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# Study protocol for the Sino-Canadian Healthy Life Trajectories Initiative (SCHeLTI): a multicentre, cluster-randomised, parallel-group, superiority trial of a multifaceted community-family-mother-child intervention to prevent childhood overweight and obesity

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## ABSTRACT

**Introduction** Childhood overweight and obesity (OWO) is a primary global health challenge. Childhood OWO prevention is now a public health priority in China. The Sino-Canadian Healthy Life Trajectories Initiative (SCHeLTI), one of four trials being undertaken by the international HeLTI consortium, aims to evaluate the effectiveness of a multifaceted, community-family-mother-child intervention on childhood OWO and non-communicable diseases risk.

**Methods and analysis** This is a multicentre, cluster-randomised, controlled trial conducted in Shanghai, China. The unit of randomisation is the service area of Maternal Child Health Units (N=36). We will recruit 4500 women/partners/families in maternity and district level hospitals. Participants in the intervention group will receive a multifaceted, integrated package of health promotion interventions beginning in preconception or in the first trimester of pregnancy, continuing into infancy and early childhood. The intervention, which is centred on a modified motivational interviewing approach, will target early-life maternal and child risk factors for adiposity. Through the development of a biological specimen bank, we will study potential mechanisms underlying the effects of the intervention. The primary outcome for the trial is childhood OWO (body mass index for age ≥85th percentile) at 5

## Strengths and limitation of this study

► Among the first multicentre, cluster randomised controlled trials to assess a cumulative impact intervention, spanning from preconception or early pregnancy to early childhood.

► Implementation of the intervention uses a health system-based approach, linking hospital to community-based care to patient-centred online motivational technologies in a continuum.

► Given the relatively small number of units of randomisation (n=36), randomisation may not be fully successful in distributing baseline risk factors in a balanced manner across study groups.

► Should this complex, multifaceted intervention prove effective, it will not be possible to determine which of its components will be primarily responsible for an observed effect on the primary outcome.

years of age, based on WHO sex-specific standards. The study has a power of 0.8 (α=0.05) to detect a 30% risk reduction in the proportion of children with OWO at 5 years of age, from 24.4% in the control group to 17% in the

intervention group. Recruitment was launched on 30 August 2018 for the pilot study and 10 January 2019 for the formal study.

**Ethics and dissemination** The study has been approved by the Medical Research Ethics Committee of the International Peace Maternity and Child Health Hospital in Shanghai, China, and the Research Ethics Board of the Centre Intégré Universitaire de Santé et Services Sociaux de l'Estrie–CHUS in Sherbrooke, Canada. Data sharing policies are consistent with the governance policy of the HeLTI consortium and government legislation.

**Trial registration number** ChiCTR1800017773.

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## INTRODUCTION

The Healthy Life Trajectories Initiative (HeLTI) is an international collaboration between the Canadian Institutes of Health Research, the National Sciences Foundation of China, the Department of Biotechnologies of India and the South African Medical Research Council, with technical support from the WHO. This initiative aims to test evidence-based strategies for childhood overweight and obesity (OWO) prevention through the implementation of parallel trials. Four separate randomised controlled trials (RCTs), two of which are cluster randomised designs (Shanghai, China, and Mysore, India) and two with simple randomisation (Soweto, South Africa, and two provinces in Canada), are in the course of implementation. The four trials are using harmonised instruments/tools for the measurement of exposures and outcomes in order to optimise the analysis of common objectives, which could be addressed by pooling the data of two or more trials. These trials will examine the cumulative effects of evidence-based intervention strategies, adapted to the specific country settings, on childhood OWO risk and indicators of maternal, infant and child health. They will begin either in the preconception period or in early pregnancy and continue through pregnancy and into early childhood. This manuscript presents the research protocol of the Sino-Canadian Healthy Life Trajectories Initiative (SCHeLTI) interventional study, currently being implemented in Shanghai.

Childhood obesity is a global health issue and is progressively affecting many low-income and middle-income countries, especially in urban areas.[1] The problem of OWO among children and adolescents has become a major public health issue and priority in China.[2 3] Prevalence of childhood OWO in 2006–2010 was estimated as 13.1% and 7.5%, respectively[4]; while in 2015 in Shanghai, rates of childhood OWO among children of 7 years of age have been reported to be as high as 36% and 21%, respectively.[5] Childhood OWO is associated with suboptimal neurocognitive functioning, socio-emotional development and poorer school performance in the children, as well as the development of type 2 diabetes, cardiovascular diseases and other non-communicable diseases, and premature death in future life.[6 7] Research focusing on the developmental origins of long-term health has recently shifted focus from infancy to risk factors in the prenatal and even preconception periods.[8]

