



BMJ Open Fit for School Study protocol: early child growth, health behaviours, nutrition, cardiometabolic risk and developmental determinants of a child's school readiness, a prospective cohort

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ABSTRACT

Introduction School readiness is a multidimensional construct that includes cognitive, behavioural and emotional aspects of a child's development. School readiness is strongly associated with a child's future school success and well-being. The Early Development Instrument (EDI) is a reliable and valid teacher-completed tool for assessing school readiness in children at kindergarten age. A substantial knowledge gap exists in understanding how early child growth, health behaviours, nutrition, cardiometabolic risk and development impact school readiness. The primary objective was to determine if growth patterns, measured by body mass index trajectories in healthy children aged 0–5 years, are associated with school readiness at ages 4–6 years (kindergarten age). Secondary objectives were to determine if other health trajectories, including health behaviours, nutrition, cardiometabolic risk and development, are associated with school readiness at ages 4–6 years. This paper presents the Fit for School Study protocol.

Methods and analysis This is an ongoing prospective cohort study. Parents of children enrolled in the The Applied Health Research Group for Kids (TARGet Kids!) practice-based research network are invited to participate in the Fit for School Study. Child growth, health behaviours, nutrition, cardiometabolic risk and development data are collected annually at health supervision visits and linked to EDI data collected by schools. The primary and secondary analyses will use a two-stage process: (1) latent class growth models will be used to first determine trajectory groups, and (2) generalised linear mixed models will be used to examine the relationship between exposures and EDI results.

Ethics and dissemination The research ethics boards at The Hospital for Sick Children, Unity Health Toronto and McMaster University approved this study, and research ethics approval was obtained from each school board with a student participating in the study. The findings will be

Strengths and limitations of this study

- The Fit for School Study will use children's health data from The Applied Health Research Group for Kids (TARGet Kids!), a well established practice-based research network, and will link these data to a valid teacher-completed tool for assessing school readiness.
- We will be able to determine whether child growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories in early childhood are associated with school readiness.
- Teacher participation in the Fit for School Study and completion of the Early Development Instrument (EDI) are voluntary, and unless it is a provincial implementation year, there is no time set aside for teachers to complete the EDI.

presented locally, nationally and internationally and will be published in peer-reviewed journals.

Trial registration number NCT01869530.

INTRODUCTION

Developmental trajectories have been evaluated in parallel research streams in the fields of child health and children's educational achievement and intersect in the area of developmental disabilities.¹ There is a gap in knowledge regarding the influence of early child growth, health behaviours, nutrition, cardiometabolic risk and development on children's readiness to learn at school. The early years help shape life trajectories and are an optimal time to monitor children's growth, health behaviours, nutrition, cardiometabolic risk and development.² Young children

visit their primary care provider on an average of 19 times in the first 5 years of life, which provides an opportunity for health professionals to intervene to promote school readiness.³ Understanding how early childhood growth, health behaviours, nutrition, cardiometabolic risk and development impact school readiness may help inform early interventions to improve school readiness, which may have lasting effects. The 'Fit for School, Fit for Life Study' (ie, Fit for School Study) will address these knowledge gaps.

Measurement of children's readiness to learn at school

The definition of school readiness has undergone significant alteration within the past four decades.^{4–6} Initially, school readiness was defined by a child's chronological age or by their reading and numeracy skills; however, it has evolved into a concept that is more socially constructed, emphasising the relationship between children and their environment, considered to be a reflection of children's developmental health.^{7–9} School readiness today comprises five distinct but related competencies at school entry to ensure children's success in their future years, namely, physical, social, behavioural, cognitive and communication competencies.¹⁰ A child's school readiness is multifaceted and can be measured using the Early Development Instrument (EDI), a population-level measure developed in 1999 by the Offord Centre for Child Studies (OCCS) at McMaster University (developed by the late Dr Dan Offord and Dr Magdalena Janus).⁴ The EDI covers five developmental domains: physical health and well-being, social competence, emotional maturity, language and cognitive development, and communication skills and general knowledge.⁴ It is a teacher-completed assessment of the skills and behaviours that contribute to a child's developmental health at school entry, providing a snapshot of their development status. It is not a diagnostic instrument and has not been used to inform clinical practice for individual children. EDI is valid for children aged 4–7 years, which in Canada includes the two kindergarten years. A number of studies have assessed the validity and reliability of the EDI to measure children's developmental health; results suggest good construct validity,^{11 12} cross-cultural validity,¹³ internal consistency reliability¹⁴ and moderate to high inter-rater reliability.⁴ The EDI's psychometric properties have been evaluated in Canada and in other countries, with scores being highly predictive of academic achievement^{15–17} and social relationships.¹⁵

The predictive validity of the EDI with academic achievement as the criterion measure has been tested in a number of settings. In British Columbia, Canada, 8152 children had EDI data in kindergarten and standardised academic achievement data in grade 4 (as measured by the Foundation Skills Assessment), and multilevel regression coefficients were 0.35 and 0.32 ($p < 0.001$) for numeracy and literacy, respectively.¹⁵ In Western Australia, 1823 children had EDI data in kindergarten and literacy and numeracy outcomes at ages 8, 10 and 12 years. The five

