback loop' by facilitating communication between families and clinicians. Moreover, they enable synthesis and integration of knowledge into the service system and into clinical practice — an important component of patient-oriented research and evidence-based care. This iterative feedback process supports families in navigating the complexities of autism and can help empower families who are often overwhelmed by the challenges of fragmented service systems,[56] during the critical early years of diagnosis and service access.

An important future direction will be measuring the clinical utility of research summary reports and study participation and the direct impact on families. This work will be undertaken by postdoctoral trainees, who through direct engagement with children with autism and their families and clinicians, will develop an end-of-study survey tool to evaluate the usefulness of the research summary report generated for parents in the management of autism. This work is being planned in partnership with

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Table 1 Measures used in the Pediatric Autism Research Cohort (PARC) Study

Instrument	Content captured	Domains	Measured timepoints	Reliability/validity
Pathways to Diagnosis Questionnaire (PDQ)[49]	Information on initial concerns and process of child's autism diagnosis	N/A	Enrolment	N/A
Sociodemographic Questionnaire (entry and follow-up versions)	Information on family sociodemographic profiles —including household composition, income, education	N/A	T1 (entry version), T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13 (follow-up version)	N/A
Autism Services Questionnaire (entry and follow-up versions)	Number and type of interventions (programs, services and activities) in which a child is involved; measures the number of hours an intervention is used, length of time involved, total out-of-pocket costs and sources of funding (private or public)	N/A	T1 (entry version), T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13 (follow-up version)	N/A
Autism Impact Measure (AIM)[41 42]	Frequency of core autism symptoms and their impact on a child's everyday life	Repetitive behaviour Atypical behaviour Communication Social reciprocity Peer interactions	T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13	440 2–17 year-olds with autism[42]: ► Internal consistency (domains): α=0.72–0.90 (impact) and 0.66–0.79 (frequency) ► Test–retest reliability: r=0.53–0.85 ► Cross-informant reliability: r=0.46–0.73 ► Concurrent validity with VABS-II: $\|r\|$=0.17–0.46; with Social Communication Questionnaire (SCQ): r=0.28–0.50 4415 3–17 year-olds with autism[41]: ► Internal consistency (all items): α=0.95–0.96 ► Concurrent validity with SCQ: r=0.15–0.60; with Repetitive Behaviours Scale—Revised (RBS-R): r=0.23–0.74
Autism Classification System of Functioning: Social Communication (ACSF: SC)[60]	Descriptive system that classifies levels of social functioning and communication among children with autism. Ratings based on optimal contextual conditions (capacity) and average performance on a daily basis (typical performance)	Communication	T1, T3, T5, T7, T9, T11, T13	Parent ratings[60]: ► Intrarater agreement: κ_w=0.61–0.69 ► Inter-rater agreement with professionals: κ_w=0.33–0.53

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Table 1 Continued

Instrument	Content captured	Domains	Measured timepoints	Reliability/validity
Autism Family Experience Questionnaire (AFEQ)[50]	Impact of interventions and resource use on family experience, quality of life and prioritized outcomes	Experience of being a parent Family life Child development Child symptoms	T1, T3, T5, T7, T9, T11, T13	Scale reliability[50]: ► Parent: α=0.85 ► Family: α=0.83 ► Child development: α=0.81 ► Child symptoms: α=0.79 ► AFEQ total: α=0.92
Young Children's Participation and Environment Measure (YC-PEM);[45] Participation and Environment Measure – Children and Youth (PEM-CY)[61]	Child's participation across three settings: home, school, and community, and perceived environmental effects on participation	Participation frequency Level of involvement Parent satisfaction with participation Environmental supports/barriers	T2, T4, T6, T8, T10, T12 (YC-PEM for <5 years of age, PEM-CY for ≥5 years of age)	YC-PEM[46]: Internal consistency: ► Frequency: α=0.58–0.83 ► Involvement: α=0.76–0.97 ► Change desired: α=0.65–0.86 ► Environmental support: α=0.85–0.96 Test–retest reliability: ► Frequency: ICC=0.16–0.71 ► Involvement: ICC=0.71–0.93 ► Environmental support: ICC=0.72–0.94 Concurrent validity with Pediatric Evaluation of Disability Inventory Computer Adaptive Test (PEDI-CAT): *r*=0.01–0.40 PEM-CY[61]: Internal consistency: ► Frequency: α=0.59–0.70 ► Involvement: α=0.72–0.83 ► Environmental support: α=0.67–0.91 Test–retest reliability: ► Frequency: ICC=0.58–0.84 ► Involvement: 0.69–0.76 ► Change desired: ICC=0.76–0.89 ► Environmental support: ICC=0.85–0.95
Vineland Adaptive Behavior Scale, third ed. (VABS-3: parent/caregiver domain-level form)[33]	Daily functional skills and adaptive behaviours	Communication Daily Living Skills Socialization Motor Skills Maladaptive Behaviour	T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, T13	Internal consistency: α=0.86–0.97 Test–retest reliability: *r*=0.62–0.92 Concurrent validity: ► With Bayley (Adaptive Behaviour domain): *r*=0.67–0.81 ► With Adaptive Behavior Assessment System Third Edition (ABAS-3): *r*=0.43–0.73[62]
Behavioral Inflexibility Scale (BIS)[47]	Rigid patterns of behaviour that contrast with the need to be adaptable to changing environmental demands	Behaviour inflexibility	T1, T3, T5, T7, T9, T11, T13	Internal consistency[47]: α=0.97 Test–retest reliability: ICC=0.92

