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Study protocol for assessing the effectiveness, implementation fidelity and uptake of attachment & child health (ATTACH™) Online: helping children vulnerable to early adversity

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Abstract

Background Exposure to early childhood adversities, such as family violence, parental depression, or low-income, undermine parent–child relationship quality and attachment leading to developmental and mental health problems in children. Addressing impacts of early childhood adversity can promote children's development, giving them the best start in life. Parental reflective function (RF), or parents' ability to understand their own and children's mental states, can strengthen parent–child relationships and attachment and buffer the negative effects of early adversity. We developed and tested ATTACH™ (Attachment and Child Health), an effective RF intervention program for parents and their preschool-aged children at-risk from early adversity. Pilot studies revealed significantly positive impacts of ATTACH™ from in-person ($n=91$ observations of 64 dyads) and online ($n=10$ dyads) implementation. The two objectives of this study are to evaluate: (1) effectiveness, and (2) implementation fidelity and uptake of ATTACH™ Online in community agencies serving at-risk families in Alberta, Canada. Our primary hypothesis is ATTACH™ Online improves children's development. Secondary hypotheses examine whether ATTACH™ Online improves children's mental health, parent–child relationships, and parental RF.

Methods We will conduct an effectiveness-implementation hybrid (EIH) type 2 study. Effectiveness will be examined with a quasi-experimental design while implementation will be examined via descriptive quantitative and qualitative methods informed by Normalization Process Theory (NPT). Effectiveness outcomes examine children's development and mental health, parent–child relationships, and RF, measured before, after, and 3 months post-intervention. Implementation outcomes include fidelity and uptake of ATTACH™ Online, assessed via tailored tools and qualitative interviews using NPT, with parents, health care professionals, and administrators from agencies. Power analysis revealed recruitment of 100 families with newborn to 36-month-old children are sufficient to test the primary hypothesis on 80

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complete data sets. Data saturation will be employed to determine final sample size for the qualitative component, with an anticipated maximum of 20 interviews per group (parents, heath care professionals, administrators).

Discussion This study will: (1) determine effectiveness of ATTACH™ Online and (2) understand mechanisms that promote implementation fidelity and uptake of ATTACH™ Online. Findings will be useful for planning spread and scale of an effective online program poised to reduce health and social inequities affecting vulnerable families.

Trial registration Name of registry: https://clinicaltrials.gov/.

Registration number: NCT05994027.

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Protocol version Version 1.

Keywords Study protocol, ATTACH™ Online, Effectiveness-implementation hybrid (EIH) Type II study, Quasi-experimental design, Parenting program, Reflective function, Parent–child interaction, Child development, Normalization process theory

Introduction

Background and rationale {6a and 6b}

Impact of early adversities on parent–child relationships and children's development and mental health

Exposure to early adversities such as family violence, parental depression, and low income, undermine children's development and mental health [1–4], with costs to society from lower school achievement, underemployment, and higher rates of chronic disease and mental health problems, over the lifespan [5]. Alarmingly, 50–70% of adult mental health problems stem from exposure to these early adversities [6–9]. Large Canadian population surveys ($n \sim 5000$) reveal that more than 25% of preschool-aged children are raised in families with at least one early adversity [10–12].

Family violence occurs in 4% of childbearing families in Canada, a statistic believed to be low due to underreporting [13]. Negative impacts of exposure to family violence on children's development and mental health are well established [14–17]. For example, 1- to 3-year-olds exposed to family violence experienced significant cognitive (i.e., problem-solving) and fine motor skill delays, assessed via the Ages and Stages Questionnaire (ASQ) – second edition (ASQ-2; $n = 51$) [18]. Similarly, 6- to 18-month-old children exposed to family violence experienced cognitive delays (i.e., communication, personal-social, and problem-solving skills) and gross and fine motor delays assessed via the ASQ-2 ($n = 750$). Affecting 7–19% of mothers [19, 20] and 10% of fathers [21] caring for children under three years of age, parental depression is also well-known to negatively impact children's development and mental health [22–24]. For example, exposed 12- and 24-month-olds ($n = 1555$) had significantly reduced cognitive development characterized by lower ASQ-2 communication scores [25], and exposed 2- to 6-year-olds ($n = 2231$) had reduced ASQ-2 cognitive and gross motor developmental scores [26]. Further, 9% of Canadian children live below the poverty line [27]. Similar impacts of low-income on children's ASQ development scores have also been observed [28, 29].

Early adversities compromise parent–child relationships, characterized by reduced parental sensitivity and responsiveness, and insecure parent–child attachment [4, 30–34]. In turn, these reduced quality parent–child relationships are linked to child/adolescent cognitive, behavioral (e.g., aggression, hyperactivity) and mental health (e.g., anxiety) problems, placing those affected on increased lifetime mental health risk trajectories [4, 34–39]. A systematic review [40] ($n = 30$ studies) revealed that reduced parental sensitivity and responsiveness undermines: (1) children's attachment security, and (2) children's development, especially in cognitive and motor domains. Findings held across a diverse range of cultures [40], including Canadian Indigenous peoples [41].

Parental behaviors and cognitions that often accompany family violence (e.g. inconsistency in infant care, hostility) [42, 43], or depression (e.g., fatigue, reduced concentration) may result in parents misreading or missing children's cues (i.e., reduced sensitivity) and failing to provide feedback appropriate to meet children's needs (reduced responsiveness) [44, 45]. In general, children's development and mental health are negatively impacted when parents are unable to: (1) recognize and respond appropriately to children's cues that signal needs, and (2) regulate their children's mental and emotional states [30], two targets addressed in the Attachment and Child Health (ATTACH™) Online program. The ATTACH™ Online program is poised to address the long-lasting negative impact on children's development and mental health resulting from reduced parent–child relationship quality in at-risk families.

Parent–child relationship quality and parental reflective function (RF)

Sensitive and responsive parent–child relationships are in part, the result of parental RF [46]—parents' capacity to understand their own and their child's thoughts, feelings, mental states, and intentions. Higher parental RF is significantly associated with parent–child relationship quality, specifically parental involvement, communication, limit setting and support of the child, independent of other predictors including adult depression, partner relationship quality, and income [47]. Parental RF enables parents to appropriately regulate their own feelings and behavior as well as their child's [48, 49]. Self-regulation is crucial for accurately perceiving and appropriately responding to a child's cues for comfort, soothing or exploration [49–51], and is characteristic of optimal parent–child relationships. For example, a parent who is unable to recognize their child's fear of separation is not likely to reassure the child that they will return, nor regulate their child's stress response effectively.