EDI domains and later literacy and numeracy skills (as measured by National Assessment Programme Literacy and Numeracy) were significantly correlated (correlations ranged from 0.11 for emotional maturity to 0.42 for language and cognitive skills). Vulnerability on the EDI domains was associated with a 1.7–2.5 and 1.8–2.3 increased odds of being in the bottom 20% of the distribution for reading skills and numeracy skills, respectively.¹⁶ In Quebec, Canada, 1134 children had EDI data in kindergarten and school achievement data in grade 1 (as measured by teacher ratings of children's reading, writing, mathematics and overall achievement); the five EDI domains explained 36% of the variance in first-grade school achievement.¹⁷

The predictive validity of the EDI with social relations as the criterion measure has been tested in British Columbia, Canada, among 7837 children who had EDI data at age 5 years and self-report data on how they think and feel about their experiences in and outside of school in grade 4 (as measured by validated Middle Years Development Instrument); multilevel regression coefficients were 0.16 and 0.10 ($p < 0.001$) for social competence and emotional maturity, respectively.¹⁵

In the province of Ontario, Canada, all publicly funded school districts currently receive support to implement the EDI from the Ministry of Education in 3-year cycles for the purpose of population-level monitoring of child development.¹⁸ This implementation occurs in the second half of the school year that children turn 5 years old (called senior kindergarten or year 2). Outside of the provincial implementation, the EDI is used for research purposes with data collected using an electronic portal through the OCCS at McMaster University. EDI data suggest that approximately 27% of Canadian children are not adequately prepared for their school experience, and if they fall behind, they tend to stay behind.^{19 20} Achieving school readiness is considered one of the most important developmental milestones that preschool children face. Identifying factors such as child growth trajectories, health behaviours, nutrition, cardiometabolic risk, and developmental factors and their association with later school readiness is important.

Early childhood growth, health behaviours, nutrition, cardiometabolic risk and developmental determinants

A few studies have investigated the relationship between neonatal variables (collected from perinatal records) and EDI outcomes.^{21–23} In 2016, Chittleborough *et al* ($n=13\,827$) found maternal age, smoking during pregnancy, parity, marital status, parents' occupation and child sex were predictive of being vulnerable on two or more EDI domains in the first year of school.²² They used the Australian Early Development Census (AEDC), a modified version of the Canadian EDI.²² In 2018, Hanly *et al* ($n=97\,989$) found children born ≤ 27 weeks' gestation were at an increased risk of being developmentally vulnerable according to the AEDC.²¹ In 2012, a Canadian study by Santos *et al* suggested that children born very preterm,

those who have low birth weight and/or those exposed to long intensive care unit/hospital stays are at an increased risk of not being ready for school according to the EDI at age 5 years.²³

A U-shaped relationship has been suggested between birth weight and cognitive development with both low and high birth weight being associated with lower cognitive development.^{24–26} A child's birth weight is only one static measure, at one point in time, whereas early child growth patterns use multiple measures of height and weight and are able to account for the dynamic variations of body mass index (BMI) and growth trends overtime. A study by Varella and Moss in 2015 measured early child growth patterns using weight-for-age z-scores at birth and at 4 and 12 months of age and found patterns of weight gain were associated with differences in IQ scores at 4 years; however, the sample was limited to children born small for gestational age.²⁷ Many of the strongest predictors of school readiness are non-modifiable; however, to inform early life interventions, it is important to identify potential modifiable behaviours, as these would provide the best return on investment.

There is limited knowledge of the impact of child growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories in early childhood on school readiness. Growth, health behaviours, nutrition, cardiometabolic risk and development are routinely assessed when children visit their primary care physician, and thus, these regularly scheduled health supervision visits provide an opportunity for health professionals to monitor as well as intervene to promote children's overall health and wellness.²⁸

Growth monitoring in early childhood is an integral part of primary healthcare for children and is recommended by the Canadian Task Force on Preventive Healthcare²⁹ and the United States Preventive Services Task Force.³⁰ Early childhood growth patterns, including BMI trajectories, help identify children who are growing outside of the range expected for their age and sex.³¹ In Canada, the prevalence of overweight and obesity among children aged 5–17 years is approximately 32%, with 15% and 6% of preschool children being classified as overweight or obese, respectively.^{32–34} Preschool children with obesity are at an increased risk of obesity in adulthood and of developing other comorbidities, including depression, cardiovascular disease, type 2 diabetes and increased mortality.^{35–42} Studies have provided some evidence demonstrating an association between obesity and cognitive deficits, independent of cardiovascular and socioeconomic factors and depression.^{43–44} The area of cognition that seems to be most impacted by obesity is executive function, as it tends to be associated with processes that are domain specific, such as motor function, attention and language.^{43–44} There is limited research on growth patterns or obesity and their effects on young children's school achievement or development prior to school entry.^{45–46} According to a study by Pearce *et al* in 2016 (n=7533), children with obesity had a

higher risk of being vulnerable on one or more domain on the AEDC.⁴⁷ More specifically a higher risk of being vulnerable in the physical health and well-being and the social competence domains compared with their normal weight peers.⁴⁷ However, this study was limited by lack of adjustment for individually based confounders, such as family income, nutrition or health behaviours.⁴⁷ The Fit for School Study measures and controls for many individual factors.

