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Preconception-early childhood telephone-based intervention to optimize growth and development among children in Canada: A Healthy Life Trajectory Initiative (HeLTI-Canada)

Submission date
05/02/2019

Recruitment status
No longer recruiting

Registration date
27/02/2019

Overall study status
Ongoing

Last Edited
17/06/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Non-communicable diseases (NCDs), including cardiovascular disease, type 2 diabetes mellitus and mental illness (especially depression), are major global contributors to premature death and disability. Cardiometabolic disease -- hypertension, coronary artery disease, and diabetes -- has risen in prevalence globally in parallel with economic development, urbanisation, an obesogenic lifestyle and obesity. Accelerated growth in infancy and early childhood is a strong risk factor for obesity in older children. Childhood overweight and obesity can further negatively impact on child development. In Canada, nearly 1 in 3 children are overweight or obese, about 1 in 4 are not developmentally prepared for school, and 1 in 5 children has a mental health problem. The HeLTI-Canada study is to determine whether exposure to a four-phase “preconception to early childhood” intervention can (1) reduce child overweight and obese states, (2) improve cardiometabolic risk factors, (3) enhance child development and school readiness by age 5 years, and (4) positively impact parental outcomes when the child is aged 5 years.

Who can participate?
Women planning to get pregnant within the next 3 years, their partners and when possible the first “sibling child”.

What does the study involve?
HeLTI-Canada is a multicentre randomized controlled trial that will include 5230 women planning to get pregnant within the next 3 years. We will recruit 786 nulliparous (no children) and 4444 multiparous women, their partners and when possible the first “sibling child”. These women will be randomly allocated in a 1:1 ratio to the 4-phase preconception-lifecourse intervention or to the control arm. Participants will be recruited all across Canada. The intervention will be provided in 4 phases: (1) preconception, (2) pregnancy, (3) infancy [0-2 years], and (4) early childhood [3-5 years]. For intervention participants, two core strategies will be used throughout the 4 phases: (1) public health nurse collaborative care and (2) individualized e-health cloud platform that includes web-based resources and multi-platform interventions. All

women will be assigned a trial public health nurse (t-PHN), hired and trained by the team, to provide telephone-based collaborative care starting within a week of randomization. The activities provided will include the standard criteria for collaborative care: (1) individual assessment; (2) structured management plan; and (3) scheduled follow-up. Part I: Telephone Assessment. At the beginning of each of the 4 intervention phases, the assigned t-PHN will telephone the woman, complete an assessment based on phase goals, and identify potential risks. Part II: Structured Management Plan. As in most collaborative care interventions, the t-PHN's role will be to: (1) educate the woman and her partner (if applicable) about identified risks and management options; (2) assess management barriers and preferences; and (3) coordinate a management plan with appropriate public health, primary care, and community services. For example, if a woman requires breastfeeding assistance, local supports will be identified. The t-PHN will follow-up on the referrals to promote uptake. Local public health nurses may subsequently refer participants to other community services or programs as necessary and this will be tracked. Part III: Scheduled Follow-Up. The t-PHN will telephone participants every 2 weeks to: (1) review management plans; (2) monitor management initiation and adherence; and (3) track targeted behaviours (e.g., nutrition, physical activity) or symptomatology (e.g., depression). Telephone contacts will last between 15 to 45 minutes based on individual needs. This monitoring will facilitate early detection of risk that can be targeted. Based on behaviour modification and reduced risk, the participant will move from the 'active phase' of the intervention to the 'continuation phase'. During this phase, participants will receive telephone follow-up every 2 months until completion of the phase (e.g., participant becomes pregnant, gives birth, or infant moves into early childhood phase at age 3 years). All participants have the option to proactively call the t-PHN as needed. Women allocated to the control group will have access to standard care provided to all women from preconception to early childhood (child age 5) but they will not receive the preconception-lifecourse intervention. Participants in the control arm will be provided access to standard care and an e-health cloud platform that includes web-based resources related to injury prevention.
All participants will be asked to complete web-based questionnaires and clinical data at baseline and at scheduled intervals during the preconception, pregnancy and postpartum periods. Biospecimen data will be collected from a sub-sample of participants.

What are the possible benefits and risks of participating?
Women and their partners in both groups will have access to all standard care preconceptionally and across the perinatal period until early childhood. Diverse safety protocols have been developed. For example, participants who screen positive for self-harm will be further assessed and referred for care as needed. We will also follow a protocol for infant/child harm if we suspect any potential child abuse/neglect. Adverse events will be reported to and monitored by a data safety and monitoring board.