Although limited, there is some evidence demonstrating the effectiveness of interventions in pregnancy and early infancy on childhood adiposity. Most studies have been conducted in developed countries, and no intervention has been started from preconception and continued into childhood.[9] Two published trials used life-course approaches that were initiated in the prenatal period and continued after birth. The interventions, which focused on maternal and infant diet and activity, showed positive effects on body mass index (BMI) among children under 2 years,[10 11] but no sustained effects at 3.5 years and 5 years.[12] Two postnatal interventions showed that advice on diet and physical activity targeting the mother[13] or the nuclear family[14] reduced child weight gain in all children[13] or in girls only.[14]

A recent systematic review of antenatal diet and lifestyle interventions[15] reported that due to the heterogeneity both of the content of interventions as well as outcome measures, no meta-analysis could be conducted. The authors recommended that future studies should assess interventions that are relatively high intensity and are sustained over time and called for standardisation of outcome measures. A Cochrane review found that among interventions provided in pregnancy, diet and exercise counselling decreased the risk of excessive gestational weight gain (GWG), gestational hypertension, macrosomia and large for gestational age in women from all BMI categories.[16] Diet counselling alone was the only intervention effective in reducing gestational diabetes rates.[16] A review of qualitative evidence[17] also highlighted the need to provide relevant and specific information to participants, to put strategies in place to reduce healthcare provider (HCP) weight bias (decrease shame, blame and stigmatisation associated with weight monitoring) and to clarify safety of diet and physical activity changes for the fetus.[16 17]

New biological OWO risk markers hold promise in obesity prevention. Recent studies highlight the role of the intestinal microbiome as a mediator of a range of exposures (feeding, diet, mode of delivery and antibiotics) linked to OWO.[18 19] Early life 'programming' effects, inducing certain epigenetic changes, may also increase vulnerability to OWO.[20 21]

Thus, in response to a request for applications from the sponsors, we designed SCHeLTI, a multicentre, cluster-randomised, parallel-group, superiority trial to fill these research gaps. SCHeLTI will assess the impact of a cumulative impact, integrated community-family-mother-child (CFMC) intervention with a sustained, professionally mediated, multifaceted integrated approach for the prevention of childhood OWO. Compared with the control group, that will receive standard care, we hypothesise that the intervention will lead to measurable differences in offspring OWO at the age of 5 years, as well as adiposity indicators and biomarkers mediated by changes in risk factors. The SCHeLTI biobank will provide a unique opportunity to identify new mechanisms guiding the development of prediction and prevention strategies.

## Objectives

The study aims to evaluate the effectiveness of the CFMC intervention on: (a) childhood OWO, including BMI for age ≥85th percentile at 5 years of age, based on WHO sex-specific standards (primary outcome); (b) Fat Mass Index (FMI) as measured by air displacement plethysmography, and other indicators of adiposity; (c) early indicators of metabolic dysfunction; and (d) modifiable family/couple risk factors for OWO, including nutrition and physical activity. In addition, through the creation of biobanks, the study has the potential to identify possible biomarkers (epigenome, microbiome and placental microRNA) predictive of FMI, OWO and metabolic dysfunction, to understand the underlying mechanisms. This initiative also aims to evaluate the safety, feasibility, and cost-effectiveness of implementing the CFMC intervention as a sustainable stakeholders-informed integrated approach to childhood OWO prevention in hospitals, Maternal Child Health Units (MCHUs) (primary care community clinic), childcare facilities and schools in China.

## METHODS AND ANALYSIS
### Study design

This is a multicentre, cluster-randomised, parallel-group, superiority trial implemented in collaboration with three maternity hospitals serving four districts: the Shanghai International Peace Maternity and Child Care Hospital (serving primarily both the Xuhui and the Minghang districts), the Changning Maternity and Child Care Hospital (serving primarily Changning District) and the Fengxian Central Hospital (serving the Fengxian District). As well, both district level hospitals in each of the districts and 36 affiliated MCHUs support the implementation of the study. A map of the four Shanghai districts collaborating in the SCHeLTI project is shown in figure 1.

A flowchart of the study design is shown in figure 2. MCHUs and their catchment areas were stratified by district (N=4) and randomly allocated to intervention and standard care groups with a ratio of 1:1 within each district. MCHUs were randomised as the intervention required training of HCPs in the MCHUs to develop their skills and practice in childhood OWO prevention strategies. We assumed HCPs who had received the training required to provide the trial intervention to study participants might modify their approach to the clinical care provided to all children receiving care in the unit. The cluster randomisation design was chosen to minimise contamination of control subjects. Usual care was selected for control group MCHUs since the research question is to determine whether the CFMC intervention is superior to the current practice. Participants in both the intervention and control groups will have the same access to the current healthcare resources, while participants in the intervention group will receive additional CFMC interventions provided by SCHeLTI.