Parents' experiences of depression and family violence [52, 53], and related past traumas or adverse childhood experiences (e.g. histories of emotional, physical, or sexual abuse) [54, 55], predict parents' negative and distorted representations of reality and frightened, frightening, or dissociated behaviors during interactions with their young children [52–55]. These parents are at risk for reduced RF, and less sensitive and responsive parent–child relationships, leaving their children at risk for insecure attachment, and long-lasting negative developmental and mental health outcomes [56, 57].

Preschool boys and girls often differ in their development and mental health [58, 59]. A study of 3-year olds ($n=1055$) revealed that boys and girls differed on communication and fine motor skills assessed via the ASQ-3 (third edition, [59]). Another study of 3-year olds ($n=7179$) showed that 12% of boys versus 6% of girls, demonstrated social-emotional problems assessed via the ASQ:Social-Emotional (ASQ:SE, [60, 61]). Further, parents may interact differently with boys and girls, given context. For example, mothers affected by intimater partner violence by men often interact more positively with their daughters than sons [62]. Therefore, it is necessary to consider the impact of biological sex when examining impacts of intervention programs, such as ATTACH™ Online, on children's development and mental health.

RF-focused intervention: ATTACH™ Online program

Preserving and promoting optimal RF in parents who are experiencing adversities enables parents to appropriately attribute affective states to their children and respond accurately to meet their children's needs, thus promoting sensitive and responsive parent–child relationships [50, 63, 64]. Therefore, targeting parental RF improvement may be an effective intervention in tackling the impacts of early adversities on children's mental health and development—the focus of the ATTACH™ Online program.

ATTACH™ pilot studies and pilot results

We conducted a series of seven pilot studies in two phases to examine the effectiveness and impacts of the in-person ATTACH™ program on parent–child relationships, attachment, parental RF, and child development. We employed randomized control trial and quasi-experimental designs, guided by the IDEAS (Innovate, Develop, Evaluate, Adapt, and Scale) Framework™ [2, 56, 65] that emphasizes adaptation of intervention methods to emerging information. ATTACH™ Facilitators were trained researchers with advanced education (doctoral and post-doctoral trainees). Both phases involved at-risk mothers and their preschool-aged children in an inner-city agency serving vulnerable low-income families and two family violence shelters. Outcomes included: (1) parent–child relationship quality assessed via the Parent–Child Interaction Teaching Scale (PCITS) [66]; (2) attachment security assessed via Ainsworth's [67] Strange Situation Procedure (SSP); (3) parental RF assessed via the Parental Reflection Function Questionnaire [68, 69], or transcribed Parent Development Interviews (PDI) [70], coded with Fonagy's 'gold standard' RF scale [71]; (4) children's development assessed via the ASQ-3 [72], and (5) children's mental health assessed via the ASQ:SE [73] and Child Behavior Checklist (CBCL) [74]. Analysis of covariance, independent and paired *t*-tests, and chi-square tests were undertaken as appropriate with one-tailed testing (*alpha = 0.05*) for directional hypotheses. Pilots were powered to identify trends in data from the small pilot samples.

In Phase 1, the first three pilot studies, ATTACH™ significantly improved children's development (ASQ-3 personal-social development; $d=0.98$) [75], parent–child relationship quality ($d=0.34$–0.95) [68, 75], and parental RF ($d=0.51$–2.0) [76]. In Phase 2, the second set of four pilot studies, ATTACH™ significantly improved children's development on the ASQ-3, specifically communication ($d=0.76$), personal-social ($d=0.44$–0.48), problem-solving ($d=0.76$), and fine motor skills ($d=0.81$) [38, 77]. It also improved parental RF ($d=0.56$–0.65), children's mental health, specifically CBCL total externalizing behavioral problems ($d=0.64$), attention ($d=0.74$), aggression, ($d=0.50$), and anxiety ($d=0.62$) and parents' and children's immune cell gene expression linked to reduced inflammation [$F(1,1794)=4.26$] [78]. An intervention-by-adversity interaction was found, whereby ATTACH™ significantly moderated the effect of mothers'

early childhood adversity on their children's immune cell gene expression [75]. When findings were pooled across all seven pilots ($n=91$ observations of 64 dyads), ATTACH™ significantly improved parental RF (OR = 2.3) and parent–child attachment security (OR = 2.29) [77]. Findings from the ATTACH™ in-person program are so compelling that the Harvard Center on the Developing Child named ATTACH™ one of its prestigious Frontiers of Innovation projects (https://developingchild.harvard.edu/innovation-application/frontiers-of-innovation). ATTACH™ Online was also pilot tested with 10 families and findings revealed positive impacts on RF. Parents demonstrated significant improvements in parental RF on the Parental Reflective Functioning Questionnaire (PRFQ) Interest and Curiosity subscale ($p=0.036$) and general RF on both the Reflective Functioning Questionnaire (RFQ) Certainty ($p=0.006$) and Uncertainty subscales ($p=0.012$) from baseline to post-intervention. Whether pilot findings for ATTACH(TM) Online can be replicated with a larger sample remains to be studied.

Integrated Knowledge Translation (iKT) and knowledge user engagement

Our iKT [79, 80] and engagement activities with knowledge users, including parents, health care professionals, and administrators in agencies resulted in targeted ATTACH™ programming and material co-development, co-adaptation, and co-evaluation. Researchers and knowledge users collaborated throughout the pilot studies in project governance, priority setting, and conduct of research. The researchers and knowledge users engaged in level 3 collaboration and community-based participatory research methods from regular meetings and meaningful opportunities for contribution [81, 82]. Key ATTACH™ intervention goals were developed with health care professionals and administrators in partner agencies. Knowledge users in community agencies reported preferring parenting programs that emphasize RF; however, they were often deemed unrealistic and cost-prohibitive to implement as typically involving months to years of intervention or psychotherapy [83–85]. For example, one well-known RF-focused program begins prenatally and lasts for 2 or more years [51, 86]. ATTACH™ was thus designed to be relatively short duration (ultimately 10 weeks reduced from 12 weeks based on parents input in pilots), and feasibly administered by professionals with undergraduate education in a health-related field, typical of partner agency staff. Agency knowledge users also indicated their typical clientele present with more than one early adversity (e.g., family violence, depression, and low-income). Further, RF-focused parenting programs often do not incorporate co-parents, defined as individuals who are a main source of parenting support (i.e., biological or step father, boyfriend, grandmother/father, other relative, friend or other support person, as appropriate) [87, 88]. Co-parents often have an important role in buffering parents from the effects of toxic stress [89–91]. Thus, ATTACH™ was co-designed in pilot work to: (1) help parents in complex circumstances affected by multiple stressors rather than narrowly defined stressors (e.g. family violence, [92]) and (2) include a variety of co-parents, in recognition of typically observed family structures of clients seeking community services and support.

