Tools and Resources to Prevent Childhood Obesity in Primary Care

by

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Abstract

Background. Tools and resources (TRs) can help to prevent obesity in children, particularly in settings that are accessible to families and well-aligned with chronic disease prevention, such as primary care. To date, little is known about the TRs that primary care providers (PCPs) currently use to prevent childhood obesity and how they can be evaluated, and if brief and novel eHealth (electronic Health) tools can be applied to help parents prevent childhood obesity when delivered in primary care.

Objectives. To *(i)* pilot test a new method to evaluate TRs that PCPs currently use for preventing childhood obesity in primary care, and report a preliminary descriptive assessment of these TRs, and *(ii)* develop, refine, and pilot test a brief eHealth tool delivered in primary care to help parents prevent obesity in children.

Methods. This doctoral thesis includes a mixed methods study (Study 1) and a multi-phased study (Study 2). The first study included individual semi-structured interviews with PCPs (Phase I) and evaluated currently used TRs across three assessment checklists (Phase II). Feedback was obtained from PCPs on our coding scheme and checklist data at follow-up (Phase III). The second study included the development of a parent-based digital screening, brief intervention and referral to treatment (SBIRT) (Phase I), which was subsequently refined using focus groups with parents and stakeholders (Phase II). The modified version was pilot tested using a randomized controlled trial in primary care to assess feasibility and preliminary impact (Phase III).

Results. For study 1, criteria on the checklists overlapped with PCPs' perceptions of the suitability of TRs, but did not reflect the logistical factors that impacted their use. PCPs (n=19) reported using 15 TRs, most of which scored 'adequate' on the three checklists. For

study 2, the SBIRT was developed by our research team and industry partners based on existing models and contemporary literature on children's lifestyle behaviors. Refinements to the SBIRT were guided by feedback from five focus groups with health care professionals (n=20), parents (n=10), and researchers (n=8); participants viewed the SBIRT as a practical, well-designed eHealth tool, but suggested improvements to specific elements, such as weight-related terms that may elicit negative reactions from parents. Lastly, the SBIRT was pilot tested with parents (n=226) in primary care. The level of recruitment (n=226/268; 84.3%) and the proportion of parents who self-selected resources (n=194/226; 85.8%) within the SBIRT supported feasibility. At one-month follow-up, a greater proportion of parents with unhealthy weight children reported discussing weight with their pediatrician compared to those with healthy weight children (χ^2=15.4; p<0.001).

Conclusions. These studies provided a unique assessment and understanding of TRs that are used to prevent childhood obesity in primary care. The mixed methods evaluation of TRs demonstrated the usefulness of combining feedback from front-line providers with objective assessment data. Our preliminary assessment of TRs that PCPs currently use in Alberta demonstrated there is room for improvement, particularly with respect to readability levels and lack of content diversity beyond nutrition and physical activity. Based on feedback from focus group participants and pilot testing of our newly-developed eHealth tool, the SBIRT was feasible in primary care and may help to nudge parents towards accessing and using TRs that can have a positive impact on children's lifestyle behaviors.

Preface

This thesis is an original work by Jillian LS Avis. The reported research studies, which form this thesis, received ethics approval from the University of Alberta Health Research Ethics Board (Panel B): Study Names "Primary care Resources for Obesity in Pediatrics (PROP)", Pro00042380, approved on October 14, 2014 and "Working with Parents to Prevent and Manage Obesity in Children", Pro00037365, approved on April 18, 2013 and renewed on June 26, 2015.

Chapter 3 of this thesis has been published as J. Avis, A. Komarnicki, A. Farmer, N. Holt, A. Perez, N. Spence, and G. Ball, "Tools and resources for preventing childhood obesity in primary care: a method of evaluation and preliminary assessment." *Patient Education and Counselling* in 2016, vol. 99, no. 5, 769 – 75. Alongside the mentorship of G. Ball, I was responsible for *(i)* designing the study, *(ii)* collecting, analyzing, and interpreting the data, and *(iii)* writing the first draft of the manuscript.

Chapter 4 of this thesis has been published as J. Avis, N. Holt, K. Maximova, T. van Mierlo, R. Fournier, R. Padwal, A. Cave, P. Martz, and G. Ball, "The development and refinement of an e-health screening, brief intervention, and referral to treatment for parents to prevent childhood obesity in primary care." *Telemedicine and e-Health* in 2016, vol. 22, no. 5, 385 – 94. Alongside the mentorship of G. Ball, I was responsible for *(i)* collecting, analyzing, and interpreting the data and *(ii)* writing the first draft of the manuscript.

Chapter 5 of this thesis is under review as J. Avis, T. C. Wild, K. Maximova, N. Browne, N. Holt, A. Cave, P. Martz, C. Ellendt, and G. Ball, "A brief eHealth tool delivered in primary care to help parents prevent childhood obesity: a randomized controlled trial" in

Pediatric Obesity. Alongside the mentorship of G. Ball, I was responsible for *(i)* collecting, analyzing, and interpreting the data and *(ii)* writing the first draft of the manuscript.

The manuscripts presented in chapters 4 and 5 of this thesis represent a nationally- and provincially-funded study (*i.e.,* Canadian Institutes of Health Research; Alberta Innovates – Health Solutions). This study was a collaborative team effort co-led by myself, Dr. Geoff Ball, and nine grant team members from Alberta Health Services, the Government of Alberta Ministry of Health, the University of Alberta, the Edmonton Oliver Primary Care Network, and the Allin Clinic.

Appendix F of this thesis has been published as J. Avis, A. Cave, S. Donaldson, C. Ellendt, N. Holt, S. Jelinski, P. Martz, K. Maximova, R. Padwal, T. C. Wild, and G. Ball, "Working with parents to prevent childhood obesity: a protocol for a primary care-based eHealth study." *Journal of Medical Internet Research – Research Protocols* in 2015, vol. 4, issue 1, e35. Alongside the mentorship of G. Ball, I was responsible for *(i)* refining the study design and *(ii)* writing the first draft of the manuscript.

Appendix H of this thesis has been published as J. Avis, T. van Mierlo, R. Fournier, and G. Ball, "Lessons learned from using focus groups to refine digital interventions." *Journal of Medical Internet Research – Research Protocols* in 2015, vol. 4, issue 3, e95. Alongside T. van Mierlo, R. Fournier, and G. Ball, I was responsible for writing the first draft of the manuscript.

Dedication

I dedicate this dissertation to my inspiring, supportive, and understanding husband, Cáthal; without him, I would not have reached my full potential.

A special feeling of gratitude to my parents, Guy and Lorraine, whose words of encouragement were always there when I needed them. I also wish to thank my intelligent, wise, and witty supervisor, Dr. Geoff Ball, who was with me every step of the way.

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I would like to recognize the staff at the Edmonton Oliver Primary Care Network and the Allin Clinic, who played an integral role in the development, refinement, and pilot testing of the novel eHealth tool presented in Study 2. I would also like to acknowledge the Department of Pediatrics graduate program director, Dr. Sujata Persad, for her guidance, and the graduate studies coordinator, Trish Kryzanowski, for her kind support.

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List of Abbreviations

BMI	Body Mass Index
CIHR	Canadian Institutes of Health Research
eHealth	Electronic Health
HCP	Health Care Professional
mHealth	Mobile Health
PCP	Primary Care Provider
PEMAT	Patient Education Materials Assessment Tool
PROP	Primary care Resources for Obesity in Pediatrics
RCT	Randomized Controlled Trial
RIPPLE	Resource Information Program for Parents on Lifestyle and Education
SAM	Suitability Assessment Measurement
SBIRT	Screening and Brief Intervention and Referral to Treatment
TEMPtEd	Tool to Evaluate Materials used in Patient Education
TRs	Tools and Resources
WCHRI	Women and Children's Health Research Institute

Chapter 1

Introduction

For my doctoral research, I conducted two studies that focused on tools and resources (TRs) to help prevent childhood obesity in primary care. In the first study, I piloted a mixed methods approach to evaluate TRs that primary care providers (PCPs) currently use for preventing childhood obesity in primary care and reported a preliminary descriptive assessment of these TRs. In the second study, I conducted a multi-phased study that included the development, refinement, and pilot testing of a parent-based digital screening, brief intervention, and referral to treatment (SBIRT) in primary care. Please note evolution of terminology over the study period; for the purpose of this thesis, the terms "eHealth tool", "digital/online/technology-based program", and "RIPPLE" (the Resource Information Program for Parents on Lifestyle and Education) all refer to the SBIRT under study.

This paper-based thesis includes two peer-reviewed publications (Chapters 3 and 4), and one manuscript that is currently under review (Chapter 5). This chapter represents the introduction to my thesis, and includes *(i)* background literature, *(ii)* identified knowledge gaps, *(iii)* my personal rationale for embarking on the reported studies, and *(iv)* the objectives of my studies that are accompanied by an outline of each chapter's contribution to my thesis. Additional peer-reviewed manuscripts, which were supplemental to my second thesis study (Avis et al., 2015a; Avis et al., 2015b) are included in Appendices F and H.

1.1. Background

1.1.1. Childhood Obesity

Obesity in children is a common and chronic health condition. The proportion of children classified as overweight or obese has more than doubled over the past twenty-five years (Shields, 2006), and approximately one-in-three Canadian children are currently classified as overweight (body mass index [BMI] 85th – 94th percentile) or obese (BMI 95th≥percentile) (Roberts et al., 2012). In childhood, such children are at increased risk for mental health concerns, such as anxiety and depression, and psychosocial adversities, such as low self-esteem, body image dissatisfaction, weight stigmatization, and bullying (Puhl 2011; Latner & Stunkard, 2003). As excess weight is likely to persist into adulthood (Singh et al., 2008), such individuals are at increased risk for chronic cardiometabolic illnesses (*e.g.,* cardiovascular disease, metabolic syndrome, type 2 diabetes) (Sun et al., 2008). Further, compared to their healthy-weight counterparts, adults with obesity tend to be of lower socioeconomic status (Finkelstein et al., 2005) and are more likely to face psychosocial consequences, including weight-based stigmatization in the workplace (Giel et al., 2012) and post-secondary institutions (Burmeister et al., 2013).

Obesity in children is complex. The complexity of obesity, which is already well-established in the adult population, is amplified in the pediatric population due to factors associated with development and dependency. First, children are not 'miniature-adults' but dynamic beings that continually develop throughout birth to adulthood. Physically, children's height and weight, which are the primary markers for determining obesity at the population-level, are rarely static. As such, unique, age- and sex-specific standards are used to determine overweight and obesity in children (Cole et al., 2000). Cognitively, unlike

adults, children are unable to fully comprehend the causes and consequences associated with obesity, and how improving lifestyle behaviors can reduce obesity-related risks. And psychosocially, depending on their stage of development, children with obesity may be treated differently than their healthy-weight peers; for example, overweight children tend to mature earlier than their non-overweight peers and adults may expect higher levels of cognitive abilities from such children, potentially resulting in disappointment (Dietz, 1998). Second, children represent a vulnerable population who are dependent on caregivers for their biological, psychological, and social needs (Hoey, 2014). Complementary to caregiver's direct support for children's needs is the home environment, and parents' role modelling, monitoring, and reinforcement of lifestyle behaviors (Faith et al., 2012). Both caregiver's direct and indirect provision of children's needs in conjunction with familial factors, such as socioeconomic status, ethnic background, and parenting style, can strongly influence two well-known obesity-related behaviors in children – diet and physical activity. Further, although children are the direct receivers of health benefits from actions taken to improve lifestyle behaviors, caregivers ultimately decide if, when, and which actions to take.

Obesity in children has a multifaceted etiology. Studies have outlined the environmental and genetic risk factors that contribute to childhood obesity, yet evidence remains incomplete because such factors are closely-related and difficult to disentangle. First, several environmental factors are associated with obesity in children. In recent years, the term, "obesogenic environment" has been coined. This term refers to the wide availability of inexpensive and highly palatable foods as well as proliferation of online technology that implicitly encourages sedentary behavior. Further, alongside urbanization and the movement of families from the dense core of cities to suburban neighborhoods, the

feasibility of, and need for, active transportation has decreased (Saelans et al., 2012). Second, studies have shown that genetic heritability may account for more than 40% of variations in children's development of obesity (Wardle et al., 2008). Based on two landmark studies (Stunkard et al., 1990; Stunkard et al., 1986), researchers concluded that up to 80% of weight may be attributed to genetic factors; adopted children's weight status as adults were comparable to their biological (*vs.* adopted) parents, and identical twins, regardless if reared together or apart, demonstrated nearly identical BMIs in late adulthood. To date, one of the most established predictors of obesity in children is biological maternal obesity (Whitaker et al., 1997).

Obesity in children is difficult to treat or manage successfully (Lau et al., 2007). Pediatric weight management represents a suitable avenue of care for children classified as overweight or obese, with most programs employing a multidisciplinary, family-centered, and lifestyle-based approach (Ball et al., 2011). Most large Canadian cities have at least one established pediatric weight management program (Ball et al., 2011), highlighting availability of services to urban families, but research has elucidated the challenges associated with tertiary-level care. First, children need to be referred to such programs by PCPs and a number of barriers at the primary care level, including PCPs' competing demands, and lack of time and hesitancy to discuss children's weights (Perrin et al., 2005), may impede the referral process. Second, of those children referred for care, up to 50% may not initiate treatment (Ball et al., 2012). Of those families that do enroll, a sizeable proportion terminate care prematurely; reasons for attrition include logistical barriers (*e.g.,* work commitments, transportation difficulties), families' mismatched treatment expectations, and lack of motivation to make positive behavior changes (Skelton et al., 2016; Dhaliwal et al.,

2014). Studies have also shown that non-Caucasian adolescents of lower socioeconomic status are less likely to complete treatment compared to their younger, more economically-advantaged Caucasian counterparts (Zeller et al., 2004). This suggests that children at high risk for obesity and its' associated health consequences may benefit the least from treatment. Lastly, of those families that remain enrolled in the program, most children tend to demonstrate weight stabilization and in few cases, modest weight loss over time (Avis et al., 2013).

1.1.2. Prevention

The prevention of any health concern occurs across the disease trajectory, which spans from time of exposure and onset of symptoms to diagnosis and treatment. Although the notion of 'prevention' implies preventing a condition *prior* to onset, in many cases, prevention can refer to the deterrence of further harm among those who are already diagnosed with a health condition. Within the context of childhood obesity, preventing obesity in children can entail both primary (*i.e.,* preventing unhealthy weight gain in healthy weight children) and secondary (*i.e.,* preventing further unhealthy weight gain in children already classified as overweight or obese) prevention. In 1981, G. Rose coined the term, "prevention paradox", which refers to mass preventative strategies that deliver population-wide benefits, but negligible individual-level gains. Although the delivery of resource-intensive interventions to high-risk individuals, such as pediatric weight management for children with obesity, may help to improve individual's disease-related symptoms, the burden of disease at the population level remains relatively unchanged (Rose, 1981). As

such, there is value in applying time- and resource-efficient prevention strategies that have the potential to reduce the burden of disease at a population-level.

To date, interventions to prevent obesity in children have been applied across multiple settings and time points from the gestational period throughout the pediatric lifespan (Dietz & Gortmaker, 2001). Most interventions have targeted children and parents for the main purpose of behavior modification (*e.g.,* reducing children's sugar sweetened beverage consumption [Avery et al., 2015] and sedentary screen time [Maniccia et al., 2011]). Studies have also been directed toward PCPs to encourage routine monitoring of children's physical growth and assessment of weight status, a task that is advocated by expert recommendations (Parkin et al., 2015) but is conducted by less than 40% of providers on a regular basis (Reed et al., 2015). To date, reviews have shown that the outcomes of prevention-focused studies are heterogeneous (Waters et al., 2011) and there is little concrete evidence to support the most effective and efficient method to improve children's lifestyle behaviors and prevent unhealthy weight gain (Dietz & Gortmaker, 2001). However, future research areas are clear. First, the involvement of health care professionals (HCPs) in the development and evaluation of prevention efforts is needed to gain insight on 'real world' clinical issues that may impact obesity in children (Visscher & Kremers, 2015). Second, as noted by Wang and colleagues (2013), few prevention-based interventions have incorporated theoretical underpinnings. As such, new approaches to prevent obesity in children should aim to understand important precursors to health behavior change, a similar observation made by Baranowski and colleagues (1998) regarding interventions to improve the physical activity of children and adults. Lastly, as shown in a recent meta-analysis (Wang et al., 2013), the majority (~75%) of childhood obesity prevention programs have been

conducted in schools and comparably few have taken place in primary care, a setting that is regularly accessed by families and has clinical priorities that are well-aligned with the prevention of chronic diseases.

1.1.3. The Primary Care Setting

In Alberta, primary care networks were developed by the provincial health care system to enhance and coordinate health services delivery in primary care. They include a multidisciplinary team of PCPs (*e.g.,* pediatricians, medical office assistants, registered dietitians and nurses), decision-makers, and administrators, all of whom work collaboratively to address needs of the local patient population. This setting represents a suitable venue for preventing obesity in children for a number of reasons (Seburg et al., 2015): *(i)* the clinical priorities of primary care are well-aligned with the primary and secondary prevention of chronic diseases, such as obesity, early in life (Perrin et al., 2007), *(ii)* primary care is often families' first point of contact with the health care system, and children's healthy lifestyle behaviors are more likely to become habitual when initiated early in life (Morinis et al., 2012), *(iii)* families typically access health care services at primary care throughout their lives, which represents an excellent setting to maintain contact with, and collect information from, families over an extended period (Starfield et al., 2005), and *(iv)* given the trusted relationship that families have with their pediatricians, providers in this setting are uniquely positioned to disseminate evidence-based research regarding obesity prevention (Morinis et al., 2012). Recommendations (Parkin et al., 2015) have reinforced the importance of preventing childhood obesity in this setting by growth monitoring all children and referring those classified as overweight or obese to specialized weight

management programs. Researchers have also reinforced the relationship between obesity prevention and primary care, with a key objective including the early detection of children's unhealthy weight gain (Bourgeois et al., 2016; Nichols & Livingston, 2002).

1.1.4. Key Players in Childhood Obesity Prevention

Parents. To optimize the effectiveness of obesity prevention efforts, parents need to play a central role. Specifically, parents set the stage for children's healthy lifestyle behaviors by fostering a supportive home environment, role-modelling healthy lifestyle habits, and monitoring and reinforcing children's behaviors (Faith et al., 2012). Parents' non-restrictive food practices, regular monitoring, and modelling of healthy eating are predictive of children's healthy dietary behaviors (Savage et al., 2007). Studies have also shown that children's physical activity behaviors are affected by parental influence (Moore et al., 1991), and parental obesity predicts childhood obesity (Whitaker et al., 1997). Ironically, some parents do not perceive their children's excess weight as a health concern, a perception that may be influenced by parents' inability to accurately recognize obesity in their children (Eckstein et al., 2006). Among those parents with accurate perceptions of their child's weight status (*e.g.,* their child meets clinical criteria for obesity and parents perceive their child as such), a sizeable proportion do not initiate healthy lifestyle changes for their children (Neumark-Sztainer et al., 2008). One possible explanation for this disconnect may be that parents report a number of challenges related to obesity prevention in children, specifically related to child- (*e.g.,* children's dietary preferences, difficulty changing children's lifestyle habits), family- (*e.g.,* economic resources such as time and cost of prevention activities), and

system-level factors (*e.g.,* neighborhood safety); notably, parents often report that barriers outweigh the facilitators to obesity prevention (Sonneville et al, 2009).

Primary Care Providers. In the context of the primary care setting, PCPs are well-suited to address childhood obesity for a number of reasons (Daniels & Hassink, 2015). First, PCPs provide care to children and their families over their pediatric life course and therefore engender rapport and trust over time. Consistently, families perceive PCPs as a reliable source of health information (Daniels & Hassink, 2015). Second, most PCPs employ a family-centered approach to children's health (Eichner et al., 2012), which is particularly important in the context of childhood obesity prevention. Lastly, recent clinical reports (Parkin et al., 2015) have highlighted the role of PCPs in *(i)* assessing the complex and interconnected factors of families that can lead to children's unhealthy weight gain, *(ii)* tailoring prevention messages to individual families based on socioeconomic, cultural, and psychological characteristics, as well as to children's developmental stage, *(iii)* screening for unhealthy weight gain at each health care visit using percentile charts, and *(iv*) educating families on obesity prevention as well as discussing evidence-based strategies to facilitate behavior modification.

Although PCPs are key players in the prevention of childhood obesity in primary care, efforts to prevent obesity in this setting have been inconsistent and uncoordinated (Epstein & Ogden, 2005); for example, a significant proportion (~65%) of children classified as overweight or obese are not notified as such by their PCP (Hansen et al., 2016). This is important given that children identified as overweight or obese in primary care are six times more likely to receive specialized weight management care compared to children who are not identified as such (Dilley et al., 2007). This practice gap is likely influenced by the

barriers PCPs report to preventing obesity in children (Story et al., 2002), which can be classified into three main categories: operational/system- (*e.g.,* limited time with patients), attitudinal- (*e.g.,* fear of offending the patient), and knowledge/training-level barriers (*e.g.,* low skill proficiency with weight-related behavior counselling) (Hearn et al., 2008). An additional, commonly reported challenge includes lack of patient education materials and online tools to assess children's weights (Flower et al., 2007). PCPs report a need for "better tools" (Teixera et al., 2015), particularly in the context of screening children's weights, counselling on obesity prevention and weight-related behaviors (Bourgeois et al., 2016), and improving coordination and communication with sub-specialties for referrals (Nelson et al., 2015).

1.1.5. Tools and Resources

Parents and PCPs represent key players in the prevention of childhood obesity, but both parties experience various challenges surrounding this task (Caballero, 2004). To support and facilitate parents and PCPs when preventing obesity in children, the use of TRs is warranted. For the purpose of this thesis, tools are task-related and require the user to perform a specific action; for example, BMI growth charts require the user to measure children's height and weight and use this information alongside age and sex to determine BMI percentile. Resources provide users with a source of information and actions are not required; for example, nutrition guidelines can be read by the user but measurements or calculations are not required. Well-known TRs include *Canada's Food Guide*, national physical activity and sedentary guidelines, and BMI growth charts (*e.g.,* Centers for Disease Control, World Health Organization), and are generally used for growth monitoring and

patient education. Some newer, evidence-based TRs directly target PCPs by enhancing their confidence and skills to counsel on obesity prevention. For example, *the 5As of Pediatric Obesity* (Sharma, 2012), outlines a step-by-step guide for providers to effectively but sensitively initiate the conversation about obesity, and *My Weight Ruler* (Cloutier et al., 2013) may help providers to communicate children's weight status to families in a more clear and concise manner compared to traditional growth charts.

Recently, novel TRs that capitalize on the widespread use and availability of the Internet and digital health technology have been applied to help prevent obesity in children. Within the home environment, eHealth (electronic health) and mHealth (mobile health) TRs have been targeted towards parents to help monitor and improve children's physical activity, dietary, and sedentary behaviors (Lappan et al., 2015). Within the health care setting, such TRs can also support PCPs when preventing children's unhealthy weight gain. For example, electronic medical records can be used to monitor children's physical development (Smith et al., 2010), and interactive, web-based training can facilitate provider's delivery of obesity counselling to families (Kolko et al., 2016). Although the application of digital health technology to address obesity in children is growing, the field remains immature and reviews have highlighted heterogeneity with regards to children's health outcomes, digital health components and modality, dose and intensity, and targeted end-users (Lappan et al., 2015).

1.2. Knowledge Gaps

TRs can help parents and PCPs to prevent obesity in children. However, there are two main knowledge gaps with respect to existing TRs used by PCPs in clinical practice, and newly-developed TRs that capitalize on eHealth technology for parents. First, of those

existing TRs available in clinical practice, little is known regarding which ones are currently used among PCPs to prevent obesity in children and how they can be evaluated. Further, although it can be speculated *why* PCPs use TRs for obesity prevention, there is no evidence to support PCPs' perceptions of specific purposes and if such TRs are suitable for families. Of the studies performed to evaluate TRs to date, foci have been limited to general pediatric education materials (D'Alessandro et al., 2001) and printed resources related to physical activity (Vallance et al., 2008). In addition, such studies have evaluated TRs using *only* assessment checklists, and the opinions of providers have not been investigated.

Second, although systematic reviews have reinforced the advantages associated with, and positive outcomes of, digital health applications for parents to prevent obesity in children (Hamel & Robbins, 2013; Nguyen et al., 2011), the majority have been time- (*e.g.,* online programs up to 52 weeks in length [Davies et al., 2012]) and resource-intensive (*e.g.,* online interventions with additional in-person or telephone components [Hammersley et al., 2016]). This suggests there is value in examining the feasibility and preliminary impact of brief and novel strategies for preventing obesity in children. One such approach that has been applied in primary care is the digital SBIRT. This eHealth tool has been used to address preventable health concerns (*e.g.,* alcoholism, cannabis use) and studies have shown this approach can exert a positive influence on intention to change behaviors as well as behavior change itself (Cunningham et al., 2009; Kaner et al., 2009). SBIRTs are particularly well-suited for obesity prevention in primary care because PCPs often have frequent opportunities to interact with families, but limited time and resources to do so. Consistent with Bray's Fluoride Hypothesis (Bray, 2004), "For Lowering Universal Obesity Rates, Implement ideas

that Don't depend on Effort" there is rationale to develop and evaluate this resource-efficient approach to help prevent obesity in children.

1.3. Personal Rationale

In the summer of 2012, I was an undergraduate research student funded by Alberta Innovates – Health Solutions. Under the supervision of Dr. Geoff Ball, I conducted a retrospective medical record review of clinical and administrative data from an Edmonton pediatric weight management clinic (Pediatric Centre for Weight and Health; Stollery Children's Hospital), which included data from 5 to 18 year olds (BMI $\geq 85^{th}$ percentile) collected from 2008 to 2012. Findings from this study (Avis et al., 2013) demonstrated that across participants (n=165), program attrition increased substantially over time (23%, 49% and 73% at three-, seven-, and 11-month follow-up time points, respectively). Among those individuals with follow-up data, weight stabilization occurred at three (n=127) and seven months (n=84). At 11-months (n=44), BMI z-score tended to decrease over time, but did not reach statistical significance (p=0.06). Given this evidence, I felt disillusioned: nearly three-quarters of families in our study terminated care prematurely, which suggested that the majority of children who initiated pediatric weight management were unlikely to achieve positive weight outcomes. This study, which represented my first exposure to clinical research, influenced my passion for studying the prevention of obesity in children.

1.4. Research Objectives & Outline of Thesis

The overarching objective of my thesis was to study TRs used to help prevent childhood obesity in primary care. To address this objective, I conducted two studies: *(i)*

Primary care Resources for Obesity in Pediatrics (PROP; Study 1) and *(ii)* the Resource Information Program for Parents on Lifestyle and Education (RIPPLE; Study 2). Chapter 2 of my thesis represents an overview of the methods used in both studies.

The objective of my first study was to pilot test a mixed methods approach to evaluate TRs that PCPs use for preventing childhood obesity in primary care and report a preliminary descriptive assessment of these TRs. Chapter 3 of my thesis presents this mixed methods study. The objective of my second multi-phased study was to develop (Phase I), refine (Phase II), and pilot test (Phase III) a digital SBIRT delivered in primary care to help parents prevent obesity in children. Chapter 4 presents the development and refinement of the SBIRT, and chapter 5 presents pilot testing of the modified SBIRT with parents in primary care using a randomized controlled trial (RCT). My thesis concludes by discussing major findings, strengths and limitations of my research, and future directions and recommendations for research and clinical practice in chapter 6.

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Chapter 2

Overview of Methods

This chapter represents an overview of the methods used in my two thesis studies. The first study, PROP, was a mixed methods study; the second study, RIPPLE, was a three-phased multi-methods study. The purpose of this methods chapter is to *(i)* explain the underlying philosophical stance of my research and *(ii)* provide additional methodological details of my thesis studies that are not included in chapters 3 to 5 due to space limitations of respective publishing journals. Appendix A includes a timeline of all study- and graduate-related activities, and Appendix B includes an overview of study-related details.

2.1. Philosophical Stance

A paradigm worldview is an overarching philosophical stance that informs the beliefs about the nature of our world. Paradigm worldviews guide the research process through researchers' epistemological (nature of knowledge) and ontological (nature of reality) beliefs, and the scientific methods that they employ. Traditionally, there has been a tension between interpretivist and positivist paradigms, which is formally known as the 'incompatibility thesis'. Broadly, such paradigms subscribe to divergent forms of reasoning (*i.e.,* inductive *vs.* deductive), methodology (*i.e.,* qualitative *vs.* quantitative), axiology (*i.e.,* value-laden *vs.* value-free), and rhetoric (*i.e.,* personal *vs.* impersonal). Towards the 1990s, researchers began to reject the incompatibility thesis (Howe, 1988), with emergence of a philosophical stance that embraced a unique approach to thinking about, and conducting, research – pragmatism.

The research paradigm that guides this thesis is pragmatism – a paradigm consistent with mixed methods research (Creswell & Clark, 2011). First, pragmatism is a philosophical stance that rejects the belief that there is only one scientific method (Tashakkori & Teddlie, 2003) and rather employs the approach of "what works" to answer the research question. Accordingly, methods of data collection are chosen to best answer the research question as opposed to how they align with the researcher's beliefs about the nature of knowledge and reality. Second, pragmatism is an inclusive stance; in addition to the acceptance of both inductive (*i.e.,* beginning with observations to discover patterns) and deductive (*i.e.,* testing existing frameworks or theories) reasoning, pragmatists employ abduction, which involves relying on the best set of explanations to understand results (Johnson & Onwuegbuzie, 2004). Lastly, this worldview is unique in that scientific questions that lend themselves to both qualitative and quantitative inquiry can be addressed using a practical approach. A frequently cited advantage of this approach is that the strengths of one method can help to mitigate the weaknesses of the other.

2.2. Study 1

2.2.1. Study Design

This mixed methods study used an embedded sequential design, which included a dominant qualitative strand followed by a supplemental quantitative strand (Figure 2.1). Specifically, data collection and analysis in the qualitative strand (Phase I), which included one-on-one, semi-structured interviews with PCPs about the TRs they use in clinical care, informed data collection in the quantitative strand (Phase II). This phase entailed collecting the TRs that participants discussed using during the interview and subsequently scoring them

using three assessment checklists. Mixing of the strands occurred when participants were invited to provide feedback on interpretations from qualitative and quantitative strands (Phase III).

2.2.2. Qualitative Method

In Phase I, the qualitative method of interpretive description (Thorne, 2008) was used to develop a rich and meaningful explanation regarding PCPs' perceptions of the TRs they use to prevent childhood obesity in primary care. This method borrows concepts and techniques from well-known qualitative methods, such as grounded theory, but distinguishes itself in which the outcomes are directly grounded in clinically-relevant applications. Specifically, interpretive description is used to develop an in-depth description of a clinical phenomenon, which can help to bridge the gap between current clinical actions and optimal practice goals (Thorne, 2008).

2.2.3. Planning & Organization

Planning of this study commenced in June 2013. The rationale for embarking on this study was two-fold: *(i)* to independently develop a standalone study for my thesis that would complement my second study, and *(ii)* to gain an understanding of currently used TRs for childhood obesity prevention in primary care. The latter was based on identified gaps in the literature (see Appendix C for issues identified through a literature search) and challenges that I witnessed firsthand based on experiences with the RIPPLE study (*e.g.,* PCPs' lack of time to prevent obesity in children).

Prior to the commencement of participant interviews, I compiled a multidisciplinary list of TRs used for obesity prevention in primary care. This list of TRs was assembled based on networking with established connections from the RIPPLE study (*i.e.,* PCPs and stakeholders from the Edmonton Oliver Primary Care Network). Specifically, in the Fall of 2014, PCPs (*e.g.,* kinesiologists, pediatricians, registered dietitians) practicing at four primary care clinics were invited to participate in one-of-two informal lunch meetings regarding their use of TRs for childhood obesity prevention. In preparation for these meetings, PCPs were asked to bring copies of TRs that they commonly used with children and families. Based on these meetings, I developed a list of 12 TRs, which formed the basis of a brief, online survey that was sent to participants one-week prior to their scheduled interviews in Phase I. This online survey (SurveyMonkey®) asked participants to *(i)* select which TRs they used to prevent childhood obesity in primary care based on my compiled list and *(ii)* list additional TRs. In preparation for each interview, I gathered the TRs that each participant reported using. Each participant was invited to bring TRs that were not included on the original list. Hard-copy versions of TRs were used to facilitate discussion regarding specific aspects of TRs.

2.2.4. Methodological Rigor

First, preexisting relationships with primary care-based stakeholders and providers from the second study was essential for me to gain a preliminary understanding of the context in which PCPs use TRs in primary care. Some pre-established relationships dated back to 2012, and my prolonged engagement in the field from the RIPPLE study was useful for two reasons: *(i)* I established rapport and trust with gatekeepers, which helped to recruit further

participants with diverse knowledge and experience and *(ii)* credibility of the study was enhanced because familiarity with the context prevented me from making premature interpretations, which can result when the researcher has limited contact with the setting. Second, given the mixed methods study design, qualitative and quantitative data were triangulated. Specifically, both participants' opinions as well as objective data generated from assessment checklists (*e.g.,* Appendix D; Suitability Assessment of Measures [SAM]) facilitated a comprehensive understanding of the TRs used for obesity prevention in children. Third, peer debriefing was independently conducted with three researchers and one research group. During these sessions, preliminary analysis was discussed and peers provided feedback on the logic of my interpretations. Lastly, I employed a member checking protocol that had a two-fold purpose: *(i)* to gain feedback from participants on preliminary qualitative analysis to verify accuracy and completeness of interpretations and *(ii)* to act as the point of interface between qualitative and quantitative data by querying participants' opinions on the quantitative scoring of TRs.

2.2.5. Knowledge Translation

Findings from this study were published in *Patient Education and Counselling* (Avis et al., 2016a) and have been presented at international (Obesity Week, Los Angeles, California; November, 2015) and local conferences (University of Alberta Annual Nutrition Symposium, Edmonton, AB; March, 2015). In January 2016, I was invited to write a guest post regarding the findings of this study on *Dr. Sharma's Obesity Notes* blog (http://www.drsharma.ca/). Lastly, an infographic was developed based on the findings of

this study (Figure 2.2), which was disseminated in February, 2016 to study participants who were encouraged to share it with colleagues.

2.2.6. Ethics

The Health Ethics Board (Panel B) at the University of Alberta approved this study (Pro00042380) in October, 2014. Appendix E includes the information sheet and consent forms that were given to participants.

2.3. Study 2

2.3.1. Study Design

This multi-methods study included three phases: development of the SBIRT (Phase I), refinement of the SBIRT (v1.0) using focus groups (Phase II), and pilot testing of the SBIRT (v2.0) using a RCT with parents (Phase III) (Figure 2.3). A manuscript outlining the protocol for this paper has been published (Appendix F; Avis et al., 2015a) and the accompanying case report form, which includes all data collected from the SBIRT, is in Appendix G. A viewpoint paper, which reflects the lessons learned from refining the SBIRT using focus groups, has also been published (Appendix H; Avis et al., 2015b).

2.3.2. Qualitative Method

In Phase II, the qualitative method of qualitative description (Sandelowski, 2000) was used to develop a rich and explicit description of participants' impressions of the newly-developed eHealth tool. This method necessitates less interpretive interference on behalf of

the researcher, therefore representing a straightforward and realistic embodiment of participant discussion (Sandelowski, 2010).