**Figure 1** Map of the four Shanghai districts collaborating in the Sino-Canadian Healthy Life Trajectories Initiative trial.[25]

## Recruitment and eligibility criteria
### Cluster level: MCHUs

Following meetings of study investigators with both MCHU administrators and staff informing them of the study design and objectives, units were selected from those with the potential to recruit at least 100 study participants annually and whose leaders were willing to commit their unit to the study. In all, 36 MCHUs located in the
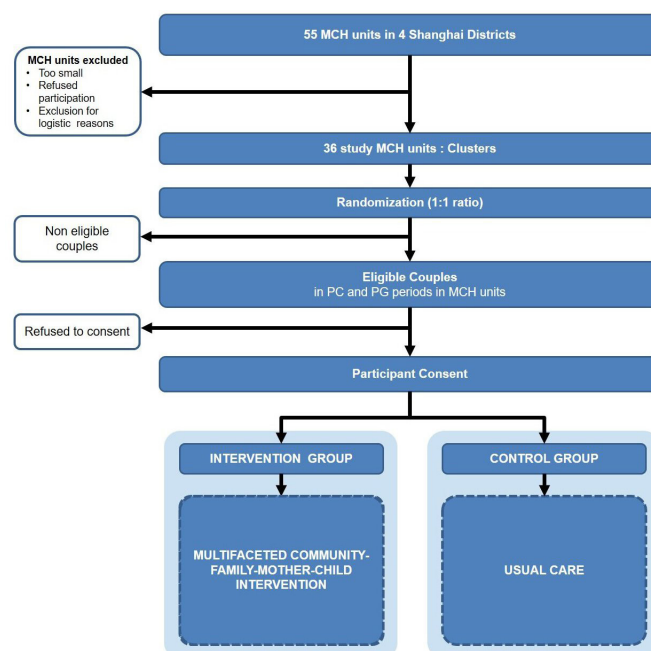


**Figure 2** Flowchart of the study design. MCH, Maternal Child Health.

four study districts were eligible and accepted to join the study.

## Inclusion criteria for women/partners/families

Inclusion criteria were (1) women aged 20–42 years; (2) Mandarin speakers and can read, comprehend and sign the consent form; (3) woman or spouse is a registered Shanghai resident, or one member of the couple has lived in Shanghai for at least 5 years; (4) plans to deliver in a participating hospital; (5) MCHU where the child will be followed after birth is the same MCHU service area where the mother is living at the time of recruitment. In addition, for those recruited in the preconception period at the time of a routine preconception health visit, women must be planning to become pregnant in the subsequent 6-month period. Criteria specific to those recruited in the first trimester of pregnancy include (1) a viable singleton pregnancy based on first trimester ultrasound and (2) less than 14-week pregnancy at enrolment.

## Exclusion criteria for women/partners/families

The presence of the following characteristics exclude candidates from participation in the trial: HIV positive, measurable viral load of hepatitis B or C, hepatitis B core or e-antigen positive, hepatitis C core antigen positive; women with known major heart conditions or other serious medical conditions; suspected or confirmed major fetal malformation, maternal drug abuse, planning to move out of the district within 5 years, and families in the preconception period who are planning conception by in vitro fertilisation.

Couples who join the study in the preconception period and who do not achieve pregnancy within 1 year of enrolment exit the study. Similarly, women who are diagnosed with a multiple pregnancy exit the study at the time of diagnosis

Women residing in the service areas of the participating MCHUs are approached by a trained research nurse or research assistant regarding possible participation in the study at the time of first presentation to hospital for routine preconception or prenatal care. After being fully informed on the implications of joining the study, including the requirement of participants to contribute to a biobank, eligible women are invited to read and to sign the study consent form. Potential participants are not informed prior to a decision on participation as to whether the MCHU catchment area where she resides is in the intervention or control group before signing the consent form and the baseline data collection.

## Randomisation, allocation to study groups and blinding

Randomisation of MCHUs is stratified by study district (N=4). This study includes two arms: the intervention group (receiving the health-promotion intervention) and the control group (no added health promotion intervention). Both groups receive usual obstetrical health services. Eligible women residing in the 36 MCH service areas are informed of the study, invited to participate

and assigned to the study group according to the allocation of the MCHU, where their child will receive routine childcare. Consenting women living in an 'intervention' MCHU catchment area are provided the study intervention, adapted to their risk level. Those from the control MCHUs receive usual preconception, prenatal and childhood care, but no study health promotion intervention. Randomisation was computer generated at the Applied Clinical Research Unit (URCA) of Centre Hospitalier Universitaire (CHU) Sainte-Justine Research Centre, Canada. In order to ensure allocation concealment, randomisation was performed after the recruitment of the MCHUs and as close as possible in time to the study initiation.