Since the completion of the pilots, additional changes to the ATTACH™ program design derived from knowledge user engagement. To address the broad range of family structures served in partners' agencies, including both sexes and diverse self-reported genders of parents, ATTACH™ was adapted to the child's primary caregiver (whether mother, father, grandparent, foster carer, cis- or trans-gender, etc.) and their source of co-parent support. As a result, ATTACH™ is more applicable across diverse family units and more realistic for implementation in community agencies. Second, ATTACH™ materials were made more ethnically diverse by changing the manual images and employing a variety of cultures in illustrative examples of RF in families. Finally, the training of ATTACH™ Facilitators has been made more accessible through an online 'ATTACH™ Teachable' program for training and accrediting health care professionals to deliver the program (see https://attach.teachable.com/). This resulted in trademarking the ATTACH™ name.

COVID-19 challenge and opportunity

In adjusting to the COVID-19 public health restrictions, the need for effective online health interventions became apparent [93]. Parents were reluctant to see health-service providers at home or clinic due to infection fears for themselves, their child and family [94–97]. Agencies also reduced in-person service delivery to parents and children. Simultaneously, knowledge users including agency staff and parents involved in the in-person ATTACH™ delivery reported that families were desperate to obtain safe support to assist them with parenting, compounded by increasing incidence of financial strain, family violence, and mental health problems [94–97]. Such challenges have contributed to burgeoning developmental and mental health problems in children [98, 99]. Providing accessible, evidence-based interventions to at-risk families in the post-pandemic recovery period may prevent children's long-term development and mental health problems. Thus, the researchers and knowledge users sought to deliver ATTACH™ virtually, rather than in-person and took part in user-engaged design of

an online intervention and data collection approach for ATTACH™. Users preferred Zoom™ [100] for intervention delivery and REDCap (www.project-redcap.org) [101] for data collection and both were successfully pilot tested for feasibility with 10 families. Thus, ATTACH™ Online is poised to address social and health inequities, amplified by the pandemic, by promoting accessibility of parenting support for vulnerable families, including those in rural and remote regions.

In summary, ATTACH™ significantly improves children's development, mental health, parent–child relationships including attachment security, as well as parental reflective function, and immune function. The evidence based, accessible ATTACH™ Online was co-developed with parents and agency partners, has been pilot tested, and is ready for testing effectiveness and examining implementation. Many vulnerable children and their families in Alberta stand to benefit, paving the way for widespread post-pandemic implementation to prevent and address the rising incidence of children's development and mental health problems. Project funding in the amount of $999,013 CAD was provided by the Canadian Institutes of Health Research from 2022–2027.

Study objectives {7}

Informed by an iKT [80] approach that involved researcher and knowledge user collaboration, engagement in project governance, priority setting, and conduct of research [80, 82, 102, 103], we propose an effectiveness implementation hybrid (EIH) Type II study of ATTACH™ Online. The two objectives of this study are to evaluate: (1) effectiveness, and (2) implementation fidelity and uptake [104] of ATTACH™ Online in naturalistic, real-world settings, delivered by community partner agencies serving families affected by early adversity in Alberta.

Objective 1

To assess the effectiveness of ATTACH™ Online on: (1a) the primary outcome of children's development, and secondary outcomes of children's mental health, parent–child relationships (including attachment quality), and parental reflective function by using validated measures before, immediately after, and 3 months after intervention, and (1b) different parent populations (i.e., for whom program works best/worst). Our primary hypothesis is ATTACH™ Online improves children's development in the cognitive domains of communication, personal-social, and problem solving. Secondary hypotheses examine whether ATTACH™ Online improves children's mental health, parent–child relationships, and parental RF. See Fig. 1.

Objective 2

To assess implementation fidelity and uptake of ATTACH™ Online in community agencies serving at-risk families in Alberta, Canada.

Trial design {8}

This EIH Type II [104] study is comprised of a quasi-experimental design evaluation of the community-agency delivered ATTACH™ Online (with measurement pre-intervention, immediately post-intervention, and 3 months post-intervention) as well as an examination of implementation fidelity and uptake [105, 106].

Objective 1: ATTACH™ Online effectiveness

A quasi-experimental design was selected to more closely approximates service delivery models in agencies that do not typically employ control groups. Moreover, given significant differences in randomized controlled trials and quasi-experimental pilot studies [75, 107], any design employing wait-list controls was deemed unacceptable and even unethical by the team including parents, health care professionals, and administrators from engagement activities during the preparation of this proposal. A stepwedge design [108] was also ruled out due to concerns with undue delays in receiving the ATTACH™ Online program. Nonetheless, evaluation of effectiveness of the online version of the program was deemed essential by the team to ensure generalizability of findings to this new intervention modality.

Objective 2: ATTACH™ Online implementation

For the primary outcome of objective 2, implementation fidelity of ATTACH™ Online will be determined by a specially developed tool [109] and qualitative interviews using Normalization Process Theory (NPT) [105, 106, 110]. These interviews will be used to explain factors that promote or inhibit implementation fidelity, and can inform strategies to support embedding implementation in practice. Developed in response to recognition of the large gap between intervention development and use in health care—the 'know-do gap'—NPT is intended to uncover factors that interfere with the routine or "normal" incorporation of interventions into health care [111]. The model explores coherence, cognitive participation, collective action, and reflexive monitoring of knowledge users with respect to the implementation of a given intervention. Thus, NPT is ideal for guiding our qualitative semi-structured interviews and analyses. Findings on the mechanisms of ATTACH™ implementation will guide activities to promote the normalization and integration of the ATTACH™ Online into routine community care for parents and children at-risk. Qualitative

	Study Period				
	Enrollment	Allocation	Post-allocation		Close-out
Timepoint	**-t1**	**0**	**+t1**	**+t2**	**+t3**
Enrollment					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
Intervention			*ATTACH™*		
Data Collection					
Demographics	X				
ACE	X				
APAS	X			X	X
ASQ-3	X			X	X
ASQ:SE	X			X	X
BRS	X			X	X
CTS2-SF	X			X	X
EDS	X			X	X
PRFQ	X			X	X
PCITS	X			X	X
Fidelity			X	X	

Notes:
ACE=Adverse Childhood Experiences Questionnaire
ASQ-3=Ages and Stages Questionnaire-3rd Edition
ASQ:SE=Ages and Stages Questionnaire Social-Emotional
ATTACH™=Attachment and Child Health Parenting Program
APAS=ATTACH™ Pre-school Attachment Screen
BRS=Brief Resilience Scale
CTS2-SF=Revised Conflict Tactics Scale-Short Form
EDS=Edinburgh Depression Scale
Fidelity=ATTACH™ Fidelity and Uptake Measure
PRFQ=Parental Reflective Function Questionnaire
PCITS=Parent-Child Interaction Teaching Scale

Fig. 1 Schedule of enrolment, ATTACH™ online intervention, and assessment

interviews will also reveal information on uptake, as well administrative data from agencies about the number of families who took part in ATTACH™ from those eligible.