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Table 1 Continued

Instrument	Content captured	Domains	Measured timepoints	Reliability/validity
Sensory Experiences Questionnaire Version 2.1, Short Form (SEQ v2.1)[48]	Sensory response patterns across social and non-social contexts	Sensory hyporesponsiveness Sensory hyper-responsiveness Sensory interests, repetitions, seeking behaviours	T1, T3, T5, T7, T9, T11, T13	Internal consistency[63]: α=0.80 Test–retest reliability: ICC=0.92

ICC, intraclass correlation coefficient.

stakeholder teams at Autism Alliance of Canada and Children's Healthcare Canada.

Questionnaire data

The format of data collection in this study (through online PROMs completed by parents) will allow for both the recruitment of a relatively large sample of children and families, as well as a convenient and safe method for participating in research. While all study information may be collected without meeting with the child/family or conducting direct assessments, we ask participants to sign a secondary consent/release form that allows for the sharing of data by their local clinical site. The planned addition of information collected through clinical practices will enrich the dataset and could provide an opportunity to collect data about goals and strategies, further supporting an iterative feedback loop where research summary reports might inform changes in clinical practice.

Data analysis

The longitudinal data collected in this study provide insights into the variable developmental trajectories of children with autism during the early years. The anticipated large sample size will allow for: (1) examining trajectories of adaptive functioning skills (communication, socialization and daily living skills); (2) examining the extent to which time-invariant covariates, including baseline diagnostic (symptom severity and age at diagnosis), socioeconomic (family income and education) and service (wait time to intervention) characteristics are associated with trajectory group membership; and examining the extent to which time-varying covariates, including symptom severity and intervention dosage over time, are associated with trajectory group membership; and (3) examining the associations between trajectories of adaptive functioning and other outcomes (social communication capacity, daily activity participation, behavioural challenges and family experience).

The analyses for all objectives will be performed using two-level growth models within a multilevel modelling (MLM) framework which is flexible to accommodate time-unstructured data when time is denoted as chronological age for long-term panel data collection.[57] The two-level growth model within MLM will enable us to examine variability within participants (level 1) and variability between participants (level 2) across assessment points. Multilevel growth mixture models will be further applied to identify unobserved trajectory subgroups. To examine the effects of the covariates of interest on trajectories, time-invariant covariates will be added as main effect terms and interactions with age at assessment, while the time-varying covariates will be added with their effects on trajectories fixed or randomly varying over time.

We hypothesise that pediatric autism symptom severity, family income and wait time to intervention will predict trajectory patterns of adaptive functioning characterized by turning points around the transition to school. The identified trajectory subgroups of adaptive functioning are expected to differ in other outcome measures (eg, social communication capacity, daily activity participation, behavioural challenges and family experience) as a support of their external validity. Assuming within-class homogeneity using *Pathways* data, the power to reject a null hypothesis in favour of a k class model over a k–1 class model was 1 across class solutions based on the bootstrap likelihood ratio tests. Under a two-class solution, the effect size for detecting a significant difference in the mean slope estimates between two subgroups was considered medium to large (Cohen's d=0.75). Using data from the *Pathways* study to calculate the intraclass correlation coefficient (ICC) of trajectories and the effective curve reliability, with such an effect size (0.75) and a sample size of 1300 from our participating prospective sites after 2 years' enrolment, accounting for a 20% attrition rate by study end would result in an effective sample size of 1040. We will use full information maximum likelihood estimation to account for missing data under the assumption that data are missing at random. Data will be analysed using STATA statistical software, V.18.0.