2.3.3. Planning & Organization

The development and refinement of this parent-based digital SBIRT occurred over a three-year period, which started in 2012. During this period, approximately 75 electronic and telephone meetings were conducted with our intervention developers, *Evolution Health Inc*., who were based out of Toronto, ON. In addition, I conducted a total of eight in-person group meetings – two with the RIPPLE study grant team, and six with our primary care-based partners (Allin Clinic, Edmonton, AB) whom were directly involved in all phases of the research study. The latter set of meetings entailed formal presentations co-led by myself and Dr. Geoff Ball, and were held biannually from 2012 – 2015 to *(i)* develop trust and rapport with PCPs from the Allin Clinic, *(ii)* incorporate our partners' needs and priorities based on their firsthand clinical experience with preventing obesity in children, *(iii)* discuss the logistics of recruitment for the RCT, and *(iv)* present and gain feedback on end-of-study findings. An end-of-study meeting was also held with grant team members for the purpose of discussing findings and next steps of our research.

In April 2013, our research team was approximately halfway through the development period when the University of Alberta communicated that a privacy impact assessment between *Evolution Health Inc.* and the University of Alberta was required. Specifically, the purpose of this assessment was to ensure that the online data collected from the SBIRT, which was digitally captured and then transmitted and stored outside of the province under the authority of *Evolution Health Inc*. would remain confidential. This

process ran longer than expected (~12 months); during this period, payment to *Evolution Health Inc*. ceased and our team was unable to continue project development without funding.

2.3.4. Methodological Rigor

In the second phase of this study, a diverse group of participants was recruited to provide input on the first version of the SBIRT. Specifically, we recruited multidisciplinary HCPs working in primary- and tertiary-level care, researchers and graduate trainees with experience in pediatrics, and parents of both healthy weight and unhealthy weight children. Although within-group perspectives regarding the SBIRT were not investigated, conducting focus groups with various stakeholders allowed us to triangulate data and gain multiple perspectives on the newly-developed eHealth tool. In addition, an informal real-time member-checking protocol (*i.e.,* at the end of each group, the moderator briefly confirmed and clarified themes that were discussed during the session) was used during focus groups to ensure the findings accurately reflected most participants' personal perspectives. Lastly, during the third phase of this study (*i.e.,* testing of our SBIRT), elements of the trial study design strengthened internal validity; random assignment of participants to groups mitigated selection bias, and blinding of participants and researchers to group allocation for the duration of the study reduced performance bias. Blinding to outcome assessment was implemented to reduce the risk of detection bias.

2.3.5. Knowledge Translation

Following the commencement of SBIRT development in 2012, I developed an infographic for our research team members and primary care-based stakeholders (Figure 2.4). Shortly thereafter, I started a newsletter called *The RIPPLE Effect* that outlined the basics of the project, progress to date, current affairs, and next steps. The newsletter was emailed to RIPPLE team members on a monthly basis, but reach and bidirectional communication was limited. With the intent of disseminating study-related news and information in a more interactive and attractive fashion, in 2014 I developed and launched a study-specific blog (https://rippleprogram.wordpress.com). To date, I have published approximately 115 posts on the blog, which have been viewed more than 3200 times by nearly 1250 individuals located across 55 countries. This blog has been an essential integrated knowledge translation strategy that has helped to maintain regular and timely communication with the RIPPLE team as well as disseminate our research to others with an interest in preventing childhood obesity around the world.

The protocol for this study (Avis et al., 2015a) and a viewpoint paper regarding lessons learned from Phase II (Avis et al., 2015b) are both published in the *Journal of Medical Internet Research – Research Protocols.* The process of, and findings from, Phases I and II of this study are published in *Telemedicine and e-Health* (Avis et al., 2016b); the manuscript regarding Phase III of this study is under review in *Pediatric Obesity.* Results of this research have been presented at international (International Congress of Obesity, Vancouver, BC; May, 2016), national (Canadian Obesity Summit, Toronto, ON; May, 2015), and local conferences (Department of Pediatrics Annual Research Day, Edmonton, AB; May, 2016; Women and Children's Health Research Institute Annual Research Day,

Edmonton, AB; October, 2015). I was also nominated on behalf of the Faculty of Medicine and Dentistry (University of Alberta) to present this study at a graduate student health research forum (Canadian Student Health Research Forum, Winnipeg, MB; June, 2015). Lastly, an infographic was developed based on the findings of Phase III of this study (Figure 2.5). This infographic was disseminated to our grant team members and primary care-based partners in March, 2016.

2.3.6. Ethics

The Health Ethics Board at the University of Alberta approved this study (Pro00037365) in April, 2013; due to unexpected delays (*i.e.,* privacy impact assessment), ethics renewal was submitted and accepted in June, 2015. Appendix I includes the information sheet and consent form that were given to participants in Phase II. Appendix J includes the information sheets and consent (parents) and assent (child) forms that were given to participants in Phase III.

Figure 2.1. Illustration of mixed methods study design

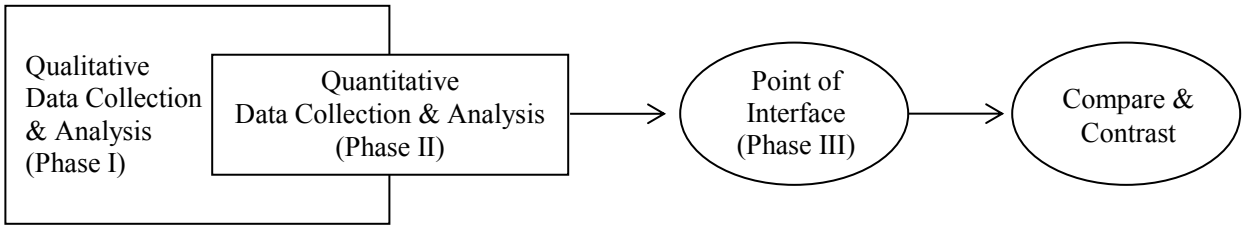


Figure 2.2. End-of-study infographic for Study 1

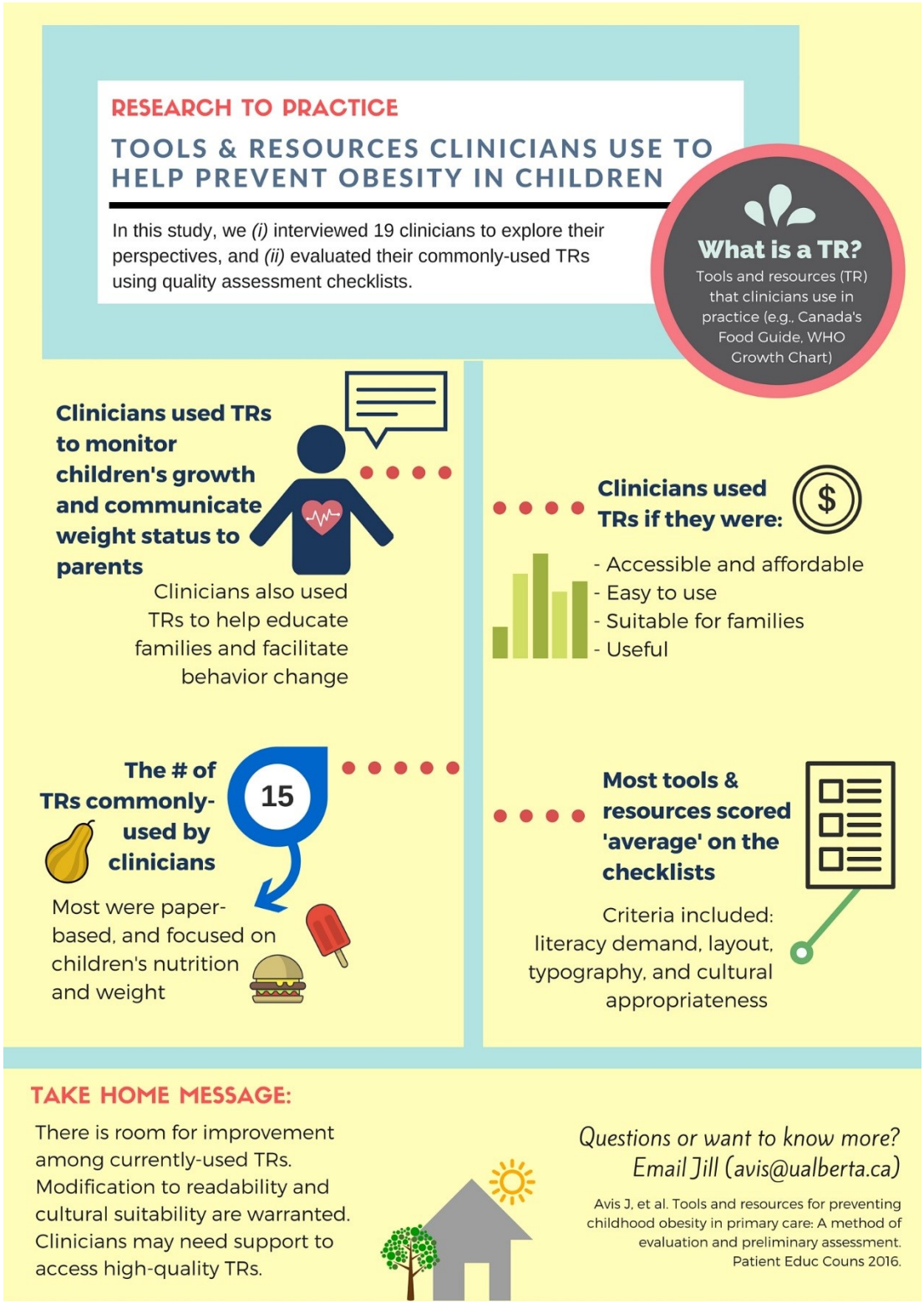


Figure 2.3. Illustration of multi-methods study design

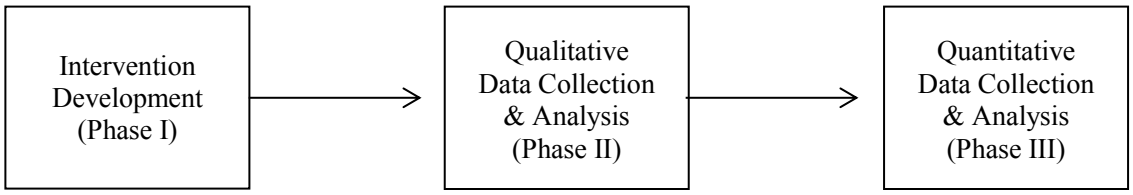


Figure 2.4. Beginning-of-study infographic for Study 2

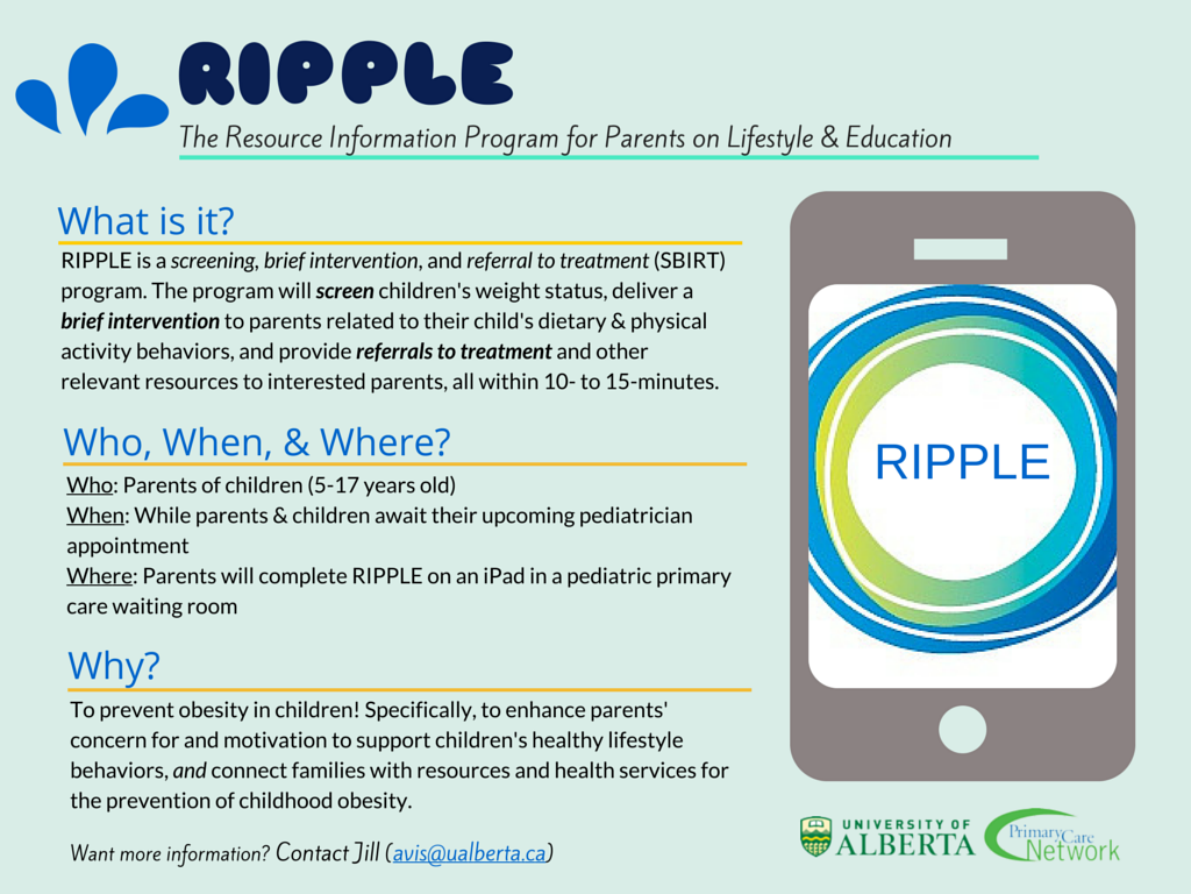
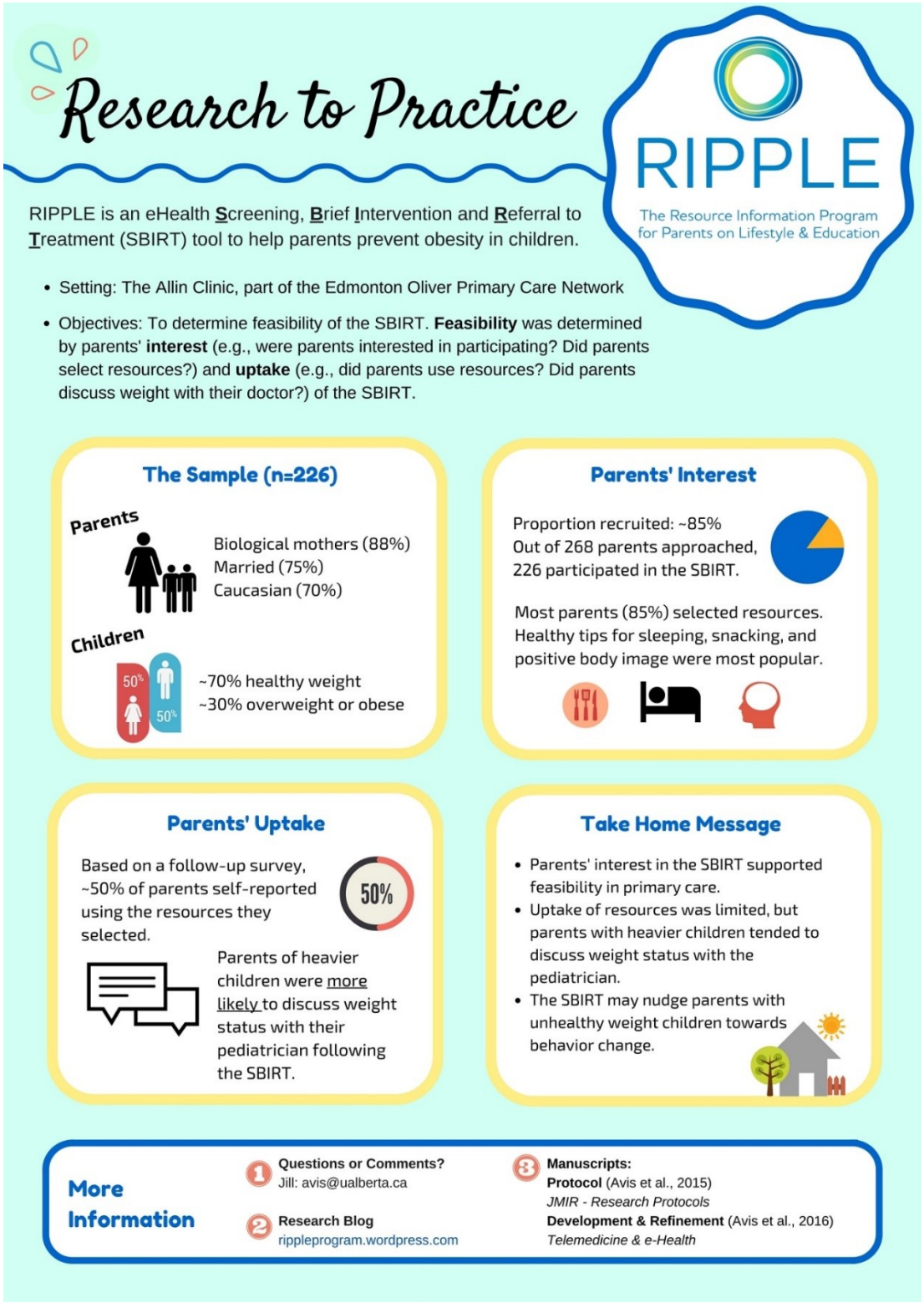


Figure 2.5. End-of-study infographic for Study 2



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Chapter 3

Avis JL, Komarnicki A, Farmer AP, Holt NL, Perez A, Spence N, Ball GD. Tools and resources for preventing childhood obesity in primary care: a method of evaluation and preliminary assessment. Patient Educ Couns 2016;99:769-75.

3.1. Abstract

Objectives. To pilot test a mixed methods approach to evaluate TRs that PCPs use for preventing childhood obesity in primary care and report a preliminary descriptive assessment of these TRs.

Methods. This mixed methods study included individual, semi-structured interviews with purposefully-sampled PCPs in Alberta, Canada; interviews were digitally recorded and analyzed thematically (Phase I). Two independent reviewers used three assessment checklists to evaluate TRs used by PCPs (Phase II). PCPs provided feedback on our coding scheme and checklist data (Phase III).

Results. Three themes described PCPs' (n=19) use of TRs: purpose of use (*e.g.,* clinical support), logistical factors (*e.g.,* accessibility), and decision to use (*e.g.,* suitability). The latter theme overlapped with constructs of suitability on the checklists. Overall, participants used 15 TRs, most of which scored 'adequate' on the checklists.

Conclusion. Phases I and II provided unique insights on the evaluation of TRs used for preventing childhood obesity. Criteria on the checklists overlapped with PCPs' perceptions of TR suitability, but did not reflect logistical factors that influenced their use of TRs.

Practice Implications. Developers of TRs should collaborate with PCPs to ensure that subjective and objective criteria are used to optimize TR suitability in the primary care setting.

3.2. Introduction

3.2.1. Tools and Resources

TRs, which for the purpose of this paper include clinical or educational programs and handouts, have been used across a number of disciplines with the goal to improve patients' awareness, knowledge, and health-related outcomes. Specifically, TRs are used to educate patients on various health conditions and concerns, as well as to support PCPs across a variety of clinical tasks. Despite the ubiquity of TRs in the world of health care, there is a lot of heterogeneity regarding evaluation. Assessment checklists have been developed and utilized to assess the suitability of TRs, but they have yet to be applied to TRs used for childhood obesity prevention, and it is unknown how ratings compare with PCPs' perceptions of suitability.

3.2.2. Childhood Obesity Prevention & Primary Care

Primary care represents most families' first point of contact with the health care system, which often includes health care delivery from a multidisciplinary team of professionals. The clinical priorities of primary care are also well-aligned with the prevention of chronic diseases, such as obesity (Perrin et al., 2014), and PCPs play an integral role in preventing childhood obesity in this setting (Daniels & Hassink, 2015). Although an increasing number of PCPs counsel children and families on obesity prevention (Nelson et al., 2015; Galuska et al., 2002), a number of barriers can impact their clinical work in this area, including a lack of useful patient education materials and clinical tools (Flower et al., 2007; Perrin et al., 2005). PCPs have also reported a need for "better tools" (Teixeira et al., 2015), particularly related to screening children's weights, counselling on

obesity prevention, and improving coordination and communication with sub-specialties for referrals (Nelson et al., 2015; Teixeira et al., 2015).

To date, TRs for obesity prevention have been used to educate children (Long et al., 2010) and parents (Rysdale et al., 2008) on obesity-related topics, including making and maintaining healthy lifestyle habits (Shapiro et al., 2008). PCPs also use TRs when counselling families (Woolford et al., 2009), assessing children's lifestyle behaviors (Bell et al., 2013), and screening children's weight status (Santos et al., 2016), which includes food guides (Totapally & Raszynski et al., 2007), national guidelines for physical activity (Vale et al., 2013), and BMI growth charts (Kuczmarski et al., 2010). Contemporary TRs have been designed to facilitate PCPs' obesity counselling efforts (Sharma, 2012) as well as to communicate children's weight status in a straightforward manner (Cloutier et al., 2013).

Although a variety of TRs are available to educate families and support PCPs in preventing childhood obesity, little is known regarding their use and suitability in clinical practice. Of the studies done to assess the suitability of TRs, foci have been limited to general pediatric educational materials (D'Alessandro et al., 2001) and printed resources related to physical activity (Vallance et al., 2008). In addition, such studies have evaluated TRs using only assessment checklists; to our knowledge, no studies have employed a mixed methods approach to quantitatively assess suitability of TRs, which can refer to the extent that materials are understood and accepted by patients (Vallance et al., 2008), and qualitatively explore PCPs' use of TRs, including both cognitive and contextual factors. Our mixed methods study included a dominant qualitative strand (Phase I) that informed data collection in a supplementary quantitative strand (Phase II), followed by participant feedback (Phase III). Specifically, our objectives were to *(i)* pilot test a mixed methods approach to evaluate

TRs that PCPs use for preventing childhood obesity in primary care (primary aim), and *(ii)* report a preliminary descriptive assessment of TRs used by PCPs (secondary aim).

3.3. Methods

3.3.1. Phase I: Qualitative Strand

Data Collection. Participants were eligible if they met the following criteria: *(i)* currently employed as a PCP, *(ii)* had at least two years of clinical experience, *(iii)* provided clinical care to children and families that included childhood obesity prevention, and *(iv)* used at least three TRs related to the prevention of childhood obesity in clinical practice. Purposive sampling was used to select study participants for demographic and clinical variation. To recruit participants, the technique of snowball sampling was used; first, participants were recruited by email and telephone through existing clinical (*e.g.,* Alberta Health Services, Edmonton Oliver Primary Care Network) and professional (*e.g.,* University of Alberta) affiliations. Then, interviews were scheduled with eligible participants. Following participation in the interview, participants were asked if they knew of potentially-suitable colleagues or peers who the researchers could contact for participation. This sampling method was continued until data saturation was achieved; data saturation was reached when no new information emerged from participant interviews. One week prior to scheduled interviews, participants were contacted to complete an online survey (SurveyMonkey®) that queried their clinical discipline, years of experience in clinical practice, information about the TRs they used for childhood obesity prevention, and of the TRs they listed, which ones were used for patient education and clinical support purposes.

Our semi-structured interview guide (Appendix K) included 13 questions with follow-up examples and probes. The guide was developed by *(i)* identifying and evaluating relevant literature, *(ii)* organizing questions thematically (*e.g.,* context, likability), and *(iii)* confirming the inclusion and exclusion of concepts and questions with team members (AK, AP). At the end of each interview, participants were asked by interviewers (JA, AK) to self-rate the suitability of each TR on a 10-point Likert scale (1[not suitable] – 10[very suitable]), with the option to rate by increments of 0.5. This question was used to quantify participants' perceptions of an intangible concept (Britten, 1995). As a token of appreciation, participants received a $10CAD gift card upon completion of the interview. Written informed consent was obtained prior to the interviews; ethical approval was obtained from the Health Ethics Board at the University of Alberta.

Data Analysis. Interviews were audio-recorded and submitted to *The Comma Police* (www.commapolice.com) for transcription. Interviews were transcribed within 5 – 7 business days of data collection to facilitate concurrent data collection and analysis. Data saturation was reached when no new information emerged from the interviews. Transcribed data were imported into *NVivo 10* (QSR, Melbourne, Australia) for management, which was followed by inductive thematic data analysis (Morse & Field, 1995). Once interviews were checked alongside their corresponding audio-recording for accuracy and completeness, each transcript was read to become familiar with the data; a broad-based coding system was then developed. This coding scheme was used to understand the relationships between various groupings and concepts. After each interview was coded, categories were grouped under general themes, and a written description was constructed to explain each theme. To enhance methodological rigor, the coding scheme was peer-reviewed by a colleague (AP) and

formally discussed with two additional researchers (NH, GB) to ensure accuracy and completeness.

3.3.2. Phase II: Quantitative Strand

Data Collection. TRs used by at least two PCPs were scored by two independent reviewers (JA, AK) using three assessment checklists – the Tool to Evaluate Materials used in Patient Education (TEMPtEd) (Clayton, 2009), the SAM (Suitability Assessment of Materials (SAM) (Doak et al., 1996), and the Patient Education Materials Assessment Tool for Printable Materials (PEMAT) (Shoemaker et al., 2014). Assessment checklists were identified by performing a literature search to identify checklists designed to assess the suitability of TRs for patients (Clayton, 2010); one of the assessment checklists (SAM) was previously used to assess modules within a childhood obesity RCT (White et al., 2013) and printed resources for physical activity (Vallance et al., 2008). Each checklist evaluated the suitability of TRs by assessing various constructs (*e.g.,* content, literacy level, layout, typography), although their design varied slightly (Table 3.1). Each TR was given a numeric (*e.g.,* 65/100) and categorical score (*e.g.,* "adequate"). Two of the assessment checklists (*i.e.,* SAM, TEMPtEd) assessed readability using the Flesch-Kincaid formula and Simple Measure of Gobbledygook (SMOG) index, respectively.

Data Analysis. Descriptive analyses were performed for participants' demographic variables and scoring of TRs using the checklists. Independent sample t-tests were used to compare differences in numeric scores of TRs by focus (*i.e.,* activity-, diet-, weight-, or multi-focus) and source (*i.e.,* Alberta Health Services *vs.* other). Cronbach's alpha was used to calculate the inter-rater reliability between independent assessors' numeric scores of TRs

on the checklists. To calculate the consistency of numeric and categorical scoring of TRs across the three checklists, Spearman correlations and Cohen's kappa were used, respectively. SPSS 22.0 (SPSS Inc., Chicago, Illinois) was used for data analysis; $p<0.05$ was considered statistically significant.

3.3.3. Phase III: Follow-up

A member checking protocol (Creswell & Miller, 2000) was used to facilitate qualitative data analysis and to follow-up with participants regarding their perspectives on the scoring of TRs using the checklists. Participants were invited by email to provide feedback on an initial coding scheme of the qualitative data (part I of follow-up) and a comparison of suitability scores of TRs between PCPs and checklists (part II of follow-up) (Appendix L). To provide context, PCPs were given printed copies of the checklists as well as descriptions of how they were used.

3.4. Results

One-on-one, semi-structured interviews were conducted with a total of 19 participants working in Edmonton (n=12) and Calgary (n=7) (Figure 3.1). Participants represented 10 primary care clinics, which varied in terms of geographic location (*e.g.,* downtown, suburban) and patient sociodemographic status. Participants varied by clinical discipline (registered dietitian [n=9], kinesiologist [n=5], registered nurse [n=3], medical doctor [n=2]) and experience (9.4±9.9 years). Most participants were female (n=16; 84.2%) and Caucasian (n=15; 78.9%).

3.4.1. Phase I

Three main themes described PCPs' use of TRs for the prevention of obesity in children in primary care, including: *(i)* purpose of use, *(ii)* logistical factors, and *(iii)* decision to use. Themes are supported with quotes from participants in Table 3.2.

Purpose of Use. Participants used TRs for two main purposes – clinical and family support. First, TRs supported PCPs in their clinical role by *(i)* facilitating the assessment and monitoring of children's growth and lifestyle behaviors (*e.g.,* diet, physical activity, sedentary activity, sleep) associated with obesity prevention, *(ii)* promoting dialogue of children's weight status and growth with families, and *(iii)* enhancing their credibility, confidence, and competency in the area of childhood obesity prevention. Participants discussed using one TR to fulfill multiple needs. For example, BMI growth charts were used to assess children's height and weight as well as facilitate dialogue about weight status and plan of action. Second, PCPs perceived the need to use TRs for families. Specifically, TRs were used to educate families on specific topics (*e.g.,* diet, physical activity) and facilitate changes in children's lifestyle behaviors, in which TRs may reinforce and remind families how to initiate and sustain healthy changes following their clinical appointment.

Logistical Factors. PCPs' implementation of TRs was influenced by logistical factors, including perceived awareness of and access to TRs. PCPs learned about relevant TRs through top-down and bottom-up processes. Most PCPs received TRs through their connection to the provincial health authority (*i.e.,* Alberta Health Services) although they viewed them, in general, as being limited in scope, pediatric-focus, and aesthetic appeal. As a result, PCPs sought out TRs that suited their clinical needs via online searching, consulting with colleagues, and/or attending conferences and workshops. PCPs also said that access to

TRs limited implementation, with cost, distribution, and production identified as barriers. Accessibility was particularly relevant for participants who had previously used a suitable TR that increased in cost or was discontinued without notice. Overall, PCPs perceived a general under-availability of 'high quality' TRs, particularly with respect to discipline-specific (*e.g.,* positive body image, mental health, physical activity, sedentary activity, sleep habits) and pediatric-targeted TRs (*e.g.,* TRs for children *vs*. parents).

Decision to Use. PCPs said their decision to use TRs was influenced by expected and experienced suitability. First, participants expressed that a 'one size fits all' approach was not suitable for meeting the needs of each family. Rather, the suitability of TRs was gauged according to family-level factors, such as *(i)* children's age, *(ii)* parents' concerns, *(iii)* cultural/language needs*, (iv)* and motivation and readiness to change. Second, PCPs assessed their use of TRs by reflecting on their own experiences and, on occasion, receiving or soliciting feedback from families at follow-up appointments. Suitability of TRs was informed by usability for themselves (*e.g.,* straightforward and quick to use with families) and for families (*e.g.,* simple to read and understand), and usefulness for themselves (*e.g.,* effective in guiding conversation with families) and families (*e.g.,* facilitated children's positive behavior changes). Perceptions of suitability were influenced by attributes of TRs, which overlapped with criteria on the checklists (*e.g.,* aesthetic appeal, readability, content, organization). PCPs' experience with TRs informed their future use, which included (*i)* reusing the same TR, *(ii)* amending the TR, *(iii)* creating their own TR, or *(iv)* finding a new TR.

3.4.2. Phase II

Fifteen unique TRs were used by PCPs (mean: 6 per PCP; min-max: 3-10) (Table 3.3). There was consistency in terms of TRs that ranked the highest by both PCPs and checklists. TRs varied with respect to purpose (patient education [n=12; 80%] *vs.* clinical support [n=3; 20%]), developing organization (Alberta Health Services [n=5; 33.3%] *vs.* other [n=10; 66.7%]), and disciplinary focus (diet [n=6; 40.0%], weight [n=4; 26.7%], physical activity [n=3; 20.0%], and multidisciplinary [n=2; 13.3%]).

Scoring of Tools & Resources. Most TRs scored 'understandable and actionable' (n=11; 73.3%) on the PEMAT, and 'superior' (n=8; 53.3%) or 'adequate' (n=6; 40%) on the SAM. On the TEMPtEd, scoring varied ('average' [n=6; 40.0%], 'above average' [n=4; 26.7%], and 'not suitable' [n=5; 33.3%]). Four TRs were top-ranked on the PEMAT and SAM, PEMAT and TEMPtEd, and SAM and TEMPtEd. While mean TR scores across the three checklists did not differ by developing organization, weight-focused TRs tended to score lower than diet-focused TRs. In addition, TRs for patient education purposes tended to score higher than TRs for clinical support purposes.

Measures of Consistency. Inter-rater reliability between assessors was excellent (PEMAT [α=0.98], SAM [α=0.94], and TEMPtEd [α=0.91]). Mean numeric scoring of TRs across the three checklists was positively and strongly correlated (PEMAT x TEMPtEd [r=0.85], PEMAT x SAM [r=0.75], TEMPtEd x SAM [r=0.71]; all $p<0.001$). However, consistency of categorical scoring of TRs across the three checklists varied (PEMAT x TEMPtEd [κ=0.46; p=0.004], TEMPtEd x SAM [κ=0.41; p=0.01], PEMAT x SAM [κ=0.07; $p>0.05$]), highlighting similarities in numeric scoring across the checklists, but differences between categorical interpretations.

3.4.3. Phase III

Out of 19 participants that were interviewed, 17 participated in the follow-up (parts I [n=9 telephone; n=7 email; n=1 in-person] and II [n=15 telephone; n=1 email; n=1 in-person]). In part I, participants reported that the visual representation and description of qualitative analysis was logical and reflected their views, and minor changes were made to terminology/wording (*e.g.,* "tools for clinical support *vs.* "tools for self"). In part II, participants preferred to discuss the categorical over the numerical scores of the TRs. Most were *(i)* interested in learning about TRs that received high scores (*e.g.,* 'above average'), but that they still wanted to examine them for suitability and *(ii)* clear that they would not discontinue their use of TRs that were rated as 'not suitable' since contextual factors and clinical acumen superseded objective suitability scores.

3.5. Discussion

Our mixed methods study revealed several relevant findings. First, PCPs discussed using TRs to meet several aims, and they gauged the suitability of TRs based on factors similar to scoring criteria on the checklists, such as cultural appropriateness, presence of motivational principles, and level of readability. Although elements of suitability overlapped between PCPs' preferences and objective ratings, there were insights unique to our qualitative findings (*e.g.,* logistical factors) that were not captured by objective scoring. Second, a total of 15 TRs were used by PCPs, with most rating 'average' in suitability according to the checklists. When data were shared with participants in the last phase of our research, most said they were unlikely to change their practices, even if their preferred TRs scored 'not suitable' based on ratings using the checklists.

Scoring of TRs using the checklists demonstrated that objective scoring did not account for the contextual (*e.g.,* need for clinical support) and logistical (*e.g.,* accessibility) factors that PCPs discussed in our interviews. Similarly, select constructs that were scored using the checklists (*e.g.,* use of the active voice, visual cues, numbers) were not constructs of suitability that PCPs prioritized. However, some elements of suitability, such as the presence of motivational principles, cultural appropriateness, and literacy level overlapped between PCPs' input and objective scoring using the checklists. Specifically, participants in our study discussed poor readability as a common limitation of most TRs, and scoring on the checklists reflected reading levels that surpassed recommendations. These corresponding results have been echoed by others, with both researchers (Brownson, 1998) and families (Swartz, 2010) reporting inadequate readability of educational handouts. Given these findings, a mixed methods approach might be helpful to prioritize major issues across TRs, and TR developers should consider suitability based on both user preferences and objective criteria.