Methods: participants, interventions, and outcomes

Participants

Objective 1

Parents, co-parents, and children Families including parents, their children under the age of 36 months, and their identified co-parenting support persons are our study population.

Objective 2

Knowledge users These include parents, health care professionals, and administrators from community partner agencies who participate in receiving or delivering the ATTACH™ Online program.

Stakeholder engagement

Building on our pilot work, we systematically engage stakeholders in our study planning, design, and implementation. Stakeholders and researchers engaged in multiple meetings at formative stages. Together, we identified ATTACH™ Online agencies for training and

delivery, made changes to the ATTACH™ Online program, designed terms of reference, and selected the outcomes of interest. Key stakeholders include the Principal Knowledge User (Pilipchuk) and members of the Community Engagement Committee. Pilipchuk is Executive Director of the Alberta Council of Women's Shelters, the provincial network organization of domestic violence shelters in Alberta that serves 40 members operating 50 agencies. She connected the team with participating shelters whose leaders (e.g., administrators such as Executive Directors and health care professionals) are key community knowledge users on the Community Engagement Committee. Other Community Engagement Committee members are agency leaders operating services for low-income teen mothers and for families at-risk or affected by significant adversity and trauma. These team members will participate in project roll-out, may be interviewed, offer advice on implementation, have opportunities to take part in ATTACH™ Online training, and independently deliver and collect data on the program. GRIPP-2SF [112, 113] will be used to report on study engagement.

Study setting {9}

Settings include approximately eight Alberta agencies serving culturally diverse clients (i.e., Caucasian, Black, Indigenous, People of Colour [BIPOC], and immigrants) affected by family violence, depression, and low-income.

Eligibility criteria {10}

Objective #1

The study inclusion criteria are: (1) parents with children between birth to 32 months of age at enrollment (our age ceiling is 36 months, based on selection of age-appropriate tools for assessing children), (2) parents who agree to participate in the ATTACH™ Online program consisting of 10 weeks of one-hour per week parent training sessions, (3) parents who agree to bring a co-parent for 2 of the 10 sessions, and (4) parents who are proficient in speaking and reading English.

Objective #2

Participants (i.e., parents, health care professionals, and administrators) must be adults (18 years of age or older), proficient in speaking and reading English, and knowledgeable or experienced in parenting programs.

Intervention {11a, 11b, 11c and 11d}

To deliver the ATTACH™ Online program, health care professionals in collaborating agencies are required to undergo 40 h of online and in-person training with ATTACH™ Master Trainers, over 2–3 months. After completion of all requirements, these knowledge users are certified Facilitators, able to deliver the ATTACH™ Online program and collect evaluation data. They will deliver the intervention independently, but supported by ATTACH™ Master Trainers. ATTACH™ Online sessions with parents take one hour, occur weekly over 10 weeks and include three components including discussions of: (1) Digital video recordings of 3–5-min parent–child play sessions, (2) Hypothetical, mildly stressful situations (e.g., infant feeding challenges), and (3) Day-to-day real-life stressful situations of parents' choosing for details, (see published papers: [75, 77, 109, 114]). During sessions, certified ATTACH™ Facilitators explore the parents' perceptions of themselves and their children's thoughts, feelings, intentions, and mental states, to maximize opportunities to practice RF. For example, a mother may be asked to consider what may be happening in her mind and the mind of her child during a shared smile in the video recorded interaction. After establishment of a therapeutic relationship with the ATTACH™ Facilitators parents invite their co-parenting support person to attend 2 sessions, usually sessions 7 and 9. Social support (e.g. information about community resources, emotional and affirmational support) is also provided as needed. Our goal is to have at least 2 health care professionals at each of the eight agencies trained to deliver the ATTACH™ Online program (for a total of 20 ATTACH™ Facilitators trained in online delivery).

Outcomes {12 including 12.1, 12.2, 12.3, 12.4, and 12.5}

A robust data collection protocol was developed during the ATTACH™ Online pilot, revealing that measures are feasible to effectively administer online and with REDCap (www.project-redcap.org). Please refer to Fig. 1.

Objective 1 primary outcome

Children's development We will employ the parent-report ASQ-3 [72] to assess newborn to 36-month-old children's development, specifically communication, personal-social skills, and problem solving) and motor (i.e. gross and fine) domains of development. The ASQ-3 is suitable for 1–66-month-olds, with questions assessing children's abilities to undertake age-appropriate tasks. Summing items in each domain provides total scores (maximum 60) with higher scores indicating more optimal outcomes. The ASQ-3 has strong internal consistency reliability (82-0.88), sensitivity (0.86), specificity (0.85) [115], and identifies children at risk for development problems [116] with age-appropriate cut-offs (i.e., delay) in each domain. Taking 10–15 min to complete, the ASQ-3 is typically administered in community agencies, thus both agencies and our pilot parents judged this measure acceptable and feasible.

Objective 1 secondary outcomes

Children's mental health We will employ the parent-report ASQ:SE [73] to assess newborn to 36-month-old children's mental health. The ASQ:SE is suitable for 1–72-month-olds, with 30 items summed to assess social-emotional development, and lower scores indicating more optimal outcomes. The ASQ:SE exhibits good internal consistency reliability (0.67–0.91), sensitivity (0.78), specificity (0.84) [73], and provides age-appropriate cut-offs to indicate risk for mental health problems. Taking 10–15 min to complete, the ASQ:SE is typically administered in community agencies, thus both agencies and our pilot parents find these measures acceptable and feasible.