Subsequent to enrolment, masking of the study group is not possible, neither for study personnel nor for participants, due to the nature of the intervention. Nevertheless, the study personnel conducting the primary outcome assessments will be masked as to the study group.

## Trial intervention

In preconception and pregnancy, study interventions are provided by a dedicated health professional within the hospital setting. Only women residing in communities served by 'intervention MCHUs' receive the study intervention. In the postnatal period, interventions are provided through the 18 MCHUs randomised to the 'intervention' group, where MCHU healthcare personnel who have been trained in the intervention will ensure its delivery.

The CFMC intervention is a multifaceted, multicomponent lifestyle intervention designed to promote healthy lifestyle regarding (a) nutrition, (b) physical activity, (c) stopping smoking, (d) stress and physical health, (e) sleep quality, (f) breastfeeding, (g) child feeding practices and (h) childhood physical activity. Women in the CFMC intervention group undergo (1) patient-centred, one-on-one, face-to-face sessions with a healthcare professional based on the model of 'Healthy Conversations'[22]; (2) access to additional group educational activities and social support; (3) text messages providing evidence-based information that is tailored to the individual woman's personal goals and barriers to behaviour change; (4) motivational web-based tools and apps for self-monitoring of the participant lifestyle goals (physical activity and diet) and to increase communication between healthcare professionals and women and families; and (5) community-based activities.

The content of the intervention is adapted according to five transition periods (preconception; pregnancy; delivery and transition to extra-uterine life; the mother's return to work 3 months postpartum and transition to childcare and school entry) reflecting the early life continuum. The intervention will promote healthy family practices and behaviours, including supporting parents and grandparents to act as role models encouraging a healthy lifestyle in the child. The intervention programme aims to complement on-going programmes targeting a healthy start in life in the community, in child

care facilities and in schools, and will be adapted to boys and girls as appropriate.

The intervention is adapted to the mother's and child's risk for the child OWO: in each phase of care (preconception, prenatal, postnatal, infancy and childhood), study personnel are trained to assess risk status at routine intervention visits (eg, first and subsequent preconception visits, first and subsequent prenatal visits, at birth, and at subsequent routine child healthcare visits). Mothers or children may be identified as being 'at increased risk' for childhood OWO, based on predefined criteria (eg, preexisting maternal obesity, excessive GWG and gestational diabetes in pregnancy, macrosomia at birth). In cases where risk factors for childhood OWO are identified, the intensity of the intervention is increased. For example, during pregnancy, Healthy Conversation visit frequency is increased and a nutritional assessment and follow-up is provided.

Consenting women living in control MCHU catchment areas will receive routine care. Current routine care includes assessment of maternal GWG and childhood growth parameters according to established protocols and notification that 'thresholds' have been reached, without further specific intervention.

No rules were prespecified for discontinuing allocated interventions to trial participants. However, specific procedures are planned in case the woman and/or the child are moving outside their initial allocated MCH to maintain the intervention (eg, phone call instead of face to face intervention). Based on the pragmatic nature of the interventions, healthy lifestyle activity co-interventions will be allowed and will be documented in both arms.

### Outcomes

The primary outcome of the SCHeLTI trial is the difference between the two treatment arms in the proportions of children with OWO defined as the proportion of children with BMI for age ≥85th percentile at 5 years of age, by sex-specific WHO standards. OWO was selected as the outcome that was considered to be most relevant to stakeholders and decision-makers, as prevention of childhood obesity has been identified as a health priority in China.[3] Secondary outcomes include the difference between the two treatment arms in (1) FMI (fat mass (kg) divided by squared height (m)) as measured by air displacement plethysmography (Bod Pod) at 5 years of age; (2) adiposity indicators as measured by skinfold thickness and waist/height ratio; (3) anthropometric indicators: distribution of BMI for age z-score, birth weight for gestational age z-score, weight for length z-score; (4) modifiable risk factors, including GWG, smoking (both direct and indirect exposures), breastfeeding, woman/family/child lifestyle, nutrition, physical activity, stress and sleep; (5) metabolic dysfunction indicators, including fasting glucose and insulin; (6) blood pressure as measured by resting systolic blood pressure; and (7) infant/child neurodevelopment measures between 3 months and 5

years of age as assessed by a specific battery of neurobehavioural test. Details regarding the specific measures to be assessed and their timing are provided in tables 1 and 2.