Although PCPs identified a small number of weight-focused TRs for use with families in primary care, most scored 'inadequate' or 'not suitable' across the three checklists that were applied. Further, these objective ratings differed from the perceptions of PCPs, highlighting several issues. First, general assessments of TRs may not accurately reflect the suitability of TRs designed for specific uses such as preventing childhood obesity. Given that obesity in children is a complex, chronic condition requiring lifelong management (Avis et al., 2014), other factors (*e.g.,* terminology) may be relevant considerations regarding TR suitability. Second, given that two of the checklists assessed the suitability of materials for patient education, most TRs used by participants for clinical

support scored ‘not suitable’. It is noteworthy that a previous report (Ben-Josesph, et al., 2009) showed parents had difficulty comprehending children’s weight status when that information was presented on a growth chart, a TR that was rated ‘not suitable’ by all three checklists. Although growth charts rated low in suitability for patient education use, participants in our study had more favorable perceptions, which may reflect the fact that PCPs use growth charts often in their day-to-day practice (Dietitians of Canada, 2010). Lastly, PCPs said they would not change their use of TRs, even for ones that scored as unsuitable because contextual factors and clinical judgement were viewed as more important deciding factors. Our qualitative data supported this finding as the suitability of TRs represented just one of many components that influenced PCPs’ use of TRs. Taken together, it is important to consider the suitability of TRs based on checklists with the knowledge that objective ratings may not accurately reflect clinicians’ perceptions of real-world suitability.

Prior to implementation of TRs in clinical practice, PCPs’ decision to use TRs was guided by logistical factors (*e.g.,* awareness, accessibility) and suitability. Overall, PCPs’ cited a lack of access to topic-specific (*e.g.,* positive body image, mental health, physical activity, sedentary activity, sleep hygiene) and pediatric-oriented TRs. Consistent with this point, none of the participants reported using TRs directly related to mental health and well-being, sedentary behaviors, or sleep hygiene. Given recent reports (LeBlanc et al., 2015; Miller et al., 2015) regarding the link between these topics and childhood obesity, there is rationale for enhancing PCPs’ awareness of and access to existing TRs on these issues and to develop new TRs related to mental health, sedentary activities, and sleep. PCPs also reported a surplus of mediocre-quality TRs, largely due to poor aesthetic quality and reading comprehension level. To compensate, many PCPs described developing their own TRs to

fulfill specific clinical needs. Together, our findings reinforce the need to have TR creators and users work collaboratively to identify clinical needs as well as develop and refine new TRs to optimize suitability and application.

3.5.1. Strengths & Limitations

There are several strengths in this study. In Phase I, preliminary analysis was peer-reviewed by fellow researchers to ensure accuracy and completeness of assigned codes; in Phase II, two reviewers independently assessed TRs using three unique checklists to mitigate risk of bias, and in Phase III, a member checking protocol was employed to gain participant feedback on qualitative and quantitative findings. This study also has limitations. Given the design of our mixed methods study, in which the number of TRs evaluated in Phase II was directly informed by PCPs' use of TRs in Phase I, our sample size of TRs (n=15) was limited. Therefore, suitability scores derived from the checklists were underpowered. In addition, because most participants were female and Caucasian, a more demographically diverse group of PCPs may have offered different perspectives in our study.

3.6. Conclusions

This study pilot tested a mixed methods approach to evaluate TRs that PCPs use for preventing childhood obesity in primary care. Our findings demonstrated that PCPs' subjective perspectives and the objective checklist ratings provided unique insights on the evaluation of TRs. While PCPs' use of TRs was influenced by various purposes and logistical issues, such concepts did not emerge from the quantitative phase of our study. Although contextual issues were unique to PCPs' perspectives, participants in our study

gauged the suitability of TRs based on factors similar to scoring criteria on the checklists. Of the TRs that were used by PCPs, most scored 'average' or 'suitable' for use with families on the checklists. PCPs expressed a general under-availability of high-quality TRs, particularly with respect to discipline-specific and pediatric-targeted TRs, and an oversupply of mediocre-quality TRs with poor readability and low aesthetic appeal, which was consistent with objective scoring on the checklists.

3.7. Practice Implications

Overall, our findings support using a mixed methods approach to evaluate TRs that PCPs use for obesity prevention in primary care. While our results demonstrated the usefulness of obtaining input from PCPs and objective scoring using checklists, in isolation, such information may be limited. To assess overall suitability and assist those developing TRs for childhood obesity prevention, scoring using checklists should be considered along with contextual factors and frontline providers' perceptions of suitability.

Table 3.1. Constructs, scoring, and interpretation of three assessment checklists

Assessment Checklist	Measured Constructs	Examples	Scoring Scale	Overall Interpretation	
				Total Score	Clinical Translation
PEMAT	a. Understandability (content, word choice, use of numbers, organization, layout, visual aids) b. Actionability	a. Purpose is evident, use of numbers is clear, informative headers, logical sequence, use of visual cues b. Material identifies one action the user can take, action is broken down into explicit steps	(0) Disagree (1) Agree (N/A) Not Applicable[1]	Score out of 24 converted to a %	≥70%: Understandable & Actionable <70%: Poorly Understandable and Actionable
SAM	a. Content b. Literacy Demand[2] c. Graphics d. Layout & Typography e. Learning Stimulation f. Cultural Appropriateness	a. Purpose evident, limited scope b. Active voice, context given c. Relevance of illustrations d. Use of subheadings e. Behaviors specific f. Cultural images and examples	(0) Not Suitable (1) Adequate (2) Superior (N/A) Not Applicable[1]	Score out of 44 converted to a %	Superior: 70-100% Adequate: 40-69% Not Suitable: 0-39%
TEMPtEd	a. Content b. Motivating Principles c. Literacy[3] d. Layout & Typography e. Graphics	a. Accurate, logical, appropriate for target audience b. Focus on specific client actions c. Simple to read and understand d. Headings to introduce topics, highlight key points e. Simple, realistic and relevant	(0) Criteria Not Met (1) Criteria Met Minimally (2) Criteria Met Adequately (3) Criteria Met Superiorly	Absolute score out of 63	Excellent: 57-63 Above Average: 51-56 Average: 45-50 Not Suitable: 0-44

[1]Checklist allowed for measured constructs to be assigned N/A (not applicable), therefore adjusted scores were possible
[2]Literacy assessed using the Flesch-Kincaid formula
[3]Literacy assessed using the Simple Measure of Gobbledygook (SMOG) index

Table 3.2. Coding scheme

Theme	Category	Description	Examples
Purpose of Use	1. Need for clinical support 2. Need for families	1a. Assessment & monitoring 1b. Communication with families 1c. Enhance credibility, confidence & competency 2a. Education 2b. Facilitate behavior change	[1a] *One of our clinics or locations we do more of a health promotion, so just a quick screening. So… plotting the child on the graph… to continue to monitor their weight and their height and their growth.* [KIN1] [1b] *So I guess I use tools to support discussions that I might be having with families around nutrition and weight management in the pediatric setting, so yeah primarily to support like in discussion.* [RD8] [1c] *It's great to have formal guidelines just to know that you're doing what is recommended, just that reassurance… and then also if a parent decides, you know that doesn't seem reasonable at all, then I can pull it up and say well this is what it is, right?* [RD4] [2a] *Yeah, I think just to provide more education to the families and to the children. I think it's used as a good reference guide for when people go home.* [RN3] [2b] *People walk out the door and forget what we told them from a practical, physical perspective so those tools are there to support the behavior when they're not with us.* [KIN3]
Logistical Factors	1. Awareness 2. Accessibility	1a. Top-down process 1b. Bottom-up process 2. Access is impacted by cost, distribution, and production	[1a] *We do have updates from Alberta Health Services so when they do have some new tools or information or journals or articles, they do send it to us.* [RD7] [1b] *Like really if you weren't following all the blogs and reading research, you might not even know about the 5As and that's one of the ones that's most discussed and researched.* [RN1] [1b] *I've looked for my tools, so just searching a lot on the Internet. I've been following a few blogs, which have been helpful* [KIN4] [2] *For myself I'd have to purchase a lot of them so that's the biggest thing so we have to look at cost in our clinics as well. If cost is an issue, then we might not have the resources.* [KIN5]

Decision to Use	1. Expected suitability 2. Experienced suitability	1a. Age of child 1b. Culture, language & literacy level 1c. Motivation & readiness to change 1d. Specific parental concerns 2a. Usability (for self and families) 2b. Usefulness (for self and families)	[1a] *I think it's clinical judgement right? So if they're teenagers, sometimes they want to read the ones that are not Peds focused, 'cause they don't identify themselves as kids.* [RN1] [1b] *So I mean I love them but they're only for certain families, okay? I mean they have to be able to read well, you know definitely not for someone whose English is a second language.* [RD3] [1c] *So it depends on how engaged the family is in terms of their willingness to change and their willingness to cooperate as a family… so, for example, like I won't always pull out the growth chart because I don't want the view to be very skewed on focusing just on weight and he's overweight and stuff like that.* [RD9] [1d] *Well, it's very different for every tool right that we use, so depending on the issues that the family may have, like they don't get enough fruits and vegetables in their diet, then you would choose a tool that would help boost their fruits and vegetables and gives them ways how to do it.* [RD5] [2a] *It's easy to get out the rip-off version, the one-page version… is very easy to use, and you can scribble on it.* [MD2] [2b] *I guess in terms of it* [tool], *it is a good, little, quick, cheap thing, but not crazy effective because I haven't looked at it in a while and because I feel like I just have that in my back pocket already. But if I had a co-worker that was seeing an overweight patient for weight management, and they were panicking about, "I don't know what to do," I could hand them this and say, this will help you.* [KIN2]

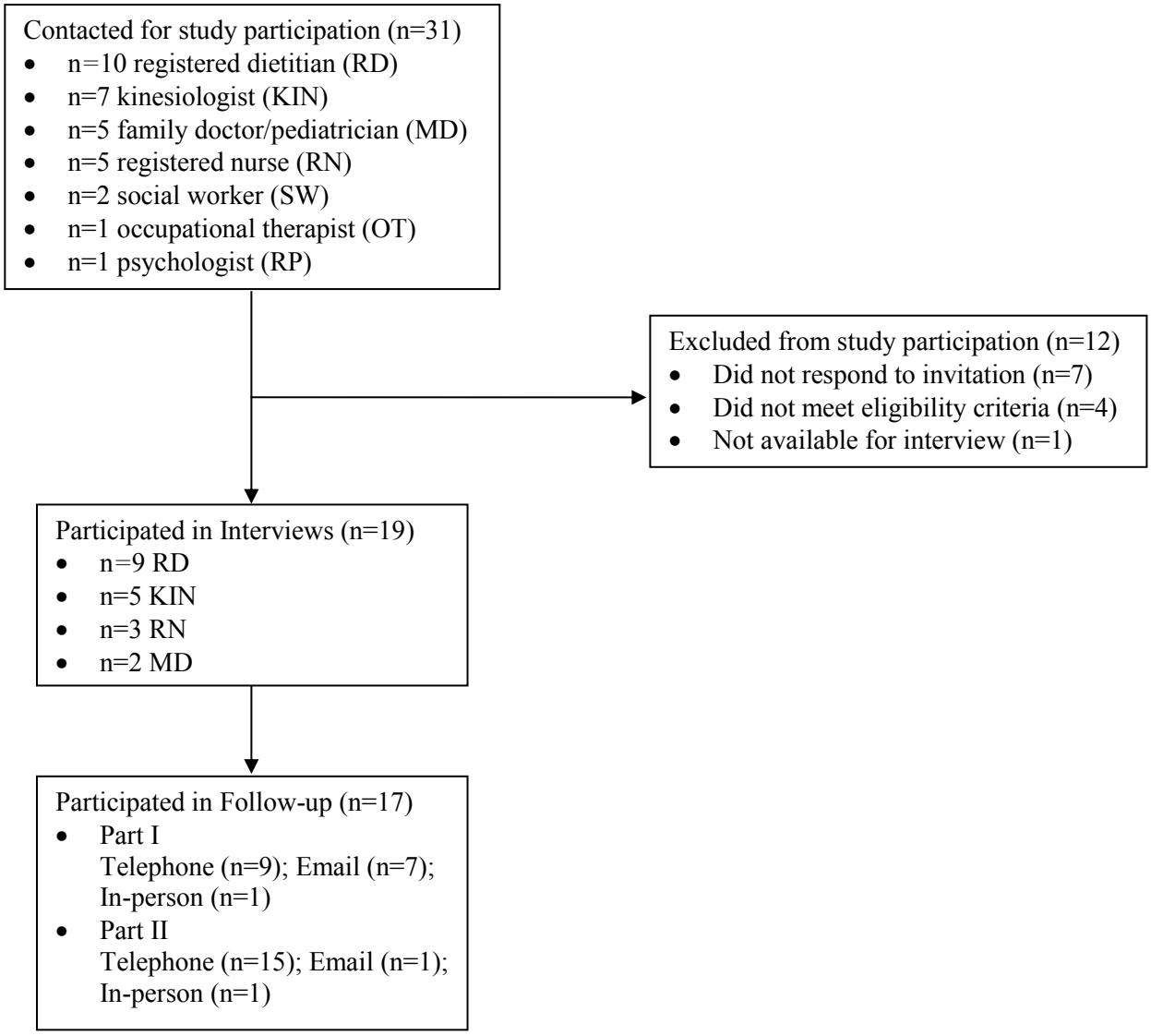
KIN: Kinesiologist; MD: medical doctor; RD: Registered Dietitian; RN: Registered Nurse
≥70% of participants are represented in the data above

Table 3.3. Assessment of TRs by PCPs and assessment checklists

	Tool / Resource	Used by (n)[1]	Type[2]	Mean PCP Score (/10)	Mean Checklist Score (%)	PEMAT (%)	PEMAT Score[3]	SAM (%)	SAM Score[4]	TEMPtEd (/63)	TEMPtEd Score[5]
Weight-focus	1. Body Mass Index Growth Charts	14	CS	7.0±2.1	37.0±13.5	27.0±0.4	PUA	31.7±0.2	NSM	33.0±4.2	NS
	2. 5As of Pediatric Obesity Management	6	CS	6.8±1.4	52.0±7.2	58.5±0.2	PUA	44.2±0.2	AM	33.5±0.7	NS
	3. AHS[6] Child's Height Ahead of Weight	5	PE	7.2±1.3	62.0±9.5	65.8±1.2	PUA	51.2±9.5	AM	43.5±0.7	NS
	4. AHS Healthy Kids, Healthy Bodies	3	PE	7.0±2.0	75.0±9.3	84.5±1.7	UA	66.0±7.7	AM	47.0±5.7	A
Diet-focus	5. Canada's Food Guide	13	PE	6.8±1.4	81.2±8.4	86.4±0.0	UA	85.7±0.0*	SM	45.0±0.0	A
	6. Magnetic Plate Model	7	PE	8.6±1.0*	84.1±4.5*	87.5±3.5	UA	78.9±7.4*	SM	54.0±1.4*	AA
	7. Healthy U Cookbook	6	PE	7.8±0.6*	83.2±8.9*	90.7±0.3*	UA	73.3±4.1	SM	54.0±1.4*	AA
	8. AHS Healthy Drinks	5	PE	6.2±1.9	76.3±5.8	81.1±3.1	UA	69.9±2.1	SM	49.0±4.2	A
	9. AHS Healthy Food Portions	5	PE	7.6±0.9	82.4±10.8	93.1±3.7*	UA	71.5±6.8	SM	52.0±0.0*	AA
	10. AHS Snacking Tips	4	PE	7.8±0.5*	69.5±6.8	75.6±4.8	UA	62.1±1.4	AM	44.5±3.5	A
Activity-focus	11. Canadian Physical Activity Guidelines	9	PE	6.8±1.3	73.2±4.2	75.0±7.1	UA	68.4±7.4	AM	48.0±1.4	A
	12. Canadian Sedentary Guidelines	7	PE	7.0±1.6	73.6±5.1	70.0±0.0	UA	71.4±3.3	SM	50.0±2.8	A
	13. ParticipACTION Website	2	PE	7.7±1.2	83.4±6.6*	91.0±0.0*	UA	79.0±4.0*	SM	50.5±0.7	AA
Multi-focus	14. Healthy U & Active Living	9	PE	6.9±1.0	72.1±2.1	73.9±1.6	UA	72.7±0.0	SM	44.0±0.0	NS
	15. Prescription Pad for Healthy Living	3	CS	6.5±0.7	66.5±1.2	67.0±6.3	PUA	65.2±4.6	AM	42.5±0.7	NS

[1]TRs were only included if used by ≥2 participants
[2]CS: Clinical Support, PE: Patient Education
[3]PEMAT scores: [UA] Understandable & Actionable Material (≥70%), [PUA] Poorly Understandable & Actionable (<70%)
[4]SAM scores: [SM] Superior Material (70 – 100%), [AM] Adequate Material (40 – 69%), [NSM] Not Suitable Material (0 – 39%)
[5]TEMPtEd scores: [E] Excellent (57 – 63), [AA] Above Average (51 – 56), [A] Average (45 – 50), [NS] Not Suitable (0 – 44)
[6]AHS: Alberta Health Services
*Top-ranked TRs

Figure 3.1. Flow diagram of participant recruitment



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Chapter 4

Avis JL, Holt NL, Maximova K, van Mierlo T, Fournier R, Padwal R, Cave AJ, Martz P, Ball GD. The development and refinement of an e-health screening, brief intervention, and referral to treatment program for parents to prevent childhood obesity in primary care. Telemed J E Health 2016;22:385-94.

4.1. Abstract

Background. Nearly one-third of Canadian children can be categorized as overweight or obese. There is a growing interest in applying eHealth approaches to prevent unhealthy weight gain in children, especially in settings that families access regularly. Our objective was to develop and refine an SBIRT for parents to help prevent childhood obesity in primary care.

Materials and Methods. Our SBIRT, entitled RIPPLE, was developed by our research team and an eHealth intervention development company. RIPPLE was based on existing SBIRT models and contemporary literature on children's lifestyle behaviors. Refinements to RIPPLE were guided by feedback from five focus groups (6–10 participants/group) that documented participants' (HCPs [n=20], parents [n=10], and researchers and graduate trainees [n=8]) perceptions of the SBIRT. Focus groups were transcribed in real-time using a court reporter. Data were analyzed thematically.

Results. Participants viewed RIPPLE as a practical, well-designed, and novel tool to facilitate the prevention of childhood obesity in primary care. However, they also perceived that RIPPLE may elicit negative reactions from some parents and suggested improvements to specific elements (*e.g.,* weight-related terms).

Conclusions. RIPPLE may enhance parents' awareness of and motivation to change their children's lifestyle behaviors, but should be improved prior to implementation. Findings from this research directly informed revisions to our SBIRT, which will undergo preliminary testing in a RCT.

4.2. Introduction

With one in three Canadian children classified as overweight or obese (Roberts et al., 2012), the prevention of childhood obesity is an urgent public health priority. Accordingly, there is need for approaches that prevent obesity in children (primary prevention) *and* manage excess weight among children with obesity (secondary prevention). This approach is consistent with recent national guidelines on the prevention of children's unhealthy weight gain in primary care (Parkin et al, 2015), a setting that families access regularly. Although most interventions for obesity prevention in children have employed a family-centered approach (Waters et al., 2011), studies have shown the benefits of targeting parents exclusively (Golan & Crow, 2004a). Interventions that target parents may be more efficient and effective than interventions that target both parents and children, a finding that likely reflects a shift in focus from children's weight to parental practices (Golan & Crow, 2004a). Because parents are key players in preventing obesity in children (Faith et al., 2012; Golan & Crow, 2004b), there is value in enhancing their awareness of and motivation to change children's healthy lifestyle behaviors. As demonstrated by theories of health behavior change, such variables are essential precursors to behavior change itself (Connor & Norman, 2005), yet they have been inconsistently applied to interventions that aim to prevent unhealthy weight gain in children (Thomas, 2006).

There is growing interest in applying eHealth approaches to prevent obesity in children (Dietz et al., 2015), and digital interventions represent a scalable approach to obesity prevention. Digital interventions have become popular, provide immediate and tailored feedback, are cost-effective, and have potential for widespread reach, which is particularly important for families in rural and remote communities (Avis et al., 2014).

Because most online interventions to address obesity-related behaviors have applied time- (*e.g.,* online programs up to 52 weeks in length [Davies et al., 2012]), and resource-intensive models (*e.g.,* online interventions with additional in-person components [Hamel & Robbins, 2013]), there is value in examining the application of brief and novel online strategies for the prevention of obesity in children. Further, delivering eHealth interventions in primary care is timely because it often represents most families' first point of contact with the health care system that extends throughout life. The provision of preventative health services for chronic diseases in this setting is proactive, efficient, and cost-effective (Haemer et al., 2011). Despite these advantages, primary care remains an underutilized venue to prevent obesity in children (Haemer et al., 2011; McQuigg et al., 2005).

The implementation of eHealth technologies has increased over recent years (Kohl et al., 2013), but high dropout (Gill et al., 2014), program ineffectiveness (Ajie et al., 2014), and poor patient treatment choices (Zikmund-Fisher et al., 2011) remain as challenges. The inclusion of stakeholders and end-users in the development of eHealth interventions may optimize patient outcomes (Campbell et al., 2007). Specifically, soliciting feedback from end-user populations may help to ensure relevance and appropriateness of content, and recruitment of stakeholders who play a role in providing care to or researching children with obesity may help to inform usefulness and novelty (Avis et al., 2015b). Accordingly, our team sought to *(i)* develop an SBIRT to enhance parents' concern about, and motivation to change, children's weights and healthy lifestyle behaviors in the primary care setting (Phase I) and *(ii)* refine the SBIRT using focus groups with parents as well as pediatric-focused HCPs, researchers, and graduate trainees (Phase II).

4.3. Materials and Methods

4.3.1. Phase I: Development

Program Type. The SBIRT, entitled RIPPLE, is intended for use in primary care with parents of children (5 – 17 years old), regardless of their weight. Eligible parents will be invited to complete RIPPLE while they await their child's upcoming pediatrician appointment. Following consent (adult) and assent (child) procedures, children's height and weight will be measured and inputted into the study-designated tablet; parents will then receive the SBIRT on the tablet, which will *screen* children's weight status, deliver a *brief* (~10 minute) *intervention* with tailored feedback, and provide a menu of resources (*referral to treatment)* for parents to select that promote children's healthy lifestyle behaviors. Although there is no universal consensus regarding the term 'eHealth', two broad themes (health and technology) help to define the concept (Hans et al., 2005), and our SBIRT fulfills both conditions. The protocol for our multi-phased study has been published (Avis et al., 2015a), and outlines in greater detail the content of the SBIRT and how parents will be recruited and enrolled in the primary care setting.

Existing Technologies. While existing technologies for obesity prevention purposes in primary care have mainly included electronic medical records (Smith et al., 2010), PCPs report a number of barriers to using them (Miller & Sim, 2004), such as uncertainty of advantages and high initial time investment. Further, while the use of electronic medical records is often a provider-driven decision, our SBIRT is intended for use by parents, which may encourage self-management of obesity-related behaviors by providing parents with tailored feedback and linking them with appropriate information and health services.

Development Process. RIPPLE was developed in partnership with *Evolution Health Inc.*, a company with a history of developing various digital SBIRTs (*e.g.,* mood and anxiety disorders [Farvolden et al., 2003]). Over two years, approximately 50 teleconference meetings with *Evolution Health* (n≈40) and in-person research team meetings (n=10) were held. A formal Privacy Impact Assessment was completed given our online collection of participant data.

SBIRT Content. Our multidisciplinary research team alongside stakeholders from the provincial government collaborated to develop the content of RIPPLE, which drew on evidence from children's nutrition (Danyliw et al., 2012; Garriguet, 2007), physical activity (Colley et al., 2011), and sedentary behaviors (Mark et al., 2006). Figure 4.1 represents the flow of the SBIRT; in exception of the brief intervention component, the SBIRT is identical for all participants. Following participant recruitment and informed consent processes, a graphical user interface leads participants through the following steps, which are completed on a tablet:

I. *Data Input.* Using a standardized measurement protocol, research assistants measure children's height (to the nearest 0.1cm) with an electronic stadiometer and weight (to the nearest 0.1kg) using a medical scale, and enter these data into the SBIRT. At this point, the tablet will be given to parents to enter demographic data about their child and family.

II. *Screening.* Using children's height and weight data, sex- and age-specific BMI percentile and weight status categories will be automatically calculated according to reference values of the Centers for Disease Control and Prevention. Then, parents will receive

objective, personalized feedback both numerically (*i.e.,* child's BMI percentile) and visually (Cloutier et al., 2013) (Figure 4.2). Given that traditional means of disseminating children's weight status to parents (*i.e.,* BMI growth charts) can result in erroneous interpretations (Ben-Joseph et al., 2009), a clearer and more concise means to communicate this information is justified. With sensitivity to parents' terminology preferences (Puhl et al., 2011), the terms *underweight* (BMI $<5^{th}$ percentile)*, healthy weight* ($\geq 5^{th}$ and $<85^{th}$ percentile)*, unhealthy weight* ($\geq 85^{th}$ and $<95^{th}$ percentile), and *very unhealthy weight* ($\geq 95^{th}$ percentile) will be used.

III. *Brief Intervention.* Parents will be randomly assigned to one of four brief interventions (two target nutrition [*Eat It!*] and two physical activity [*Move It!*]) or an eHealth control group [*Heads Up!*], which will undergo testing in a future RCT. Parents assigned to *Heads Up!* will only be given general information regarding children's lifestyle behaviors. *Eat It!* includes two questions (one on children's intake of grain products, one on intake of sugar-sweetened beverages), and *Move It!* includes two questions (one on children's duration of daily moderate-to-vigorous physical activity, one on amount of daily screen time). Following their responses, parents will receive *normative* or *injunctive* feedback; the former will compare parents' responses to normative data from the Canadian pediatric population (*e.g.*, Canadian Health Measures Survey [Tremblay et al., 2010]; Figure 4.3) and the latter will compare parents' responses to national recommendations (*e.g., Canada's Food Guide to Healthy Eating* [Health and Welfare Canada, 1992]). Across these four arms, the aim is to elicit a *cognitive discrepancy* (the potential difference between parents' internalized beliefs and the feedback they receive),

which will be assessed using *thought listing* (Cacioppo & Petty, 1981). Parents will be offered a menu of adjectives and instructed to select as many as they like to describe their immediate thoughts and feelings. This method may provide insight into cognitive processes (Cacioppo et al., 1997). Specifically, parents' reactions may be associated with the magnitude of the elicited cognitive discrepancy, which may influence their motivation to change children's lifestyle behaviors (Neal & Carey, 2004).

IV. *Menu of Resources (Referral to Treatment).* Parents will be presented with a menu of resources, which was developed in collaboration with our research team and stakeholders in primary care. Parents will be given the option to select as many online handouts (*e.g.,* sedentary behavior guidelines, tips on healthy snacking) and/or information on community services (*e.g.,* outpatient dietitian counselling, pediatric weight management services) as desired, which will be automatically included in the emailed tailored report. Although classically titled, 'Referral to Treatment', the aim of our SBIRT is to provide resources for parents of healthy weight children (*e.g.,* online handouts for use at home) and information on services for parents of unhealthy weight children (*e.g.,* services in the community). Compared to traditional means of resource dissemination (*i.e.,* hard-copy handout from PCP), provision via eHealth may help to reduce social barriers and provide anonymity to families (An et al., 2009), and encourage parent's independent selection of resources that are relevant to their children.

V. *Questionnaire.* A brief survey was adapted (with permission) from Campbell et al. (2011) to query parent's concern about children's weight status and motivation to change

children's lifestyle behaviors. Parents assigned to *Eat It!* or *Move It!* will receive an 8-item questionnaire to assess *(i)* concern about children's weight status (1 question), *(ii)* intention to discuss children's weight with the pediatrician (1 question), *(iii)* intention to use selected resources over the next month (1 question), and *(iv)* motivation and confidence to change children's diet (5 questions in *Eat It!*) and physical activity (5 questions in *Move It!*). Parents assigned to *Heads Up!* will receive a 13-item questionnaire that includes questions from both *Eat It!* and *Move It!*.

VI. *Tailored Report.* An optional tailored report will be sent to parents via email once they complete the SBIRT. The report includes children's weight status, parents' responses to and feedback from the brief intervention (or information from the control group), and the resources they selected. The report will also remind parents that in one month, the research team will follow-up with a brief survey (similar to Section V) via email, which will *(i)* reassess their concern about children's weight status and motivation to change children's lifestyle behaviors, and *(ii)* assess their use of selected resources and if they discussed their child's weight with the pediatrician immediately following the SBIRT.

Theoretical Framework. Informed by previously developed and tested SBIRTs, RIPPLE included several theoretical underpinnings from various frameworks, such as the Health Belief Model (Rosenstock, 1974) and Norm Activation Model (Schwartz, 1977). Consistent with the former, it is hypothesized the SBIRT will act as a *cue to action* to facilitate behavior change by creating a discrepancy between parents' perceptions of their children's lifestyle behaviors and the feedback they receive. By creating a cognitive

discrepancy between parents' perceptions of their children's behaviors and normative feedback, the Norm Activation Model (de Groot & Steg, 2009) postulates that parents who report children's behaviors as 'average' or 'excellent' relative to their peers may be reinforced via feelings of pride; conversely, parents who report children's behaviors as 'subpar' relative to peers may be nudged towards change via feelings of guilt (Onwezen et al., 2013). Additional details regarding theoretical components related to the SBIRT are published (Avis et al., 2015a).

4.3.2. Phase II: Refinement

Data Collection. Eligible participants included parents, HCPs, researchers and graduate trainees with a primary focus on pediatrics. Participants were purposefully sampled for diversity in experience and expertise in order to gather multifaceted perspectives on RIPPLE. Parents were recruited via word-of-mouth from the Department of Pediatrics (University of Alberta); HCPs, researchers, and trainees were recruited from a local pediatric primary care clinic, a pediatric weight management clinic, and the University of Alberta. A graduate trainee (JA) trained in qualitative methods led participant groups through the SBIRT by entering standardized data and projecting the content onto a large screen. Following completion of the SBIRT, participants' impressions regarding likeability, acceptability, satisfaction, and feasibility were queried (Appendix M**;** interview guide). As a token of appreciation, all participants received a $25(CAD) gift card. Ethical approval was obtained from the Health Research Ethics Board at the University of Alberta. The Consolidated Criteria for Reporting Qualitative Research (Tong et al., 2007) was used to report our research (Appendix N).

Data Analysis. Focus group data were transcribed in real-time by a court reporter (Scott et al., 2009), and the timeliness of transcription (~1 week) facilitated concurrent data collection and analysis. Data saturation was reached when no new information emerged from focus groups. Interviews were checked alongside their corresponding recording for accuracy and completeness, and the researchers familiarized themselves with the transcripts prior to analysis. Thematic analysis (Morse & Field, 1995) was used. Transcripts were coded line-by-line, and an initial coding scheme was developed after analysis of the first transcript, which was used to analyze subsequent interviews. After each group discussion was coded, themes were grouped into general categories, and written descriptions were developed. Data were managed and analyzed using *NVivo 10* (QSR, Melbourne, Australia). Analyses were reviewed independently by two senior team members (NH, GB) to verify accuracy and completeness of the coding scheme.

4.4. Results

Five focus groups (6–10 participants/group) were conducted with a total of 38 participants, including parents of children aged 12.5±5.5 years old (n=10), and pediatric-focused HCPs (n=20) and researchers and trainees (n=8). Most participants were female (n=31; 81.6%) and Caucasian (n=29; 76.3%). Thematic analysis of the focus group data revealed two main themes – perceived strengths and weaknesses (Table 4.1).

4.4.1. Perceived Strengths

RIPPLE May Facilitate Obesity Prevention in Children. Overall, most participants viewed RIPPLE as a unique opportunity to enhance parents' awareness of their

children's weights and lifestyle behaviors. Analysis suggested five main categories within this theme. First, RIPPLE may alleviate barriers that families face when preventing obesity in their children, such as motivation to make healthy changes. Second, RIPPLE may connect parents with relevant resources to facilitate the primary and secondary prevention of obesity in children. Third, RIPPLE has the potential to enhance parents' awareness of children's weight status as well as dietary, physical activity, and sedentary behaviors via novel means of communication. Fourth, the SBIRT provided quick and informative tailored feedback, unlike most routine tests in primary care. In particular, participants valued the normative feedback comparing children's lifestyle behaviors to their peers. Lastly, RIPPLE may act as a catalyst by nudging parents to initiate a conversation about children's weight status with their pediatrician following participation in the SBIRT.

A Well-Designed Tool. First, RIPPLE included appropriate language and was suitable in length and look. Most participants said language pertaining to nutrition and physical activity was clear and informative, and that the SBIRT looked "spiffy". Second, most participants thought RIPPLE would be a feasible tool in primary care, and HCPs said it matched their needs for the prevention of chronic diseases. Third, the content of RIPPLE was deemed relevant for parents, and participants voiced that materials related to children's intake of sugar-sweetened beverages and screen time would be helpful to most parents, particularly those accustomed to receiving information on nutrition and physical activity. Lastly, although a minority of participants expressed that some parents may be unfamiliar with tablets, most thought usability of the SBIRT was straightforward, and participants did not report difficulty following navigation.

4.4.2. Perceived Weaknesses

Parents May React Negatively. Across the five focus groups, participants reported that RIPPLE may elicit negative reactions (*e.g.,* fear, guilt, shame) from some parents in response to learning that their child's weight status was in the *obese* category. While most participants viewed potential negative reactions as a disadvantage, some viewed it as a strength whereby parents' potential concern and fear may instigate positive behavior change.

Room for Improvement. Participants identified specific elements of RIPPLE that required modification. First, additional resources (*e.g.,* behavior change techniques, body image, restaurant eating, sleep requirements) were recommended for inclusion. Second, participants identified the need to enhance the clarity of instructions, descriptions, and terms. Many participants found it difficult to understand the instructions for parents to select information in the Menu of Resources (Section IV), and the description of content in the tailored email report was vague. Third, participants expressed concern that images used within RIPPLE should reflect cultural diversity beyond "white, blue-eyed people". Lastly, participants recommended improving weight-related terminology. Although most participants thought the terms could be stigmatizing, interestingly, this was not an issues raised by parents. This may be reflective of HCP's, researcher's, and trainee's experience with and expertise in the area of childhood obesity. Among those that demonstrated concern, suggestions included emphasizing that weight is only one indicator of children's health status.

4.5. Discussion

The aim of our study was to develop and refine an SBIRT designed to enhance parents' awareness of and motivation to change children's weight status and healthy lifestyle behaviors. Findings from our focus groups revealed a number of perceived strengths and weaknesses of RIPPLE. Participants agreed that RIPPLE was a well-designed tool that could be incorporated into primary care to help prevent childhood obesity, but participants thought that RIPPLE may elicit negative reactions from parents, and some elements should be improved prior to use with parents.

Based on our findings, participants valued the immediate and personalized feedback parents could receive as well as the connection with resources for obesity prevention in children. Such elements are consistent with previous reports (Gillison et al., 2013) that emphasize the importance of tailoring information to families, and equipping them with the necessary tools to support children's healthy weights. Participants also expressed RIPPLE may help to alleviate barriers by sparking a conversation about weight between parents and pediatricians, a topic pivotal to parents' awareness of children's weight status, but one that is difficult to initiate (Walker et al., 2007). Because awareness of children's weight status represents an important first step towards obesity prevention (Duncan, 2011; Mathieu et al., 2010), it is noteworthy that most participants thought RIPPLE would enhance parents' awareness of children's weight and encourage healthy lifestyle behaviors. However, among parents who hold an accurate perception of their child's weight status, which may be as low as 20 – 25% (Duncan et al., 2015), only 50 – 60% initiate healthy lifestyle changes (Neumark-Sztainer et al., 2008). These statistics reinforce the potential value of correcting parents' misperceptions of their children's weight status *and* enhancing their motivation to

change children's nutrition and physical activity behaviors. Although participants reported that RIPPLE may facilitate parents' mindfulness of children's weight status and healthy lifestyle behaviors, they did not characterize RIPPLE as a driver of behavior change. This finding aligns with the role of eHealth interventions as adjuncts rather than alternative means to traditional care; in other words, standalone eHealth technologies are unlikely to drive sustainable behavior change (Patel et al., 2015) and may be most useful when used concurrently with relevant resources.