Patient and public involvement

Families as participants were first engaged with the *PARC Study* during the development and selection of study outcome measures and the research summary report prior to the feasibility phase. Input from families and the clinical team was sought at all stages, from selection of measures to implementation logistics; this collaborative process was essential, as the overarching consideration was to develop 'pragmatic' (ie, real life) study procedures that would minimise burden on both clinicians

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and families, thereby increasing uptake at all levels. This stakeholder-driven process included families who provided insights on the research assessment protocol, including the selection of adaptive functioning skills as the primary trajectory outcome. The development of a novel AERP was participant-informed and is intended to enhance communication among families, researchers and clinicians to facilitate decision-making processes leading to more personalized and coordinated intervention service plans. This innovative AERP is not provided via routine clinical care and offers participating families an evidence-based way to track their children's development and increase their own awareness and knowledge about autism care and management. Study findings will be shared and discussed with participants throughout the duration of the study via regular study update reports, newsletters, webinars and presentations at annual meetings organized in collaboration with community stakeholders such as Autism Alliance of Canada and other local autism organizations.

ETHICS AND DISSEMINATION

Ethics approval

All study protocols and materials have been approved by the local Research Ethics Board (REB) of each site involved in the project: McMaster University Integrated Ethics Board project #2902; Child & Community Resources ethics approval via McMaster HiREB project #2902; CHEO REB project #13587; Queen's University Health Sciences and Affiliated Teaching Hospitals REB project #6031260; University of Alberta ethics board project #Pro00138682; University of Manitoba Health REB project #HS25807; and Hebrew University of Jerusalem ethics board project #0207-19-COM. All parents/respondents will provide informed consent electronically when enrolling in the study.

No major risks to participants are anticipated during this study. It is possible that respondents may experience boredom or discomfort when answering some questions about their child; they are encouraged to save questionnaires in progress if breaks are needed. It is also possible that the research summary reports might cause distress if they reveal a child is not progressing as well as a caregiver may have expected. Participants are encouraged to contact their local site study team if questions or concerns arise.

Data are collected digitally, reducing the need for physical security measures. The security of the online data collection platform has also received ethics approval and conforms to required standards (compliant with: Personal Information Protection and Electronic Documents Act (PIPEDA), Personal Health Information Protection Act (PHIPA) and International Organization for Standardization (ISO); private key encryption; audit trails; study site segmentation). Identifying information will be restricted to a minimum number of the study staff; when data are downloaded from the online database, they are deidentified and allocated with a unique study code prior to sharing.

Dissemination

Study findings will be shared and discussed with participants and stakeholders throughout the duration of the study via regular study update reports, newsletters, webinars and presentations at annual meetings organized in collaboration with our community partners. To increase the study's clinical utility, we have embedded our research within existing practices in clinical centres. To ensure relevance to knowledge users, we have partnered with Autism Alliance of Canada, Children's Healthcare Canada, the Public Health Agency of Canada, Autism Ontario and Autism Speaks Canada. Resulting evidence will be directly communicated to government leaders working with study investigators on provincial and national programs (including Canada's National Autism Strategy). The study team will also leverage the national network and knowledge translation expertise of our partners and collaborators to disseminate study results to pediatric clinics. Findings will be disseminated through relevant research conferences and seminars, as well as published in peer-reviewed journals.

DISCUSSION

Adaptations and lessons learned

We consider the *PARC Study* to be a next generation *pragmatic* longitudinal study, focusing on decision-makers in real-world settings and, importantly, focusing on practical solutions rather than a strict prescription of a certain intervention to be tested experimentally.[29] The results of the feasibility study allowed us to implement various protocol changes to improve aspects of the study's administration, recruitment and participant experience, as well as its scientific robustness. These changes were made to reflect real-life settings and circumstances, taking a 'pragmatic approach to pragmatism'[58] — making adaptations when sensible, while striving not to compromise the study's scientific quality.

Some measures used during the feasibility phase were changed in the *PARC Study*. While the initial assessment battery included the Resource Use Questionnaire (RUQ),[59] a semi-structured interview to capture service usage and out-of-pocket costs in children with neurodevelopmental disabilities, its length meant it was burdensome both in terms of time required from families to complete (~1 hour) and for staff to schedule, resulting in low completion rates. The RUQ was replaced with a self-completed questionnaire (the Autism Services Questionnaire). Likewise, the original assessment battery in the feasibility phase did not include the AIM, VABS-3, BIS or SEQ. Our clinical colleagues felt that pediatric symptomology or functioning was not adequately captured in the feasibility study, and so these measures were added to the protocol as they allow for the relatively brief self-reporting

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of key indicators; whereas sensory issues were brought up by family advisors as a key priority.

Most importantly, the point of recruitment changed between the feasibility study and the current *PARC Study*. Whereas recruitment originally took place at the time-of-service initiation, this process is heavily influenced by various policy changes impacting waitlists for interventions. This protocol moved recruitment closer to the point of diagnosis; not only are diagnostic services more stable, but this will also allow us to better understand those critical months immediately after diagnosis, including the time families spend on waitlists prior to intervention initiation.