Parent-Child Relationship Quality and Attachment will be measured with the PCITS [66] and ATTACH™ Preschool Attachment Screening tool (APAS) developed for this study. The PCITS [66] is an observational binary measure of relationship quality in an everyday teaching situation, designed for children 36 months or younger. Considered the gold standard for the assessment of parent–child relationship quality, PCITS consists of 73 items categorized into 6 subscales including parental sensitivity to cues, responsiveness to distress, cognitive growth fostering, and socio-emotional growth fostering, child clarity of cues and responsiveness to parent as well as parent total, child total, and parent–child total scores. Reliability and validity are well established [117] and was a strong measure of intervention impact in our pilot studies [68, 75, 118]. The observation typically takes 5 min and is video recorded to enhance the accuracy of data coding. ATTACH™ Facilitators who are health care professionals in agencies will be trained to collect the video recordings via Zoom™. A robust Zoom data collection protocol was developed during the ATTACH™ Online pilot study for PCITS. Coders, reliable at 90th percentile with the University of Washington and who retained > 95% intrarater reliability over the course of pilot studies on 10% of recoded videos, will code all video recorded interactions. Coders are trained and supervised by Letourneau who has been a certified PCITS trainer since 1996 and has consistently maintained reliability in the delivery of the PCITS.

The ATTACH™ Preschool Attachment Screening (APAS) tool, designed to be used with children between 24 months – 60 months, was developed to screen attachment pattern, based on coding a 5-min free play session in which a primary caregiver (parent, guardian, or custodian) is asked to "frustrate" the child by removing the desired toy of interest from the child during a play session. Such frustration tasks are commonly used in studies that examine children's emotion regulation (e.g., [119–123, 124]). During the 5-min free play session, caregivers are instructed to 'play with their child as they normally would' for the first three minutes of the play session, and then after receiving a cue from the camera person (usually three tapping sounds made by tapping on the camera) the caregiver is signaled to remove and disallow the child from playing with a favored toy (by holding the item behind the caregiver's back) for one minute to induce mild frustration in the child. Then after receiving another cue from the camera person (usually three tapping sounds made by tapping on the camera) the caregiver is signaled to return the desired toy of interest to the child for the last minute of play.

Coders focus on the child's response during the frustration portion of the play session and how the caregiver may (or may not) repair the breach in the dyadic play. The child's response to this stressful event provides valuable information about the caregiver- child relationship and the child's attachment pattern. Trained coders observe the child's response and have reliably and validly classified the child's attachment pattern as either secure (Type B) or insecure (Type A, C, D) [124].

Parental RF This will be assessed via the PRFQ [125], an 18-item measure, with subscales assessing: (1) pre-mentalizing, (2) certainty about mental states, and (3) interest and curiosity about mental states. Higher scores indicate higher levels of parental RF. The PRFQ has good internal consistency (0.7–0.84) and takes 5 min to complete. Pilot testing revealed the PRFQ detected intervention impacts and was acceptable to parents. In our other work [68], we show that scores on the PRFQ associate significantly ($p < 0.05$) with the gold standard Parental Development Interview [70] coded with Fonagy's 11-point scale [71]. Given the gold standard requires 1–2 h per parent interview, followed by 1 h to check automated transcriptions, and 3 h of coding per interview (~6 h total), the use of the PRFQ reduces parent burden, costs, and is feasible to implement in agencies.

Objective 2 primary outcomes

Implementation fidelity assessment ATTACH™ Online implementation fidelity will be assessed via a published, validated, ATTACH™ specific fidelity tool [109] that was developed to assess health care professionals' adherence and delivery of key ATTACH™ intervention elements (i.e., video feedback of parent–child interactions, real life stressful and hypothetical situation reviews). Fidelity will be assessed more broadly by NPT interviews with parents, health care providers, and agency administrators by eliciting participants' perceptions of facilitators and

barriers to achieving fidelity of delivery of ATTACH™ Online elements and potential remedial strategies.

Objective 2 secondary outcomes

Uptake of ATTACH™ Online by agency clients will be quantified as a percentage score based on the number of families delivered ATTACH™, divided by the number of eligible families in a given agency. NPT interviews will further determine participants' perceptions of facilitators and barriers to uptake and potential strategies to promote uptake.

Participant timeline {13}

Objective 1

Pre-intervention Prior to starting ATTACH™ Online, pre-intervention assessment data including observations, questionnaires, and administrative sources are collected.

ATTACH™ Online The program begins after the pre-intervention data collecction is completed–usually the following week. ATTACH™ Online sessions are described above in {11}:

Post-intervention phase The ATTACH™ Online intervention must be complete before post-intervention assessment which includes parents' provision of observational and questionnaire data.

Delayed post-intervention Three months after the post-intervention data collection is complete, parents will be reassessed, providing questionnaire data.

Objective 2

To describe implementation fidelity and uptake of the ATTACH™ Online intervention and to explore the mechanisms influencing these outcomes, recruitment for participation in NPT interviews will begin shortly after the first family completes the ATTACH™ Online program. Recruitment will continue until data saturation is attained, i.e., the degree to which new data repeats or is redundant with what was expressed in previous data [126, 127]. We will employ a stopping rule. Data collection in a category (parent, health care professional, and administrator) will cease when three interviews in a row offer less than 10% new information (i.e., only one question of the 13–15 interview guide questions offers new information).

Sample size {14 including 14.1}

Objective 1

Quantitative component We will examine pre-intervention/post-intervention differences from the primary outcome of development, and our secondary outcomes of children's mental health, parent–child relationship and attachment quality and parental RF with 100 parents and children (aged newborn to 36 months). We will recruit 100 families, to attain a sufficiently powered N of 80 families with complete data, assuming up to 20% incomplete data. This is based on power of 0.90, and two-tailed *alpha* ($p < 0.05/3 = 0.0167$, given Bonferroni correction applied for separate comparisons using three developmental outcomes. Pilot data from the in-person ATTACH™ program tests revealed effect sizes for child development, ranging from $d = 0.44$–0.98 for communication, personal social, problem-solving skills [75, 77, 107]. Thus, eighty complete participant family data sets will be sufficient to detect conservatively moderate effect sizes for within group differences ($d = 0.44$) for each of the three developmental outcomes (communication, personal-social, problem-solving) between pre-intervention and immediately post-intervention. Multiple discussions with agency knowledge suggest feasibility to recruit an average of 8–10 families (including parents, co-parents, and children) from each agency from rosters of parents currently seeking service and to retain them for 3 months post-intervention for follow-up. Any longer was deemed unrealistic given potential for parent relocation.

Objective 2

ATTACH™ Online implementation From discussions with agency administrators, it will be feasible to recruit 20 parents, 20 health care professionals, and 20 administrators (total n = 60) for interviews.