Most participants expressed that RIPPLE would be a practical tool for use in primary care. Specifically, participants said that content of the SBIRT was well-aligned with the goals of primary care, such as the prevention of chronic diseases. As well, the eHealth intervention was an appropriate length (10 – 15 minutes from start-to-finish), and the straightforward navigation and friendly aesthetic appeal were engaging for participants. Although one focus group consisting of researchers and trainees voiced that RIPPLE may be difficult to incorporate into primary care if children were too demanding of parent's attention, their opinions may reflect previous experiences with recruiting families for more time- and resource-intensive interventions. Overall, our findings regarding practicality are aligned with recent studies that have highlighted the importance and timeliness of developing scalable interventions for childhood obesity (Foster et al., 2012).

Many participants thought RIPPLE may elicit negative reactions, particularly for parents whose children are obese. This view was consistent with previous research (Kubik et al., 2008), highlighting the need to deliver weight-related information in a sensitive, direct, and non-judgmental manner. In doing so, this may increase the likelihood that information is well-received and useful for families, especially given that providers' insensitivity

represents a primary reason for non-engagement and non-return to obesity-related services (Turner et al., 2011). Because using eHealth to screen children's weight status remains novel (Lee et al., 2015), this feedback emphasizes the need to develop interventions with care since sharing weight-related terminology and information with families may be perceived negatively by parents and children.

4.5.1. Strengths & Limitations

There are several methodological strengths in both phases of the present study. In Phase I, development of intervention content was a collaborative team effort, and the opinions and priorities representative of various groups (*e.g.,* multidisciplinary HCPs, researchers) contributed to the final product. There are two main strengths in Phase II. First, perspectives of the intervention were solicited from the end-user population (*i.e.,* parents) *and* relevant stakeholders in the field (*i.e.,* HCPs, researchers, graduate trainees). This is important because it helps to alleviate the *concordance gap*, a theoretical difference between the needs and priorities of patients, and tools solely developed and endorsed by HCPs (van Mierlo et al., 2015). Second, the transcription of focus group discussions was captured in real-time using a court reporter, and the prompt turnaround time from focus group discussion to transcription enabled concurrent data collection and analysis, an important tenet of qualitative research (Morse et al., 2002).

It is important to acknowledge the limitations of this study. First, given the ethical principle of confidentiality, we were unable to program our SBIRT to automatically send participants' information to their PCP. Although participants will be encouraged to discuss information they receive from RIPPLE with their pediatrician at their upcoming

appointment, this conversation cannot be enforced. Second, focus group participants were predominantly female and Caucasian, so a more diverse group may have yielded different findings. However, this sample of parents is representative of our target population for the next phase of our research. Third, due to time constraints during the focus groups and because the SBIRT is programmed for a future RCT, each focus group was only shown and asked to provide feedback on one-of-five potential arms within RIPPLE. However, because all components of the SBIRT are identical with exception to the brief intervention, the majority of content shown to focus groups participants was similar. Last, we did not investigate (directly) any differences between stakeholders' perspectives on the SBIRT; therefore, findings regarding distinct groups' opinions (*e.g.,* parents *vs.* researchers) may have been overlooked.

4.6. Conclusions and Future Directions

The development of RIPPLE was a multidisciplinary, cross-sectoral collaboration that was based on existing SBIRT models and contemporary literature on children's lifestyle behaviors. Feedback from participants highlighted perceived strengths and weaknesses of RIPPLE, which will undergo preliminary testing in a RCT with parents (n=200) in a primary care clinic (ClinicalTrials.gov Identifier: NCT02330588) (Avis et al., 2015a). Results of our RCT will confirm a number of practical issues (*e.g.,* feasibility in primary care, level of recruitment, suitability of outcome measures). Our findings will also determine which, if any, of our five intervention groups (four experimental, one control) influences parents' motivation to change children's healthy lifestyle behaviors.

Table 4.1. Coding scheme

Theme	Subtheme	Category	Sample Quotes
I. Perceived Strengths	RIPPLE may facilitate the prevention of obesity in children	Alleviate barriers	*Some of those other barriers might be removed on the family's side of, "I didn't want to ask about this" or "I hate every time my doctor brings this up; I'll look into these resources myself."* [HCP4] *I think about the barrier that this intervention is likely to address and say the – one of the major barriers is lack of concern.* [RT2]
		Connects parents with resources & services	*Parents, then, are connected with resources in the community and know where to go if they want help.* [HCP12] *Getting them linked in, so they have a concern, it helps direct them to further services. This isn't going to solve the world's problems, but it might direct them to an appropriate agency that can get them involved.* [HCP7]
		Enhances awareness	*I think it really gives them a good – just an opportunity for parents to have an 'aha' moment where they say, "oh, I never really considered that this was a problem for my child!"* [HCP3] *This intervention addresses three types of awareness: awareness of the weight status of the child, awareness of level of physical activity, and some awareness about eating patterns.*[RT2]
		Provides instant feedback	*I also like that you get something right away for yourself that you can use. It's about your child, so you're very interested in that, and you get information right away.* [P1] *I really like that you do it and then you get the result, like, an email that's just condensed. That's great.* [P5]
		Starts the conversation	*It's opening a door for ongoing dialogue.* [HCP7] *It will help open that conversation with patients for physicians who don't typically bring that up.* [RT5] *Like, if you can't talk about it, you can't change it, so this is kind of that starting point to bring up the discussion.* [RT4]
	RIPPLE is a practical, well-designed tool	Appropriate language, length[1] & look	*I think the questions are straightforward. It's… you haven't used any medical terms that you should explain to them or take extra time.* [HCP15] *Easy to complete in a short period of time while you're waiting in the waiting room.* [P8] *I think visually it's really nice to look at. It's clean. It's not cluttered.* [HCP6] [1]Negative Case: >50% of participants in one focus group voiced RIPPLE was too long: *…it's pretty lengthy. Like, a lot of reading and I don't know if they'll be frustrated with doing it.* [HCP19]
		Fits into primary care[2]	*You get that information and you can go in and discuss it right away with the pediatrician. It's a good thing, so you don't sit there and stew about your child being either underweight or overweight. You can have that conversation right now.* [P5] [2]Negative Case: >50% of participants in one focus group voiced it would be difficult to incorporate RIPPLE into primary care: *I think about cranky children and children being sick and coughing and*

			whiny, and so I just wonder how many interruptions you will get in the survey and you have a highly motivating toy that you're giving to the parent and not the child. [RT7]
		Relevant content	*It's Chow Down. We're talking about food, so I really like that choice.* [HCP1] *It's saying good job as a parent… we recognize you have lots to balance and with your busy lifestyles.* [HCP3]
		Straightforward to navigate	*Very user friendly.* [HCP2] *Straightforward, easy to use. It's logical.* [P8] *There's not – none of those, like if not go to question whatever, or like there's nothing complicated like that. Pretty straightforward.* [HCP4]
II. Perceived Weaknesses	RIPPLE may elicit negative reactions from parents	Guilt & shame	*I think parents could potentially really personalize the fact and have a lot of guilt. My child is in the 95th percentile of weight; I'm the worst parent ever.* [RT3] *If you got that back… my first reaction would be, like, embarrassment or shame.* [RT4]
		Fear[3]	[Moderator]: *What are your thoughts about that terminology?* [HCP7]: *Scary. It would be a fear response, I think, for a parent.* [HCP8]: *Yeah.* [3]Negative Case: >50% of participants in one focus group viewed parents' negative reactions as an advantage: *It would make them more concerned, which is probably a good thing.* [P2]
	RIPPLE is a working tool with room for improvement	Additional resources for parents	*I think it would be nice to see some resources that relate to body image and to bullying.* [HCP10] *I think sleep hygiene is really important when we think about the choices and the decisions we make as part of our day-to-day behavior.* [RT7]
		Enhance clarity of select instructions, descriptions & terminology	*I just still have this fogginess in my head about these questions and the yes' and no's and whether the parent really know what they're getting into if they check the box.* *It's a bit confusing in terms of what's a handout, what's a service, what's something else.* [HCP4]
		Incorporate cultural diversity	*Given the diversity of families that you're dealing with, a lot of the pictures just seem to be white, blue-eyed people.* [RT1] *Overall I got kind of the sense that this was kind of geared for more white kids.* [RT7]
		Improve sensitivity of weight-related terminology	*That's a tough one, because unhealthy implies the child is unhealthy, but we know that weight and BMI are only part of health.* [HCP4] *I think it's [terminology] is sensitive, but I think it could be more sensitive…'Very unhealthy' is harsh but I don't know what the other alternatives are.* [HCP9]

Quotes are from parents (P), health care professionals (HCP), and researchers and graduate trainees (RT).
The majority of participants are represented in the quotes above.

Figure 4.1. Flow of the SBIRT

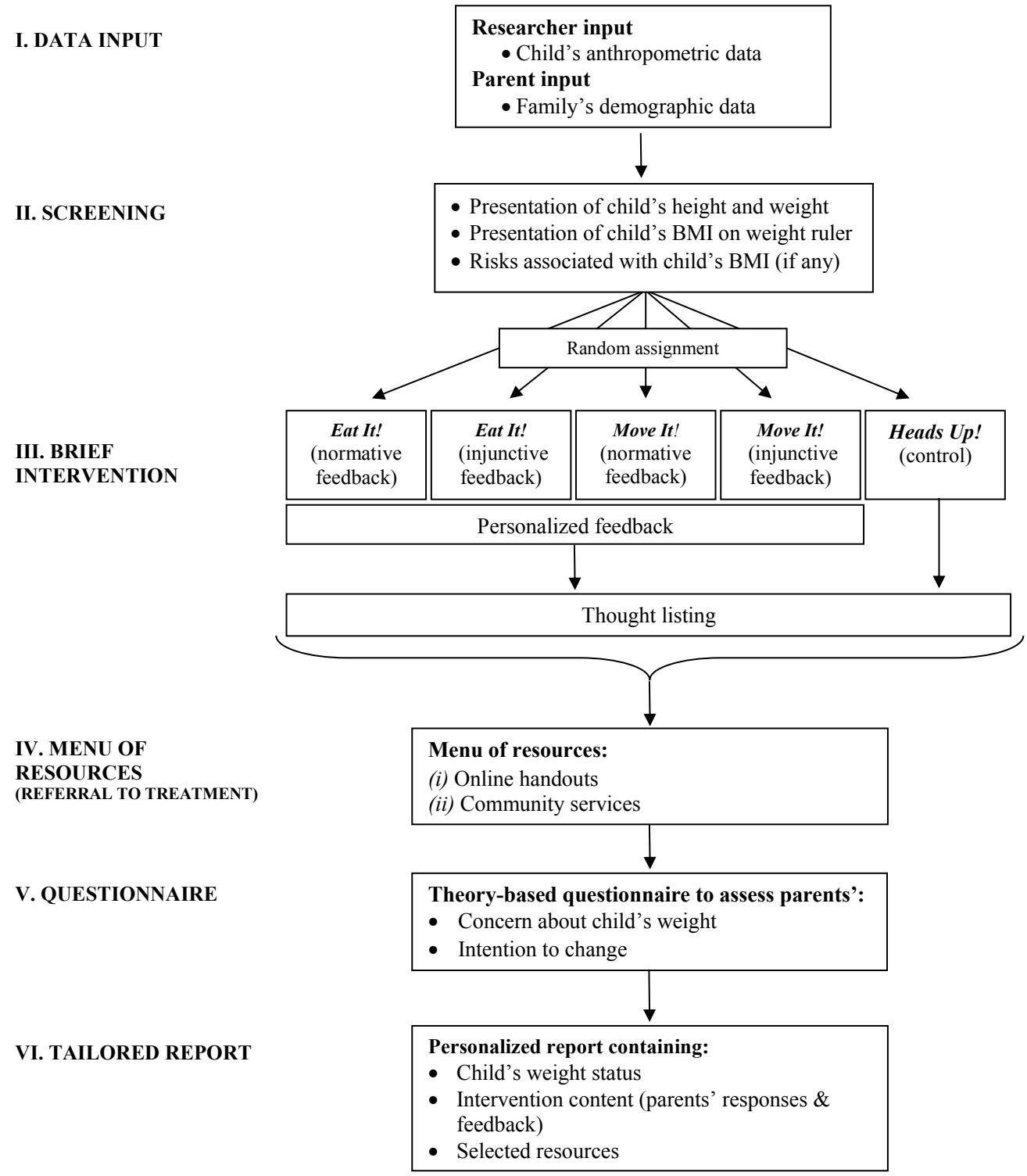


Figure 4.2. Example of weight screening feedback

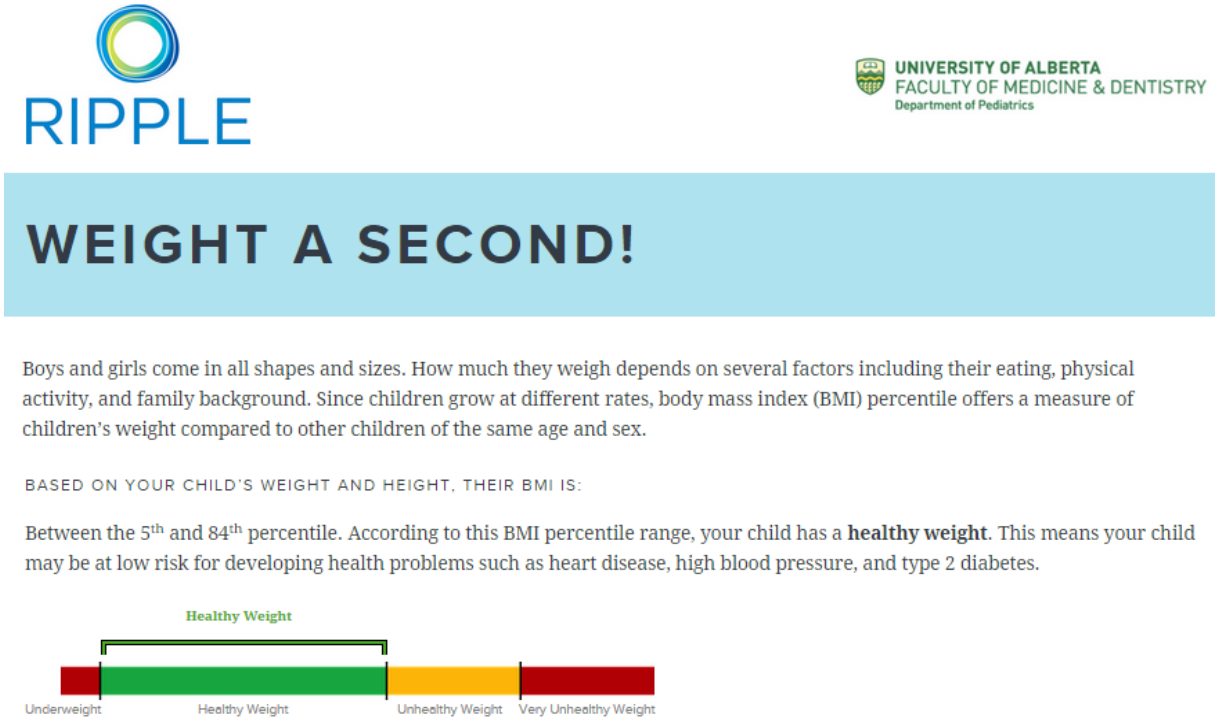
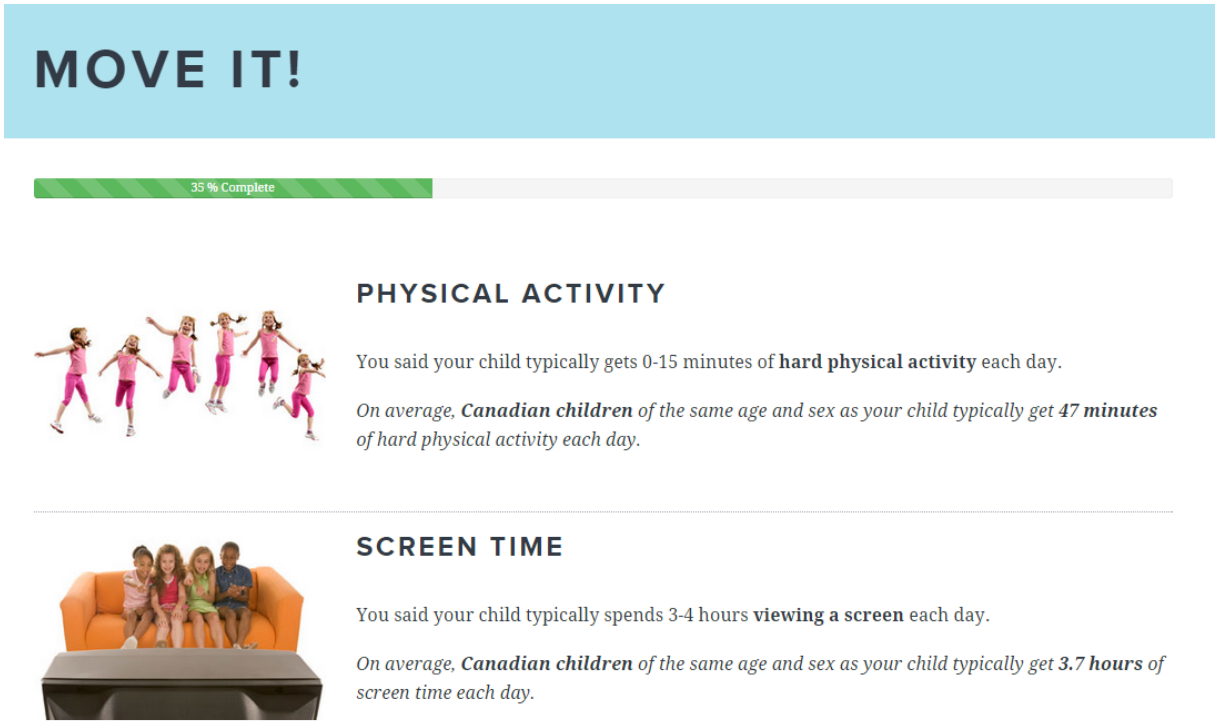


Figure 4.3. Example of normative feedback



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Chapter 5

Avis JL, Wild TC, Maximova K, Browne NE, Holt NL, Cave AJ, Martz P, Ellendt C, Ball GD. A brief eHealth tool delivered in primary care to help parents prevent childhood obesity: a randomized controlled trial. Pediatr Obes; Under Review.

5.1. Abstract

Objectives. To determine the feasibility and preliminary impact of a digital SBIRT delivered in primary care to help parents prevent childhood obesity.

Methods. Parents of children (5 – 17 years old) were recruited from a primary care clinic. Children's measured height and weight were entered into the SBIRT on a study-designated tablet. The SBIRT screened for children's weight status, block randomized parents to one-of-four brief interventions or an eHealth control, and provided parents with a menu of optional obesity prevention resources (*i.e.,* online handouts, information on community services). Feasibility was determined by parents' interest in, and uptake of, the SBIRT. Preliminary impact was based on parents' concern about children's weight status and intention to change lifestyle behaviors post-SBIRT.

Results. Parents (n=226) of children (9.9±3.4y) were primarily biological mothers (87.6%) and Caucasian (70.4%). The proportion of participants recruited (84.3%) along with parents who selected optional resources within the SBIRT (85.8%) supported feasibility. Secondary outcomes did not vary across groups, but non-Caucasian parents classified as inaccurate estimators of children's weight status reported higher levels of concern and intention to change post-SBIRT.

Conclusions. Our innovative, digital SBIRT was feasible in primary care and might nudge parents with unhealthy weight children towards behavior change.

Trial Registration. ClinicalTrials.gov, Identifier: NCT02330588

5.2. Introduction

There is evidence to support targeting parents to prevent unhealthy weight gain in children (Golan & Crow, 2004). Parents can foster a supportive home environment, role-model healthy lifestyle habits, and monitor and reinforce children's lifestyle behaviors (Faith et al., 2012). Yet, a substantial proportion of parents inaccurately estimate children's weight status and many do not perceive their children's excess weight as a health concern (Perez & Ball, 2015), which may impede or delay preventive actions (Mathieu et al., 2010). Further, among those parents who are accurate estimators of their children's weight status, only 50 to 60% are likely to encourage healthy lifestyle behaviors for their children (Neumark-Sztainer et al., 2008). These data highlight the need to develop and test novel approaches designed to help parents support children's healthy weights.

Digital technologies, such as eHealth applications, have several capabilities and characteristics that are amenable to research in the health care setting. For instance, they have the potential to increase access to services (Rosa et al., 2015), reduce social barriers and provide anonymity to patients (An et al., 2009), and alleviate challenges (*e.g.,* lack of time, resources) that PCPs often report when delivering prevention-related care (Yarnall et al., 2003). Digital technologies may be well-suited to preventing childhood obesity because they can enhance the speed of delivery and convenience of limited obesity-related health services (Lappan et al., 2015). Further, recent studies (Bianchi-Hayes et al., 2015; Turner et al., 2015) have shown that parents are receptive to the use of technology to facilitate positive health behavior change. Although reviews have reinforced the advantages of digital health applications for children and families (Turner et al., 2015; An et al., 2009), most have been

time and resource-intensive (Hammersley et al., 2016) and little is known about brief and novel strategies to prevent childhood obesity.

One such approach is the SBIRT, which has been applied in primary care to prevent and screen for substance abuse (Kaner et al., 2009) and mental health concerns (Sorsdahl et al., 2015). SBIRTs can be delivered electronically, and studies have shown this approach can exert a positive influence on intention to change unhealthy habits and potentially help to initiate behavior change itself (Kaner et al., 2009). In childhood obesity, SBIRTs align with preventive health services since they can be designed to screen for children's weight status, a clinical practice that is recommended (Parkin et al., 2015) but difficult to implement (Reed et al., 2015). Accordingly, the objective of our study was to conduct a pilot RCT to determine the feasibility (primary outcome) and preliminary impact (secondary outcome) of a parent-based digital SBIRT designed to prevent childhood obesity in primary care.

5.3. Methods

5.3.1. Participants and Recruitment

Eligible parents of children were recruited from the waiting room of a pediatric primary care clinic between July to October, 2015; parents were invited by the study coordinator (JA) or research assistant (NB) to participate in a brief eHealth tool on a study-designated tablet. Parents awaiting their child's upcoming pediatrician appointment were eligible to participate if *(i)* their child (5 – 17 years old) presented with non-urgent medical issues, *(ii)* they self-identified as the child's primary caregiver (*e.g.,* mother, father, legal guardian), and *(iii)* they were able to read and speak English fluently. Families typically waited a period of time before their medical appointments started, and this time was used to

(i) coordinate with the intake nurse to identify eligible families, *(ii)* recruit participants, *(iii)* obtain informed, written consent (adult) and assent (child), *(iv)* measure and record children's height (cm) and weight (kg), and *(v)* deliver the SBIRT to parents on a study-designated tablet. From start-to-finish, this process took approximately ~20 minutes. Parents received a token of appreciation ($25 CAD gift card) upon completion of the SBIRT and at that time they were encouraged to participate in the one-month follow-up survey sent via email. The Health Research Ethics Board at the University of Alberta (Edmonton, AB) reviewed and approved this study.

5.3.2. Study Design

The protocol for this study has been published (Avis et al., 2015a) and the trial is registered (ClinicalTrials.gov, Identifier: NCT02330588).

Intervention. Content and flow of the SBIRT, entitled RIPPLE, is shown in Supplementary Materials Figure 1. The SBIRT was delivered on a study-designated tablet and included the following components:

I. *Data input*. Medical office assistants working within the pediatric primary care clinic measured children's height (to the nearest 0.1cm) using an electronic stadiometer and weight (to the nearest 0.1kg) using a medical scale, which was part of the routine clinical process. Anthropometric data were entered into the SBIRT program on a study-designated tablet and given to parents to enter *(i)* demographic data (*e.g.,* ethnicity, socioeconomic status), *(ii)* perception of their child's weight status (*i.e.,* very

underweight, a little underweight, just right, a little overweight, very overweight), and *(iii)* contact information (*i.e.,* email).

II. *Screening*. Using children's height and weight data, sex- and age-specific BMI percentile and weight status categories were automatically calculated according to reference values of the Centers for Disease Control and Prevention (2000): *underweight* (BMI <5th percentile)*, healthy weight* (≥5th and <85th percentile)*, unhealthy weight* (≥85th and <95th percentile), and *very unhealthy weight* (≥95th percentile). Parents received this information both numerically and visually using a weight ruler (Supplementary Materials Figure 2a) (Cloutier et al., 2013).

III. *Brief Intervention.* Parents were randomly assigned to one-of-four brief interventions or the eHealth control group. Two of the brief interventions were nutrition-based (*Eat It!*) and two were physical-activity (*Move It!*) based. The nutrition-based interventions included two questions about portion size and sugar-sweetened beverages; the activity-based interventions included two questions about screen time and moderate-to-vigorous physical activity (MVPA). Within each of the nutrition and physical activity interventions, parents received either *injunctive* [I] (*i.e.,* guidelines for Canadian children; for example, "children should get at least 60 minutes of MVPA per day") or *normative* [N] feedback (*i.e.,* referent data from Canadian children; for example, "children of the same age and sex as your child typically get 47 minutes of MVPA every day"), so our four brief intervention groups included *Eat It!* [I], *Eat It!* [N], *Move It!* [I], and *Move It!* [N] (Figure 2b; Supplementary Materials). The eHealth control group

(*Heads Up!*) did not include a brief intervention but rather general information on children's healthy lifestyle behaviors (Figure 2c; Supplementary Materials); parents in this group still received screening of children's weight status and a menu of resources for obesity prevention.

IV. *Menu of resources* (referral to treatment). Parents were presented with a menu of resources, which constituted online handouts (*e.g.,* physical activity and sedentary behavior guidelines, tips on healthy snacking) and information on community services (*e.g.,* dietitian counselling, pediatric weight management services) that were compiled by our grant team and primary care-based research partners. Information on community services were focussed on parents with children classified as overweight or obese for weight management purposes. Parents were given the option to select as many handouts and/or services as desired; a total of 14 online handouts and six community services were provided (Supplementary Materials Figure 2d).

V. *Survey.* A brief survey (Campbell et al., 2011) was adapted (with permission) to assess parents' concern about children's weight status and intention to change children's lifestyle behaviors. To assess concern, parents were asked "How concerned are you about your child's present weight or body size?" (0=not concerned; 4=very concerned). To assess intention to change children's diet (for *Eat It!* and *Heads Up!*) or physical activity (for *Move It!* and *Heads Up!*) parents were asked either, "How ready are you to change your child's eating habits?" or "How ready are you to change your child's level

of physical activity?" (0=not ready; 4=very ready), respectively, using a 5-point Likert scale.

VI. *Tailored email report.* Parents were provided with the option to receive an automatically-generated tailored report to their personal email. The report included *(i)* children's weight status, *(ii)* parents' responses to, and feedback from, the brief intervention (or information from the eHealth control), and *(iii)* the resources they selected. The report also reminded parents that they would receive a brief follow-up survey in one-month, which assessed *(i)* their use of selected obesity prevention resources and *(ii)* if they discussed their child's weight with the pediatrician immediately following the SBIRT.

Trial Procedures. Participants enrolled in this double-blinded, parallel-design RCT were automatically assigned a unique, non-identifying number. The allocation sequence was electronically generated within the SBIRT, and parents were assigned to one of the four intervention groups or the eHealth control using blocked randomization (five arms, block size of five) to ensure equal group sizes (n≈45/arm, equal allocation ratio of 1:1). Research personnel were blinded to participants' intervention assignments unless participants asked for assistance (n=11). Participants were also blinded; prior to enrollment, participants received information that was sufficient to obtain informed consent, but inadequate so as to decipher between group assignment.

5.3.3. Outcomes and Measurement

Our primary outcome was feasibility of the SBIRT, which included parents' interest in, and uptake of, the SBIRT. Parents' interest was determined by the proportion of parents that *(i)* enrolled among those approached to participate, *(iii)* self-selected resources from the SBIRT, and *(iii)* 'opted in' to receive the tailored email report. The latter two were recorded by back-end programing of the SBIRT. Specifically, the SBIRT automatically coded *(i)* if parents selected resources, *(ii)* which resources parents selected, and *(iii)* if parents chose to have the optional tailored report emailed to them. Uptake was determined by parents' use (actual and self-reported) of obesity prevention resources, and the proportion of parents that reported discussing children's weight with their pediatrician immediately following the SBIRT. Parents' actual use of resources was also determined via back-end programming of the SBIRT; links to selected resources were included in the optional tailored email, and we were able to determine if resources were downloaded by parents. At one-month post-SBIRT, parents were emailed a brief follow-up survey that asked: "Over the past month, did you use the online resources that you selected during the RIPPLE program?" and "I discussed my child's weight with the pediatrician last month when I completed the RIPPLE program." (0=yes; 1=no).

Secondary outcomes informed preliminary impact of the SBIRT and included parents' concern about children's weight status and intention to change children's lifestyle behaviors immediately following the SBIRT (see 'V. *Survey*' component of the intervention for measurement).

5.3.4. Statistical Analyses

Continuous and categorical variables were summarized descriptively using means (SD) and proportions. Group differences by weight status, demographic characteristics, and primary and secondary outcomes were assessed using independent sample *t* tests and one-way ANOVA with Tukey adjustments for *post hoc* analysis (continuous variables), and Chi square analysis (categorical variables). Spearman's rho was used for nonparametric correlations. Children's age- and sex- adjusted BMI percentiles were calculated according to the Centers for Disease Control and Prevention (2000); for analyses purposes, children were classified as having a *healthy* (BMI $\geq 5^{th}$ and $<85^{th}$ percentile) or *unhealthy weight* ($\geq 85^{th}$ and $<95^{th}$ percentile or $\geq 95^{th}$ percentile)[1]. Parents were classified as *accurate* or *inaccurate estimators* based on the concordance between their perception of children's weight status and children's measured weight status. Analyses were performed using *SPSS version 22.0* (SPSS Inc., Chicago, Illinois), and *EpiInfo7* (Centers for Disease Control and Prevention, Atlanta, Georgia) was used to calculate BMI z-score. $P<0.05$ was considered statistically significant.

5.4. Results

Demographic and anthropometric characteristics of participants did not differ across groups (Table 5.1). Based on measured height and weight data, children (9.9±3.4y; 50.9% males) were classified as underweight (5.8%), healthy weight (67.3%), overweight (16.4%), or obese (10.6%); mean BMI z-score was 0.4±1.1. Compared to children with an unhealthy

[1]Although underweight children may also be considered 'unhealthy', for the purpose of this report, children who were *underweight* (BMI $<5^{th}$ percentile) were not included in the *unhealthy weight* category.

weight (*i.e.,* overweight and obese), more healthy weight children had parents who were married (61.7% *vs.* 79.3%; χ^2=7.2, p=0.007), Caucasian (59.0% *vs.* 74.5%; χ^2=5.1, p=0.02), and with a post-secondary education (36.1% *vs.* 54.2%; χ^2=5.9, p=0.02). One-third (n=76; 33.6%) of parents were inaccurate estimators of their children's weight status; most (n=69; 90.8%) underestimated children's weight status, the majority (n=48; 70.0%) with unhealthy weight children.

5.4.1. Primary Outcomes

A total of 226 participants were recruited from July to October 2015 (Figure 5.1). Figure 5.2 shows the proportion of parents across all primary outcomes, which did not differ across study groups; however, parents assigned to the brief intervention groups were less likely to select resources compared to the eHealth control group (χ^2=4.8; p=0.03).

Most parents selected resources (85.8%; 194/226); of these, parents selected online handouts (76/194; 39.2%), information on community services (5/194; 2.6%), or both (113/194; 58.2%). On average, parents selected six resources (mean: 6.4±4.8; range: 0 – 20); the top-three commonly selected resources included handouts on sleeping (n=139; 71.6%), snacking (n=112; 57.7%), and positive body image (n=108; 55.7%). There was a positive correlation between the total number of resources selected by parents and *(i)* their reported levels of concern about their children's weight (r=0.25; p<0.001) and intention to change lifestyle behaviors (r=0.20; p=0.002), and *(ii)* children's BMI z-score (r=0.19; p=0.003). Parents who selected (*vs.* did not select) resources differed by children's BMI z-score (0.5±1.1 *vs.* -0.04±1.1; p=0.02) and intention to change lifestyle behaviors (2.6±1.2 *vs.* 2.0±1.5; p=0.01).

Approximately 60% of parents completed the one-month follow-up email survey; parents (n=136) who completed the follow-up survey were more likely to be married (*vs.* not married) compared to parents who did not complete the survey (65.3% *vs.* 42.1%; χ^2=5.7, p=0.02). At follow-up, parents who reported discussing (*vs.* not discussing) children's weight with the pediatrician differed by children's BMI z-score (0.5±1.2 *vs.* 0.2±0.9; p=0.03) and concern about child's weight status (1.1±1.4 *vs.* 0.4±0.8; p=0.001). Discussion of weight also differed by children's weight status (unhealthy *vs.* healthy weight [80.6% *vs.* 42.4%; χ^2=15.4, p<0.001]) as well as parents' education level (high school *vs.* post-secondary [61.5% *vs.* 44.3%; χ^2=4.0, p=0.045]) and estimation accuracy of children's weight status prior to screening (accurate *vs.* inaccurate [44.4% *vs.* 68.9%; χ^2=7.2, p=0.007]).

5.4.2. Secondary Outcomes

Parental concern about children's weight status and intention to change children's lifestyle behaviors did not differ across brief intervention or eHealth control groups. However, children's demographic and anthropometric characteristics, and parents' weight status estimation data varied by parental concern and intention to change (Table 1; Supplementary Materials); non-Caucasian (*vs.* Caucasian) parents as well as those classified as inaccurate (*vs.* accurate) estimators of children's weight status reported higher levels of concern about their children's weight status post-SBIRT (1.1±1.4 *vs.* 0.6±1.0, p=0.005; 1.2±1.3 *vs.* 0.5±1.0, p<0.001, respectively). Similarly, parents of children classified as overweight or obese reported higher levels of concern and intention to change compared to their healthy weight counterparts (p<0.001). Compared to parents less ready for change,

parents who 'strongly agreed' that they were ready to change children's lifestyle behaviors were more likely to have children with an unhealthy weight (χ^2=11.0; p=0.001) and be classified as inaccurate estimators of children's weight status (χ^2=5.1; p=0.02).

5.5. Discussion

Our newly-developed, digital SBIRT designed to help parents prevent childhood obesity was feasible in the primary care setting. Parents who selected resources during the SBIRT and reported discussing their children's weight with the pediatrician tended to have heavier children, suggesting the eHealth tool may nudge parents who are at risk for having children with obesity towards behavior change.