Physical activity, sedentary behaviour, sleep and nutrition have been associated with academic achievement. A systematic review examining the relationship between physical activity and cognitive development (n=13 studies) in children 0–4 years found that increased physical activity was associated with improved cognitive development.⁴⁸ Another systematic review examining the relationship between sedentary behaviour and cognitive development (n=96 studies) found unfavourable or no association between screen time and cognitive development, and favourable or no association between reading/storytelling and cognitive development, but due to heterogeneity, meta-analyses were not possible.⁴⁹ A recent cross-sectional study from our group showed mobile screen use was associated with increased risk of communication delays in infants aged 18 months.⁵⁰ Furthermore, according to a systematic review (n=26 studies), poor sleep quality and inadequate quantity (ie, chronic sleep deprivation) among children aged 1–17 years were related to worse behavioural and/or cognitive outcomes, but the strength of the association was low and there was a high degree of heterogeneity.⁵¹ Another study found sleep deprivation (≤ 7 hours per day) was associated with lower school readiness in preschool children.⁵² A systematic review including combinations of movement behaviours (ie, sleep, sedentary behaviour and physical activity) (n=10 studies) in children 0–4 years found children following movement behaviour guidelines (eg, high sleep, low sedentary behaviour and high physical activity) had improved outcomes, including cognitive function.⁵³

Sufficient dietary intake of macronutrients and micronutrients, as well as healthy eating behaviours, are important for young children in order to achieve optimal health.⁴¹ A review by Taras in 2005 among school-aged (5–18 years) children found school performance was positively influenced by school breakfast programmes.⁵⁴ In contrast, skipping breakfast was associated with temporary decreases in late morning measures of cognitive function among children aged 9–11 years.⁵⁵ Other nutritional problems such as iron deficiency anaemia and low 25-hydroxyvitamin D have been associated with poor developmental outcomes in children.^{56–58} Based on results from studies in adults, measures of cardiometabolic risk in children such as dyslipidaemia and insulin sensitivity may be associated with poor school readiness.^{59–61} While factors such as physical activity, sedentary behaviours, sleep, nutrition and early childhood development are thought to influence the ability of a child to thrive in a school environment, they have not yet been empirically tested in young children preparing to start school.

Fit for School Study: protocol overview

The Fit for School Study is a prospective cohort of children ages 0–5 years enrolled in The Applied Health Research Group for Kids (TARGet Kids!), the largest primary care practice-based research network in Canada (<http://www.targetkids.ca>). Early childhood data are linked with EDI data, which are collected prospectively from the OCCS.^{4 62} The overall rationale for the Fit for School Study is to better understand whether child growth, health behaviours, nutrition, cardiometabolic risk and developmental exposures in early childhood are prospectively associated with school readiness. If early exposures are identified, then interventions to promote components of school readiness can be developed and evaluated in the primary care setting. This protocol serves as the first step in this process as it explains the study rationale and objectives, outlines the study protocol, including methodological considerations, and presents a discussion of some implementation challenges.

Study objectives and hypotheses

The *primary objective* of the Fit for School Study is to determine if growth patterns, measured by BMI trajectories, in healthy children aged 0–5 years are associated with overall vulnerability in school readiness at ages 4–6 years, as measured by the EDI. We hypothesise that, independent of other health behaviours and developmental trajectories, unhealthy BMI trajectories will be associated with increased overall vulnerability in school readiness.

Secondary objectives include determining (1) if other health trajectories, including health behaviours (physical activity, sedentary behaviour and sleep duration), nutrition (nutritional risk as measured by NutriSTEP⁶³ and micronutrient deficiencies) and cardiometabolic risk (non-high-density lipoprotein (HDL) cholesterol, insulin and glucose levels) in healthy children aged 0–5 years, are associated with school readiness at ages 4–6 years; (2) if developmental trajectories including risk of developmental delay, child temperament and emotion regulation, as measured by developmental screening tools, in healthy children 0–5 years of age are associated with school readiness at ages 4–6 years; (3) if BMI trajectories are associated with various aspects of school readiness (ie, the five EDI domains separately); (4) the impact of BMI trajectories on EDI at 4–5 years (year 1 or junior kindergarten (JK)) compared with 5–6 years of age (year 2 or senior kindergarten (SK)); and (5) whether EDI results change over time from 4 to 6 years of age.

We hypothesise that children with unhealthy child growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories will be at increased risk of reduced school readiness compared with children with normal child growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories.