Recruitment {15}

Objective 1

ATTACH™ Online effectiveness Every partner agency will recruit 2–5 health care professionals for ATTACH™ Online training to become the ATTACH™ Facilitators. To partake in ATTACH™ Online, participants will be identified through partner agencies. We will recruit up to 100 parents and their newborn to 36-month-old children to retain 80 complete pre- and post-intervention data from approximately eight Alberta agencies. Parents will be recruited from rosters of parents currently seeking services at these agencies. ATTACH™ Online information

sheets and brochures will be posted on agency implementation sites. Agency staff will assist with recruitment as participants seek their services in routine care.

Objective 2

ATTACH™ Online implementation Parents, health care professionals providers, and administrators from each of the 10 agencies will be recruited via convenience sampling methods.

Methods: data collection, data management, statistical methods, monitoring, and analysis

Data collection methods {18a (18a.1, 18a.2) 18b}

Objective 1: ATTACH™ Online effectiveness

Knowledge users at agencies and researchers agreed to reduce parent burden from data collection. Thus, demographic data will be obtained from agency administrative records as much as possible, e.g., ethnicity, sex, gender, first language, marital status, education, employment, number of children, and age (parents and children) at baseline. To further reduce burden, many measures have been selected from intake data collection already conducted in agencies, e.g., ASQ-3 [72]. We will include covariate measures of adversities that are often administered at parent intake for: (1) Depressive symptoms with the Edinburgh Depression Scale (EDS) [128, 129], a 10-item self-report tool to measure depression with sensitivity of 66.7–69% and specificity of 67.7% that takes 5 min to administer, (2) Family violence with the Revised Conflict Tactics Scale-Short Form (CTS2-SF) [130], a 20-item questionnaire with internal consistency of 0.79–0.95 that takes 3 min to complete, and (3) Parents' adverse childhood experiences with the Adverse Childhood Experiences (ACE) [131] Questionnaire, consisting of 10 questions, with extensive reliability and validity data that takes less than 3 min to complete. To assess the covariate of parent strengths in the face of adversity, the Brief Resilience Scale (BRS) [132] will also be administered, a 6-item tool with internal consistency ranging from 0.80–0.91 that takes 3 min to complete. All questionnaire data will be collected at baseline, immediately post-intervention, and 3 months post-intervention by agency health care professionals/ATTACH™ facilitators, who will be trained and supervised to collect questionnaire data via REDCap (www.project-redcap.org) using iPads provided during the ATTACH™ training.

Objective 2: ATTACH™ Online implementation

Basic demographic data will be collected from knowledge users, including age, sex, gender, employment, and education. Fidelity will be assessed via the published, validated, ATTACH™-specific fidelity tool [109] completed by health care professionals after every ATTACH™ Online interaction with parents. Uptake information will be obtained from agency administrative data via a brief survey given to agency leaders. NPT interviews will further examine implementation fidelity and uptake and mechanisms to promote more optimal delivery of ATTACH™ Online. Interviews will begin shortly after the initially enrolled parents complete the intervention and continue until data saturation. An NPT-guided interview was created to assess implementation and finalized with input from knowledge users engaged in review, feedback and decision making and pilot tested before use. Interviews will be digitally audio recorded with Zoom [100] and automatically transcribed verbatim with Otter.ai [133, 134], and checked for accuracy, with privacy protections in place to guard participant identity and personal information.

Data management {19}

Partner agencies will collect the ATTACH™ Online participants' data via iPads with REDCap software installed, as per best practice recommendations [101, 135, 136]. Agency health and professoinals/ATTACH™ Online Facilitators will be trained and supervised to employ the iPads and REDCap as part of the ATTACH™ Online Training Program. Partner agency health care professionals/ATTACH™ Online Facilitators will be provided with a login information to access the baseline, immediate post-intervention, and delayed post-intervention questionnaires. After logging in, Facilitators will ask the participant to fill out the questionnaires, which will only request de-identified data (except for required linkage to consent, filed separately); data will be automatically shared to the REDCap website after completion. Any data sharing or communication from the partner agencies will be done via the University of Calgary domain specific email account. Digital video data will be saved on the iPads and uploaded to secure Box on the cloud (https://www.box.com/en-ca/capture). The staff at the local agencies will be trained to delete any digital data from the iPads, once securely uploaded. Digital copies of transcripts and audio files will be kept in a secure network location administered by the University of Calgary's Information Technology services and accessible only to the research team. Data collected from administrative sources for assessment of uptake will be shared and stored securely. Any data sharing or communication from the partner agencies will be done via the University of Calgary domain specific email account.

All the information contained in our analyses and summaries will be anonymous and based on group data. Published reports will not identify participants by name, address, agency, or any other personal

information. Furthermore, all research team members are aware of the importance of maintaining participant anonymity and are required to sign a confidentiality agreement.

Statistical methods {20a (20a.1), 20b and 20c}

We will analyze the demographic characteristics of the sample with measures of central tendency and frequencies as appropriate. Alpha will be set a priori at 0.05 (two-tailed) unless testing directional hypothesis (one-tailed).

Objective 1: ATTACH™ Online effectiveness

For (1a), to evaluate ATTACH™ Online program effects on children's development (primary outcome), children's mental health, parent–child relationship and attachment quality, and parental RF (secondary outcomes) immediately post-intervention and at 3 months post-intervention, we will employ repeated measures analysis of variance (ANOVA), paired-t-tests, and chi-square tests to examine outcomes between baseline, immediate post-intervention, and delayed post-intervention assessments. We will undertake three sets of analyses for our primary hypotheses tests. For (1b), to determine whether ATTACH™ Online is equally effective across parent populations (and for whom it works best/worst), we will examine differences among sub-groups derived from known covariates through use of independent samples *t*-tests (two groups, e.g., child sex), ANOVAs (more than 2 groups, e.g., race/ethnicity), repeated measures analysis of covariance (with identified covariate) and linear regression models (continuous covariate, e.g., age, years of education).

Additionally, we will consider child sex as a covariate and stratification variable in our analyses. We will include both mothers and fathers in the ATTACH™ Online implementation and examine impacts on parents as a group, with separate analyses for mothers and fathers, even though fathers are likely to be far fewer in number than mothers. (One of our partner agencies serves many fathers). We will also consider gender in our analyses. Parents will report the gender that they identify with, preferred pronoun, and preferred term for themselves as a parent, e.g. mother, father, or another word. While insufficient numbers will likely limit interpretability, we will consider parents' characterizations as cis-, trans-gender, or gender-diverse in analyses. For children, while it is unlikely that preschoolers will be non cis-gender, we will consider parent-reported child gender in our analyses, to the degree possible. These analyses will help determine how the ATTACH™ Online may affect different sex and gender-based patient populations.