Where is the study run from?
Mount Sinai Hospital (Sinai Health), Toronto, Canada

When is the study starting and how long is it expected to run for?
July 2017 until December 2032

Who is funding the study?
Canadian Institutes of Health Research

Who is the main contact?
Dr. Cindy-Lee Dennis, Principal investigator.
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Study website
https://www.helticanada.com/

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
HLC – 154502

Study information

Scientific Title
A preconception-early childhood telephone-based intervention with tailored e-health resources for women and their partners to optimise growth and development among children in Canada: A Healthy Life Trajectory Initiative (HeLTI-Canada)

Acronym
HeLTI Canada

Study objectives
Among women (and their partners) planning a pregnancy, when compared to usual care, we hypothesize that the complete 4-phase “preconception to early childhood” life-course intervention will:
1. Reduce child overweight and obese states
2. Improve cardiometabolic risk factors
3. Enhance child development and school readiness by age 5 years (objective 1)
4. Positively impact parental outcomes when the child is aged 5 years (objective 2)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 12/01/2024, Lunenfeld-Tanenbaum Research Institute (Sinai Health) (700 University Avenue, Suite 8-600, Toronto, M5G 1Z5, Canada; 416-586-4875; REB.

Office@sinaihealth.ca), ref: CTO 1776
2. Approved 14/01/2020, St. Michael's Hospital (30 Bond St, Toronto, Toronto, M5B 1W8, Canada; 416-864- 6060; researchethics@unityheath.to), ref: CTO 1776

Study design
Randomized controlled multicenter trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community, Internet/virtual

Study type(s)
Prevention

Participant information sheet
https://www.helticanada.com/about-the-study/

Health condition(s) or problem(s) studied
Obesity among children

Interventions
Current interventions, as of 17/06/2024:

The intervention will be provided in 4 phases: (1) preconception, (2) pregnancy, (3) infancy [0-2 years], and (4) early childhood [3-5 years]. Each phase has time-sensitive goals based on child obesity risk factor meta-analyses and comparable to the international HeLTI studies.

Participants assigned to the intervention arm will receive (1) public health nurse collaborative care and (2) access to an individualized e-health cloud platform that includes web-based resources and multi-platform interventions pertaining to preconception risk factors. We will combine these two different strategies to provide a comprehensive, personalized intervention from preconception to early childhood.

Participants assigned to the control arm will receive access to an e-health cloud platform that includes web-based resources that pertain to safety only.

The study will be conducted with 5230 women planning (intending) to get pregnant. We will recruit 786 nulliparous (15%) and 4444 multiparous (85%) women, their partners, and, when possible, the first “sibling child.” These women will be randomly allocated in a 1:1 ratio to the 4-phase preconception-life-course intervention or to usual care, using web-based central randomization. An “index child” conceived after randomization (n = 3660; 70%) will be followed until age 5 years and assessed for the primary and secondary outcomes. Pregnancy, infancy (age 2 years), and parental outcomes will also be assessed. In addition, among the 4444 primiparous women planning their second pregnancy, their preceding first child (called the “sibling child”), aged 6 months (eligible range 3 to 12 months) when the mother is randomized, will also be followed until age 5 years. This concurrent randomized trial will compare those intervention

phases specific to infancy and early childhood vs. usual care in these “sibling” children. This added component will allow us to estimate the additional effect of the preconception + pregnancy phases of the intervention (which are only received by the index child), beyond that of the infancy + early childhood phases of the intervention (which are also received by the sibling child), while fully preserving randomization.

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Intervention Type
Behavioural

Primary outcome measure
Child overweight and obesity rate (at age 5 years) measured as the proportion of children with BMI >85 percentile using the WHO growth reference ranges, by sex, at age 5 years. Height /length and weight will be measured using standardized instruments and procedures.