METHODS AND ANALYSIS

Participants and study design

Parents of healthy children aged 0–5 years attending scheduled health supervision visits at participating paediatric

or family medicine group practices are approached to participate and provide informed consent to enrol in the TARGet Kids! practice-based research network. Children with any acute or chronic conditions (with the exception of asthma, high functioning autism and obesity), severe developmental delay and families unable to communicate in English are excluded. Detailed information on the TARGet Kids! (www.targetkids.ca) cohort methodology has been previously described.⁶² Children are recruited for the Fit for School Study through TARGet Kids! from 2014 to 2020. If participants are enrolled in kindergarten (year 1 or 2) during the Fit for School Study period, parents are contacted to provide necessary information required to collect the EDI, including the name of their child's school board, school and teacher (see the Study procedures section for more details). In Ontario, Canada, kindergarten encompass 2 years of non-mandatory schooling before entry to grade 1. Children start year 1 (or JK) in September of the calendar the year they turn 4 years old and year 2 (or SK) the year they turn 5 years old. While non-mandatory, majority of children eligible attend kindergarten.

TARGet Kids! data are collected at multiple time points during the first 5 years of life. Routine height and weight data are also collected by the practices outside of TARGet Kids! scheduled visits. Baseline demographic characteristics are obtained based on questions used in the Canadian Community Health Survey.⁶² Child growth, health behaviours, nutrition, cardiometabolic risk and developmental measures, as well as physical measurements (height and weight) are collected at every visit, and blood pressure is collected at 3 years of age and older. The height and weight of the parent accompanying the child to their primary care visit are also measured. Non-fasting laboratory blood tests are collected at recruitment and requested at subsequent primary care visits to determine iron status (serum ferritin, C reactive protein and haemoglobin), vitamin D status (25-hydroxyvitamin D) and components of cardiometabolic risk (non-HDL cholesterol, total cholesterol, HDL cholesterol, glucose and insulin levels).

Measurements

Exposure variables

The primary exposure is BMI trajectories over the first 5 years of life using the WHO growth standards.⁶⁴ Trained research personnel embedded in each TARGet Kids! practice site follow a protocol to measure children's weight and height at each health supervision visit based on the WHO guidelines for measuring a child's growth.⁶⁵ Weight is measured using a baby scale for children less than 2 years of age and a precision digital scale (Seca model 703, Germany; measurement accuracy $\pm 0.025\%$) for children older than 2 years. Length is measured using a calibrated length board for children less than 2 years of age, and height is measured using a calibrated stadiometer (Health o Meter, model 500KL, USA) for children older than 2 years. BMI is calculated by dividing weight

in kilogram by length/height in metres squared. We will calculate zBMI using the igrowup (<61 months) packages for SAS V.9.4, which are based on the WHO growth standards.^{66–68} Using WHO age-standardised and sex-standardised zBMI provides a measure of BMI relative to the median BMI of children of the same age and sex in the WHO growth standards.⁶⁴

Secondary exposures are other health trajectories, including (1) health behaviours (physical activity, sedentary behaviour and sleep duration); (2) nutrition (nutritional risk and micronutrient deficiencies); and (3) cardiometabolic risk. Physical activity is measured by parent-reported average outdoor play in minutes per day. Sedentary behaviour is measured by parent-reported average daily screen time in minutes per day. Sleep duration is parent-reported in minutes per day. Nutritional risk is measured using a validated screening questionnaire called NutriSTEP, completed by a parent.⁶³ Micronutrient deficiencies (including iron and vitamin D status) are measured from blood/serum samples analysed at the Mount Sinai Services Laboratory. Cardiometabolic risk is measured using blood pressure, non-HDL cholesterol, insulin, glucose, waist circumference and the cardiometabolic cluster score (the sum of z-scores from systolic blood pressure, glucose, triglycerides, waist circumference and inverse HDL cholesterol). Additional details about the cardiometabolic cluster score used in TARGet Kids! are published elsewhere.^{69 70}

Additional secondary exposures include developmental measures (risk of developmental delay, child temperament, and emotion regulation) as measured by developmental screening tools, including the LookSee checklist by Nipissing District Developmental Screen,⁷¹ the Infant–Toddler Checklist⁷² and the Child Behaviour Questionnaire,⁷³ each completed by a parent.

Outcome variables

The EDI is a 103-item measure completed by teachers that assesses children's skills and behaviours in five developmental domains (as listed above). The EDI was developed for use in children ages 4 to 6 years, attending kindergarten at either ages 4 to 5 (Year one or JK) or ages 5 to 6 (year 2 or SK).⁴ It takes approximately 7–20 min per child to complete the EDI. Scores range from low (0) to high¹⁰ for each core question and the domain scores are calculated as the mean score of all valid answers (thus each domain also has scores ranging from 0 to 10) indicating a child's skill level or frequency of exhibiting a behaviour.⁴

The EDI results are reported as mean scores on each domain, as vulnerability on each of the domains and/or as an 'overall vulnerability'. Children are considered vulnerable in an EDI domain if their score falls below the 10th percentile of the scores' distribution on that domain (based on provincial standards established after the first population-level implementation).⁷⁴ The EDI does not require entry of the child's name or require any extra work on the child's part. It does not affect the child's class attendance, is not related to the teachers reporting

or evaluation of the child's progress at school and is not placed on the child's school record. Beyond the developmental items, the EDI also includes child demographic variables (date of birth, sex and first language); designation of 'special educational needs', if any; teacher report of additional special concerns on the child's functioning at school (physical, vision and hearing); child's special skills (eg, in dance or art); a diagnosis, if known; participation in an early intervention programme; preschool or child care; and teachers' judgement on whether they feel the child needs further assessment.