To our knowledge, RIPPLE represents the first parent-based digital SBIRT designed to prevent childhood obesity in primary care. Similar to other recent reports (Sterling et al., 2015), our SBIRT was feasible to integrate into the day-to-day activities of a busy clinical setting. Of those invited to participate, nearly 85% were enrolled, a finding consistent with the upper end of recruitment proportions (*i.e.,* 50 – 85%) reported by other studies that have tested SBIRTs in primary care (Roy-Byrne et al., 2014; Kaner et al., 2013; Kypri et al., 2004). In addition, a high proportion of parents selected resources during the SBIRT, with commonly selected ones representing topics that may not typically arise in the context of obesity prevention (*e.g.,* positive body image, sleep habits). Notably, nearly all of the participants assigned to the eHealth control group selected resources compared to 80% in the brief intervention groups. This suggests that weight screening and the provision of information on children's healthy lifestyle behaviors may optimally impact parents. Lastly, although parents' interest to participate in the novel eHealth tool was evident, uptake of

resources was limited – a finding consistent with others that have demonstrated the minimal long-term impact of SBIRTs in primary care (Strobbe, 2014; Babor et al., 2007). This highlights that while the eHealth tool may nudge parents towards preventive action, additional resources to impact health outcomes beyond the short-term are warranted.

There is evidence to support future research and application of our SBIRT. First, parents with heavier children and those families characterized by factors associated with obesity in children (*e.g.,* misperception of children's weight status [Maximova et al., 2008]) may have been positively impacted by the SBIRT. Specifically, parents with heavier children who were classified as inaccurate estimators of children's weight status, as well as parents with lower levels of education, were more likely to report discussing their child's weight with the pediatrician. This evidence suggests the SBIRT may act as a catalyst for parents to initiate a discussion about children's weight with their pediatrician. Second, compared to their Caucasian counterparts, non-Caucasian parents who underestimated their children's weight status reported greater levels of concern about children's weight status and intention to change lifestyle behaviors following the SBIRT. Although these constructs were not measured pre- and post-SBIRT, parents reported high levels of intention to change *following* the SBIRT, a finding that contrasts reports that have characterized inaccurate weight estimators as *less* likely to intend to change compared to their accurate peers (Merema et al., 2008). As such, we speculate that the SBIRT might influence psychological precursors to behavior change (Rosenstock, 1974), particularly among parents of children who might be at greatest risk for obesity.

5.5.1. Limitations

First, our SBIRT was brief and did not include data collection of parents' self-reported concern and intention pre- and post-intervention. It is possible that those parents who reported high levels of concern and intention to change post-SBIRT might have felt this way prior to the study. Although we can speculate that the SBIRT might positively impact parents of children at risk for obesity, this interpretation must be made with caution; concern about children's weight status and intention to change lifestyle behaviors are complex constructs to measure. In comparing our findings to previous studies (*e.g.,* Merema et al., 2008), our measurement of these constructs differed in terms of when (*e.g.,* before or after presentation of children's weight status) and how (*e.g.,* 5-point Likert scale) they were measured. Second, we aimed to measure parents' objective use of self-selected resources using the back-end programming functionality available through the tailored email report. However, we may have underestimated the impact of our SBIRT if parents accessed resources related to obesity prevention through alternative means (*e.g.,* web-searching). Lastly, the nature of this developmental study was to determine feasibility of the SBIRT and it was not sufficiently powered to specifically detect group differences with respect to secondary outcomes.

5.6. Conclusions

Our novel, parent-based digital SBIRT screened children's weight status, delivered a brief intervention or eHealth control on children' healthy lifestyle behaviors, and provided a menu of resources to facilitate obesity prevention in children. Parents' interest to participate in the SBIRT supported feasibility in primary care, with a large proportion of

participants, particularly those with heavier children, selecting resources during the SBIRT. Parents of children with overweight and obesity were also more likely to report discussing their children's weight with their pediatrician. Together, our data suggests that this eHealth tool may nudge parents towards preventative action. Findings from this pilot RCT will be used to inform the development of a larger-scale evaluation of our SBIRT across multiple primary care-based settings.

Table 5.1. Demographic and anthropometric characteristics of parents and children

			Intervention or Control Group[1] Mean ± standard deviation (95%CI) for continuous variables; n(%) for categorical variables				
		Total (n=226)	**Move It [I] (n=46)**	**Move It [N] (n=46)**	**Eat It [I] (n=44)**	**Eat It [N] (n=43)**	**eHealth Control (n=47)**
Parent	Sex						
	Male	28 (12.4%)	4 (8.7%)	9 (19.6%)	5 (11.4%)	5 (11.6%)	5 (10.6%)
	Female	196 (86.7%)	42 (91.3%)	37 (80.4%)	39 (88.6%)	38 (88.4%)	42 (89.4%)
	Ethnicity						
	Caucasian	159 (70.4%)	33 (71.7%)	33 (71.7%)	28 (63.6%)	32 (74.4%)	33 (70.2%)
	Non-Caucasian	67 (29.6%)	13 (28.3%)	13 (28.3%)	16 (36.4%)	11 (25.6%)	14 (29.8%)
	Education Level[2]						
	High school	114 (50.7%)	22 (47.8%)	22 (48.9%)	21 (47.7%)	23 (53.5%)	26 (55.3%)
	Post-secondary	111 (49.3%)	24 (52.2%)	23 (51.1%)	23 (52.3%)	20 (46.5%)	21 (44.7%)
	Relationship Status[3]						
	Married	167 (74.6%)	38 (82.6%)	36 (80.0%)	29 (65.9%)	33 (76.7%)	31 (67.4%)
	Not married	57 (25.4%)	8 (17.4%)	9 (20.0%)	15 (34.1%)	10 (23.3%)	15 (32.6%)
	Household Income (CAN)[4]						
	≤$60 000	74 (35.2%)	18 (40.0%)	12 (27.3%)	15 (36.6%)	12 (30.8%)	17 (41.5%)
	>$60 000	136 (64.8%)	27(60.0%)	32 (72.7%)	26 (63.4%)	27 (69.2%)	24 (58.5%)
Child	Sex						
	Male	115 (50.9%)	30 (65.2%)	25 (54.3%)	20 (45.5%)	23 (53.5%)	17 (36.2%)
	Female	111 (49.1%)	16 (34.8%)	21 (45.7%)	24 (54.5%)	20 (46.5%)	30 (63.8%)
	Age (y)	9.9±3.4 (9.4 – 10.3)	10.3±3.9 (9.1 – 11.4)	9.6±3.5 (8.5 – 10.6)	9.8±3.6 (8.6 – 10.9)	9.7±3.2 (8.7 – 10.6)	10.2±2.9 (9.3 – 11.1)
	Age category						
	Child (5-12y)	175 (77.4%)	31 (67.4%)	37 (80.4%)	34 (77.3%)	36 (83.7%)	37 (78.7%)
	Adolescent (13-17y)	51 (22.6%)	15 (32.6%)	9 (19.6%)	10 (22.7%)	7 (16.3%)	10 (21.3%)
	Ethnicity						
	Caucasian	168 (74.3%)	33 (71.7%)	35 (76.1%)	32 (72.7%)	36 (83.7%)	32 (68.1%)
	Non-Caucasian	58 (25.7%)	13 (28.3%)	11 (23.9%)	12 (27.3%)	7 (16.3%)	15 (31.9%)
	Body Mass Index (BMI; kg/m^2)	18.8±4.7 (18.2 – 19.4)	17.9±3.6 (16.8 – 18.9)	18.1±3.1 (17.2 – 19.0)	19.1±3.9 (17.9 – 20.3)	19.4±6.9 (17.3 – 21.5)	19.5±5.1 (18.0 – 21.0)
	BMI percentile	60.5±29.4 (56.6 – 64.4)	50.9±29.9 (42.0 – 59.8)	61.2±27.4 (53.1 – 69.3)	64.7±31.1 (55.2 – 74.2)	59.4±29.5 (50.4 – 68.5)	66.2±27.9 (58.1 – 74.4)
	BMI z-score	0.4±1.1 (0.3 – 0.5)	0.04±1.1 (0.3 – 0.4)	0.4±0.9 (0.1 – 0.6)	0.7±1.1 (0.3 – 1.0)	0.4±1.1 (0.04 – 0.7)	0.6±1.2 (0.2 – 0.9)
	Weight Status[5]						
	Healthy weight	152 (71.4%)	34 (85.0%)	32 (71.1%)	24 (57.1%)	29 (70.7%)	33 (73.3)

	Overweight/obese	61 (28.6%)	6 (15.0%)	13 (29.9%)	18 (42.9%)	12 (29.3%)	12 (26.7%)

[1]All group comparisons p>0.05
[2]Missing data (*i.e.,* participant reported "don't know" or "prefer not to say); total (n=225), Move It [N] (n=45)
[3]Missing data; total (n=224), Move It [N] (n=45), Control (n=46)
[4]Missing data; total (n=210), Move It [I] (n=45), Move It [N] (n=44), Eat It [I] (n=41), Eat It [N] (n=39), Control (n=41)
[5]Cases excluded (*i.e..,* children classified as underweight); total (n=213), Move It [I] (n=40), Move It [N] (n=45), Eat It [I] (n=42), Eat It [N] (n=41), Control (n=45)

Figure 5.1. CONSORT 2010 flow diagram

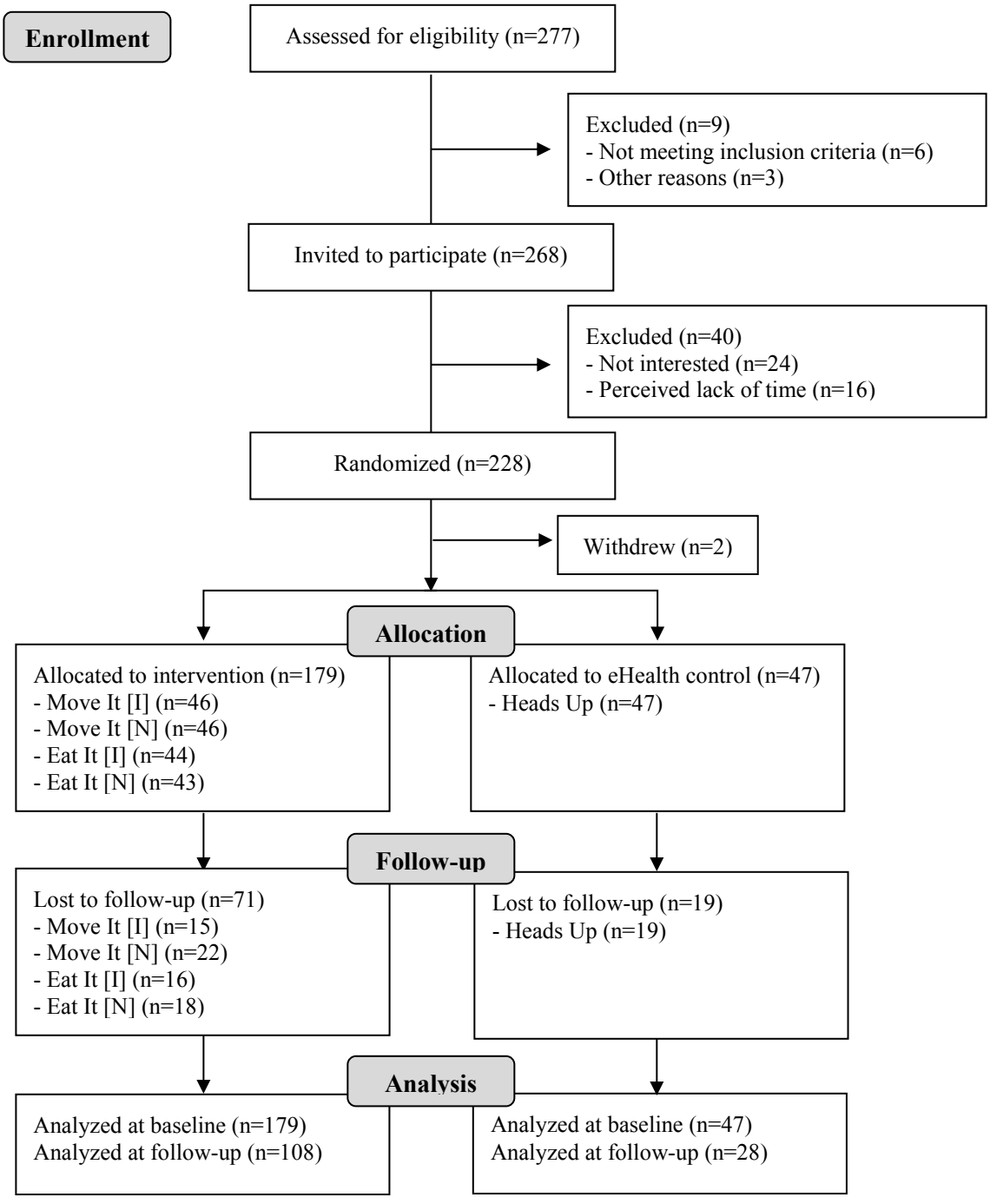
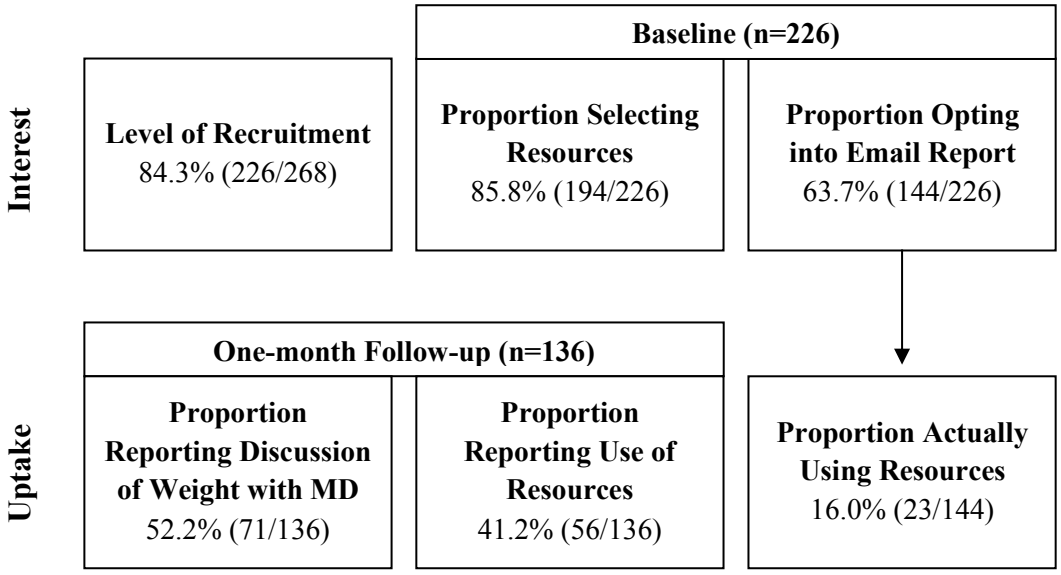
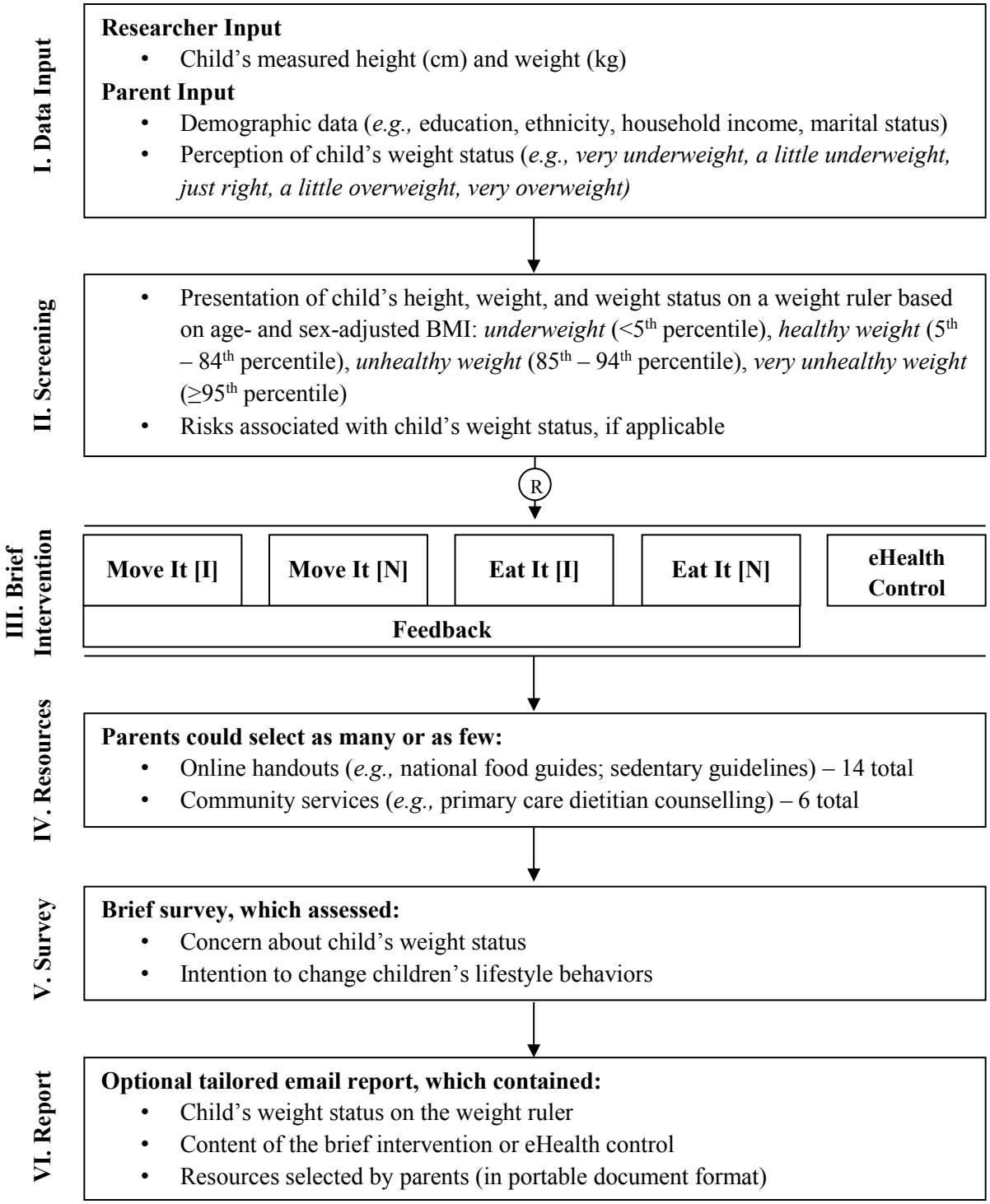


Figure 5.2. The proportion of parent participants included across primary outcomes, including parents' *(i)* interest in and *(ii)* uptake of the SBIRT



Supplementary Materials Figure 1. Flow of the SBIRT[1]



[1]Note that participant's interface with the tablet included steps I to V in one continuous process.

Supplementary Materials Figure 2a. An example of the feedback received by parents during the screening phase of the SBIRT

RIPPLE

UNIVERSITY OF ALBERTA
FACULTY OF MEDICINE & DENTISTRY
Department of Pediatrics

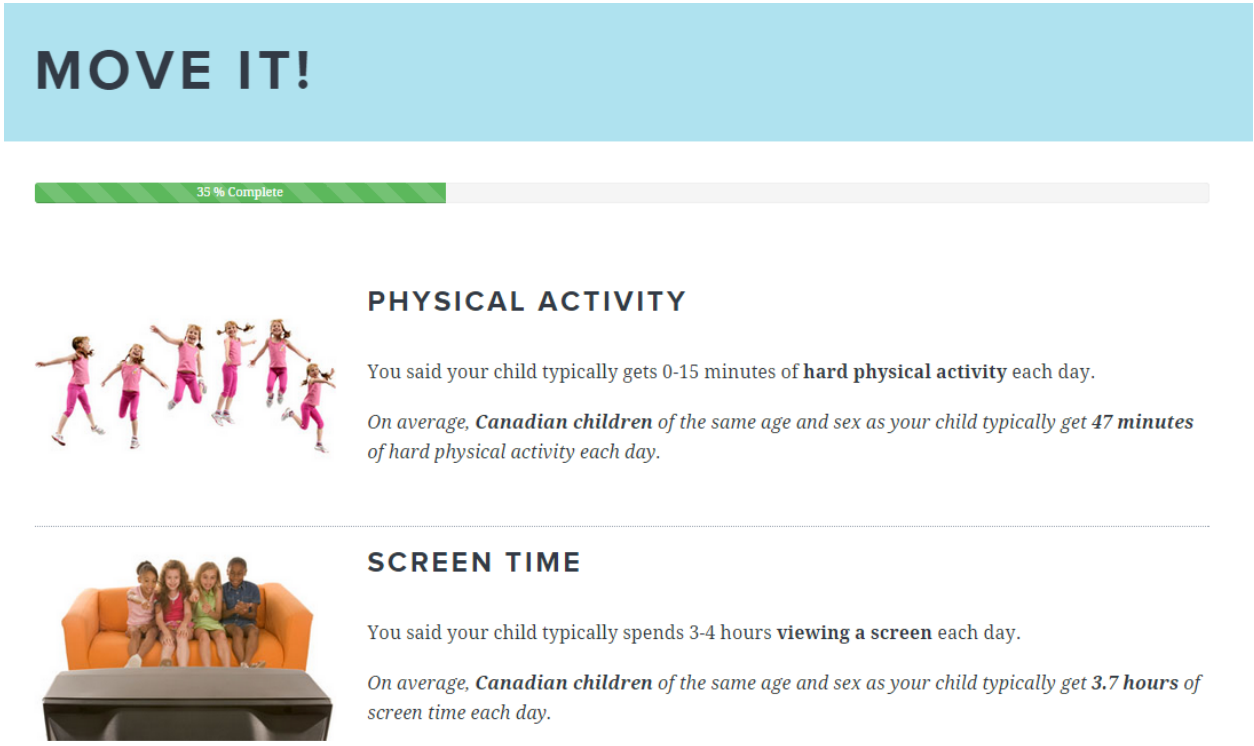
WEIGHT A SECOND!

Boys and girls come in all shapes and sizes. How much they weigh depends on several factors including their eating, physical activity, and family background. Since children grow at different rates, body mass index (BMI) percentile offers a measure of children's weight compared to other children of the same age and sex.

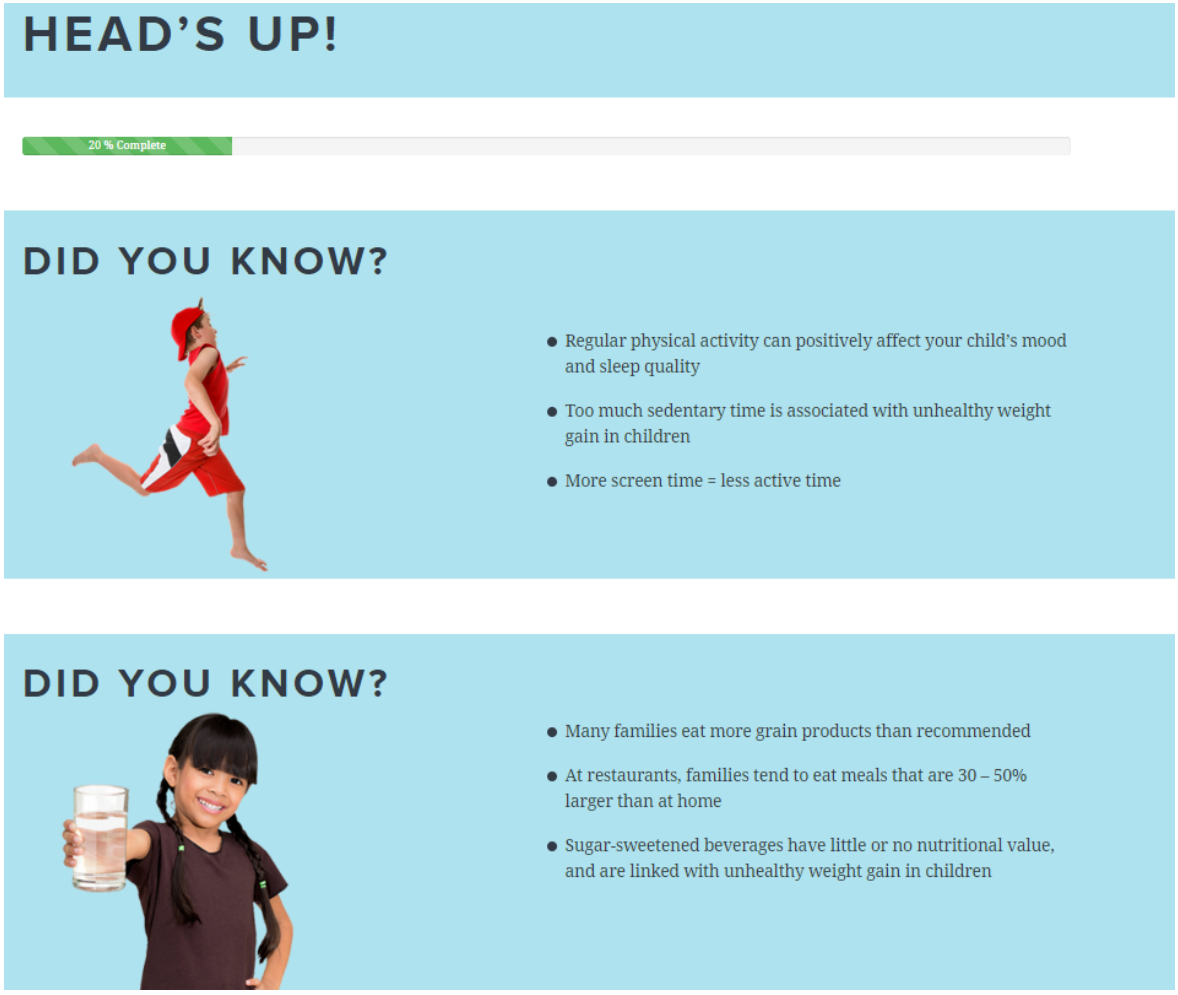
BASED ON YOUR CHILD'S WEIGHT AND HEIGHT, THEIR BMI IS:

Between the 5th and 84th percentile. According to this BMI percentile range, your child has a **healthy weight**. This means your child may be at low risk for developing health problems such as heart disease, high blood pressure, and type 2 diabetes.

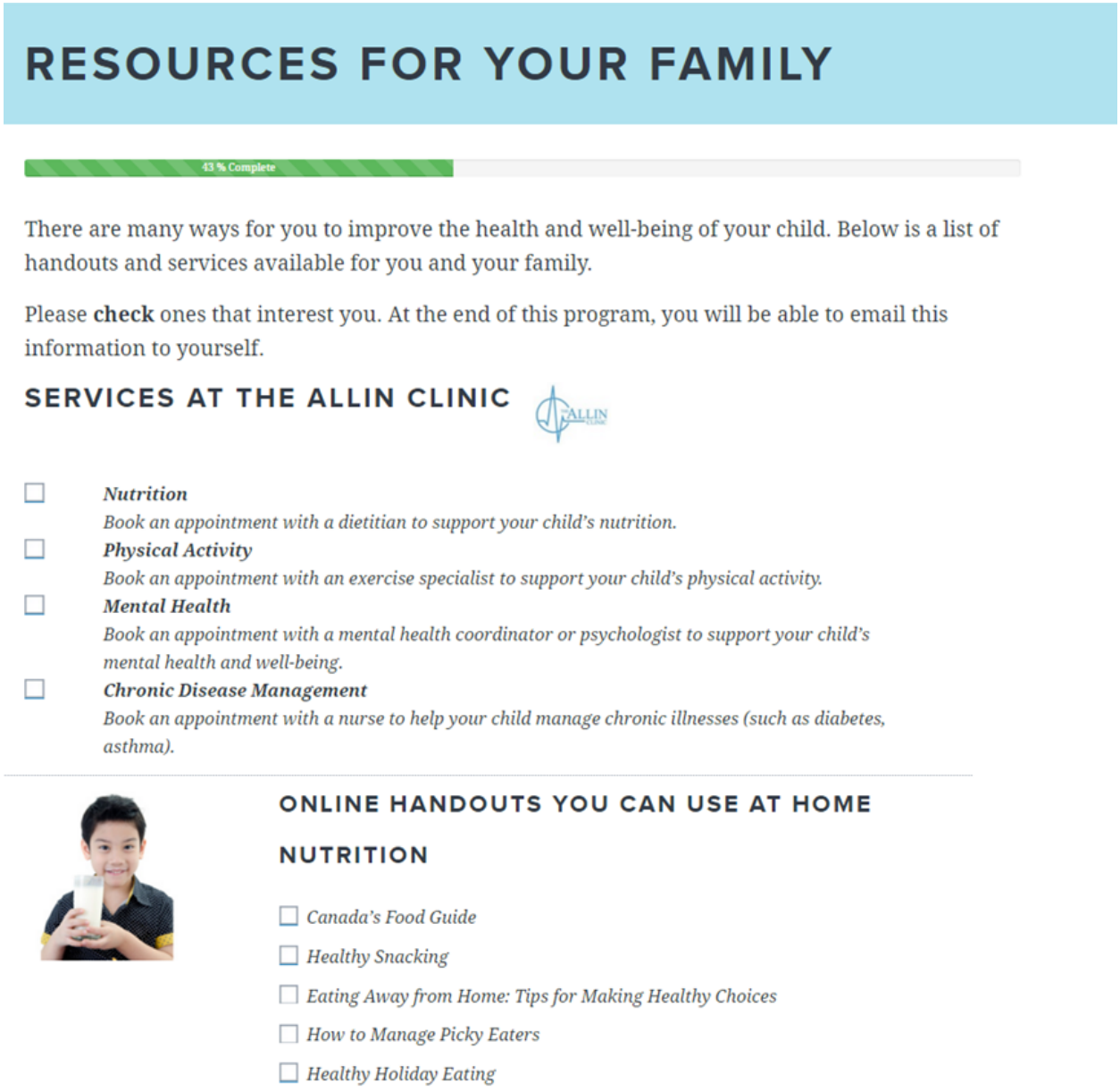
Supplementary Materials Figure 2b. An example of the normative feedback received by parents in one of the brief interventions, *Move It!*



Supplementary Materials Figure 2c. Information provided to parents in the eHealth control group, *Heads Up!*



Supplementary Materials Figure 2d. An example of the menu of optional resources (*i.e.*, online handouts, information on community services) presented to parents in the SBIRT



Supplementary Materials Table 1. Differences across secondary outcome variables by demographic and anthropometric characteristics

	Concern (mean ± sd)	**Effect**	**Intention** (mean ± sd)	**Effect**
Ethnicity (Parent)				
Caucasian (n=159)	0.6±1.0	**p=0.005***	2.4±1.3	**p=0.048***
Non-Caucasian (n=67)	1.1±1.4		2.8±1.3	
Ethnicity (Child)				
Caucasian (n=168)	0.7±1.1	NS	2.4±1.3	**p=0.04***
Non-Caucasian (n=58)	1.0±1.4		2.8±1.3	
Weight Status Estimation				
Accurate (n=150)	0.5±1.0	**p<0.001***	2.4±1.3	**p=0.04***
Inaccurate (n=76)	1.2±1.3		2.8±1.3	
Weight Status*				
Underweight (n=13)	1.8±1.2[b]		2.7±1.1	
Healthy weight (n=152)	0.3±0.7[a]	F=50.3	2.3±1.3[a]	F=8.5
Overweight (n=37)	1.1±1.1[b,c]	**p<0.001***	3.1±1.0[b]	**p<0.001***
Obese (n=24)	2.5±1.6[b,d]		3.3±0.8[b]	

*Statistically significant *post hoc* analyses (all p≤0.001): a<b; c<d

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Chapter 6

Discussion & Conclusions

6.1. Overview of Findings

The papers presented in this thesis studied TRs used to help prevent childhood obesity in primary care. The first study, which pilot tested a mixed methods approach to evaluate TRs, focused on existing TRs that PCPs use for preventing obesity in children. In the second study, a novel eHealth tool to help parents prevent obesity in children was developed, refined, and pilot tested in primary care. Together, the two studies in my thesis provided a unique assessment and understanding of TRs, both existing and newly-developed that are used to prevent childhood obesity in the primary care setting.

6.1.1. Study 1

The aim of this study (Avis et al., 2016a) was to pilot test a mixed methods approach to evaluate TRs that PCPs use for preventing childhood obesity in primary care, and to report a preliminary descriptive assessment of these TRs. First, this study established the usefulness of obtaining input from PCPs *and* objective assessment checklists to comprehensively evaluate the TRs used with children and families in primary care. Findings demonstrated that PCPs' views regarding the suitability of TRs overlapped with criteria on the assessment checklists, such as aesthetic properties, readability level, and content organization. However, PCPs discussed logistical issues, including awareness of and access to TRs, which were aspects not captured by the checklists. Additional characteristics of TRs, including usefulness and usability, were important aspects that informed PCPs' decisions to (re)use

TRs. Second, of the TRs that were used by PCPs, most rated 'average' or 'suitable' according to scoring checklists; the majority of weight-focused TRs scored 'inadequate', which was consistent with participants' views regarding the under-availability of high-quality TRs to help prevent obesity in children.

6.1.2. Study 2

The aim of this study (Avis et al., 2016b; Avis et al., 2015a; Avis et al., 2015b) was to develop, refine, and pilot test a novel eHealth tool delivered in primary care. The SBIRT was developed by our research team and an eHealth development company, and was based on existing models and contemporary literature on children's lifestyle behaviors. Findings from the second phase of this study demonstrated the usefulness of obtaining feedback from a diverse group of participants on the first version of the SBIRT. Parents as well as HCPs, researchers, and graduate trainees communicated that the newly-developed eHealth tool was well-designed with a friendly aesthetic appeal, and may help to connect parents with relevant resources for obesity prevention. However, they also expressed that the SBIRT was lacking in terms of cultural diversity and may elicit negative reactions from parents with children classified as overweight or obese. Based on this feedback, specific aspects of the SBIRT were modified to form the second version of the tool. Version 2.0 was pilot tested with parents in a pediatric primary care waiting room using a RCT. Results from this phase of the study suggested that the SBIRT was feasible for use in this setting, particularly based on parents' interest to participate. Although uptake of resources at one-month post-SBIRT was limited, parents of heavier children were more likely to discuss children's weight with their

pediatrician, highlighting that our eHealth tool may help to nudge parents towards preventative action.

6.2. Discussion

Based on the results of my thesis research, four main themes regarding TRs for preventing childhood obesity in primary care will be discussed, including: *(i)* methods of evaluation, *(ii)* purpose and preliminary impact, *(iii)* characteristics, including suitability, usability, usefulness, and modality, and *(iv)* feasibility and implementation.

6.2.1. Methods of Evaluation

Three distinct methods – mixed, qualitative, and quantitative methods – were used to evaluate TRs in this thesis. In the first study, a novel method was piloted to triangulate participant input and objective scoring on currently used TRs. In the second study, focus groups were used to refine the first version of the SBIRT, followed by a RCT that helped to determine feasibility and preliminary impact, which broadly correspond to formative and outcome evaluations, respectively. Formative evaluation, which is conducted during the early phases of a study, involves the development and modification of content and structure to align with the needs and priorities of the target audience; outcome evaluation represents a more traditional approach, and includes assessing the impact of a program, tool, or intervention (Berkowitz et al., 2008). In the context of TRs, both forms of evaluation are essential to ensure that newly-developed TRs are appropriate, relevant, and useful for the end-user.

Based on findings from our mixed methods study, ratings of tools – objective and subjective – should be interpreted with caution when studied in isolation. While the evaluation of TRs using the assessment checklists captured important and relevant elements of suitability, the contextual factors that participants expressed were distinct and would have gone undocumented if the study had employed a purely deductive approach. As such, studies that have primarily focused on the quantifiable assessment of TRs (*e.g.,* general pediatric educational materials [D'Alessandro et al., 2001]) may reflect an incomplete evaluation of the TRs under study. Further, an additional aspect of this study included gathering feedback from participants on the objective ratings of TRs, which demonstrated an unexpected finding; participants said they would not change their use of TRs, even for ones that scored as unsuitable according to the checklists. This was because contextual factors and their clinical judgement were viewed as more important deciding factors, which demonstrated the value of a comprehensive approach to evaluate currently-used TRs.