Secondary outcome measures
Child outcomes (all at age 5 years):
1.1 The reduction of the mean age and sex-adjusted BMI z-scores at age 5 as well as growth trajectories, as measured by BMI z scores from birth to age 5. BMI-z scores will be defined using

the WHO growth standards, and reference ranges, as appropriate by age. Head circumference will be measured as part of the growth trajectory.
1.2 Cardiometabolic risk (CMR) will be measured as the sum of z-scores from waist circumference, systolic blood pressure, glucose, triglycerides, and (inverse) high-density lipoprotein (HDL). Individual measures will also be examined as continuous variables. Other measures including diastolic blood pressure, blood measures (total cholesterol, LDL, non-HDL, HbA1c, CRP, and insulin) will be collected.
1.3 Health Behaviours:
1.3.1 Dietary intake will be measured using the parent-reported Canadian adaptation of the automated self-administered 24-hour dietary assessment tool (ASA24-Canada).
1.3.2 Physical activity, screen time, and sleep will be measured using questions adapted from the Canadian Health Measures Survey and the 24-hour movement guidelines for children and youth.
1.4 Development and mental health: Cognitive development will be measured using the Wechsler Preschool and Primary Scale of Intelligence (WPPSI-IV) and executive function using the Neuro-PSYchological Assessment NEPSY-II administered by psychometrists.
1.5 Behavioural development will be measured using the Strengths and Difficulties Questionnaire and the Child Behavioural Questionnaire (CBQ).
1.6 Emotional development will be measured using the parent-reported, Age-specific Ages and Stages Questionnaire Socio-emotional Scale (ASQ-SE).
1.7 School readiness will be measured using the Early Development Instrument (EDI).
1.8 Health care utilization will be collected using provincial administrative data (e.g. ICES in Ontario). This will include measurement of routine child outpatient health visits, including adherence to vaccination schedules as per provincial standards; and non-routine outpatient health visits, emergency department visits and unplanned hospital admissions (rate/year, specific diagnoses, and procedures).

Parental Outcomes.
2.1 Weight: Assessed by self-report for women and their partners during the preconception period (12 months and 36 months post-randomization), pregnancy (28 weeks gestation), and postpartum at 24, 36, 48 and 60 months. Overweight and obesity will be calculated using BMI >25 and >30 kg/m2 respectfully as cutoffs.
2.2 Waist circumferences will be assessed for women and their partners during the preconception period (12 months and 36 months post-randomization), pregnancy (28 weeks gestation), and postpartum at 24, 36, 48 and 60 months.
2.3 Mid-upper arm circumference will be assessed for mothers and their partners postpartum at 24, 36, 48 and 60 months.
2.4 Blood pressure and blood measures (e.g., total cholesterol, HDL, TRG, LDL, insulin, glucose, HbA1c, CBC, ferritin and folate) will be collected from mothers postpartum at 24, 36, 48 and 60 months.
2.5 Dietary intake will be measured using the Canadian Diet History Questionnaire II and assessed for women and their partners during the preconception period (12 months and 36 months), from mothers during pregnancy by 28 weeks gestation, and postpartum from mothers at 24 and 60 months and from mothers' partners at 60 months.
2.6 Physical activity will be assessed by questions adapted from the Canadian Community Health Survey, Canadian Health Measures Survey from women and their partners during the preconception period at 12, 24 and 36 months post-randomization, from mothers and their partners during pregnancy by 28 weeks gestation, and from mothers and their partners postpartum at 12, 24 and 60 months.
2.7 Screen time will be assessed for women and their partners during the preconception period (12, 24 and 36 months post-randomization), during pregnancy (by 28 weeks gestation), and postpartum at 12, 24 and 60 months.
2.8 Parent sleep will be assessed by the Pittsburgh Sleep Quality Index (PSQI) during the