The primary outcome is the overall dichotomous vulnerability score (0=not vulnerable and 1=vulnerable) based on vulnerability on *one or more* of the five EDI domains. Secondary outcomes include the mean scores of the five separate EDI domains, which vary from 0 (low ability) to 10 (high ability).

Demographic and nutrition variables

Potential confounding variables include child age,⁷⁴ sex⁷⁴, child's birth weight⁷⁵, maternal⁷⁶, mageternal BMI⁷⁴, maternal education^{52 75}, maternal ethnicity⁷⁷, family income⁷⁴, family immigrant status⁷⁸, household composition (ie, single or dual parent households)⁷⁴, parental employment status⁷⁹, breastfeeding duration⁸⁰, smoking during pregnancy⁸¹, and child's exposure to smoke⁸² (see table 1). These variables were selected a priori and will be collected using parent-reported questionnaires.

Study procedures

Recruitment and retention

A letter is sent in the mail or via email to parents of eligible TARGet Kids! participants within a month of the start of the school year (kindergarten age). Parents are asked to participate by providing the name of their child's school board, school and teacher (see figure 1), which is then sent securely to the OCCS via a secure file transfer site. Also, in Ontario, the Ministry of Education mandates the collection of the EDI data in the second year of kindergarten every 3 years by teachers in the public school system. Thus, there are two streams of data collection in this study:

1. **Primary stream:** For year 1 (JK) and Year 2 (SK) students in the non-provincial EDI implementation years, teachers are contacted via e-mail with an invitation to participate. If teachers agree, they are sent instructions on how to access and complete the electronic EDI questionnaire. Reminder emails are sent to teachers by the OCCS between January and May of the school year.
2. **Alternative stream:** For year 2 (SK) students in the provincial EDI implementation years, the EDI scores are extracted from the provincial database at OCCS, matching the TARGet Kids! participants based on school board, school name, teacher name and student demographic data (date of birth, sex, postal code). This avoids the need to burden teachers twice.

Table 1 Measures for Fit for School Study**BMI**

Age-standardised and sex-standardised BMI z-scores are calculated using the WHO standards.¹⁹ The weight and length or height of the participants were measured by trained staff.¹⁹

Physical activity, screen time, sleep duration and nutritional risk

Outdoor free play	'Aside from time in daycare and preschool, on a typical weekday, how much time does your child spend outside in "unstructured free play"?'
Sedentary behaviour	'On a typical weekday/weekend day, how many minutes did your child spend awake in a room with (1) the television on: __ min; (2) videos or a DVD on: __ min; (3) playing the computer: __ min; and (4) playing a game: __ min (playing video game consoles, eg, PlayStation, Xbox or Nintendo Wii, and playing handheld devices, eg, iPhones, iPads, tablets or Nintendo DS video games)?' as well as 'On the last weekday/weekend day, how many minutes did your child spend awake in a room with (1) the television on: __ min; (2) videos or a DVD on: __ min; (3) playing the computer: __ min; and (4) playing a game: __ min (playing video game consoles, eg, PlayStation, Xbox or Nintendo Wii, and playing handheld devices, eg, iPhones, iPads, tablets or Nintendo DS video games)?'
Sleep duration	'How many hours does your child usually spend sleeping in a 24-hour period? __ hours'.
Nutritional risk	The NutriSTEP total score is determined based on the score of the 17-item nutrition screening questionnaire, which indicates the child's nutrition risk. A total score of 20 or less indicates a low risk, a total score of 21–25 indicates a moderate risk, and a total score of 26 or greater indicates a high risk. ⁴¹
Fruit and vegetable consumption	'My child usually eats fruit more than three times a day, three times a day, two times a day, once a day or not at all', as well as 'My child usually eats vegetables more than two times a day, two times a day, once a day or not at all'.
Body stores of iron	Iron deficiency is determined using ferritin (serum ferritin <14 µg/L). ⁶⁰
Body stores of vitamin D	Vitamin D status will be determined using 25-hydroxyvitamin D levels. Vitamin D, a fat soluble steroid, has the ability to be produced in the skin by being ingested from dietary sources or exposure to sunlight. ⁴⁸ Low levels of 25-hydroxyvitamin D during early life may result in impairments in neurocognitive development, which poses a concern. ⁴⁹ A longitudinal study including 474 children identified a significant increase in the odds of a mild language impairment at the age of 5 or 10 years with a 25-hydroxyvitamin D deficiency during the second trimester of pregnancy. ⁵⁰
Cardiometabolic risk (non-high-density lipoprotein cholesterol, insulin and leptin levels)	Low-density lipoprotein, in addition to total cholesterol levels, has been positively associated with performance on some cognitive tasks. ^{51 52} Insulin and glucose are metabolic measures associated with neurocognitive outcomes and obesity. They have also been shown to have an association with hippocampal function and cognition. ⁵³