### Biospecimen collection and management

Core biological specimens, including serum (biomarkers), plasma (biomarkers), buffy coat (genetics/epigenetics), placental tissue (RNA, genetics/epigenetics), stool (microbiome), vaginal swabs (microbiome), breast milk (microbiome and epigenetics) and urine (biomarkers and pollutants), will be collected throughout the study using predefined standard operating procedures on every willing participant and stored in a biobank (table 3). In accordance with Chinese regulations, SCHeLTI biospecimen will be analysed in China. Proposed mechanistic studies will be focused on microbiome, microRNA and epigenetic changes.

### Data collection and management

The data management centre is located at the Ministry of Education and Shanghai Key Laboratory of Children's Environmental Health, Xinhua Hospital, and is supported by the URCA of CHU Sainte-Justine Research Centre in Montreal. A core set of anthropometric measures, lifestyle/health questionnaires and biological specimens will be collected at scheduled research visits. Children's height and weight, to be used in deriving the primary outcome, will be measured at 5 years of age by research personnel who are masked as to the treatment group and who have undergone training by experts in anthropomorphic measures. All the data will be collected by trained data collection personnel and captured on an electronic case report form (eCRF). The data management platform is based on the Research Electronic Data Capture (REDCap) software. The study data management centre conducts ongoing data monitoring activities and audits on study data from all participating sites, and is responsible for maintaining accurate, complete and up-to-date records of the eCRFs for each research participant, for generating queries and preparing reports. The REDCap database has embedded data-security functions to ensure confidentiality.

Our trial has established a rigorous strategy to minimise loss to follow-up, including (1) use of electronic records both in hospitals and in MCHU clinics to maintain contact with participants; (2) linking study visits to clinic visits to optimise convenience; (3) weekly text messaging and periodic telephone calls; (4) providing participants priority access to standard services to increase efficacy and reduce waiting times for routine hospital visits, and (5) conducting postnatal follow-up visits in the MCHUs, close to the family residence, thus reducing participants burden. In cases where participants fail to attend the visit where the primary outcome is assessed, anthropometric measures will be abstracted from data collected at the time of routine standard healthcare visits conducted by MCHU personnel.

**Table 1** Measures and timepoints for the child in the SCHeLTI trial

| Time point | Domains | Assessment | Birth | 6 weeks | 3 months | 6 months | 12 months | 24 months | 36 months | 60 months |
|---|---|---|---|---|---|---|---|---|---|---|
| Measures | OWO based on BMI | Height/length | X | X | X | X | X | X | X | X |
| | | Weight | X | X | X | X | X | X | X | X |
| | FMI | FMI measured by Bod Pod | | | | | | | X | X |
| | Growth indicators | Birth weight for gestational age | X | | | | | | | |
| | | Large/small for gestational age | X | | | | | | | |
| | | Waist to height ratio | | | | | | X | X | X |
| | | Skinfold thickness | | | X | X | X | X | X | X |
| | | Mid upper arm circumference | | X | X | X | X | X | X | X |
| | | BMI for age z-score | X | X | X | X | X | X | X | X |
| | | Weight for length/height z-score | X | X | X | X | X | X | X | X |
| | Secondhand smoke exposure | | | X | X | X | X | X | X | X |
| | Nutrition | Solid food introduction | | X | X | X | X | X | | |
| | | 3-day diary | | | | | | X | | X |
| | | Chinese Preschoolers' Eating Behavior Questionnaire[26] | | | | | | | X | |
| | Screen time | Screen-Time Based Sedentary Behaviour Questionnaire[27] | | | X | X | X | X | X | X |
| | Physical activity | Preschool-Age Children's Physical Activity Questionnaire[28] | | | | | | | X | X |
| | Sleep | Brief Infant Sleep Questionnaire-Chinese version[29–31] | | | X | X | X | X | | |
| | | Children's Sleep Habits Questionnaire[32 33] | | | | | | | X | X |
| | Metabolic dysfunction indicators | Fasting glucose | | | | | | | | X |
| | | Fasting insulin | | | | | | | | X |
| | Blood pressure | Resting systolic and diastolic blood pressure | | | | | | X | X | X |
| | Infant/child neurocognitive assessment | | | | | | | | | |
| | Temperament | Infant Behavior Questionnaire[34] | | | | x | x | | | |
| | | Early Child Behavior Questionnaire[35] | | | | | | x | | |
| | | Child Behavior Questionnaire[36] | | | | | | | | x |
| | Behaviour | Strengths and Difficulties Questionnaire[37 38] | | | | | | X | X | X |
| | Early language acquisition | MacArthur Short Form Vocabulary Checklist: Level 1[39 40] | | | | | x | | | |
| | | MacArthur Short Form Vocabulary Checklist: Level 2[39 40] | | | | | | x | | |