Focus groups were used as a method to evaluate the newly-developed SBIRT in the second, multi-phased study. Focus groups are commonly used to gain consumer feedback on products in marketing and advertising research (Calder, 1977) and to obtain participants' views on concepts and experiences in qualitative research (Wong, 2008). However, this method remains relatively novel when used for the purpose of refining eHealth tools. Based on our experiences (Avis et al., 2015b), while this technique helped to elicit meaningful feedback from participants in a time-efficient manner, a number of challenges were experienced. For example, unlike most health research focus groups in which participants discuss intangible concepts, focus groups for refining eHealth tools query participants' views on concrete elements, such as navigation and graphical layout. Given this difference, special

consideration to preserve the context of participants' input on specific intervention components were necessary. Accordingly, we followed recommendations (Scott et al., 2009) regarding a practical solution to this unique challenge, which included the use of a court reporter for real-time data capture. As the focus group moderator, the experience of using a court reporter was positive; I was able to focus my full attention on facilitating the group discussion without being distracted by taking notes or adjusting the voice recorder. In addition, the turnaround of transcripts was quick, which enabled me to perform concurrent data collection and analysis.

A RCT was conducted to determine the feasibility and preliminary impact of the refined eHealth tool. This method of evaluation is suitable to determine if the 'active ingredient' of an intervention works. Within the context of obesity prevention, researchers have noted that, "a perfect trial is virtually impossible" (Stevens et al., 2007). Accordingly, during the planning phase of this trial, special consideration was given to the selection of study outcomes, risk of participant attrition, and generalizability of findings from our pilot RCT. First, trials related to obesity often include children's weight status as a primary outcome. Although impact on weight is important to measure, it is less meaningful for brief, short-term approaches. In our trial, the preliminary impact of the SBIRT was determined by mediating variables (*i.e.,* parents' concern about children's weight status, intention to change lifestyle behaviors), which are important precursors to help understand hard endpoints, such as weight status. Notably, in a recent systematic review of parent-based eHealth interventions to reduce childhood obesity, only one study demonstrated a significant reduction in children's weight-related outcomes, but half reported positive behavior change outcomes (Hammersley et al., 2016). As previously suggested (Avis et al., 2016b), this

finding aligns with the role of eHealth tools as adjuncts rather than alternative means to prevent obesity in children. Second, high levels of attrition in pediatric weight management are well-documented (Dhaliwal et al., 2014). To mitigate risk of attrition, which has also been high in online interventions (Dorkin et al., 2011), in-person recruitment to develop rapport and trust with participants was combined purposefully with the online delivery of the SBIRT, a strategy that I believe was effective for recruiting *and* retaining participants in the trial at follow-up. Lastly, while pilot studies are essential to assess preliminary aspects of feasibility and impact, it is important not to overgeneralize findings. Accordingly, the next steps of our research entail a cluster RCT to determine the effectiveness of the eHealth tool across multiple primary care settings in urban and rural locations across Canada.

6.2.2. Purpose & Preliminary Impact

Based on the summative qualitative findings from this thesis, which included data from HCPs (n=39), parents (n=10), and researchers and graduate trainees (n=8), TRs for childhood obesity prevention are multipurpose and can help to support families and PCPs when preventing obesity in children. First, TRs that act primarily as educational materials, such as national food guides and sedentary guidelines, can help to inform parents on specific topics related to obesity. Such TRs represent an essential foundation of information, particularly for families less familiar with evidence supporting children's healthy lifestyle behaviors. TRs may also help to facilitate changes in children's lifestyle behaviors by reinforcing concepts that are discussed during clinical appointments and reminding families about healthy nutrition, physical activity, and sedentary behaviors for children. Given that healthy behavior changes are difficult to sustain, even when introduced early in life (Wen et

al., 2015), TRs may act as an effective conduit for behavior change. Second, newly-developed TRs that employ innovative digital technologies can serve additional purposes, as focus groups participants from our second study expressed that the eHealth tool could enhance parents' awareness of children's weight status and connect them with relevant resources related to obesity prevention (Avis et al., 2016b). Participants' views on the purposes of the newly-developed SBIRT were reinforced by findings from our RCT. Specifically, pilot testing demonstrated that the eHealth tool may have a positive impact on parents with unhealthy weight children; parents with children classified as overweight and obese (*vs.* healthy weight) were more likely to discuss children's weight status with their pediatrician immediately following the SBIRT. Further, such parents also reported higher levels of concern and intention post-SBIRT. This highlights that the newly-developed eHealth tool may help to nudge parents at high risk for having children with obesity towards the initiation of healthy behavior change *and* help to connect them with online information and community services for obesity prevention.

TRs can also support PCPs when providing obesity-related care to families. Based on our interviews with a multidisciplinary sample of providers, the most commonly used TRs were growth charts and *Canada's Food Guide*. PCPs reported that both TRs were dual-purpose: first, they were used to assess and monitor children's growth and gauge dietary status; second, they were used as a starting point for conversation regarding the guidelines and recommendations for children's healthy weights and nutrition behaviors. Although less common, some PCPs used newer, evidence-based TRs, such as the *5As of Obesity* (Vallis et al., 2013). This TR, which was originally developed to guide PCPs when counselling patients on smoking cessation, has been adapted to counsel patients on obesity (Vallis et al., 2013).

Some PCPs expressed this was an invaluable resource that provided a clear step-by-step guide on how to engage families in a discussion about obesity. For example, the resource instructs providers to first *Ask* patients for their permission to discuss the topic of obesity. Although seemingly straightforward, such actions may be challenging for PCPs to perform because they may be hesitant to initiate the discussion of obesity for fear of adversely impacting the patient-provider relationship (Walker et al., 2007).

6.2.3. Characteristics

Suitability. Suitability refers to the degree to which a TR meets the needs and priorities of the user. Findings from this thesis highlighted that although TRs can serve multiple purposes for families, a 'one size fits all' approach is not appropriate. Based on PCPs' perspectives, they gauged the suitability of TRs by family-level factors, including children's age, specific parental concerns, and families' cultural and language needs, and motivation and readiness to change children's healthy lifestyle behaviors. Further, PCPs discussed that the TRs developed and distributed by the provincial health authority (*i.e.,* Alberta Health Services) were not suitable for many families; most resources were text-heavy without graphical relief and cultural diversity was lacking. Following the use of TRs, PCPs reflected on their experiences of using TRs, and suitability was determined by elements of usability and usefulness, as discussed below. Notably, indicators of suitability were not consistent between PCPs and scoring checklists across all TRs. For example, one TR that was viewed favorably by most PCPs scored as 'not suitable' by all three checklists, a finding that is consistent with previous reports regarding the use of growth charts with parents (Ben-Joseph et al., 2009).

Consistent with PCPs' views that TRs lacked cultural diversity, participants from our focus group study believed that the original version of our SBIRT was primarily suited to Caucasian families. They expressed that modifications were necessary for the eHealth tool to be suitable for families of various ethnic backgrounds and for parents with unhealthy weight children. Following refinements, such as the incorporation of culturally-diverse images, pilot testing demonstrated that the SBIRT may have a particularly positive impact on non-Caucasian parents with heavier children. Although it cannot be stated with certainty, this finding may reflect our efforts to optimize suitability to a wider range of families in primary care.

Usability. Usability refers to ease and practicality of use of a TR. In our mixed methods study, PCPs expressed that the usability of TRs was a key factor to determine if they were appropriate for use in clinical practice. Specifically, PCPs reported on the usability for themselves (*e.g.,* straightforward to navigate) and for families (*e.g.,* simple to read and understand). PCPs' perceptions of usability overlapped with scoring elements on the checklists, such as organization and typography. These elements were not unique to criteria on the checklists or PCPs' perspectives; focus group participants said that the inviting aesthetic appeal of the newly-developed SBIRT would encourage parent's participation, and brevity of content was practical for implementation in a busy primary care clinic waiting room. They also expressed that the straightforward and user-friendly navigation would facilitate ease of use of the eHealth tool. Such findings regarding usability are not unique to this thesis, and have been reverberated by other studies with respect to eHealth and mHealth tools (Vélez et al.., 2014), clinical monitoring tools (Daniels et al., 2007), and resources for patient education (Kuosmanen et al., 2010).

Usefulness. Usefulness refers to the degree to which a TR is helpful to the user, and in the context of childhood obesity prevention, can help to improve healthy lifestyle behaviors and prevent unhealthy weight gain in children. The usefulness of TRs was another important factor according to the perspectives of PCPs, parents, researchers, and graduate trainees. PCPs reported that usefulness for themselves (*e.g.,* effective in guiding conversations with families) and for families (*e.g.,* facilitating children's healthy behavior change) directly informed their decisions to use TRs. Similarly, focus group participants expressed that the SBIRT could help to *(i)* enhance parents' awareness about children's weight status, *(ii)* initiate the conversation about obesity between PCPs and families, and *(iii)* connect parents with relevant and appropriate resources online and in the community. Such views were consistent with findings from our pilot RCT. First, although the majority of parents with overweight and obese children underestimated their weight status pre-SBIRT, upon completion of the SBIRT, such parents reported higher levels of concern and intention to change lifestyle behaviors. Second, compared to those who did not select optional resources within the SBIRT, parents who did select resources tended to have heavier children and were more likely to discuss children's weights status with their pediatrician. Together, this suggests the eHealth tool may be useful to enhance parents' concern about children's weight status *and* nudge parents with heavier children towards healthy lifestyle changes.

Notably, indicators of *usefulness*, such as the ability of TRs to help parents initiate conversation about weight status with their pediatrician, are context-specific and rooted in the discipline under study. In comparison, elements of *usability*, such as layout and literacy demand, can be applied to a variety of TRs, and literature outside the scope of this thesis has

reinforced similar aspects related to ease and practicality of use of other TRs (Koneczny & Matern, 2005). This suggests that while elements such as aesthetic appeal, content, navigation, and readability may help to universally assess the usability of TRs, gauging the usefulness of TRs is likely context-, discipline-, user-, and task-specific.

Modality. Modality refers to the means in which a TR is delivered. In this thesis, two modalities were studied – online and hard-copy format. Although the modality of TRs was not investigated directly in our mixed methods study, most TRs used by PCPs (14/15; 93.3%) were in hard-copy format. Ironically, the one online-based TR scored in the top quartile across two assessment checklists, yet was reportedly used by only two participants in the study. This finding is in contrast to evidence suggesting pediatric-focused providers tend to prefer online as opposed to hard-copy materials (Jackson et al., 2007), but this may reflect the logistical barriers that PCPs face to locating and using online TRs. Given parents' positive reception to the incorporation of technology-based information into pediatric weight management programs (Bianchi-Hayes et al., 2015), there is rationale to better understand barriers to and encourage use of online TRs for PCPs to help prevent obesity in children in primary care.

Testing of our newly-developed eHealth tool in the second study demonstrated that the online mode of delivery in primary care was feasible and potentially effective in connecting parents with resources to facilitate obesity prevention in children. Unlike most eHealth tools used to address childhood obesity (Hammersley et al., 2016), ours was not multi-modal (*i.e.,* no additional in-person, telephone, or hard-copy components). Although only 60% of parents participated in a survey via email one-month after using the eHealth tool, this level of retention is within the range of levels reported previously in similar eHealth

studies (Madras et al., 2009; Kaner et al., 2007). Despite some studies (*e.g.,* Kaner et al., 2013) reporting higher levels of retention than ours, most have relied on either in-person or telephone contact. Our data revealed that following up with parents by email can yield a comparable level of retention while using fewer resources (*e.g.,* personnel, time, money), a feature that highlights the potential for future scale-up and spread of our eHealth tool.

6.2.4. Feasibility & Implementation

Feasibility, which refers to the degree to which a TR can be put into practice, can influence long-term implementation of TRs in primary care. Implementation of TRs applies similar principles to that of knowledge translation and reinforces why studying the feasibility of TRs is important. First, implementation of TRs may help to bridge the gap between health services recommendations and actual clinical practices, and may also improve patient care (Graham & Tetroe, 2007); second, the development of TRs often requires clinical and/or health services research, and in absence of implementation, the development of TRs is resource-inefficient.

Findings from our second study demonstrated that the incorporation of a novel, eHealth tool in primary care was feasible. Prior to pilot testing, participants from the refinement phase predicted that the eHealth tool would be practical in primary care because it could deliver important obesity-related information to parents in a short period of time. Findings from our RCT reinforced participants' thoughts regarding feasibility in primary care. Not only were parents willing and interested to participate in the novel SBIRT, which is demonstrated by our high level of recruitment, but none of the participants were unable to complete the SBIRT due to lack of time before their upcoming appointment. This highlights

practicality of implementing this approach in a primary care waiting room. Notably, given that this study was conducted over a three-year period of time, and multiple in-person, electronic, and telephone meetings were held with our primary care partners, a close working relationship was developed, which likely contributed to the success of this pilot study. Other studies that have piloted new approaches in primary care have reported similar observations based on the engagement of clinic personnel (Carduff et al., 2016), and experts have advocated for early engagement of decision-makers and stakeholders to increase the feasibility, implementation, and maintenance of new approaches in practice (Swinburn et al., 2004).

Implementation of TRs was discussed by PCPs in our first study, and their decisions to implement TRs in their day-to-day practice was gauged by characteristics, such as usability and usefulness. However, such elements appeared to be necessary but insufficient for TRs to be adopted into clinical practice, as logistical factors may also impact implementation. First, the use of TRs may be influenced by issues regarding accessibility, such as cost, distribution, and production. For example, while one-third of PCPs used a top-ranked TR, many could not implement it in clinical practice due to issues surrounding cost and inconsistent distribution. Second, difficulty overcoming barriers may represent another reason why TRs are not implemented in care. Although the majority of participants in our study reported using growth charts to monitor children's weight status, studies have shown that a sizable proportion of providers do not regularly use this tool (Perrin et al., 2004) – a practice that is inconsistent with clinical guidelines (Parkin et al., 2015). This discrepancy suggests that PCPs may not implement TRs if they compete with existing barriers to preventing obesity, such as lack of time during a short appointment (Perrin et al., 2005).

6.3. Strengths and Limitations

There are a number of strengths of my thesis research. In the first study, verification strategies were employed to enhance trustworthiness of the qualitative data. First, credibility was bolstered by member checking during follow-up interviews. The majority of participants (n=17/19) participated in these follow-up interviews, which served two main purposes: *(i)* to confirm accuracy and completeness of their perspectives in the data, and *(ii)* to elaborate on the themes and other participants' thoughts that may have differed from their own. Second, this study took place approximately two years after the second study commenced in primary care, and therefore I had considerable experience working in this setting. This prolonged engagement prevented me from drawing naïve assumptions due to lack of experience with the day-to-day activities in primary care. Third, initial coding schemes were peer reviewed with fellow researchers at various time points throughout analysis to ensure accuracy and completeness of assigned codes and tentative themes. Lastly, triangulation of qualitative and quantitative data helped me to develop a rich and in-depth assessment and understanding of the purpose, characteristics, and use of TRs for preventing obesity in children in primary care. Although the use of both study designs to answer the research question was more time- and resource-intensive than if one of the methods had been used alone, this mixed methods approach demonstrated a unique perspective that can guide the evaluation of existing, and development of new, TRs in clinical practice.

In the second study, three distinct phases were systematically built one upon another to develop a novel eHealth tool to enhance parents' concern about children's weight status and intention to change lifestyle behaviors, as well as connect them with relevant resources for obesity prevention. From the onset of this study in 2012, I developed a close working

relationship with decision-makers, pediatricians, and support staff at the Edmonton Oliver Primary Care Network to *(i)* include their input on priority topic areas to educate parents on with regards to childhood obesity prevention, *(ii)* gain their feedback on the first version of the eHealth tool to ensure it met their clinical needs and priorities, and *(iii)* address any questions or concerns regarding the logistics of recruitment and future contact with patients. Through this process, our team built a unique eHealth tool that was well-received by participants and feasible for use in a busy primary care clinic.

There are also limitations of this research. Overall, the majority of participants in this thesis were Caucasian (overall [203/283; 71.7%]; Study 1 [15/19; 78.9%]; Study 2, Phase II [29/38; 76.3%]; Study 2, Phase III [159/226; 70.4%]). Although this ethnic composition may accurately reflect the local population in which the sample was taken from, the findings must be interpreted with caution in regards to populations that are more ethnically diverse. In addition, the sample in this thesis was also predominantly female (*i.e.,* maternal primary caregivers) (overall [243/283; 85.9%]; Study 1 [16/19; 84.2%]; Study 2, Phase II [31/38; 81.6%]; Study 2, Phase III [196/226; 86.7%]). Although this is an accurate representation of primary caregivers who tend to participate in research related to pediatric obesity (for example, Avis & Jackman, et al., 2015) and other pediatric-related illnesses (MacDonald et al., 2010), researchers should strive to have a broader representation of female and male caregivers, particularly given that male caregivers represent the minority in pediatric health research (Gicevic et al., 2016). With regards to pediatric obesity research, some researchers have even recommended targeting fathers to test the impact of interventions to prevent and manage obesity in children (Khandpur et al., 2014; Freeman et al., 2012).

An important limitation to acknowledge in the first study of my thesis was the low sample of TRs that were evaluated. Because the number of TRs that were evaluated in the quantitative strand of this study was directly informed by the participants who reported using them in the qualitative strand, only fifteen TRs were evaluated; therefore, testing for statistically significant differences between diet- (n=6), weight- (n=4), activity- (n=3), and multidisciplinary-focused (n=2) TRs was not possible. In the second study, a methodological limitation was that a pre- and post-test design to determine if the eHealth tool impacted parents' concern about children's weight status or intention to change lifestyle behaviors was not employed. As such, it cannot be concluded with certainty that individuals with statistically higher self-reported levels of concern and intention were impacted by the eHealth tool, or if they felt this way *prior* to the study.

6.4. Future Directions

6.4.1. Research

Based on the first study that piloted a new method to assess TRs for childhood obesity prevention, there are three future directions. First, an important next step includes applying a larger selection of TRs used for obesity prevention in children. Because the number of TRs assessed in this study was directly informed by PCPs, with the total sample of PCPs (n=19) being relatively small due to the qualitative nature of the dominant strand, only 15 TRs were evaluated. Second, there is a need to apply this method of evaluation to childhood obesity prevention TRs that are used beyond primary care clinics in Alberta. Given that all participants were Albertan-based PCPs, one-third of TRs were developed and produced by Alberta Health Services, the provincial health authority. By assessing TRs developed by and

used within various provincial health authorities, this may help to identify high-quality TRs across Canada for the purpose of obesity prevention in children. This is important because participants reported creating their own TRs to compensate for TRs that were either of poor quality or that did not exist; collaborating with colleagues from across Canada could help to prevent the duplication of effort and resources. Lastly, this novel method of evaluation can be applied to other health-related TRs. Given the clinical nuances associated with various pediatric health disciplines, this method may also help to elucidate unique, context-specific factors associated with the use of TRs for other clinical purposes.

Findings from our RCT demonstrated that the newly-developed eHealth tool was feasible in a fast-paced pediatric primary care setting. Although group differences across primary or secondary outcomes were not observed, preliminary results suggested the SBIRT may have a particularly positive impact on parents at high-risk for having children with obesity. Specifically, compared to their accurate peers, parents classified as inaccurate estimators of children's weight status and those with lower levels of education, were more likely to report discussing children's weight with their pediatrician post-SBIRT. In addition, compared to their Caucasian counterparts, non-Caucasian parents who underestimated their children's weight status reported higher levels of concern about children's weight status and intention to change lifestyle behaviors following the SBIRT. Although the eHealth tool was originally designed as a universal obesity prevention approach, there may be value in targeting a refined version of the tool towards non-Caucasian families of lower socioeconomic status. Future directions of this research include a cluster RCT to determine the effectiveness of our SBIRT across multiple primary care-based settings, which is aligned with researchers' calls to rigorously evaluate obesity prevention interventions in primary

care (Seburg et al., 2015). This study design, which has been employed by others in the field (Sterling et al., 2015), will specifically help us to determine *(i)* the impact of a modified version of the SBIRT, and if/how it differs by families' sociodemographic and children's weight status characteristics, and *(ii)* the potential for scale up and spread of the SBIRT, which may differ based on the patient demographics, available resources, and priority areas for disease prevention across primary care sites.

6.4.2. Practice

There are two future directions for clinical practice based on this thesis. First, findings from the first study highlighted the value in using a mixed methods approach to evaluate TRs that PCPs use for obesity prevention in primary care. Although the results demonstrated the usefulness of evaluating TRs using assessment checklists in addition to obtaining input from PCPs, in isolation, such information may be limited. To assist those developing TRs for childhood obesity in the future, suitability scores using checklists should be considered along with contextual factors *and* frontline providers' perceptions of TRs. Second, upon testing a modified version of the eHealth tool using a cluster RCT, we hope to identify content for the brief intervention component that will optimally impact parents. From there, I foresee this eHealth tool could be incorporated into an independent, self-sustaining kiosk in the pediatric primary care setting. Although this tool could be made available to the public via mHealth, based on pilot testing of this study, application within primary care is imperative because *(i)* parents can follow-up with their pediatrician immediately post-SBIRT, which is particularly important for parents who are concerned or

upset following communication of their child's weight status, and *(ii)* primary care is the source of many resources and services that can help to propel parents towards healthy lifestyle behaviors change.

6.5. Recommendations

There are a number of recommendations that can be derived from the research that comprises this thesis. First, this thesis highlights the importance of TRs that focus on concepts beyond nutrition and physical activity. In the first study, none of the participants reported using TRs related to issues of mental health and well-being, sleep hygiene or sedentary screen time. Recent research (Yoong et al., 2016) has shown such topics are important in the context of preventing and managing childhood obesity, yet interviewed PCPs reported such TRs are difficult to find. Further, based on findings from the second study, it is evident that parents are interested in receiving information on these novel topics; within the 'referral to treatment (resources)' portion of the eHealth tool, the most commonly selected online handouts by parents included healthy tips on sleep hygiene, positive body image, and healthy snacking. Together, this highlights a gap in clinical practice; research has demonstrated the importance of such novel topics in the context of obesity prevention and parents are interested in receiving such information, yet based on the first study such TRs are not commonly used in primary care.

Second, the preliminary assessment of TRs used for obesity prevention in primary care demonstrated high readability levels; according to two readability indices (*i.e.,* Flesch-Kincaid, SMOG), the majority of TRs had readability levels that were classified as 'not

suitable' (*i.e.,* reading level 9th grade or above), and this finding was reinforced by participants in the qualitative portion of the study. As such, this suggests a need to reduce the literacy demand of future versions of existing TRs as well as newly-developed TRs. This is particularly relevant for families with English as a second language – a subsection of the population that childhood obesity tends to disproportionately impact.

Third, the process of conducting focus groups to refine the SBIRT was productive, yet challenging. Specifically, while participants provided rich, in depth data on the strengths and weaknesses of the newly-developed eHealth tool, the process was resource-intensive. Based on our experiences with this method of evaluation, our team published a viewpoint paper that highlights lessons learned (Avis et al., 2015b). Recommendations for researchers conducting this method of evaluation have been outlined into simple, yet effective strategies; for example: *(i)* explicitly state at the onset of the focus group that the purpose of the discussion is to assess the current SBIRT rather than create a new one, *(ii)* prepare for feedback, both critical and constructive, particularly if you as the focus group moderator are responsible for developing the product that is being assessed, and *(iii)* leverage the potential "digital expert" in the group by acknowledging their experience and expertise but kindly deferring their input if it overshadows that of fellow participants.

Lastly, digital health approaches to address pediatric health issues may be feasible and useful in busy primary care settings. As demonstrated in the pilot RCT, a high proportion of parents were interested in the eHealth tool based on the level of recruitment and proportion of parents that selected resources. In addition, only two participants out of the total number initially recruited (n=228) withdrew from the study. Although uptake of the SBIRT was modest, it is still clinically meaningful that approximately 50% of parents who participated

in the follow-up survey reported discussing children's weight with their pediatrician. These results, which demonstrate the feasibility and preliminary impact of this novel eHealth tool in a busy, fast-paced clinical setting, suggest potential application to other pediatric health issues, such as mental illness. Like obesity in children, research has shown that parents perceive primary care as an appropriate setting to address children's mental health; however, there are barriers surrounding this task, including sensitivity of the subject and PCPs' perceived lack of time to initiate conversation on such a complex health concern (Sayal et al., 2010). Although the development of our eHealth tool took approximately two years, the majority of this time was used to develop digital navigation components, visual design and layout, and randomization procedures; comparably, approximately 35% of time was invested into the actual content of the SBIRT, including information on children's lifestyle behaviors and resources for obesity prevention. As such, future researchers could employ our SBIRT as a platform to screen for children's mental health concerns, deliver a brief intervention using a RCT design, and help connect parents with relevant resources. This process would likely be time- and resource-efficient given that the majority of modifications would entail content substitution.

6.6. Conclusions

This thesis provided a unique assessment and understanding of TRs for preventing childhood obesity in the primary care setting. TRs that are used for obesity prevention are multipurpose and can help PCPs and parents to prevent obesity in children in unique ways. While our preliminary assessment of TRs that PCPs currently use in Alberta demonstrated that most scored 'adequate', there is room for improvement, particularly with respect to

readability levels and lack of content diversity beyond nutrition and physical activity. Those responsible for developing new TRs should corroborate criteria on assessment checklists with input from PCPs to account for the logistical factors and clinical context that may impact use. Newly-developed TRs that capitalize on digital technology possess unique features that can educate parents on obesity prevention and potentially act as a catalyst to initiate healthy behavior change. Pilot testing of our newly-developed, digital SBIRT designed to help parents prevent childhood obesity was feasible in a fast-paced pediatric primary care clinic. Our findings also demonstrated that this eHealth tool may nudge parents towards preventative action, but further testing is needed to determine effectiveness and potential for long-term scalability in the primary care setting.

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Appendices

Chapter 2: Overview of Methods

Chapter 3: Study 1

Chapter 4: Study 2; Phases I & II

Appendix A. Timeline of graduate training[2]

	2012		2013				2014				2015				2016			
	Summer	Fall	Winter	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter	Spring	Summer	Fall	Winter	Spring	Summer	Fall
Study 1																		
Ethics application										X								
Tool kit development										X								
Phase I – data collection & analysis											X	X						
Phase II – data collection & analysis												X	X					
Phase III – follow-up													X					
Findings dissemination														X	X			
Study 2																		
Ethics application				X									X					
Phase I – SBIRT development		X	X				X	X	X									
Hiatus – privacy impact assessment				X	X	X												
Phase II – data collection & analysis										X	X							
Phase II – SBIRT refinement											X	X						
Phase III – data collection & analysis													X	X				
Findings dissemination												X		X		X	X	
Graduate Activities																		
Coursework (12*)		X				X		X										
Candidacy exam										X								
Ethics training			X															
Defense																		X

[2]Note that the studies are not presented in chronological order (*i.e.,* study 2 preceded study 1)

Appendix B. Overview of study-related details

Study Name	Study	Objective	Method	Sample	Publication Status	
Primary care Resources for Obesity in Pediatrics (PROP)	Study 1	• To pilot test a mixed methods approach to evaluate TRs that PCPs use for preventing obesity in primary care • To report a preliminary descriptive assessment of TRs used by PCPs	Mixed methods	n=19	Published in *Patient Education & Counselling* (2016)	
Resource Information Program for Parents on Lifestyle and Education (RIPPLE)	Study 2, Phase I	• To develop an SBIRT for parents to help prevent childhood obesity in primary care			Published in *Telemedicine and e-Health* (2016)	*
	Study 2, Phase II	• To refine the newly-developed SBIRT (v1.0)	Focus groups	n=38		
	Study 2, Phase III	• To test the feasibility and preliminary impact of the refined SBIRT (v2.0)	Randomized controlled trial	n=226	Under review at *Pediatr Obes*	

*Additional publications: (*i*) protocol paper, and (*ii*) a viewpoint paper, both published in *Journal of Medical Internet Research – Research Protocols* (2015).

Appendix C. Identified barriers to preventing childhood obesity in primary care

<table>
<tr><th></th><th colspan="3">Resources</th></tr>
<tr><th></th><th>Staff/Clinical Personnel</th><th>Time/Money</th><th>Tools</th></tr>
<tr><td>System Barriers</td><td>Lack of:
• Specialists available for referral[2]
• On-site dietitians to meet with families[3]
• Community support services[5]</td><td>Lack of:
• Time to treat[2,7,8,10,14,18,21,23]
• Insurance reimbursement for patient[2,14,18,23]
• Reimbursement for physician/nurse[5,8,10]</td><td>Lack of:
• Access to BMI charts and accurate height/weight data[1]
• Height and weight not routinely measured[9]
• Tools to calculate BMI[1]
• Patient education tools and information[3]</td></tr>
<tr><th></th><th colspan="2">Barriers Experienced…</th><th></th></tr>
<tr><th></th><th>with Parent</th><th>with Child</th><th></th></tr>
<tr><td>Family & Treatment Barriers</td><td>Lack of:
• Perception of child’s weight problem[3,7]
• Motivation to change family behavior[4,5,16,18,22,23]
• Involvement[5]
• Interest[14]</td><td>Fear of:
• Adversely affecting patient-physician relationship[3,7]
• Damaging child’s self-esteem (obesity is a sensitive topic)[7]</td><td>Priority

Obesity was ranked as a low priority compared to other chronic conditions[2]
• Other issues of imminent concern in childhood and adolescence (STIs, smoking, drinking, pregnancy) often take precedence over childhood obesity which tends not to have immediate effects[2]</td><td>Assessment

Inconsistent methods used to assess weight[8]
• Qualitative assessment (clinical impression)
• Majority used (62-82%)
• Quantitative assessment (BMI, WC)
Less than half (44%) of physicians intend to measure BMI[11]
• Complexity involved in explaining BMI to patient & family[20]</td></tr>
<tr><th></th><th colspan="2">Training/Education</th><th>Ability (self-efficacy)</th><th>Awareness</th></tr>
<tr><td>Clinician Factors</td><td colspan="2">Lack of:
• Familiarity with BMI screening recommendations[1]
• Adequate knowledge and skills to counsel on childhood obesity [2,5,7,12,14]
• Lack of formal or specialized training[2,12]
• Lack of nutrition counselling training[21]</td><td>Low self-efficacy in terms of behavioral management strategies[2,3,5,15,17,19]
• Perceived competence was strongly correlated to comfort level and counseling patients on weight loss[2]
• Physicians not confident in answering parent questions, e.g: “how much weight should my child lose?”[17]
Limited self-efficacy and unrewarding to treat[16,19]
Low motivation to counsel patients (often due to high relapse rates)[21]
Previous attempts resulted in poor patient compliance to physician recommendations[16]</td><td>Only 25% of clinicians were aware of Expert Committee Recommendations to Treating Childhood Obesity
• Of this group, only 23% found it helpful[6]</td></tr>
</table>

<table>
<tr><td>Envi. Factors</td><td colspan="2">School Environment
Access to unhealthy food/meals at school[3,4]
Physical activity at schools is often limited[3]</td><td>Home Environment/Family Lifestyle
Obesogenic family lifestyle factors:
• Fast food[4,6]
• Television[4]
• Insufficient physical activity[4]</td><td>Both/Other
Convenient availability of fast food and sugar sweetened beverages [3]</td></tr>
<tr><td rowspan="2">Attitudes</td><td colspan="2">Clinician Attitudes Toward…</td><td colspan="2" rowspan="2">Parent
Parents perceive a lack of support from physicians[9]</td></tr>
<tr><td>Treatment
Perceived ineffectiveness of physician role to treat childhood obesity[1,5,10,13,15,19,21]
• Insufficient data to support effectiveness of primary care physicians' role[14]
• Physicians experienced poor success on previous attempts[19]
• Lack of evidence for effectiveness of obesity treatments in general[7]
• General pessimism that physician advice will be effective[7,23]</td><td>Obesity
Physician attitude towards obesity tends to be negative (negative stereotype) [5,13]

GPs & nurses view childhood obesity as more of a social/family/lifestyle/behavioral problem rather than a medical/biological problem[7,9,13,15]</td></tr>
<tr><td colspan="4">Incongruence between parents & physicians:
• 86% of parents and 73% of physicians ($p<0.001$) feel physicians should be involved in weight management of children[9]</td></tr>
</table>

[1]Flower et al. (2007)
[2]Jelalian et al. (2003)
[3]Perrin et al. (2005)
[4]Spivack et al. (2010)
[5]Story et al. (2002)
[6]Rhodes et al. (2007)
[7]Walker et al. (2007)
[8]Barlow et al. (2002)
[9]Gage et al. (2013)
[10]Dalton et al (2011)
[11]Khanna et al. (2009)
[12]Forman-Hoffman et al. (2006)
[13]Foster et al. (2003)
[14]Lyznicki et al. (2001)
[15]Ogden & Flanagan (2008)
[16]Campbell et al. (2012)
[17]Lee (2013)
[18]Nichols & Livingstone (2002)
[19]Cade & O'Connell (1991)
[20]Woolford (2008)
[21]Rodondi et al. (2006)
[22]Ariza et al. (2012)
[23]Bardia et al. (2007)

Appendix D. Example of an assessment checklist

SAM Scoring Sheet

Material being evaluated: _____

Points

2	points for a superior rating	0	points for a not suitable rating
1	point for an adequate rating	N/A	if the factor does not apply to this material

Factor to be rated	Score	Comments
1 Content		
(a) Purpose is evident		
(b) Content is about behaviors		
(c) Scope is limited		
(d) Summary or review included		
2 Literacy Demand		
(a) Reading grade level		
(b) Writing style–active voice is used		
(c) Vocabulary uses common words		
(d) Context is given first		
(e) Learning aids via road signs		
3 Graphics		
(a) Cover graphic shows purpose		
(b) Type of graphics		
(c) Relevance of illustrations		
(d) List, Tables, etc. explained		
(e) Captions used for graphics		
4 Layout and Typography		
(a) Layout factors		
(b) Typography		
(c) Subheads are used		
5 Learning Stimulation/Motivation		
(a) Interaction is used		
(b) Behaviors are modeled and specific		
(c) Motivation–self-efficacy		
6 Cultural Appropriateness		
(a) Match in logic, language, experience		
(b) Cultural image and examples		

S = Total SAM Score (count up all factors) _____

M = Total maximum Score = 44

N = No. of N/As above = ___ X 2 = _____

T = Adjusted Total maximum score (M - N) _____

Pecentage Score = S ÷ T _____ %

Interpretation of suitability score. _____ (superior, adequate, not suitable)

Appendix E. Information sheets and consent forms

UNIVERSITY OF ALBERTA

PARTICIPANT INFORMATION SHEET

Title of Project: Primary care Resources for Obesity in Pediatrics (PROP)

Principal Investigator:
Dr. Geoff Ball
Associate Professor, Department of Pediatrics
Phone: 780-342-8465
Email: gdball@ualberta.ca

Project Coordinator:
Ms. Jillian Avis
PhD Candidate, Department of Pediatrics
Phone: 780-342-8449
Email: avis@ualberta.ca

Background

A growing number of Canadian boys and girls have an unhealthy weight. About 25% of children are either overweight or obese, so there is an urgent need to address this health issue. Primary care is a feasible and suitable setting for childhood obesity prevention and management, however, clinicians report a number of challenges when providing such care to families. Educational tools and resources, such as Canada's Food Guide and Body Mass Index Growth Charts, may help health professionals to overcome challenges. To date, such tools have been used to *(i)* promote families' awareness and understanding of healthy lifestyle behaviours, *(ii)* help families to initiate and sustain healthy lifestyle behaviours, *(iii)* facilitate clinicians' provision of care to families regarding obesity prevention and management, and *(iv)* promote communication regarding children's healthy weight and lifestyle behaviours between clinicians and families.