Recruitment and response bias

The longitudinal and multilevel measurement aspects of this study will require a time commitment from participants, despite designing the assessment battery so as not to overburden respondents. Each assessment timepoint takes approximately 1–2 hours to complete (and is variable depending on skip patterns in some questionnaires — see table 1) and occurs every 6 months. The time commitment may influence recruitment, and over the duration of the study may reduce completion rates. To help address this, during recruitment it is explained that respondents can complete each questionnaire at their own pace and are encouraged to pause and save in progress if needed. The online database also sends out automatic reminders. Additionally, participants receive a CAD$20 thank-you gift card for their time.

The study does not currently have the capacity to translate materials into every requested language, although the online platform does have multilingual capabilities; this may result in bias when recruiting families. Likewise, the shift from pen-and-paper questionnaires to online completion may be more convenient for some but does result in barriers to participation for those without adequate internet access, which is noted as a study limitation. Demographic information collected via questionnaire will be analysed alongside data on family functioning, stress and challenging behaviours to identify factors associated with survey non-completion, which could inform protocol adjustments intended to address and mitigate these potential biases.

Response bias is also a concern in the *PARC Study* due to the reliance on parent/caregiver-reported measures. However, a strength of these PROMs is their robust psychometric properties in children with autism. They also provide valuable insight into caregivers' perspectives regarding their child's experiences in real-life situations, which might not be well captured by clinical observation measures.

Significance and outlook

The *PARC Study* represents a next generation pragmatic longitudinal study that integrates research and clinical practice to address stakeholder-driven priorities. Use of an innovative AERP facilitates communication among researchers, clinicians and families and closes the 'feedback loop' with ongoing research summary reports. The projected recruitment across all sites will result in a cohort of over 1300 children, making the *PARC Study* potentially one of the largest autism cohort studies in the world investigating early trajectories of children with autism. Not only does the large sample size provide additional power to explore our study objectives, but the locations represent diverse geographical and socioeconomic strata of the population (ie, increased generalizability) while also providing an opportunity to explore additional comparisons between differing health systems across Canada and internationally.

Building on these strengths in study design, we will investigate interindividual and intraindividual growth of clinically meaningful autism outcomes across more densely spaced time intervals with possible trajectory turning points around sensitive periods like the transition to school to better capture autism *chronogeneity*. Importantly, we will examine how diagnostic, socioeconomic and service factors influence the development of adaptive functioning skills over time using dynamic-oriented analytic approaches. As a multi-national (Canada and Israel) and multi-provincial (Canada) inception cohort, this study is uniquely positioned to derive valuable knowledge that will help guide clinical decision-making processes and promote personalized early intervention packages that can be adapted based on a child's progress and changing context, from the point of diagnosis and through transition to school.

The *PARC Study* represents a timely coordinated effort to generate the current, real-world evidence needed to advance care and directly inform the design and implementation of provincial autism programs and Canada's National Autism Strategy, while extending evidence globally.

Summary

As an inception cohort in which the association of socioeconomic and service-related factors on the natural course of autism will be studied systematically for the first time, the *PARC Study* is uniquely positioned as a pragmatic study to provide valuable knowledge currently lacking in the research literature on the developmental progressions of adaptive functioning. This will move us beyond the current 'one-size-fits-all' approach and inform the development of evidence-based programs and policies that consider the unique and changing needs of all children and families living on the autism spectrum. Using an integrated knowledge translation and exchange approach with ongoing stakeholder engagement, the *PARC Study* will serve as a prototype for meaningful and impactful research that addresses the research priorities identified by autism stakeholders, including families, clinicians and policy makers.

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Supplementary Table 1. Timepoint assessments based on age at enrollment

Child's age at enrollment into PARC Study	Age at timepoint assessment													Total # of timepoints
	TP 2.0	TP 2.5	TP 3.0	TP 3.5	TP 4.0	TP 4.5	TP 5.0	TP 5.5	TP 6.0	TP 6.5	TP 7.0	TP 7.5	TP 8.0	
2.0 years	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**13**
2.5 years		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**12**
3.0 years			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**11**
3.5 years				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	**10**
4.0 years					✓	✓	✓	✓	✓	✓	✓	✓	✓	**9**
4.5 years						✓	✓	✓	✓	✓	✓	✓	✓	**8**
5.0 years							✓	✓	✓	✓	✓	✓	✓	**7**
5.5 years								✓	✓	✓	✓	✓	✓	**6**
6.0 years									✓	✓	✓	✓	✓	**5**
6.5 years										✓	✓	✓	✓	**4**
7.0 years											✓	✓	✓	**3**

PARC = Pediatric Autism Research Cohort; TP = timepoint