Objective 2: ATTACH™ Online implementation

The fidelity assessment tool will be quantified by evaluating adherence to program content elements; each element is coded as Yes (attempted = implemented as intended) or No (not attempted = never asked or failed to perform) [109]. To be considered satisfactory, content fidelity is expected to be 90% or higher for Yes category, or 10–20% or lower for No category [109]. After all participants have been recruited, administrative data will be used to assess uptake with scores tabulated for each agency. Data on variables such as health care professionals' years of experience, age, gender will be collected and considered for their impacts on fidelity and uptake. Qualitative analysis of NPT interviews will involve the stages of thematic analysis including familiarization, coding, theme development, and data reporting [137]. Theme and sub-theme development will be deductive, using a priori codes dictated by interview questions to explain factors that promote or inhibit ATTACH(TM) Online from being embedded in agency practice. Two trainees will code the data, supervised by Letourneau, who is experienced in qualitative data analysis. Coding will inform when data saturation is reached. Data will be managed with Dedoose [138]. Data from parents, health care professionals, and administrators will be coded separately, and coding trees examined for similarities and differences *post-hoc*. Once themes and sub-themes are finalized, findings summarized in draft reports will be shared with key informants as a validation check [139]. Data from parents, health care professionals, and administrators will be coded separately, and coding trees examined for similarities and differences *post-hoc*.

Methods: monitoring

Data monitoring {21a, 21b}

Because this is a social intervention, not a drug or pharmaceutical trial, there is no data monitoring committee or interim analysis [114].

Harms {22}

Observed incidents such as mental health crises, will be documented and managed as necessary by agency personnel delivering ATTACH™ Online (e.g., by providing appropriate comfort measures as well as mental health referrals). It is important to note that ATTACH™ Facilitators are also employees of health and social service agencies who serve the clients/participants. If the investigators or ATTACH™ Facilitators interacting with these families observe child abuse, they will report it to the Law Enforcement Authorities, as is required by law.

Auditing {23}

As ATTACH™ is a social intervention rather than a drug or pharmaceutical trial, there is no data auditing [114].

Ethics and dissemination

Research ethics approval and consent or assent {24 and 26a}

Ethics approval has been obtained from the Conjoint Health Research Ethics Board (CHREB; Ethics ID: REB20-0903) of the University of Calgary, and all participants undergo a process seeking their informed consent. The University of Calgary is the lead agency conducting this study and partner agency research sites rely on CHREB's approval as part of their agency ethics protocols. All funding and research guidance flows from the University of Calgary and while partner agencies will typically not have access to the study data, nor have direct involvement in data analysis or data storage, some knowledge users involved in the project may become more involved, requiring their addition to the ethics file as needed with all appropriate safeguards for participant safety, anonymity, and confidentiality maintained. All participants will be asked to provide informed consent. The process of informed consent involves verbal consent secured at each stage of the process, including recruitment, screening, intervention, and data collection. Participants will be provided with an electronic consent form for their signature. This will be retained by the study investigators and participants will receive a signed copy. We have created different consent forms for the intervention participation and individual interviews to clearly indicate to what participants are consenting (see Appendix 1; Appendix 2).

The voluntary nature of the study will be reinforced verbally throughout the consent process and, indeed, throughout the course of the participants' involvement in the study data collection. They may choose not to answer some questions, or to withdraw from the study at any time without affecting their receipt of the ATTACH™ Online program, health care or other partner agencies' services. If they choose to no longer participate (at any time including once data analysis has begun), we will retain their data for attrition analyses, unless asked explicitly to remove data from the study, in which case we will attain the participants' unique numeric identification (see below, Confidentiality) and delete all relevant data. Staff at the participating agencies will avoid any coercion by letting the potentially interested families know that their participation is completely voluntary, and that they can withdraw any time. Access to agency services will not be affected by participation or withdrawal.

Ethics approval has been received for an adaptive honorarium schedule of gift cards that provides increased compensation commensurate with increased parent burden. This schedule emerged from numerous collaborative conversations with parents and agency health care professionals, and administrators. Study participants will be offered $100.00 in Amazon gift cards in increasing value over 10 sessions. Moreover, each NPT interviewee will be given a $30 gift card, in compensation for a 60–90-min NPT interview.

Protocol amendments {25}

There have been no amendments to the protocol.

Consent or assent {26b}

In ancillary studies, participants' data and biological specimens are not subject to additional consent provisions.

Confidentiality {27}

All data will be held confidentially and stored on a secure network drive. To ensure anonymity, participants will be assigned unique numeric codes in place of names. There will be no use of personal email accounts or emails for communication or for sharing of data. To ensure that participants understand the privacy and confidentiality nature of the study, the staff will ensure that they sign the consent form at the beginning of the study. Additional steps may include reiterating the privacy and confidentiality nature of the study before initiating the video recording.

The partner agencies' ATTACH™ Facilitators will collect demographic information about parents. Apart from the consent form (stored separately), partner agencies will only share de-identified data associated with participants' unique numeric codes, with the ATTACH™ Online team. The demographic information will be used to describe the sample in publications. The interactions between the parents and children will be video recorded for the purpose of assessing the quality of parent–child interaction and attachment, and these digital video data will be password protected and encrypted. Participants will only be identified by an ID number, so researchers will not have access to any identifying information. Any identifying information will be removed from the beginning and replaced with an ID number for analysis. Only the research team will have access to questionnaire response data. All information provided by participants will be kept confidential, except when it needs to be reported as required by law (such as when participants express a desire to do harm to themselves or others). Participants will not be identified in any publications or presentations that result from this research. The findings will be presented at health conferences and published

in scientific journals as aggregate data. Any information that could identify participants will not be included.

Declaration of interests {28}

No competing interests are declared by the authors.

Access to data {29}

Data used and/or analyzed during this study may be made available by the corresponding author upon request and in compliance with the University of Calgary and ATTACH™ Online program research collaboration and data transfer guidelines.