Developmental measures

NDDS	The NDDS response options are 'yes' or 'no'. One or more no responses (ie, the child does not demonstrate the behaviour) indicate the need for further assessment and/or referral. This is known as the 'one-flag' rule; currently, the instructions of the 18-month NDDS recommend a one-flag rule to follow-up with the healthcare and/or childcare professional regarding the child's development. ⁶¹
CBQ	The CBQ provides a comprehensive assessment of reactive and self-regulative temperamental behaviours in young children. The CBQ assesses temperament across three domains: surgency, negative affectivity and effortful control. The CBQ is a validated measure of child temperament for children aged 3–7 years. ⁵⁶ We are also using versions for younger children, called the Infant Behaviour Questionnaire and the Early Childhood Behaviour Questionnaire, for children aged 3–12 months and 18–36 months, respectively.
ITC	The 24-item parent-completed ITC was developed as a screen for communication delays in children between 6 and 24 months of age. It is designed to identify seven developmental milestones of social communication, including emotion and use of eye gaze, use of communication, use of gestures, use of sounds, use of words, understanding of words and use of objects. ⁵⁷

Other variables

Child's birth weight	'What was your child's birth weight? __ lb __ oz (or __ g) and then converted to kilograms'.
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Continued

Table 1 Continued

Breastfeeding duration	'For how long has your child been breast fed?' Response is categorised as never being breast fed if the response was a duration of 0 months and those who were currently breast feeding have a duration equal to the child's current age in months.
Child exposure to smoke and smoking and pregnancy	Child exposure to smoke: 'Does any member of your household smoke cigarettes? Yes/no'. Smoking and pregnancy: 'Please check all non-prescribed medications and substances that your child's biological mother took during her pregnancy: (1) cold/influenza medication, (2) cigarettes, (3) alcohol, (4) other—please explain, (5) none, (6) child is adopted (unknown)'.

CBQ, Child Behaviour Questionnaire; ITC, Infant-Toddler Checklist; NDDS, Nipissing District Developmental Screen.

For both streams, data are stored and scored at the OCCS and subsequently sent to TARGeT Kids! through a secure data transfer site.

Statistical analysis

Exposure data from the TARGeT Kids! research network will be merged with EDI outcome data following the secure data transfer from the OCCS to the Applied Health Research Centre at St. Michael's Hospital. Baseline characteristics of the study sample will be analysed using SAS V.9.4 statistical software and R V.3.5 (<http://www.R-project.org>). We will compare the baseline demographics of TARGeT Kids! participants with and without

EDI data available. The proposed study completion date is spring 2020, at which point the following primary and secondary analyses will be performed.

The *primary analysis* will examine the effect of BMI trajectories on risk of not being ready for school (according to EDI scores). Trajectories, referring to an estimated growth over a period of time, will be examined. We plan to use a two-stage process. *Stage 1* will use the latent class growth model (LCGM) to first determine BMI trajectory groups, under the assumption that the population studied is composed of several distinct groups of children defined by their BMI trajectories, permitting the trajectories to