Continued

**Table 1** Continued

| Time point | Domains | Assessment | Infant age |  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|
|  |  |  | Birth | 6 weeks | 3 months | 6 months | 12 months | 24 months | 36 months | 60 months |
|  | Language development | Peabody Picture Vocabulary Scale[41 42] |  |  |  |  |  |  |  | X |
|  | Cognitive development | Ages and Stages Questionnaire-3[43 44] |  |  | X | X | X | X | X | X |
|  | General ability/IQ | Wechsler Preschool and Primary Scale of Intelligence-IV[45 46] |  |  |  |  |  |  |  | X |
|  | Executive functioning | Behavior Rating Inventory of Executive Functions[47 48] |  |  |  |  |  |  | X | X |
|  | Parenting stress | Parenting Stress Index–Short Form[49 50] |  |  |  | X |  |  |  |  |
|  | Parenting style | Child Rearing Practices Report Questionnaire[51 52] |  |  |  |  |  | X |  | X |

BMI, body mass index; FMI, Fat Mass Index; OWO, overweight and obesity; SCHeLTI, Sino-Canadian Healthy Life Trajectories Initiative.

## Study oversight and monitoring

WF, IM, LB, FO, JZ, YW, Z-CL, PCKL and H-FH are members of the Trial Steering Committee. FO at the Shanghai Key Laboratory of Children's Environmental Health and BM at URCA are responsible for data monitoring and data quality. Internal monitoring of the study is performed by auditors designated by the Trial Steering Committee. External monitoring will be conducted by experts delegated by the sponsors. Nigel Rollins, from the WHO, is responsible for technical support and trial monitoring. The four trials in the HeLTI consortium have a single Data Monitoring Committee (DMC). To guide the work of this DMC, a DMC Charter has been developed, including harmonisation of the definitions of adverse events and serious adverse events as well as the variables to be assessed at the times of reviews of trial progress. No interim analysis for the primary outcome is planned. Participant recruitment will be completed before the first child reaches 5 years of age.

## Process monitoring and evaluation

An intervention monitoring plan and related standard operating procedures were developed for SCHeLTI, based on the NIH Behavior Change Consortium guidelines.[23] The plan includes (1) harmonisation of the study intervention components around defined processes, goals and desired outcomes, while encouraging care provider adaptation to participants' perceived needs; defining indicators of intervention delivery (intended number of contacts, duration, indicators of contact content, format—that is, face to face versus virtual); (2) standardisation of intervention training, provider certification (theoretical training, practical simulations and direct supervision during the pilot phase), periodic post-initial training recertification and skills monitoring (in vivo or recorded observation and semi-quantitative scoring of adherence to intervention delivery guidelines); and (3) monitoring of receipt of intervention, including participant use of self-help APP (web-based software application) for documentation of achievement of goals set in Healthy Conversations sessions. Process indicators include the proportion of persons who received the study intervention according to plan, ratio of delivered to planned intervention contacts, proportion of contacts respecting intended duration, proportion of monitored visits assessed as meeting quality standards and proportion of participants engaging in self-monitoring of goal attainment through the study APP. Contextual factors that will be reported include facilitators and barriers to study implementation in participating hospitals, in maternal child health community clinics, as well as family characteristics such as relocation, parents occupational and educational level and grandparent involvement in study interventions and in childcare.

## Sample size and power

We performed a sample size calculation for the primary outcome OWO in children at 5 years of age. We used a conservative estimate of the intracluster correlation coefficient of 0.03. We aim for less than 15% of missing data on key variables at 5 years of age and thus 85 children per cluster are expected to undergo the primary outcome assessment at age 5 years. Based on these parameters, a sample size of 18 MCHUs per study group is required to achieve a power of 80% to detect a risk reduction of 30%, from 24.4% in the control group to 17% in the intervention group. If, however, loss to the follow-up is as high as 30%, the study will have a power of 80% to detect a risk reduction of 34%, from 24.4% in the control group to 16% in the intervention group. The estimated rate of OWO in the control group of 24.4% was based on unpublished data from the Shanghai Birth Cohort (personal communication). For the main secondary continuous outcomes, FMI and BMI z-score, the study will have a power of 80% to detect a 0.19 SD difference with an average cluster size of 85 retained children per cluster at