preconception period (12, 24 and 36 months post-randomization), during pregnancy (by 28 weeks gestation), and postpartum at 2, 6, 12, 24, 36, 48 and 60 months.
2.9 Mental Health:
2.9.1 Depression symptoms will be measured by the:
2.9.1.1 Patient Health Questionnaire – 9 (PHQ-9) -- From women and their partners during the preconception period (12, 24 and 36 months post-randomization), during pregnancy (by 28 weeks gestation), and postpartum at 24, 36, and 60 months.
2.9.2.2 Edinburgh Postnatal Depression Scale (EPDS) from primiparous women and their partners during pregnancy (by 28 weeks gestation) and postpartum at 2, 6, and 12 months.
2.9.3 Anxiety will be measured by the GAD-7 and life stress by the Life Stressor Checklist-Revised (LSC-R) from women and their partners during the preconception period (12, 24 and 36 months post-randomization), pregnancy (by 28 weeks gestation), and postpartum (24 and 60 months).
2.9.4 Perceived stress will be measured using the Perceived Stress (PSS) questionnaire from women and their partners during pregnancy (by 28 weeks gestation).
2.9.5 Self-Efficacy will be measured using the GSE questionnaire from women and their partners during pregnancy (by 28 weeks gestation).
Relationship satisfaction with partner will be assessed by the Dyadic Adjustment Scale (DAS) from women and their partners during the preconception period (12, 24 and 36 months post-randomization), pregnancy (by 28 weeks gestation), and postpartum (6, 12, 24, 36, 48 and 60 months).
2.9.6 Social support will be measured from women and their partners during the preconception period (12 and 36 months post-randomization), pregnancy (by 28 weeks gestation), and postpartum (24 and 60 months).
2.9.7 Co-parenting will be determined by the Coparenting Relationship Scale, parenting style, including authoritarian and permissive parenting, by the Parenting Scale, parenting self-efficacy by the Parenting Sense of Competence Scale (PSOC) parenting stress by the Parenting Stress Index Short-Form (PSI-SF) from women and their partners during the preconception period (12 months post-randomization) and postpartum (6, 24, 36 and 60 months).

Infant/early child outcomes:
3.1 Height/length and weight from birth to age 5 years
3.2 Weight gain velocity in the first year
3.3 Percentage of children who cross their growth centile curve at age 0-4 years
3.4 Health Behaviours at age 0-4 years:
3.4.1 Breastfeeding will be assessed using WHO definitions
3.4.2 Nutritional risk by the Nutrition Screening Tool for Every Preschooler (NutriSTEP)
3.4.3 Physical activity, screen time, and sleep by questions adapted from the Canadian Health Measures Survey and the 24-hour Movement Guidelines for Early Years (0-4)
3.5 Development and mental health at age 0-4 years:
3.5.1 Language development determined by the Infant Toddler Checklist (ITC)
3.5.2 Temperament by the Infant Behaviour Questionnaire(IBQ) for children ages 6-15 months, the Early Childhood Behavior Questionnaire (ECBQ) for children ages 18-36 months
3.5.3 Emotional development by the age-specific Ages and Stages Questionnaire Social Emotional scale (ASQ-SE), developmental delay by the Ages and Stages Questionnaire (ASQ-3)

Overall study start date
01/07/2017

Completion date
01/12/2032

Eligibility

Key inclusion criteria
Current inclusion criteria as of 17/06/2024:

1. Non-pregnant female
2. No child OR a child between 3-12 months postpartum
3. Planning a pregnancy in the next 3 years
4. Understands written English,
5. Resides in Canada

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Previous inclusion criteria:

1. Non-pregnant female
2. No child OR one child between 3-12 months postpartum
3. Planning a pregnancy in the next 3 years
4. Understands written English,
5. Resides in Ontario or Alberta

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
5230 non-pregnant women + partners (male or same-sex) + any children age 3-12 months old

Key exclusion criteria
Current exclusion criteria as of 17/06/2024:

1. Type 1 diabetes

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Previous exclusion criteria:

1. Type 1 diabetes
2. Two or more children

Date of first enrolment
14/01/2021

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Canada

Study participating centre
Mount Sinai Hospital (Sinai Health)
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Sponsor type
Government

Website
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ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
We plan to publish the study protocol with all HeLTI co-investigators named as authors. For HeLTI Canada specifically, we plan to publish results from formative work.

Intention to publish date
01/12/2032

Individual participant data (IPD) sharing plan
The Healthy Life Trajectories Initiative (HeLTI) was launched as a joint initiative between the Canadian Institute of Health Research, the Department of Biotechnology of India, the South African Medical Research Council, the National Science Foundation of China and the World Health Organisation. Data sharing and access arrangements are included in the overall HeLTI governance document. The HeLTI consortium is in the process of establishing a Data Access Portal though which investigators can view and request access to data/biospecimens within individual HeLTI country or multiple country datasets. Data access will follow country-specific guidelines and is expected to require submission of a detailed research plan (including study rationale, hypothesis, analytic methodologies and funding support to complete the study /analyses). Once the study is completed the researchers will be required to submit all analytical and derived data with metadata to be integrated into the HeLTI country datasets, so that it is available to other researchers.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Fidelity assessment protocol	07/04/2023	11/04/2023	Yes	No
Other publications	Governance model for the HeLTI Consortium	16/05/2023	17/05/2023	Yes	No