Dissemination policy {31a, 31b, 31c}

Our team including researchers and the Community Engagement Committee members, will generate an array of dissemination products, including traditional high-impact peer-reviewed papers and presentations as well as innovative products such as in-services, social media posts, infographics, and opinion-editorials. Principal knowledge user Pilipchuk will share progress/findings in the network of the Alberta Council of Women's Shelters, promoting widespread ATTACH™ Online program uptake. We will continue our ongoing ATTACH™ webinar series (see https://attach.teachable.com/ p/webinar-series), sharing progress and emerging findings with a wide audience. Publications will adhere to CIHR's open access policy (http://www.cihr-irsc.gc.ca/e/46068.html) as well as CIHR's sex and gender-based analysis policy (http://www.cihr-irsc.gc.ca/e/ 50,833.html). Reporting guidelines will be employed in published papers, e.g., Consolidated Standards of Reporting Trials (CONSORT) [140, 141], Template for Intervention Description and Replication (TIDieR) checklist [142], GRIPP-2SF [112, 113], and Consolidated Criteria for Reporting Qualitative (COREQ) [143] research.

Discussion

Harvard University's Center on the Developing Child suggests that achieving improved development and mental health of children exposed to early adversity (e.g. family violence) requires effective early interventions focused on supporting parent–child relationships [2, 56, 65]. Interventions that focus on promoting parental RF in the context of parent–child relationships have perhaps the greatest potential to improve development and mental health for these at-risk children [85, 144]. Should the findings reveal effectiveness and mechanisms for ATTACH™ Online that facilitate implementation fidelity and uptake, efforts will be undertaken to spread and scale the program across Alberta, and ultimately Canada and globally, addressing societal health inequities that begin in early childhood from exposure to adversities. We have thoroughly pilot tested all approaches and the current study will evaluate of the effectiveness of ATTACH™ Online with a larger sample. Our naturalistic design and deliverables are feasible, based on past and planned engagement and extensive pilot work, and partnership with agencies delivering the program in the context of their services for families affected by adversities. Findings on the mechanisms of ATTACH™ implementation will guide activities to promote the normalization and integration of the ATTACH™ Online into routine community care for parents and children at-risk of developmental and mental health problems. Successful implementation of ATTACH™ Online has the potential to promote health equity of families affected by toxic stress and could serve as a population health strategy [145].

Status of trial

Recruitment in progress; start date of recruitment: Fourth-quarter, 2022.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12887-024-05232-w.

Supplementary Material 1.

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Adherence to national and international regulations

Not applicable.

Administrative information

Note: the numbers in brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/).

Section/item	Item No	Description
Administrative information		
Title	#1	Study Protocol for Implementing and Testing Attachment & Child Health (ATTACH™) Online: Helping Children Vulnerable to Early Adversity
Trial registration	#2a and #2b	https://clinicaltrials.gov/ Registration number: NCT05994027 Date of registration: July 22, 2023
Protocol version	#3	May 1, 2023, Version 1
Funding	#4	This study is funded by the Canadian Institute of Health Research (CIHR) Mental Health in the Early Years (MHITEY) Multi-Year Grant

Section/item	Item No	Description
Roles and responsibili-ties	#5a	Nicole Letourneau, Owerko Centre at the Alberta Children's Hospital Research Institute, University of Calgary, Calgary, AB Role: Nominated Principal Applicant, Knowledge Mobilization Lead Lubna Anis, Owerko Centre at the Alberta Children's Hospital Research Institute, University of Calgary, Calgary, AB Role: Researcher/ Master trainer Cui Cui, Children's hospital of Chongqing Medical University, China Role: International student Ian D. Graham, University of Ottawa, Ottawa, ON Role: Principal Applicant Kharah Ross, Centre for Social Sciences, Athabasca University, AB; Department of Psychology, University of Calgary, AB Role: Principal Applicant Kendra Nixon, University of Manitoba, Winnipeg, MB Role: Principal Applicant Jan Reimer, Alberta Council of Women's Shelters, Edmonton, AB Role: Knowledge User Miranda Pilipchuk, Institution Alberta Council of Women's Shelters Role: Principal Knowledge User Emily Wang, Hull Social Services Role: Knowledge User Simone Lalonde, University of Calgary, Calgary, AB Role: Person with Lived Experience (Patient/Parent), Knowledge User Suzanna Varro, University of Calgary, Calgary, AB Role: Person with Lived Experience (Patient/Parent), Knowledge User Maria Jose Santana, University of Calgary, AB Role: Principal Applicant Ashley Stewart-Tufescu, University of Manitoba, Winnipeg, MB Role: Principal Applicant Angela Soulsby, University of Manitoba, Calgary, AB Role: Member of the Parent/Patient Engagement Committee (PEC) Barbara Tiedemann, University of Calgary, Calgary, AB Role: Patient (Parent), Knowledge User Leslie Hill, Discovery House Family Violence Prevention Society, Calgary, AB Tiffany Beks, Hull Social Services, Calgary, AB Role: Knowledge User Martha Hart, Owerko Centre at the Alberta Children's Hospital Research Institute, University of Calgary, Calgary, AB Role: Collaborator/ Project Lead
	#5b	CIHR funded, investigator-initiated trial and implementation design study; N. Letourneau (Principal Investigator) Contact: Nicole.letourneau@ucalgary.ca
	#5c	Study initiated by an investigator where the funders are not involved in the design of the study, collection of data, analysis of data, or writing the protocol for the study
	#5d	The ATTACH™ Team Executive Committee will oversee all project activities, chaired by N. Letourneau and co-chaired by Pilipchuk with support from Ross and Stewart-Tufescu and people with lived experience Lalonde and Varro and Community Engagement Committee Co-Chairs Pilipchuk and Wang. Project Manager Hart will also serve on the Executive Committee along with Nixon

Authors' contributions

Conceptualization: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Literature review: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Study Protocol Development: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Validation: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Writing—original draft preparation: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Writing—review and editing: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Resources: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. Funding acquisition: NL, LA, CC, IDG, KR, KN, JR, MP, EW, SL, SV, MJS, AST, AS, BT, LH, TB, and MH. All of the co-authors have read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Ethics approval has been obtained from the Conjoint Health Research Ethics Board (CHREB; Ethics ID: REB20-0903) of the University of Calgary, and all participants will undergo a process of informed consent. The University of Calgary is the lead agency conducting the study and partner agency research sites rely on CHREB's approval as part of their agency ethics protocols. All funding and research guidance flows from the University of Calgary and partner agencies will not have access to the study data, nor will they be involved in data analysis or data storage. The participants will be asked to provide informed consent. We have created different consent forms for the individual interviews and intervention participation to clearly indicate to parents what they are consenting to participate in (see Appendix 1 and 2).

Consent for publication

Not applicable.

Competing interests
The authors MH and NL are co-owners of the for-profit and not-for-profit companies engaged in delivering ATTACH™. All other authors have no competing interests to report.

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