Although clinicians use a number of tools in care, little is known about *if* and *how* they facilitate clinicians' provision of obesity-related care for families. Along these lines, this study was designed to explore clinicians' views on the different types of tools and resources used to prevent and manage childhood obesity in primary care.

Study Purpose

The primary purpose of this study is to explore clinicians' views regarding the use and effectiveness of tools and resources used to prevent and manage childhood obesity in primary care.

Procedures

The graduate student will provide participants with a study explanation and an invitation to participate. Procedures for obtaining informed and written consent will follow. Interviews with participants will last approximately 60 minutes, be digitally recorded for transcription, and be held at a location convenient for the participant (*e.g.,* clinic office).

Possible Benefits

The interview may help to heighten clinicians' awareness of and sensitivity to obesity, health, and well-being in families, especially those at risk of or with obesity. Also, as a token of appreciation, we will offer you a $10 gift card (*e.g.,* Chapters, Starbucks).

Possible Risks

There are no unusual risks involved with participating in this study.

Voluntary Participation & Freedom to Withdraw

Your participation in this study is completely voluntary. You are under no obligation to participate. You can also decide to stop participating at any time.

Confidentiality and Anonymity

Your study information will be kept confidential. Personal names will not be used in any public research presentations or publications. Only research team members will have access to and perform analyses of study data. All original data collected for this study will be held a minimum of 5 years after study completion.

Additional Contacts

If you have questions about this study, please contact Dr. Geoff Ball (Principal Investigator). If you have questions about your rights as a research participant, please contact the Human Research Ethics Office (780-492-2615). The Human Research Ethics Board has reviewed and approved this study.

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UNIVERSITY OF ALBERTA

PARTICIPANT CONSENT FORM

Title of Project: **Primary care Resources for Obesity in Pediatrics (PROP)**

Principal Investigator: **Dr. Geoff Ball** 780-342-8465 (p); gdball@ualberta.ca (e)

	Yes	No
Do you understand that you have been asked participate in a research study?	☐	☐
Have you read and received a copy of the study Information Sheet?	☐	☐
Do you understand the benefits and risks involved with participating in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at anytime, without having to give a reason?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to personal information you share with us during this study?	☐	☐

Who explained this study to you? _____

I agree to take part in this study. YES ☐ NO ☐

_____
Printed Name

_____ _____
Signature Date (dd/mm/yyyy)

I believe that the person signing this form understands this study and voluntarily agrees to participate.

_____ _____
Signature (Principal Investigator) Date (dd/mm/yyyy)

Geoff D.C. Ball, PhD, RD; Associate Professor
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Appendix F. Protocol manuscript

Avis JL, Cave AJ, Donaldson S, Ellendt C, Holt NL, Jelinski S, Martz P, Maximova K, Padwal R, Wild TC, Ball GD. Working with parents to prevent childhood obesity: a protocol for a primary care-based eHealth study. JMIR Res Protoc 2015a;4:e35.

Abstract

Background. Parents play a central role in preventing childhood obesity. There is a need for innovative, scalable, and evidence-based interventions designed to enhance parents' motivation to support and sustain healthy lifestyle behaviors in their children, which can facilitate obesity prevention.

Objectives. (i) Develop a digital SBIRT to enhance parents' concern about and motivation to support children's healthy lifestyle behaviors; (ii) refine the SBIRT by assessing end-user acceptability, satisfaction, and usability through focus groups; (iii) determine feasibility and preliminary efficacy of the refined SBIRT eHealth tool using a RCT.

Methods. This is a three-phased, multi-method study that includes SBIRT development (Phase I), refinement (Phase II), and testing (Phase III). (Phase I) Theoretical underpinnings of the SBIRT, entitled RIPPLE, will be informed by concepts applied within existing interventions and content will be based on literature regarding healthy lifestyle behaviors in children. The SBIRT platform will be developed in partnership between our research team and a third-party intervention development company. (Phase II) Focus groups with parents as well as HCPs, researchers, and trainees in pediatrics (n=30) will explore intervention-related perceptions and preferences. Qualitative data from the focus groups will inform

refinements to the aesthetics, content, structure, and function of the SBIRT. (Phase III) Parents (n=200) of children (boys and girls; 5–17 years old) will be recruited from a primary care pediatric clinic while they await their children's clinical appointment. Parents will be randomly assigned to one of five groups (four intervention groups; one control group) as they complete the SBIRT; the randomization function is built into the tool. Parents will complete the SBIRT using a tablet that will be connected to the Internet. Subsequently, parents will be contacted via email at one-month follow-up to assess *(i)* change in concern about and motivation to support children's dietary and physical activity behaviors (primary outcome) and *(ii)* use of online resources and referrals to health services for obesity prevention (secondary outcome).

Results. This research was successfully funded and received ethics approval. Development of the SBIRT started in Summer 2012 and we expect all study-related activities to be completed by Fall 2016.

Conclusions. The proposed research is timely and applies a novel, technology-based application designed to enhance parents' concern about and motivation to support children's healthy lifestyle behaviors and encourage use of online resources and community services for childhood obesity prevention. Overall, this research builds on a foundation of evidence supporting the application of SBIRTs to encourage ('nudge') individuals to make healthy lifestyle choices. Findings from Phase III of this study will directly inform a cluster RCT to study the effectiveness of our intervention across multiple primary care-based settings.

Background

Childhood obesity is an urgent public health issue. Approximately one-third of Canadian children are overweight or obese (Roberts et al., 2012), a proportion that has doubled over the past 25 years (Shields, 2006). Pessimistically, the impact of most interventions for managing childhood obesity has been modest to date (Oude Luttikhuis et al., 2009), a point that highlights the need for innovative strategies that are designed to prevent unhealthy weight gain among healthy weight children (primary prevention) *and* manage excess weight among children with overweight and obesity (secondary prevention). To optimize the effectiveness of such approaches, parents need to play a central role. Specifically, parents set the stage for children's healthy lifestyle behaviors by fostering a supportive home environment, role-modelling healthy lifestyle habits, and monitoring and reinforcing children's behaviors (Faith et al., 2012; Golan & Grow, 2004). Paradoxically, some parents do not perceive their children's excess weight as a health concern (Zehle et al., 2007), a perception that may be influenced by parents' inability to accurately recognize obesity in their children (Eckstein et al., 2006). Among parents who have an accurate perception of their child's weight status (*e.g.,* their child meets clinical criteria for obesity *and* parents perceive their child to have obesity), only 50 – 60% initiate and sustain healthy lifestyle changes (Neumark-Sztainer et al., 2008). These results suggest that interventions that attempt to correct parents' inaccurate perceptions of their children's weight status *and* enhance their concern about and motivation to support children's healthy lifestyle behaviors may be useful.

Obesity is a common health issue, so interventions to prevent obesity need to be accessible, affordable, and scalable in order to reach a large target audience. The widespread

use and availability of the Internet highlights its potential value as a vehicle to deliver obesity prevention interventions (Whiteley et al., 2008); eHealth and mHealth interventions are contemporary terms used to describe health care services and practices that are supported by electronic infrastructure. The benefits of these types of interventions include their ability to offer immediate and tailored feedback, cost-effectiveness, and potential for widespread reach (Tate, 2009). Web-based interventions may specifically enhance health services by *(i)* removing social barriers and providing anonymity (An et al., 2009), *(ii)* overcoming limited availability of obesity-related health services (Ball et al., 2011), and *(iii)* compensating low confidence and skill levels reported by providers (He et al., 2010; Perrin et al., 2005). Systematic reviews have reinforced such advantages for web-based interventions for both children (Nguyen et al., 2011; An et al., 2009) and parents (Manzoni et al., 2011), reporting statistically- and clinically-meaningful improvements in obesity-related outcomes and lifestyle behaviors.

To date, the majority of online interventions to address obesity-related behaviors have applied time- (*e.g.,* online programs up to 52 weeks in length [Davies et al., 2012]), and resource-intensive (*e.g.,* online interventions with additional in-person components [Hamel & Robbins, 2013]) models, suggesting there is value in examining the application of brief and novel online strategies for the prevention of obesity in children (Rao et al., 2011). One such approach includes SBIRTs – time-limited approaches that include an initial screening step followed by delivering a short intervention, usually within a 10 – 20 minute period, with options to refer users to treatment and other supportive resources. Fundamental to SBIRTs is the FRAMES model (Miller & Rollnick, 2002), which *(i)* personalizes **f**eedback to communicate unique health outcomes and positive behavior change to the

participant, *(ii)* emphasizes personal **r**esponsibility for behavior change, *(iii)* provides **a**dvice on how to initiate and sustain change(s), *(iv)* creates a **m**enu of change options, *(v)* expresses **e**mpathy, and *(vi)* emphasizes **s**elf-efficacy for change. Historically, SBIRTs have been used to address preventable health concerns (*e.g.,* alcoholism, cannabis use) and studies have shown this approach can exert a positive influence on intention to change behaviors as well as behavior change itself (Kaner et al., 2009). SBIRTs are particularly well-suited for obesity prevention in primary care, as PCPs often have frequent opportunities to interact with families, but limited time and resources to do so. Furthermore, because primary care represents most families' first point of contact with the health care system (Starfield et al., 2005), the provision of preventative health services, particularly for the primary prevention of chronic diseases, is proactive, efficient, and cost-effective. As well, families tend to access primary care-based health services throughout the life course, so it represents a suitable environment to capture longitudinal data.

With these issues in mind, it is hypothesized that a digital SBIRT targeting parents will increase their awareness of children's weight status and enhance parents' concern about and motivation to support children's healthy lifestyle behaviors. The program will have a prevention approach designed to benefit parents with children from across the body weight continuum. Specifically, our SBIRT will encourage parents of children with healthy weights to seek resources to eat healthfully and be physically active to maintain their weight status; it will also guide parents of children with unhealthy weights to access information and health services to improve their children's weight status and associated health risks. Our three-phased, multi-method study includes the following objectives: (1) Develop a digital SBIRT designed to raise parents' awareness of their children's weight status and lifestyle behaviors;

(2) Refine the SBIRT by assessing acceptability, satisfaction, and usability using focus groups with pediatric HCPs, researchers, and parents; and (3) Determine the feasibility (pilot testing) and impact (pragmatic trial) of the intervention through a RCT design, which will include administering our SBIRT to a sample of parents and collecting data at baseline and one-month post-intervention to assess *(i)* changes in parents' concern about and motivation to support children's dietary and physical activity behaviors (primary outcome), and *(ii)* families' use of resources and health services for the prevention of childhood obesity (secondary outcome).

Methods

Study Design

This study includes intervention development (Phase I), refinement (Phase II), and testing (Phase III). Such a design is appropriate when a number of research-related parameters (*e.g.,* adverse events, cost-effectiveness, feasibility, power calculation for sample size) remain unknown (Thabane et al., 2010).

Study Setting

This study is being conducted in the primary care setting and will be performed in the waiting room while parents and children await their upcoming pediatrician appointment. Specifically, we are working in partnership with colleagues who lead the Edmonton Oliver Primary Care Network, one of more than 40 networks in the province. In Alberta, primary care networks were developed by our provincial health system to enhance and coordinate health services delivery in primary care. They include family physicians, a multidisciplinary

team of HCPs, decision-makers, and administrators, all of whom work collaboratively to address the needs of the local patient population. This setting represents a suitable venue to address the primary and secondary prevention of childhood obesity because *(i)* primary care networks are often families' first point of contact with the health care system, *(ii)* the goals and priorities of are well-aligned with primary and secondary prevention of chronic diseases, and *(iii)* patients typically access health care services in primary care throughout the life course, which represents an excellent setting to maintain contact with and collect information from families over an extended period (Kubik et al., 2008; Starfield et al., 2005).

Phase I: Development

Our eHealth tool, entitled RIPPLE, will be developed in partnership with *Evolution Health Inc.*, a web-based intervention development company based in Toronto. Content in the SBIRT will be incorporated from current literature on children's healthy lifestyle behaviors, including dietary, physical activity, and sedentary behavior habits (*e.g.,* Slater et al., 2010; Whitaker et al., 2003; Steinbeck, 2001), and theoretical underpinnings of the SBIRT will be informed by concepts used in existing interventions (*e.g.,* the Norm Activation Model; Schwartz, 1977). Consistent with the Health Belief Model (Rosenstock, 1974), the SBIRT will be designed to act as a *cue to action*, in which the intervention will prompt parents to initiate and sustain healthy lifestyle changes for children. Specifically, the SBIRT will act as a trigger by creating a discrepancy between parents' perceptions of their children's dietary and physical activity habits and either *normative* or *injunctive* feedback; parents will receive either *normative* feedback on how their child relates to reference norms drawn from the Canadian pediatric population for eating (Garriguet, 2007) and physical

activity (Colley et al., 2011), or *injunctive* feedback, which includes national recommendations (Health Canada and the Canadian Society for Exercise Physiology, 2002). By providing parents with two types of feedback, we will determine if injunctive or normative feedback is more salient for parents in the context of supporting their children's healthy lifestyle behaviors.

Based on SBIRTs previously developed by *Evolution Health Inc.* (*e.g.,* Cunningham & van Mierlo, 2009) our SBIRT will *screen* children's weight status, which will include sharing this information with parents, as well as deliver a *brief intervention* to parents related to their children's lifestyle behaviors, and provide *referrals to treatment* and other supportive resources for parents. Specifically, the guided user interface within the online program will include the following steps: *(i)* Data input (children's height [cm] and weight [kg] will be measured by the study-designated research assistant using a wall-mounted electronic stadiometer and an electronic medical scale; the research assistant will enter this data into the SBIRT on a study-designated tablet [iPad] and then pass the tablet to the parent); *(ii)* Screening (parents will receive objective, personalized feedback both numerically based on their children's BMI percentile and visually using a healthy weight ruler [Cloutier et al., 2013]); *(iii)* Brief Intervention (parents will be randomly assigned to complete one of four brief questionnaire-based interventions or the control group [*Heads Up!*]; the latter includes information on children's lifestyle behaviors only. Two interventions will include nutrition-based-questions [*Eat It!*] and two interventions will include physical activity-based questions [*Move It!*]. In each of the two interventions, parents will receive either *normative* or *injunctive* feedback. Between-group differences in primary and secondary outcomes will be assessed to determine the differential impact of the intervention across the five groups of

parents); *(iv)* Toolkit (parents will be presented with a menu of online handouts and community services to choose from); *(v)* Theory-based measurement (to understand how the SBIRT works to influence parents' intentions, a brief questionnaire has been adopted from Campbell *et al.* (2011) and will assess parents' concern about and motivation to support children's dietary and physical activity behaviors; and *(vi)* Tailored report (parents will receive a personalized report that will include their children's weight status, their responses to the intervention questions as well as the feedback they received, and the resources they selected from the toolkit). To measure changes in primary (parental concern about and motivation to support changes in children's lifestyle behaviors) and secondary outcomes variables (families' use of resources and health services), parents will be contacted at one-month follow-up to complete the same theory-based measurements they completed at baseline and a brief questionnaire to assess their use and/or intention to use the suggested resources and community services. By design, the SBIRT will require parents to indicate their preferred mode of contact for receiving the one-month follow-up measure and questionnaire (*e.g.*, mail, telephone, email), which is designed to optimize participant retention.

Phase II: Refinement

Following intervention development, focus groups with parents (of children aged 5 to 17 years), and pediatric-focused HCPs (primary, secondary, and/or tertiary providers with experience in childhood obesity prevention and management), health services administrators, and researchers (faculty and trainees in the field of pediatrics and obesity) will be used to assess acceptability, satisfaction, and usability of the SBIRT. Parents will be

recruited via word-of-mouth at the local university where the research is being conducted; a minimum of ten parents will be recruited in order to gain an adequate representation of the caregiver perspective. Consistent with reports regarding the difficulties in organizing and running focus groups with specific populations (Kidd & Parshall, 2000; Smithson, 2000), mechanisms to obtain parents' perspectives (*e.g.,* one-on-one individual interviews) will be used if necessary. Using the recruitment technique of snowball sampling, HCPs, administrators, and researchers (n=20–25) will be purposefully sampled for demographic variation in participant groups (*e.g.*, disciplinary orientation, experience). This estimated sample size is consistent with methodological recommendations (Sandelowski, 1995) and similar previous investigations (Farnesi et al., 2011; Holt et al., 2008), which will enable us to attain a high level of data saturation.

In a private room, the researcher trained in facilitating focus group interviews will provide eligible participants with a study explanation and formal invitation to participate; informed, written consent will be obtained. Focus groups will occur over 4–5 sessions (6–8 participants per group) and be 60–90 minutes in duration. The facilitator will lead groups step-by-step through the SBIRT (version 1.0) by entering standardized data and projecting the web-based content onto a screen. Interviews will include open-ended questions to query *(i)* participants' overall impressions of the intervention, *(ii)* factors related to participants' acceptability of and satisfaction with the intervention, and *(iii)* theoretical underpinnings of the SBIRT. Probes will include prompts on SBIRT perceptions, preferences, and how to best incorporate the program into existing clinical processes; perceived strengths, limitations, and areas for improvement will also be explored. A closing discussion will query perceptions of

the need for long-term support within and beyond primary care and how this support should be provided.

Focus group discussions will be transcribed in real-time using a court reporter, which optimizes transcription accuracy and ensures confidentiality (Scott et al., 2009). Data will be managed and analyzed using *NVivo 10* (QSR, Melbourne, Australia). Qualitative data analysis is a cognitive process that includes comprehending, synthesizing, theorizing, and re-contextualizing (Morse & Field, 1995), and the method of qualitative description (Sandelowski, 2000) will be used to develop a basic description of the data. Data will be analyzed in a line-by-line process. From the initial analysis, a coding scheme will be developed to identify all meaningful units and new themes will be added as necessary. Once each discussion is coded, themes will be grouped under general categories and a written description will be constructed to explain each category. To enhance methodological rigor, we will *(i)* triangulate participants' views by interviewing HCPs, researchers, and parents, *(ii)* employ concurrent data collection and analysis to inform amendments to the interview guide, and *(iii)* implement a real-time member checking protocol to ensure findings accurately reflect participants' personal perspectives; at the end of each group, the moderator will confirm and clarify discussed themes.

Phase III: Pilot Testing

The objective of this phase is to pilot test the refined SBIRT with parents (n≈30) to determine the feasibility of incorporating the intervention in primary care, including *(i)* accuracy of the randomization procedures, *(ii)* ability to retain participants at follow-up, *(iii)* practicality of clinician involvement, *(iv)* suitability of the primary and secondary outcome

measures, and *(v)* time to complete the intervention in the primary care waiting room. All of these elements are important to assess prior to determining the effectiveness of a newly-developed intervention (Leon et al., 2011, Thabane et al., 2010). Upon recruitment and one-month follow-up, the researchers will cease participant recruitment for a two-week period to assess issues regarding feasibility; at this time, modifications may be made to study processes and procedures before initiating the pragmatic trial.

Phase III: Pragmatic Trial

Trial Design. A parallel-group, double-blinded RCT will be used to assess the effectiveness of the intervention. The trial will be registered publically (ClinicalTrials.gov identification number: NCT02330588) and adhere to CONSORT (Consolidated Standards of Reporting Trials) guidelines (Moher et al., 2001). Participants will be recruited and enrolled by an RA and RIPPLE will assign a unique, non-identifying number to participants. The allocation sequence will be electronically generated within the SBIRT and to reduce the risk of selection bias, participants (n=200 parents) will be randomly assigned to one of five groups (*Eat It!* [normative], *Eat It!* [injunctive], *Move It!* [normative], *Move It!* [injunctive] or the control group [*Heads Up!*]) using blocked randomization (5 arms; block size of five) to ensure equal group sizes (n=40/arm; equal allocation ratio of 1:1) throughout the study. To reduce risk of performance bias, the RCT will be double-blinded; specifically, the study-designated researcher coordinator (JA) will not be aware of participants' intervention assignment, unless participants request assistance with the program, thus potentially revealing their assignment. Research personnel will be blinded for the remainder of recruitment, as well as outcome assessment, in order to minimize the risk of detection bias

(Higgins et al., 2011). As well, study participants will not be aware of their assignment to the intervention or control groups. Prior to the intervention, participants will receive information that is sufficient to obtain informed consent, but inadequate so as to decipher between intervention groups. Although contamination is a possibility given the close proximity of participants, given that only one participant can be recruited at a time, enrollment and recruitment will be staggered and the opportunity for participants to discuss the intervention with each other is unlikely.

Sampling & Recruitment. Parents of children awaiting their pediatrician appointment will be recruited for the RCT. During this time, the research coordinator will liaise with the intake nurse to identify families who are suitable for study participation. Families will be eligible for study inclusion if *(i)* children present with non-urgent medical issues, *(ii)* children are 5–17 years of age, and *(iii)* children attend their appointment with at least one parent. Parents (*e.g.,* mothers, fathers, legal guardians) will be eligible if they *(i)* self-identify as a child's primary caregiver and *(ii)* speak and read English. The nurse will also help to differentiate urgent (*e.g.*, febrile, acute asthma attack) and non-urgent (*e.g.*, medical check-up, asthma follow-up) presentations, of which only the latter will be approached for recruitment. Families who are identified as eligible by the clinic nurse will be approached by the research coordinator in the waiting room of the primary care clinic. Average wait times in the Edmonton Oliver Primary Care Network are 15–30 minutes, so this time will be used to *(i)* recruit participants *(ii)* obtain informed, written consent (adult) and assent (child), *(iii)* measure and input children's anthropometric data, and *(iv)* deliver the brief, online intervention to parents on the study-designated tablet. If families present with more than one child and both are interested in participating, only the child with the next

upcoming birthday will be enrolled; this will be done to ensure that each study participant represents an independent case. As a token of appreciation and to encourage parents to complete the one-month follow-up measure, parents will be given a $25 (CAD) gift card to a local business (*e.g.,* grocery store).

PCPs at this site have historically had ~2,500 patient encounters per year, similar to other primary care clinics (Yarnall et al., 2003), so our research staff will recruit families on approximately two days per week over several months to accumulate our study sample. Given the design of the SBIRT, parents will also need adequate time to complete everything at once (*i.e.,* saving and completing the intervention at a later date will not be possible within the SBIRT). With time constraints in mind, families will be approached to participate in the study if we (clinical/ administrative staff, research team) believe parents will have sufficient time (15–20 minutes) to complete the intervention and research procedures while waiting for their scheduled clinical appointment. Although it is a potential barrier that some recruited parents may be unable to complete the program while they wait, previous studies have supported the feasibility of brief online interventions under similar conditions (*e.g.,* Freeborn et al., 2000). Assuming 20–30% attrition at one-month follow-up (Dhaliwal et al., 2014), complete data from approximately 150 parents is expected. Based on primary care client demography, this sample size will allow us to enroll a diverse group of families that vary by age, ethnicity, family income, and weight status.

Data Collection. Within the SBIRT, we will collect the following information (see Case Report Form in Appendix G): families' demographic information, children's weight status, resources chosen by parents, and parents' responses to both the intervention questions (unless allocated to the control group) and the questionnaire (see Phase I in Methods).

Data Management & Analysis. Security measures that adhere to provincial and federal privacy requirements will be integrated into the program. Access to the SBIRT will be password protected, all data transactions between the web and data services will be encrypted, and the server will be located behind a firewall to safeguard personal data. Data from the server will be exported to a database supported by *Evolution Health Inc.* built to optimize data accuracy, verification, retrieval, and security.

Quantitative data analyses will be performed using *SPSS 21.0* (SPSS Inc., Chicago, IL, USA). Continuous variables will be described by univariate summaries and frequency distributions will be determined for categorical variables. Box plots and histograms will display continuous variables and bar charts will display categorical variables. Level of recruitment and participant characteristics (*e.g.,* sex, weight status, demographics) will be calculated to assess enrolment tendencies and biases in sub-groups; level of retention, or the proportion of participants who remain in the study at one-month follow-up, will be calculated to assess the likelihood of attrition within and between sub-groups. Statistical significance will be set at $p<0.05$.

Results

This is a three-phased, multi-method study designed to build, refine, and complete testing of a SBIRT to enhance parents' concern about and motivation to support children's healthy lifestyle behaviors. Development of the SBIRT commenced in Summer 2012 and expected date of completion is Fall 2016. The Health Research Ethics Board at the University of Alberta (Edmonton, AB) has approved this study.

Discussion

Distinctive Features. This paper highlights the study protocol for the development, refinement, and testing of a novel SBIRT designed to enhance parents' concern about and motivation to support children's healthy lifestyle behaviors as well as link them with relevant resources to help prevent childhood obesity in primary care. Historically, SBIRTs have been developed and applied to facilitate positive changes related to addictive behaviors (*e.g.,* cannabis use, problem drinking). A recent review and meta-analysis of SBIRTs for screening of alcohol consumption in primary care found that the majority of participants across 22 trials demonstrated positive behavior change (*i.e.,* reduced consumption) at 12-month follow-up (Kaner et al., 2009); a finding that suggests the positive effects of this brief approach may have the potential for longevity. Furthermore, in comparison to lengthier online interventions (≥60 minutes), positive outcomes of brief interventions were not statistically different, highlighting that the dosage of exposure is not necessarily proportionate to the treatment effect – thus, justifying the use of a time- and resource-limited approach. In addition to the potential for positive behavior change, specific program elements unique to SBIRTs (*e.g.,* automatic screening procedures, personalized feedback, menu of resources) are well-suited for primary care. Although this setting prioritizes frontline prevention of chronic diseases, PCPs report a number of barriers and challenges to fulfilling this task (He et al., 2010; Spivack et al., 2010). Our intervention may address this deficit and reduce the pressures and expectations faced by PCPs who often lack confidence and skill in preventing childhood obesity (Perrin et al., 2005). Our SBIRT may also help families to overcome limited availability of health services for the secondary prevention of childhood obesity (*e.g.,* multidisciplinary weight management clinics, outpatient dietitian

counseling). Lastly, our SBIRT for parents may enhance existing resources and health services for obesity prevention in children; for instance, the intervention may remove social barriers and provide anonymity for families that are reluctant to receive care and support in-person.

Although the application of SBIRTs to the prevention of obesity in children remains untested, recent systematic reviews (Nguyen et al., 2011; An et al., 2009) have highlighted the advantages associated with online interventions, (*e.g.,* family-based Internet programs; Internet counselling; web-based interactive behavior programs) that are aligned with RIPPLE with respect to the aim of obesity prevention in children. For example, an online primary care-based program for preventing childhood obesity was well-received by clinicians and families, in which clinicians were more likely to speak with families about healthy weights, and parents intended to increase their children's vegetable and fruit intake post-intervention (Kubik et al., 2008). It is noteworthy, however, that the majority of such interventions have focused on time- and resource-intensive models, approaches that are often difficult to implement and sustain, particularly in primary care. Additionally, given that online approaches represent a relatively new niche of study, little is known regarding the impact of online interventions on weight-related health outcomes and intentions to change lifestyle behaviors (Smith et al., 2013). Taken together, there is real need to develop and evaluate brief, web-based interventions to help connect families with relevant resources that may *nudge* them towards healthy behavior changes in a setting where parents are already present and waiting.

Study Strengths. This study was developed in direct response to health systems gaps and priority areas in Canada. To date, the research team has received strong support from

HCPs and provincial health care organization decision-makers, highlighting the support for and relevance of our research. Second, this research will directly inform how such a brief, parent-based approach to address childhood obesity can be incorporated into everyday clinical practice in primary care. Providing families with tailored feedback, practical resources, and information on local health services will help to overcome clinical barriers associated with the primary and secondary prevention of obesity in children. Lastly, findings from this developmental study will inform a future clinical trial to test effectiveness of the intervention; specifically, results from the RCT will *(i)* help to estimate preliminary effect sizes of the SBIRT, informing a sample size calculation for a future RCT, *(ii)* confirm our ability to recruit and retain participants from primary care, and *(iii)* determine appropriateness of primary and secondary outcomes, and follow-up time points.

Study Limitations. We acknowledge that our SBIRT is new and remains untested. Given this reality, there are a number of program components (*e.g.,* duration of follow-up time period) that have been informed by related projects (*e.g.,* Delamater et al., 2013; Laws, 2004). Because a number of research-related parameters remain unknown, our study design includes modifying the intervention (Phase II) prior to formal testing (Phase III), which will facilitate refinement of program structure, function, language and aesthetics before initiating testing with parents in Phase III. We also appreciate that most SBIRTs have investigated participants' motivation to change their own individual behaviors whereas our study assesses the motivation of parents to help change their children's behaviors, in other words, surrogate motivation. Given this degree of separation, parents' motivation may neither accurately reflect children's motivation to make lifestyle behavior changes nor be sufficient to initiate

behavior change. These are relevant issues that will be explored further in follow-up research that will build on this initial study.

Conclusions & Future Directions

Our applied health services research is timely and the objectives align with research priorities to prevent obesity in children. This protocol study encompasses the development, refinement, and testing of a parent-based digital SBIRT that will directly inform the feasibility of incorporating such an approach into everyday clinical practice. By providing families with tailored feedback and information on applicable resources and community services, our SBIRT will encourage family self-management of obesity-related behaviors in primary care. Findings from this study will confirm a number of feasibility-related parameters in the pilot study (*e.g.,* feasibility of incorporation into primary care, levels of recruitment and retention, suitability of primary and secondary outcome measures) and preliminary effectiveness of the intervention, which will be tested in a future cluster RCT.

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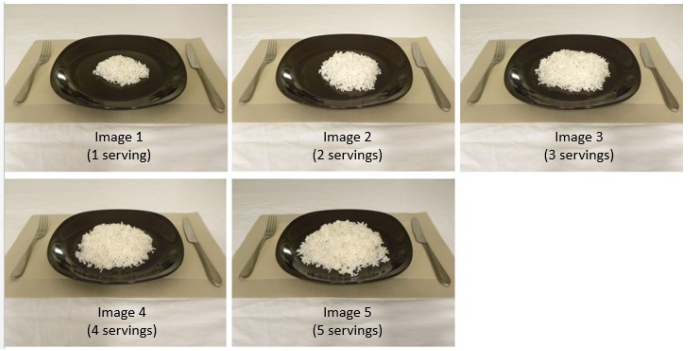
Appendix G. Case report form

Question	Specific Details of Data Entry
Researcher Entry	
1. Enter the child's measured height.	To the nearest 0.00cm
2. Enter the child's measured weight.	To the nearest 0.00kg
Parent Entry: Pre-Intervention	
1. Please enter your contact information:	
a. Primary Phone Number	xxx-xxx-xxxx
b. Secondary Phone Number (optional)	xxx-xxx-xxxx
c. Email	
d. Parent's First Name	
e. Child's First Name	
2. What is your child's sex?	Male/Female
3. What is your child's date of birth?	mm/dd/yyyy
4. What is your relationship to the child?	Biological mother, Biological father, Step-mother, Step-father, Adoptive mother, Adoptive father, Foster mother, Foster father, Grandmother, Grandfather, Sister, Brother, Aunt, Uncle, Cousin, Legal guardian, Prefer not to say
5. Are you the child's primary caregiver?	Yes/No
6. What is your ethnic background?	White (*e.g.,* Northern European), Aboriginal (*e.g.,* Metis), Asian (*e.g.,* Chinese), Black (*e.g.,* African American), Latino (*e.g.,* Mexican), Southeast Asian (*e.g.,* East Indian), Mixed, Other
7. What is your child's ethnic background?	White (*e.g.,* Northern European), Aboriginal (*e.g.,* Metis), Asian (*e.g.,* Chinese), Black (*e.g.,* African American), Latino (*e.g.,* Mexican), Southeast Asian (*e.g.,* East Indian), Mixed, Other
8. What is your total household income?	$0–20 000, $20 001–$40 000, $40 00–$60 000, $60 001–$80 000, $80 001–$100 000, over $100 000, Prefer not to say, Don't know
9. What is your highest level of education?	Some high school, Completed high school, Some college/university, Completed college/university, Graduate degree, Prefer not to say
10. What is your current relationship status?	Single, Common Law, Married, Divorced, Separated

11. How would you describe your child's weight?	Very underweight, A little underweight, Average, A little overweight, Very overweight

Parent Entry – *Eat It* Intervention

1. For a typical supper (evening meal), what portion of rice does your child eat?	Images 1 – 5 (shown below), Not applicable, Don't know 
2. On a typical day, how many sugar-sweetened beverages does your child drink? [Sugar-sweetened beverages include regular soft drinks, sweetened fruit juices, flavored milk, sports drinks, and energy drinks.]	0, ½, 1, 2, 3, 4, 5 or more, Not applicable, Don't know

Parent Entry – *Move It* Intervention

1. On a typical day, how many minutes of moderate-to-vigorous physical activity does your child get? [What does moderate-to-vigorous physical activity look like? Most children will 'huff and puff', get red in the face, and sweaty.]	0–15, 16–30, 31–45,46–60, 61–75, 76–90, More than 90, Not applicable, Don't know
2. On a typical day, how many hours does your child spend viewing a screen for leisure purposes? [Screens include cell phone, computer, tablet, television, and video games. Screen time *does not* include school- or work-related activities.]	Less than 1, 1–2, 3–4, 5–6, More than 6, Not applicable, Don't know

Parent Entry: Post-Intervention for *Eat It*[1]

1. How concerned are you about your child's weight or body size?	1 – 5 (1:Not Concerned; 5:Very Concerned)
2. How important is it to you, right now, to change what your child eats?	1 – 5 (1:Not Important; 5:Very Important)

3. How much, at this moment, do you personally want to change what your child eats?	1 – 5 (1:Not At All; 5:Very Much)
4. How confident do you feel about succeeding in changing your child's eating habits?	1 – 5 (1:Not Confident; 5:Very Confident)
5. How confident do you feel about succeeding in having your child eliminate regular soda, fruit, juice, or sports drinks?	1 – 5 (1:Not Confident; 5:Very Confident)
6. How ready are you to change your child's eating habits?	1 – 5 (1:Not Ready; 5:Very Ready)
7. I intend to discuss my child's weight with our doctor today.	1 – 5 (1:Strongly Disagree; 5:Strongly Agree)
8. During the next month, I intend to use the resources and/or services that I selected in the previous section of this program for my child.	1 – 5 (1:Strongly Disagree; 5:Strongly Agree)

Parent Entry: Post-Intervention for *Move It*[1]

1. How concerned are you about your child's weight or body size?	1 – 5 (1:Not Concerned; 5:Very Concerned)
2. How important is it to you, right now, to have your child engage in a more physically active lifestyle?	1 – 5 (1:Not Important; 5:Very Important)
3. How much, at this moment, do you personally want to change your child's level of physical activity?	1 – 5 (1:Not At All; 5:Very Much)
4. How confident do you feel about succeeding in changing your child's level of physical activity?	1 – 5 (1:Not Confident; 5:Very Confident)
5. How confident are you that you can engage your child in one hour of moderate-to-vigorous physical activity each day?	1 – 5 (1:Not Confident; 5:Very Confident)
6. How ready are you to change your child's level of physical activity?	1 – 5 (1:Not Ready; 5:Very Ready)
7. I intend to discuss my child's weight with our doctor today.	1 – 5 (1:Strongly Disagree; 5:Strongly Agree)

8. During the next month, I intend to use the resources and/or services that I selected in the previous section of this program for my child.	1 – 5 (1:Strongly Disagree; 5:Strongly Agree)

Parent Entry: Post-Intervention for *Heads Up!*[2]

[1]Questions have been adopted, with permission, from Campbell et al. (2011).
[2]Includes questions from the Post-Intervention for *Eat It!* (1 – 6) and *Move It!* (2 – 8).