**Table 2** Measures and timepoints for the mother in the SCHeLTI trial

| | Domains | Assessment | Mother | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| | | | Prenatal | | Postnatal | | | | | | |
| Periods | | | | | | | | | | | |
| Timepoint | | | Preconception | Pregnancy | 6 weeks | 3 months | 6 months | 12 months | 24 months | 36 months | 60 months |
| Measures | OWO based on BMI | Height | X | X | | | | | | | |
| | | Weight | X | X | X | X | X | X | X | X | X |
| | Adiposity indicators | Skinfold thickness | X | X | | | | | | | |
| | | Waist circumference | X | | | | | | | | X |
| | Pregnancy outcomes | GWG | | X | | | | | | | |
| | | Gestational diabetes | | X | | | | | | | |
| | Smoking history | | X | X | | X | X | X | X | X | X |
| | Secondhand smoke exposure | | X | X | | X | X | X | X | X | X |
| | Breastfeeding | The Breastfeeding Self-Efficacy Scale[53 54] | X | X | X | X | X | X | | | |
| | Nutrition | Food Frequency questionnaire[55] | X | X | | | | | | | |
| | Physical activity | Global Physical Activity Questionnaire[56 57] | X | X | | | | X | | X | X |
| | Sedentary behaviour | Adult Sedentary Behaviour Questionnaire[58 59] | X | X | | | | X | | X | X |
| | Sleep | Pittsburgh Sleep Quality Index[60 61] | X | X | | | X | X | | X | X |
| | Self-efficacy | General Self-Efficacy Scale[62 63] | | | | | | | | | |
| | Stress | Perceived Stress Scale[64] | X | X | | X | | X | | X | X |
| | Anxiety | General Anxiety Disorder-7[65 66] | X | X | | X | | X | | X | X |
| | Depression | Edinburgh Postnatal Depression Scale[67 68] | X | X | | X | | X | | X | X |
| | | Patient Health Questionnaire-9[69 70] | X | X | | X | | | | | |
| | Social support and Stress | Social Provision Scale[71] | X | X | | X | | X | | X | X |
| | Metabolic dysfunction indicators | Fasting glucose | X | X | | | | | | | |
| | | Fasting insulin | X | X | | | | | | | |
| | Blood pressure | Resting systolic and diastolic blood pressure | X | X | X | X | X | X | X | X | X |

BMI, body mass index; GWG, gestational weight gain; OWO, overweight and obesity; SCHeLTI, Sino-Canadian Healthy Life Trajectories Initiative.

5 years. For FMI, this corresponds to a mean difference of $0.35 \, kg/m^2$, assuming a mean FMI of $2.97 \, kg/m^2$ and SD of $1.84 \, kg/m^2$ at 5 years of age.

### Implementation and feasibility

Commencing in January 2019 and continuing for a 2.5-year period, trained nurse-research assistants will recruit 4500 women/partners/families presenting either for preconception care (N=1800, 50 per cluster, 36 clusters) or for prenatal care (N=2700, 75 per cluster, 36 clusters). Of the 1800 preconception care participants, we expect approximately 900 (50%) will achieve a viable pregnancy within 1 year of enrolment. This assumption is based

on observed pregnancy rates in the first year following the launching of recruitment. For the primary outcome assessment at 5 years of age, a 15% combined rate of voluntary withdrawals and loss to follow-up is expected. Of the 3600 pregnant women expected to be included, 3060 children are expected to be seen at 5 years of age.

### Statistical analysis plan

We will assess the comparability of the treatment groups at the cluster and individual levels using descriptive analyses of baseline characteristics of participants/infants and cluster level characteristics of participants/infants. The distribution of risk factors for childhood obesity at

**Table 3** Core biological specimens collected in the Sino-Canadian Healthy Life Trajectories Initiative trial

| Timepoint | Preconception<br>Baseline visit | Pregnancy<br><14 weeks | 15–28 weeks | 29–36 weeks | Delivery<br>Delivery Day 0 | Delivery<br>Day 0–7 | Postnatal<br>6 weeks | 3 months | 6 months | 12 months | 24 months | 60 months |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Mother | Blood | Blood | Blood | Blood | Blood | Saliva | Breast milk | Breast milk | | Blood | | Blood |
| | Saliva | Saliva | Saliva | Saliva | | Buccal swab | Vaginal swab | Skin swab (areola breast) | | | | |
| | Buccal swab | Buccal swab | Buccal swab | Buccal swab | | Breast milk | Stool | | | | | |
| | Urine | Urine | Urine | Urine | | Skin Swab (areola breast) | Skin swab (areola breast) | | | | | |
| | | Stool | Stool | Stool | | | | | | | | |
| | | | Vaginal swab | Vaginal swab | | | | | | | | |
| Father | Blood | Blood | | | | | | | | | | |
| Child | | | | | Cord blood | Saliva/buccal swab | Stool | Stool | Stool | Saliva buccal swab | Saliva | Blood |
| | | | | | Placenta | Heel blood | | | | Stool | buccal | Stool |
| | | | | | | Stool | | | | Finger prick blood | Swab | Saliva |
| | | | | | | | | | | Stool | | buccal swab |