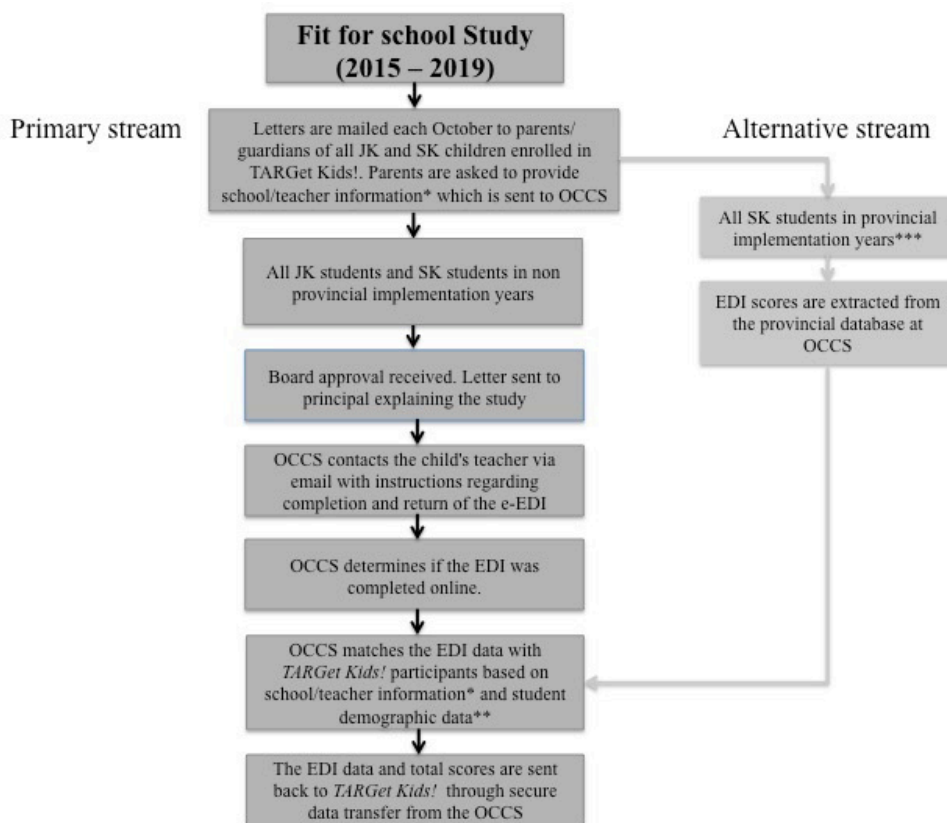


Figure 1 The process of Fit for School Study recruitment and data collection. Note: the alternative stream was developed to avoid asking the teachers to complete the EDI twice. *, school board, school name and teacher's name; **, date of birth, sex and postal code; ***, EDI collected by all SK teachers in publicly funded school districts in Ontario during provincial implementation years (3-year cycles). EDI, Early Development Instrument; JK, junior kindergarten or year 1; OCCS, Offord Centre for Child Studies; SK, senior kindergarten or year 2.



vary continuously throughout the population. Bayesian information criterion will be used to determine the best fitting model to the data, as well as the number and type of trajectories. *Stage 2* will use generalised linear mixed models (GLMMs), in which trajectories from stage 1 (primary exposure variable) will be used to examine the relationship with the EDI while accounting and adjusting for clustering of children within schools and by sex. A binary outcome will be used, defined as whether a child is vulnerable on one or more of the five EDI domains (0=not vulnerable and 1=vulnerable).

The *secondary analysis* will use the same two-stage process to examine the effects of the other health trajectories, such as health behaviours (physical activity, sedentary behaviour and sleep duration), nutrition (nutritional risk and micronutrient deficiencies) and cardiometabolic risk (non-HDL cholesterol, insulin and glucose levels), as well as developmental trajectories (risk of developmental delay, child temperament and emotion regulation) on risk of not being ready for school (according to EDI scores). Stage one will again use LCGM to determine groups of trajectories, and stage 2 will use GLMM to examine the relationship of each health trajectory on the EDI primary outcome measure (overall vulnerability). We also plan to look at the relationship between trajectories from stage 1 (both primary and secondary exposures) and the continuous score of each of the five EDI domains. Lastly, we will compare the EDI results of children from their first and second year of kindergarten to see how they changed over time. The overall dichotomous vulnerability scores (0=not vulnerable and 1=vulnerable) for children aged 4–5 years and 5–6 years will be compared. We will also explore other methods to determine growth trajectories in order to decide on the best approach.

Sample size

In order to estimate the sample size needed for this study, zBMI data from the ongoing TARGeT Kids! longitudinal cohort were used to categorise children by growth trajectory groups (proc Traj, SAS⁸³). The growth trajectory groups were based on 32 261 observations from 4734 subjects, with all subjects having at least three zBMI measurements before 42 months of age. According to preliminary Fit for School Study results from year 1, the overall estimated proportion of kindergarten children ages 5–6 years (year 2 or SK) in TARGeT Kids! at risk of not being ready for school was 21%. The estimated proportion of children not being ready for school in each zBMI group was calculated by combining the preliminary EDI data with a yes response to the question ‘Does your child receive any extra resources at school?’ as a proxy for vulnerability in school readiness, collected via a standardised parent-completed questionnaire used in TARGeT Kids!. This resulted in the estimated proportions of vulnerability in each zBMI group of being 0.190, 0.203, 0.213 and 0.259. If a logistic model were used to estimate the differences in school readiness between zBMI trajectory groups, a sample size of 1200 would allow us to detect

a relative risk of 1.49 between two of the zBMI groups (α -level=0.05, 80% power).

Knowledge translation

TARGeT Kids! is a collaboration between child health researchers, primary care practitioners (paediatricians and family physicians), parents and their children. This study incorporates integrated knowledge translation with practising primary care physicians in the TARGeT Kids! network and teachers in the school setting. It provides capacity building for trainees across multiple disciplines, providing a foundation for future studies on growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories in children. The findings obtained from this research will be directly distributed to the participating physicians and parent representatives during annual meetings with all of the TARGeT Kids! research team, staff and policy leaders. Results of the study will be disseminated to the Ontario district school boards and the assistant deputy minister of education. An information webinar about the study rationale and goals has been developed and shared with teachers by the OCCS through their website (<https://edi.offord-centre.com/>).⁸⁴ The results of the study will be shared with the academic community through research publications, as well as local, national and international presentations at conferences. Information will be distributed to stakeholders, including the Canadian Paediatric Society, Ontario College of Family Physicians, Ontario Medical Association, Ontario Ministry of Health and Ontario Ministry of Education.