baseline will be assessed according to study groups. For participants in the intervention group, we will evaluate the compliance to the recommended treatments. Intent-to-treat analyses will be used for the primary and main secondary outcomes in children at 5 years of age (eg, OWO rate, FMI, % fat mass, BMI z-score, resting blood pressure, fasting glucose and insulin). Analyses will be stratified by sex. Considering the clustering of data, we will use mixed modelling and adjust, if needed, for prespecified potential risk factors associated with outcomes (such as size of MCH, level of care, maternal age, parity and socioeconomic status). Mixed models with random intercept/slope effects and fixed effects (for the intervention) will be used to estimate the intervention effect. To assess the overall and stratified 'trajectory' effect of the intervention over the child's life course (through repeated measures of anthropometric indicators), repeated measure generalised estimating equations with an exchangeable covariance matrix will be used, where the time-intervention interaction term will be used to evaluate the intervention effect in children at 5 years of age. Due to possible heterogeneity of effects for key outcomes according to the time of initiation of the intervention (eg, preconception vs early pregnancy), we will conduct a subgroup analysis stratifying by this variable, testing for heterogeneity.

## Patient and public involvement
In preparation for designing the intervention, a qualitative study (unpublished) was conducted in participating healthcare facilities with the goal of assessing the views, attitudes, values and expectations of parents, grandparents of children (with and without OWO) and HCofs regarding childhood obesity prevention and management. Current practices and challenges were assessed. Parents expressed their views on their health information needs regarding childhood obesity, both with respect to content and potential modes of communication. Parents placed a priority on two modes: direct, face-to-face counselling by health professionals and information provided by health professionals through virtual sources such as apps. As well, a survey (unpublished) was conducted among pregnant women to identify the most frequent barriers to adopting a healthy lifestyle. The design of the intervention, including training of intervention providers, was adapted based on the results of both the qualitative study and the survey. Prior to launching the trial, we held workshops with hospital and MCH centre administrators and HCPs to obtain feedback regarding the proposed multi-layered intervention to ensure that it was tailored to their specific context. Ongoing feedback from stakeholders at hospital and community levels concerning practical issues in implementation is obtained through quarterly meetings and feedback sessions.

## ETHICS AND DISSEMINATION
### Ethical considerations
The study protocol has been approved by the medical research ethics committees of both the International

Peace Maternity and Child Health Hospital (GKLW2017-01) and the CIUSSS de l'Estrie-CHUS hospital (MP-31-2019-2967). Confidentiality of information is maintained by strict control of access to the research database, and by ensuring that participant identifiers are coded in the main data set, with nominative information stored on a separate secure site. Preconception participants who do not achieve pregnancy within 1 year of enrolment and who request medical assessment for potential subfertility issues will be offered a consultation at a hospital fertility service at no cost to the couple. The study consent form provides for the sharing of results of laboratory analysis, contingent on approval by Chinese regulatory agencies. Ancillary studies based on the trial biobank will require ethics approval from the institutional review boards of the above hospitals. This trial has been registered at the Chinese Clinical Trial Registry (http://www.chictr.org.cn/showprojen.aspx?proj=30062).[24] This trial will be reported according to the CONsolidated Standards of Reporting Trials Statement (http://www.consort-statement.org/consort-2010). It was deemed necessary to design and implement a framework in which data sharing can be conducted in an organised and ethically considered manner. We have thus developed a specific Governance Framework that sets overarching standards for ensuring the security and quality of resources held in SCHeLTI. This Governance Framework is also harmonised with the international framework, which streamlines sharing policies across all participating cohorts in the HeLTI initiative.

## Protocol amendment

There were no protocol amendments.

## Dissemination

SCHeLTI is part of an international consortium that receives technical support from the WHO. The results of SCHeLTI and the other three harmonised HeLTI trials will serve to inform WHO guidelines regarding the prevention and management of childhood obesity. As well, SCHeLTI's Knowledge Users network includes representatives from the Canadian Obesity Network, the Chinese Centre for Disease Control, the Public Health Agency of Canada and the Society of Obstetricians and Gynaecologists of Canada. This network will create unique opportunities for public health policy development and knowledge transfer.

The results of the trial will be presented at international scientific meetings and will be submitted for publication to peer-reviewed, open access journals. Key results will be shared with the principal stakeholders, including study participants, via the trial APP-communication platform, MCHUs, hospitals and local and regional government agencies involved in planning maternal and child health services. In accordance with the governance policy of the international HeLTI consortium, while respecting national regulations regarding data sharing, our goal is to share data among researchers both within and external to the consortium, as we have prospectively harmonised indicators of exposures and outcomes across the four HeLTI. The sharing of data across trials for joint analyses will be facilitated.

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