Patient and public involvement

We did not directly include participants’ parents or the public in the design of this cohort protocol; however, a previous study consulted with parents of TARGeT Kids! participants to identify top research priorities using the James Lind Alliance’s methodology⁸⁵ and the objectives outlined in the Fit for School Study were informed by these research priorities. We are planning to present the preliminary results to a committee that includes parent representatives in the hopes of including participants’ parents in the interpretation of the results and the dissemination plan.

ETHICS AND DISSEMINATION

The Fit for School Study was granted ethics approval by the Research Ethics Boards at The Hospital for Sick Children, Unity Health Toronto and McMaster University. We have also obtained research ethics approval from each school board with a student participating in the study. Most of the TARGeT Kids! practice sites are located in the Greater Toronto Area; therefore, the largest school boards with students who are study participants are the Toronto District School Board, and the Toronto Catholic District School Board.

The findings will be disseminated through peer-reviewed publications, and presentations (oral and posters) at local, national and international scientific meetings. We also plan to disseminate the results to school boards and the ministry of education.

DISCUSSION

The Fit for School Study aims to better understand how early child growth, health behaviours, nutrition, cardiometabolic risk and development affect a child's readiness to learn at school. The strengths of this study include its large sample size, longitudinal design, prospective data collection of participants yearly and inclusion of detailed measures of child growth, health behaviours, nutrition, cardiometabolic risk and development in the years prior to school entry. This study is also novel as EDI data are collected for both kindergarten years, enabling inclusion of the developmental growth during kindergarten in the models.

Parent participation in both TARGet Kids! and the Fit for School cohort is voluntary, and thus, the sample is at risk of selection bias. The generalisability of the TARGet Kids! cohort was assessed by comparing sociodemographic characteristics (including household income, maternal age, maternal education and maternal ethnicity) with the 2012–2013 and 2014–2015 Canadian Health Measures Survey and the 2006 Canadian Census data; the sociodemographic characteristics of TARGet Kids! participants were comparable with those of the Canadian population with the exception of TARGet Kids! participants having slightly higher household incomes and higher maternal education levels.⁸⁶ Parents are asked to provide additional information about their child's school for the Fit for School cohort and we expect a proportion of parents will decline or not respond; thus, we plan to compare the sociodemographic characteristics of the Fit for School subpopulation to the entire TARGet Kids! population so that readers can understand the generalisability of the results.⁸⁶

Study challenges and limitations

Obtaining research ethics board approval from each school board was both resource and time intensive as each school board has a separate process, timeline and requirements for ethics approval. In year 1, ethics approval was sought and received from the three largest school boards in the Fit for School geographical area, and three additional school boards granted approval of the study within the second school term. Some children participating in TARGet Kids! attend private school, and this raises challenges as there are no designated private school research ethics boards, and private schools do not participate in the provincial implementations of the EDI. For school boards where we were unable to obtain ethics approval, we were granted ethics approval by our institutional research ethics board to request that

parents provide teachers with the information needed to complete the EDI. Teachers' participation is voluntary in all situations.

At the time that parents consent to participate in the Fit for School Study, they may not yet have information about the name of their child's school board, school or teacher. Collecting this information is needed so that the teachers can be contacted by the OCCS, and this is an operational challenge. We do not expect the parents who do not respond, but as mentioned previously, we plan to describe the baseline sociodemographic characteristics in order to understand the generalisability of the results. Additionally, teacher participation is voluntary, and unless it is a provincial implementation year, there is no time set aside for teachers to complete the EDI. We obtained institutional ethics approval to offer teachers a gift card towards purchasing supplies and books for their classroom. This token of appreciation will be executed according to each school board's own research ethics board policy.

Another challenge is linking participant data from TARGet Kids! with their EDI results during a provincial implementation year. TARGet Kids! participants were assigned a unique identification code. Probabilistic linkage was used after the child's school information was sent to the OCCS and the teacher completed the EDI. A positive match was required on five of the following six variables: the school board name, school name, teacher's name, child's date of birth, child's sex and postal code. Missing EDI records may have been a result of an improper match on more than one of these six variables, a teacher not completing the questionnaire (either by choice or because he/she was on leave) or a child left the school. We have now amended our protocol to collect the Ontario Education Number to improve our ability to match the participants with parental consent and a completed EDI questionnaire to their records. Another challenge involves missing exposure data. We plan to address this issue by enhancing our data through collection from the electronic medical record in the primary care practices, and linking our cohort with provincial data holdings from the Institute for Clinical Evaluative Sciences.

CONCLUSION

The Fit for School Study aims to identify whether early child growth, health behaviours, nutrition, cardiometabolic risk and developmental trajectories impact school readiness. This study will contribute knowledge that will enhance our efforts to identify, implement and evaluate interventions for the promotion of school readiness in young children. This protocol is the first step in this process by outlining the study objectives, rationale, description of the methods and a discussion of some implementation challenges.

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Contributors

CSB, JAO, KMN, CMB and MJ conducted the literature search. CSB and MJ designed the research study. CSB, CK, GL, JLM, MM, PCP, JRS, MST, ED and CR-W helped to refine the study design. CSB, JAO, KMN, CMB and MJ drafted the manuscript. All authors read and approved the final manuscript.

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