Appendix H. Lessons learned manuscript

Avis JL, van Mierlo T, Fouriner R, Ball GD. Lessons learned from using focus groups to refine digital interventions. JMIR Res Protoc 2015b;4:e95.

Abstract

There is growing interest in applying novel eHealth approaches for the prevention and management of various health conditions, with the ultimate goal of increasing positive patient outcomes and improving the effectiveness and efficiency of health services delivery. Coupled with the use of innovative approaches is the possibility for adverse outcomes, highlighting the need to strategically refine digital practices prior to implementation with patients. One appropriate method for modification purposes includes focus groups; although a well-established method in qualitative research, there is a lack of guidance regarding the use of focus groups for digital intervention refinement. To address this gap, the purpose of our paper is to highlight several lessons our research team learned in using focus groups to help refine digital interventions prior to use with patients.

Background

Digital interventions have an important role to play in promoting health and well-being among patients. However, this mode of delivering information and interaction is not without pitfalls (Zikmund-Fisher et al., 2011), a reality that highlights the importance of developing and refining interventions in a thoughtful, systematic manner prior to implementation (Campbell et al., 2007). One available method for refining digital

interventions is focus groups, an approach used traditionally in the fields of marketing and advertising research to solicit consumer feedback on concepts and products (Merton, 1987). Focus groups, now a frequently used method in qualitative research, are unique in that they enable the collection and analysis of three complementary forms of data – individual- and group-level data, and data generated based on participant interaction (Onwuegbuzie et al., 2009). This feature is valuable because the researcher can explore multiple units of analysis to understand the research question. Additionally, focus groups are advantageous as they often allow for the spontaneous discussion of topics (*e.g.,* Butler, 1996) that may otherwise go unvoiced in other methods of data collection, such as individual interviews.

Focus groups have been used to assess individuals' perceptions of and refinements for changes to the structure, content, and utility of digital interventions. For example, focus groups have been applied to study single, standalone interventions (Waterlander et al., 2014; Fukuoka et al., 2011), educational resources for patients (Gray et al., 2014; Weaver et al., 2013), and the usability of several comparable tools (Grindrod et al., 2014). Despite these examples, there remains a lack of guidance for using focus groups in the context of digital health, and specifically, digital intervention refinement; to date, most recommendations have emphasized the use of focus groups for non-digital interventions (Grindrod et al., 2014) and recruiting participants into focus groups (Benavides-Vaello et al., 2004). To address this gap, our purpose was to highlight several lessons that we learned from our collective experience (Avis et al., 2015; van Mierlo et al., 2015; van Mierlo et al., 2014) in using focus groups to help develop and refine digital interventions.

Lessons Learned

In a recent study that has been registered with ClinicalTrials.gov (NCT02330588; Avis et al., 2015a), our research team used focus groups to refine a newly-developed online SBIRT designed to enhance parents' awareness of and motivation to change children's healthy lifestyle behaviors. The following are practical lessons learned from conducting these focus groups.

Use a Checklist to Plan, Track, and Report Aspects of the Focus Group

As qualitative research involves the exploration of complex phenomena, explicit and comprehensive reporting can be a challenge. An additional hurdle is clearly articulating the research team's background, study design, coding process, and key findings, which may be particularly important when researchers acting as focus group moderators are intellectually and potentially financially invested in the digital intervention under study. For transparency and to enhance methodological rigour, a checklist can help to organize and articulate all of the relevant processes and procedures the research team undertook in their research with focus groups. For example, the Consolidated Criteria for Reporting Qualitative Research (Tong et al., 2007) is a 32-item checklist that can be used to report criteria in three domains (research team and reflexivity [*e.g.,* researchers' credentials, relationship(s) with participants], study design [*e.g.,* theoretical framework, participant selection], and analysis and findings [*e.g.,* methodology, use of verification strategies]).

Have a Helper

Participants can perceive focus groups for refining digital interventions as opportunities to share their thoughts and opinions about the intervention as well as query the

rationale for different intervention elements. However, the focus group moderator has a demanding position to facilitate the flow of discussion and strategically channel participant's feedback, often within a predetermined time period. Therefore, he/she needs to strike a balance between respectfully allowing participants to 'tell their stories' and contribute meaningfully while adhering to their interview guide that is typically designed to solicit feedback on a range of issues related to the intervention. With this in mind, the inclusion of an assistant or collaborator in the focus group can help to keep everyone on time and on task, as well as alleviate the moderator of distracting and time-consuming tasks, such as note-taking. For instance, if the discussion is running long or the group tends to get side-tracked by one or two individuals, the assistant or collaborator might say: "Unfortunately we are running short of time; could we follow-up with you regarding your thoughts at a later point?" This strategy allows the moderator to maintain their emphasis on the interview questions and process as well as complete the focus group in a timely manner.

Prepare for Constructive Feedback

In contrast to many traditional focus groups, which are often used to explore and solicit perspectives related to abstract and conceptual phenomena, focus groups for refining digital interventions are more targeted, querying participants' opinions on a tangible product in which the researchers (often including the focus group facilitator) may have painstakingly developed. It is not unusual for the research team members to have an emotional response to criticism when blood, sweat, and tears have been generated through the intervention development phase. It is essential to prepare oneself for unexpected remarks as the moderator's negative expressions and/or feedback may unduly sway participants from

communicating their true thoughts and feelings, which may compromise the credibility and usefulness of the data.

Tailor Questions to Participants

It is valuable to obtain perspectives from a diverse group of stakeholders when developing a new intervention. For instance, if developers plan to target substance abuse behaviors in adolescents, it makes sense to solicit feedback from adolescents themselves (the target audience), but also other relevant stakeholders (*e.g.,* HCPs, parents, teachers) who may have a keen interest in the tool or who may play a role in referring or recommending the intervention to adolescents. Depending on the degree of homogeneity in each focus group, moderating questions and facilitating probes may need to be tailored for language and content. In our experience, we tailored discussion questions to groups of parents and HCPs who were more interested in practical issues (*e.g.,* diversity of information and health services to promote healthy nutrition in families) versus researchers who showed a greater affinity for academic elements (*e.g.,* assessing parents' motivational constructs that can predict behavior change) of the intervention.

Preserve Context When Capturing Data

Unlike focus groups in which participants are encouraged to discuss intangible concepts (*e.g.,* an experience or process), focus groups for refining digital interventions typically query participants' views on concrete elements (*e.g.,* aesthetics, ease and logic of navigation). Given this difference, capturing the discussion of focus group participants with a digital audio recorder and subsequent transcription may not preserve the context of

intervention details to which participants refer (*e.g.,* "I like the font and images you used on this page"). To improve the accuracy of data capture in focus groups, Scott *et al*. (2009) proposed real-time data transcription using certified court reporters that includes transcribing focus group discussions into text similar to processes used in court hearings and depositions. We have used this approach and realized several benefits, including *(i)* the transcription is highly accurate, *(ii)* additional context can be included into transcripts if desired, *(iii)* turnaround is quick (3-4 business days), enabling concurrent data collection and analysis, an important tenet of qualitative research (Morse et al., 2002) even if several focus groups are planned over a short period of time, and *(iv)* the moderator can focus his/her full attention on facilitating the group discussion without concern for data collection.

Assess the Current Intervention – Don't Create a New One

Developing or white-boarding unique concepts for digital interventions can be exciting and it is not atypical for focus group members who are highly-engaged to suggest the addition of digital elements outside the scope of the current intervention (*e.g*., incorporation of avatars, chat rooms, and other social media components). An important task of the moderator is to manage and concentrate participants' feedback to the task at hand. Particularly when refining an intervention, as much of the design, structure, and functional elements have already been established, it is important to stay focused on more proximal aspects of refinement (e.g., likability, feasibility, and utility) of the *current* intervention. It may also be helpful for the moderator to explicitly discuss the objectives of the focus group and the kinds of modifications that are possible before the group discussion begins in order for participants to have clear expectations.

Leverage the "Digital Expert"

In our experience, focus groups often contain at least one "digital expert", a member with personal or professional experience in design, information architecture, or computer programming. Depending on the nature of the contributions and how the moderator manages the discussion, the digital expert can exert a positive or negative influence on the group discussion. An attentive moderator can leverage the digital expert to help channel group discussion on intervention attributes; acknowledging the individual's experience and expertise as well as utilizing probes to draw out information and insights relevant to the current intervention can engender rapport, respect, and openness throughout the group. Issues that arise beyond the scope of the focus group can be respectfully deferred to a later date, which allows the digital expert to contribute additional information while not detracting from the goal at hand.

Conclusions

Refining digital interventions using focus groups presents unique challenges and opportunities. Based on our experience to date, we have learned a number of lessons, including *(i)* transparency of the research process can be facilitated through the use of a checklist to plan, track, and report important aspects of the focus group, *(ii)* some participants may misperceive focus groups as an unimpeded opportunity to discuss the intervention and efforts should be employed to optimize use of time, *(iii)* the moderator may be heavily invested (emotionally and /or financially) in the intervention and should be prepared for critical comments from participants, *(iv)* the refinement process may benefit from a number of different perspectives, so tailoring the discussion questions and probing follow-up

questions is advisable, *(v)* special consideration for capturing data is required so that the context of the discussion remains clear and accurate at the data analysis phase, *(vi)* the moderator should specify the purpose, which includes refining the existing intervention rather than developing a new one, and *(vii)* a "digital expert" may be present within the group, so the moderator should plan accordingly to manage individual contributions in order to effectively facilitate the group discussion. These practical lessons may be particularly relevant for clinicians and researchers working to refine new digital interventions. Such a process is likely to increase in frequency as health care delivery evolves to adopt novel interventions designed to optimize patient outcomes and improve health care availability, accessibility, and acceptability.

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Appendix I. Information sheets and consent forms

UNIVERSITY OF ALBERTA

PARTICIPANT INFORMATION SHEET (HEALTH PROFESSIONALS)

Title of Project: Working with Parents to Prevent and Manage Obesity in Children

Principal Investigator:
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Project Coordinator:
Ms. Jillian Avis
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Email: avis@ualberta.ca

Background

A growing number of Canadian boys and girls have an unhealthy weight. About 25% of children are either overweight or obese, so there is an urgent need to address this health issue. Parents play a key role in helping their children to be as healthy as possible. For example, parents can help to *prevent* unhealthy weight gain in children who currently have a healthy body weight. This can include ensuring that children eat healthy foods and are physically active every day. In addition, parents can help to *manage* obesity in children who currently have an unhealthy weight. This can include meeting with health care professionals to understand children's health risks and to get information about how to improve their children's health. Along these lines, this study was designed to help parents prevent and manage childhood obesity.

We recently developed a short, online program for parents called **RIPPLE** (**R**esource **I**nformation **P**rogram for **P**arents on **L**ifestyle and **E**ducation). RIPPLE is completed by parents using an iPad. RIPPLE is designed to increase parents' motivation to prevent and manage obesity in their children by connecting them with local community resources and educational tools. Because RIPPLE is a new program, we want to gain insight and opinions about the likeability, acceptability, satisfaction, and feasibility of RIPPLE before we begin using the program with parents.

Study Purpose

The goals of this research are to:

1. Gain opinions from pediatric-focused clinicians, researchers, trainees, and administrators to refine the structure, function, language, and aesthetics of RIPPLE prior to testing the program with parents.

2. Determine how RIPPLE can be incorporated into the day-to-day operation of a pediatric primary care clinic.

Procedures

A research assistant (RA) will provide participants with a study explanation and invitation to participate. Procedures for obtaining informed and written consent will follow. Participants will be recruited through the Edmonton Oliver Primary Care Network, Alberta Health Services, Alberta Health, Pediatric Centre for Weight and Health, and the University of Alberta. Focus groups will consist of ~5 – 8 participants, last for 60 – 90 minutes, be transcribed in real time by a court reporter, and held at a location convenient for participants (*e.g.,* Edmonton Oliver Primary Care Network boardroom, Edmonton Clinical Health Academy). In a step-by-step manner, the study RA will lead groups through the RIPPLE program by entering sample (dummy) data into the program; a digital projector will be used to project the content on a wall for the group to view and follow along. At each stage of the program, the focus groups will be presented with open-ended questions to explore a range of issues, such as program-related preferences, perceptions, and experiences. Results will be consolidated across focus groups, and the data will be used to inform edits and refinements to the RIPPLE program. As a token of appreciation, we will offer you a $25 gift card (*e.g.,* Starbucks).

Possible Benefits

By viewing and suggesting refinements and edits to the RIPPLE program, participants may acquire insight into family issues related to the prevention and management of childhood obesity, such as sensitivity to obesity, health, and well-being in families.

Possible Risks

There are no unusual risks involved with participating in this study.

Voluntary Participation & Freedom to Withdraw

Your participation in this study is completely voluntary. You are under no obligation to participate. You can also decide to stop participating at any time.

Confidentiality and Anonymity

Your study information will be kept confidential. Personal names will not be used in any public research presentations or publications. Only research team members will have access to and perform analyses of study data. All original data collected for this study will be held a minimum of 5 years after study completion.

Additional Contacts

If you have questions about this study, please contact Dr. Geoff Ball (Principal Investigator). If you have questions about your rights as a research participant, please contact the Human Research Ethics Office (780-492-2615). The Human Research Ethics Board has reviewed and approved this study.

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UNIVERSITY OF ALBERTA

PARTICIPANT INFORMATION SHEET (PARENTS)

Title of Project: Working with Parents to Prevent and Manage Obesity in Children

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Project Coordinator:
Ms. Jillian Avis
PhD Candidate, Department of Pediatrics
Phone: 780-342-8449
Email: avis@ualberta.ca

Background

A growing number of Canadian boys and girls have an unhealthy weight. About 25% of children are either overweight or obese, so there is an urgent need to address this health issue. Parents play a key role in helping their children to be as healthy as possible. For example, parents can help to *prevent* unhealthy weight gain in children who currently have a healthy body weight. This can include ensuring that children eat healthy foods and are physically active every day. In addition, parents can help to *manage* obesity in children who currently have an unhealthy weight. This can include meeting with health care professionals to understand children's health risks and to get information about how to improve their children's health. Along these lines, this study was designed to help parents prevent and manage childhood obesity.

We recently developed a short, online program for parents called **RIPPLE** (**R**esource **I**nformation **P**rogram for **P**arents on **L**ifestyle and **E**ducation). RIPPLE is completed by parents using an iPad. RIPPLE is designed to increase parents' motivation to prevent and manage obesity in their children by connecting them with local community resources and educational tools. Because RIPPLE is a new program, we want to gain insight and opinions about the likeability, acceptability, satisfaction, and feasibility of RIPPLE before we begin using the program with parents.

Study Purpose

The goals of this research are to:

1. Gain opinions from parents to refine the structure, function, language, and aesthetics of RIPPLE prior to testing the program with parents in primary care.

Procedures

A research assistant (RA) will provide participants with a study explanation and invitation to participate in an individual, one-on-one interview. Procedures for obtaining informed and written consent will follow. In a step-by-step manner, the study RA will lead participants through the RIPPLE program by entering sample (dummy) data into the program; the

participant will then be presented with open-ended questions to explore a range of issues, such as program-related preferences, perceptions, and experiences. This data will be used to inform edits and refinements to the RIPPLE program. As a token of appreciation, we will offer you a $25 gift card (*e.g.*, Starbucks).

Possible Benefits

By viewing and suggesting refinements and edits to the RIPPLE program, participants may acquire insight into family issues related to the prevention and management of childhood obesity.

Possible Risks

There are no unusual risks involved with participating in this study.

Voluntary Participation & Freedom to Withdraw

Your participation in this study is completely voluntary. You are under no obligation to participate. You can also decide to stop participating at any time.

Confidentiality and Anonymity

Your study information will be kept confidential. Personal names will not be used in any public research presentations or publications. Only research team members will have access to and perform analyses of study data. All original data collected for this study will be held a minimum of 5 years after study completion.

Additional Contacts

If you have questions about this study, please contact Dr. Geoff Ball (Principal Investigator). If you have questions about your rights as a research participant, please contact the Human Research Ethics Office (780-492-2615). The Human Research Ethics Board has reviewed and approved this study.

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UNIVERSITY OF ALBERTA

PARTICIPANT CONSENT FORM

Title of Project:	**Working with Parents to Prevent and Manage Obesity in Children**
Principal Investigator:	**Dr. Geoff Ball** 780-342-8465 (p); gdball@ualberta.ca (e)

	Yes	No
Do you understand that you have been asked participate in a research study?	☐	☐
Have you read and received a copy of the study Information Sheet?	☐	☐
Do you understand the benefits and risks involved with participating in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time without having to give a reason?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to personal information you share with us during this study?	☐	☐

Who explained this study to you? _____

I agree to take part in this study. YES ☐ NO ☐

_____
Printed Name

_____ _____
Signature Date (dd/mm/yyyy)

I believe that the person signing this form understands this study and voluntarily agrees to participate.

_____ _____
Signature (Principal Investigator) Date (dd/mm/yyyy)

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Appendix J. Information sheets and consent and assent forms

UNIVERSITY OF ALBERTA

PARENT INFORMATION SHEET

Title of Project: Working with Parents to Prevent and Manage Obesity in Children

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Project Coordinator:
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Background

A growing number of Canadian boys and girls have an unhealthy weight. About 25% of children are either overweight or obese, so there is an urgent need to address this health issue. Parents play a key role in helping their children to be as healthy as possible. For example, parents can help to *prevent* unhealthy weight gain in children who currently have a healthy body weight. This can include ensuring that children eat healthy foods and are physically active every day. In addition, parents can help to *manage* obesity in children who currently have an unhealthy weight. This can include meeting with health care professionals to understand children's health risks and to get information about how to improve their children's health. Along these lines, this study was designed to help parents prevent and manage childhood obesity.

We recently developed a short, online program for parents called **RIPPLE** (**R**esource **I**nformation **P**rogram for **P**arents on **L**ifestyle and **E**ducation). RIPPLE is completed by parents using an iPad. The goal of this research is to test the program with a group of parents and to see whether the program helps parents to prevent and manage obesity in their children.

Study Purpose

To test if the RIPPLE program increases parents' motivation to prevent and manage obesity in their children. RIPPLE is designed to encourage parents to use resources that encourage healthy nutrition and physical activity. RIPPLE also helps to connect families with health services that can help to prevent and manage childhood obesity.

Procedures

While you are waiting for your doctor's appointment at the Allin Clinic, a research assistant will invite you to participate in the study. If you agree, the study activities will take ~15 minutes. First, a clinic nurse will measure your child's height and weight. After the research assistant enters your child's height and weight information into the iPad, you will use the iPad to complete the RIPPLE program. The program will include brief questions about your child's nutrition or physical activity habits. After you respond to all of the questions, the program will offer you some education resources related to preventing and managing obesity in children. About one month after you complete the program at the Allin Clinic, we will contact you (either by phone or email, whichever

you prefer) to ask you a few questions about the education resources. As a token of appreciation, we will offer you a $25 gift card after you complete the RIPPLE program.

Possible Benefits

RIPPLE may help parents to become aware of their children's nutrition and physical activity habits. The program may also identify concerns parents have about their children's health and well-being, especially in relation to unhealthy weight. RIPPLE may increase parents' awareness of their children's weight status. Finally, the program may help parents to learn about and access information and resources to improve their children's health.

Possible Risks

There are no unusual risks involved with participating in this study. However, it is possible that some issues could arise when discussing children's unhealthy weights. Talking about obesity and health can be emotional for some people. If this study leads you or your child to feel distressed, the research assistant and the administrative staff at the Allin Clinic will help you to find a health care professional for you and/or your child to speak with.

Voluntary Participation & Freedom to Withdraw

Your participation in this study is completely voluntary. You are under no obligation to participate. You can also decide to stop participating at any time. Whether you choose to participate in this study or not, your decision will not change the health care your family receives at the Allin Clinic, either now or in the future.

Confidentiality and Anonymity

Your study information will be kept confidential. Personal names will not be used in any public research presentations or publications. Only research team members will have access to and perform analyses of study data. Your responses to the RIPPLE questions will be stored on a secure, password-protected computer server. The RIPPLE program will automatically assign you a study identification number, so you will not have to enter personal identifying information into the program. All original data collected for this study will be held a minimum of 5 years after study completion.

Additional Contacts

If you have questions about this study, please contact Dr. Geoff Ball (Principal Investigator). If you have questions about your rights as a research participant, please contact the Human Research Ethics Office (780-492-2615). The Human Research Ethics Board has reviewed and approved this study.

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PARENT CONSENT FORM

Title of Project: **Working with Parents to Prevent and Manage Obesity in Children**

Principal Investigator: **Dr. Geoff Ball** 780-342-8465 (p); gdball@ualberta.ca (e)

	Yes	No
Do you understand that you have been asked participate in a research study?	☐	☐
Have you read and received a copy of the study Information Sheet?	☐	☐
Do you understand the benefits and risks involved with participating in this research study?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Do you understand that you are free to withdraw from the study at any time, without having to give a reason and without affecting your future medical care?	☐	☐
Has the issue of confidentiality been explained to you?	☐	☐
Do you understand who will have access to personal information you share with us during this study?	☐	☐

Who explained this study to you? _____

I agree to take part in this study. YES ☐ NO ☐

_____
Printed Name (Parent or Legal Guardian)

_____ _____
Signature (Parent or Legal Guardian) Date (dd/mm/yyyy)

I believe that the person signing this form understands this study and voluntarily agrees to participate.

_____ _____
Signature (Principal Investigator) Date (dd/mm/yyyy)

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UNIVERSITY OF ALBERTA

CHILD INFORMATION SHEET + ASSENT FORM

Title of Project: Working with Parents to Prevent and Manage Obesity in Children

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Email: avis@ualberta.ca

Why are we doing this study?
We are doing a research study to test a new program. The program is called RIPPLE. It is for parents, and is done online using an iPad. The RIPPLE program asks your parents questions about you, including how much you eat and how much you exercise. We are trying to understand if RIPPLE will be good for parents. RIPPLE is designed to help them to help you be as healthy as possible.

Why am I being asked to be in this study?
We are asking you to be in this study because you are attending a doctor appointment at the Allin Clinic. We are inviting all boys and girls attending the Allin Clinic for an appointment with their parents.

What do I have to do?
If you decide to be in this study, we will collect some information from you, including your height, weight, and date of birth. You do not have to do anything else for this study. Your parents will do the most of the work! They will answer some questions on the iPad. These questions are part of the RIPPLE program.

Will it help?
This study will help your parents to learn some things to help you be as healthy as possible.

Do I have to be in this study?
You do not have to be in this study. It is completely voluntary. If you decide that you want to stop participating in this study after we start, that's OK, too. Nobody will be upset or angry.

Do I get anything for being in this study?
To say thank-you for being in this study, we will give you and your Mom or Dad a $25 gift card.

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What happens after this study?
Once the study ends, we will write a report about what we learned. This report will not include your name or that you were in the study. No details about individual children, parents, or families will be included. All information will be anonymous. The report will help us to share what we learned with other researchers, health care professionals, and families to be as healthy as possible.

Your signature
You need to sign this form to show that you agree to do this study. Your mom or dad will sign a separate form to do this study, too.

Questions
If you have any questions about this study, you can ask your Mom or Dad. You can also talk to the research assistant or Dr. Geoff Ball if you have questions. Dr. Ball's phone number is 780-342-8465; his email is gdball@ualberta.ca

I agree to be in this study. **YES ☐** **NO ☐**

Signature (Child)	Date (dd/mm/yyyy)
Signature (Parent or Legal Guardian)	Date (dd/mm/yyyy)
Signature (Principal Investigator)	Date (dd/mm/yyyy)

Appendix K. Interview guide

Thank you for sharing your time with me today. I want to remind you that this interview will last approximately 60 minutes.

The purpose of this interview is to explore the context of your tool use, and your views on the likability and usability of tools to prevent childhood obesity in primary care. For the purpose of this interview, when I say 'tool' I mean any clinically-based device, handout, or program that can be used to prevent obesity in children; for example, a body mass index growth chart.

Although I will ask you a number of questions today, there are no correct or incorrect answers. The information you share with me during this interview will be audio-recorded and transcribed for data analysis purposes; all information will remain anonymous and confidential.

[Display selected tools in front of participant throughout interview, as indicated by the pre-interview survey]

Main Questions	Probes
I. Introduction	
1a. What does obesity prevention mean to you as a health care provider?	<u>Probe for specific details (1a/b):</u> • Health focus *vs.* weight focus • What is the goal? • Would you classify it as prevention (*vs.* management)?
1b. What type of tasks does this include?	• Talk about weight • Counsel on lifestyle changes • Track progress
2a. Given your clinical experience and the tools you reported using with families, what is a tool, and what aspects does it possess? 2b. **<u>How</u>** do tools fit into your practice or what purpose do they serve for obesity prevention with children and families? 2c. **<u>Why</u>** do you use tools?	<u>Probe for specific details:</u> • Context • Characteristics of patients • Same tools for all children and families? • Is use of tools contingent on one another? • Tools for you as a professional *vs.* tools for families?

3a. What are your overall thoughts on tools that providers use for obesity prevention? 3b. Is there anything lacking?	Probe for specific details: • Content (*e.g.,* mental health) • Effective with patients? • Official *vs.* your own?
II. Context	
4. What are your thoughts on the **current availability** of tools?	Probe for specific details: • Selection of tools
5. How do you come to **learn** about a tool?	Probe for specific details: • AHS *vs.* personal searching • Top-down *vs.* bottom-up approach?
6. What do you think influences **uptake/implementation** of a tool?	Query *Diffusion of Innovations* Concepts: • Relative advantage (better than without?) • Compatibility (fit the audience/need)? • Complexity (easy to use?) • Triability (can it be tried before adopted?) • Observability (results of innovation visible and easily measurable?)
III. Likability & Usability of Tools	
7a. In general, what are characteristics that you **like** or **dislike** about tools? 7b. Of the three tools you selected, what do you **like** and **dislike** about them?	Probe for specific details (7a/7b): • Aesthetics (Graphics, Layout, Quality, • Content (Relevant to families, Age appropriate, Complexity, Literacy Demand, Motivating) • Feasibility (Avenue of delivery, Convenience, Time requirement)
8. What do you think makes a tool **usable** for the purpose of obesity prevention in children?	• Jill: write down definition
9a. In keeping with your thoughts on what makes a tool usable, to what extent are the **tools you selected usable?**	Probe for specific details: • Reference participants' definition of a 'usable' tool

9b. What specific **aspects** of these tools make them usable for **you/families**? [*only ask if not answered yet*]	• Other usability characteristics: - Accessible - Aesthetically pleasing - Brief - Content - Enhances Motivation - Graphics Layout
10a. What are your thoughts on the use of tools for **you** *vs.* the use of tools for **patients**? 10b. Are there tools that are usable for you and not patients, and v.v.? 10c. When you *use* a tool, what is the end goal you wish to achieve?	• For YOU *vs.* for PATIENTS • *E.g.,* usable for you but not usable for families, and vice versa.
IV. Future Directions	
11. As a health care provider, what do you feel are pertinent next steps for tools for obesity prevention in children?	Probe for specific details: • Ability to tailor information • Uni- *vs.* bidirectionality • Online- *vs.* paper-based • Enhance motivation
V. Closing Remarks	
12. Based on our discussion today, how would you rate each of the tools you use to prevent obesity in children? 13. At this point I would like to summarize the key points from our discussion. • Is there anything I missed? • Is there anything we didn't talk about that you think would be good to discuss?	On a scale from 0 to 10 (take into account discussion from today) 10 = most suitable and usable tool [Summarize key points from discussion]

[At this point, the interviewer will conclude the interview, stop recording, and thank the participant for their participation].

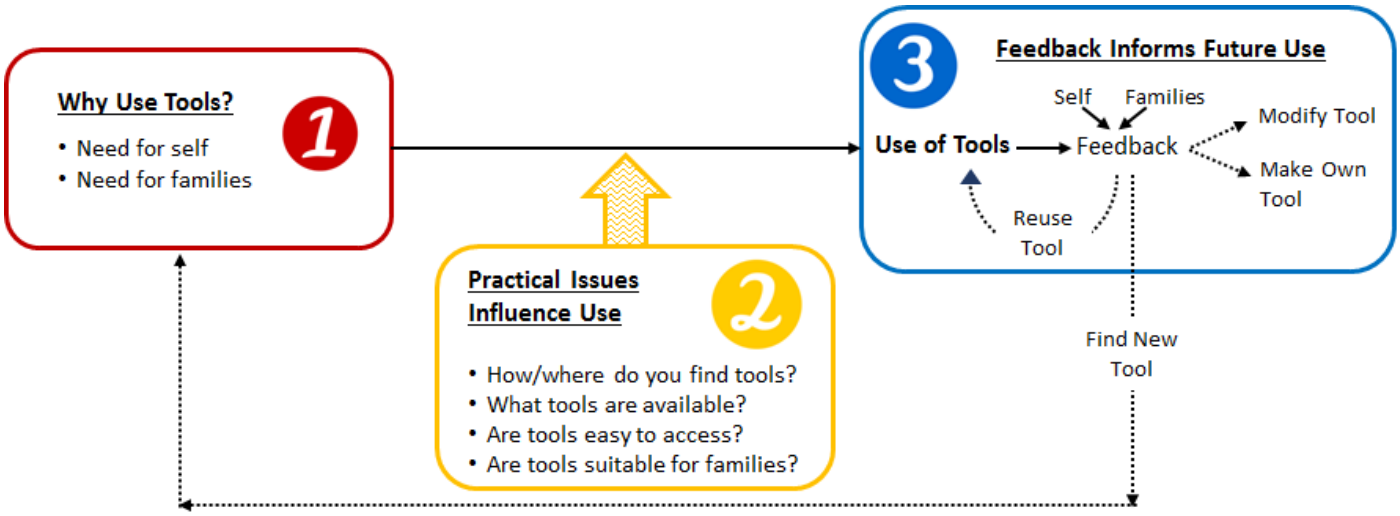
Appendix L. Participant follow-up guide

Part I: Qualitative Data Analysis

A total of 19 health care professionals participated in the interviews. Based on our analysis, the figure below represents how tools were used with families for the purpose of obesity prevention in children.

Your Turn:

- What do you think of the results?
- Do you feel the findings represent your perspective? (Please note: these findings are representative of *all* participants and may not entirely represent your perspective)
- Do you have anything to add?



1. **Why tools are used:**
   - Tools may be used for yourself as well as families
   - For clinicians, tools act as a clinical support; specifically, tools are used to facilitate communication with families and assess children's growth and lifestyle behaviors
   - Tools for families act mainly to educate as well as enhance motivation to change lifestyle behaviors

2. **Practical issues influence use of tools:**
   - Use of tools may be facilitated or impeded by practical factors, including:
     - Location (*e.g.,* being proactive and finding them yourself)
     - Availability (*e.g.,* low availability of mental health and physical activity tools)
     - Accessibility (*e.g.,* online *vs.* hard-copy)
     - Suitability (*e.g.,* appropriate language and terminology)

3. **Feedback informs future use of tools:**
   - After using tools, informal feedback from yourself as well as solicited feedback from families (if they return for a follow-up visit) helps to inform future use

- In the future, one of four options may be made, including: *(i)* reuse the same tool, *(ii)* modify the tool to better suit your clinical needs, *(iii)* make your own tool, or *(iv)* find a new tool.

Part II: Quantitative Data Analysis

In the qualitative interviews, health care professionals reported using a total of 15 tools[1] (the tools **you** reported using are highlighted in the table below). Each tool was evaluated using an assessment checklist[2] and compared to study participants' ratings of each tools.

[1]Tools were only included in analysis if used by ≥2 participants.
[2]Based on scores derived from the checklist, individual tools could be categorized (from least positive to most positive): 'not suitable', 'average', 'above average' or 'excellent'.

Your Turn:

- What are your thoughts on clinicians' average ratings of the tools?
- What are your thoughts on how clinicians' ratings compare with scoring on the checklist?
- Does scoring on the checklist influence your opinion of the tools?
- Do you have anything to add?

Focus	Tool	Your Ratings (mean; /10)	Standardized Assessment	
			Checklist Score (mean/10)	Clinical Translation
Weight-focus	AHS Child's Height Ahead of Weight	7.2	6.9	Not Suitable
	AHS Healthy Kids, Healthy Bodies	7.0	7.5	Average
	Body Mass Index Growth Charts	7.0	5.2	Not Suitable[3]
	5As of Pediatric Obesity Management	6.8	5.3	Not Suitable[3]
Diet-focus	Magnetic Plate Model	8.6	8.6	Above Average
	Healthy U Cookbook	7.8	8.6	Above Average
	AHS Snacking Tips	7.8	7.1	Average
	AHS Healthy Food Portions	7.6	8.3	Above Average
	Canada's Food Guide	6.8	7.1	Average
	AHS Healthy Drinks	6.2	7.8	Average
Activity-focus	ParticipACTION Website	7.7	8.0	Above Average
	Canadian Sedentary Guidelines	7.0	7.9	Average
	Canadian Physical Activity Guidelines	6.8	7.6	Average
Multi-focus	Healthy U & Active Living	6.9	7.0	Not Suitable
	Prescription Pad for Healthy Living	6.5	6.7	Not Suitable

[3]Please note: of the 15 tools identified by participants, 2 were used predominantly for clinician-use only. These two tools scored as 'Not Suitable' because they were understandably considered too complex for parents; this primarily highlights that the checklist is *not* the only way to assess tools.

Appendix M. Focus group interview guide

Thank you for sharing your time with me today. I would like to remind you that our discussion will last approximately 90 minutes.

The purpose of this focus group is to share our newly-developed online intervention with you, which is called RIPPLE (the Resource Information Program for Parents on Lifestyle and Education). Because RIPPLE is new, it is important for us to hear your perspective so we can modify it and make it as good as possible to meet the needs of parents in primary care. Please keep in mind that parents will complete the program on a tablet while they wait for their child's pediatrician appointment in a primary care clinic.

Although I'll ask you all a number of questions today, there are no correct or incorrect answers. I am just interested in your feedback so we can make improvements to the program. The information you share with us during the focus group will be transcribed by a court reporter [briefly introduce] *and all information will remain confidential and anonymous. Please note that I am interested in hearing from everyone in today's group, so if necessary I may call on more quiet members to share their thoughts.*

Before we start our discussion, I have a couple of things to note:

1. *I'm going to walk you through the program just as a parent would experience it from start to finish. While I do this I ask you to consider the whole program and even take notes throughout if you like. After the focus group is over, I will invite you to share your thoughts if you did not get a chance to share them during the focus group discussion.*
2. *RIPPLE is a randomized controlled trial. This means parents will be randomly assigned to one of three different intervention groups. One group is called Eat It (dietary q's); one is called Move It (PA q's); one is the control (info only). Because we are only running through the intervention once today, you will only get to see one potential intervention that parents will be assigned to. Therefore, I have printed off the other interventions and the control, which I will draw your attention to when the time comes* [show papers].

[The moderator will use a laptop and projector to go through the intervention step-by-step].

Main Questions	**Probes**
I. Likeability	
1. [Transition question] What is your overall impression of the program?	
2a. What do you **<u>like</u>** about the program? 2b. What do you **<u>dislike</u>** about the program?	<u>Probe for specific factors (2a/2b)</u>: • Aesthetics (colours, graphics) • Content (language, questions) • Format • Theoretical underpinnings

3a. In your opinion, was RIPPLE too long, too short, or just right?	Probe for specific factors (*e.g.*): • Do you have any suggestions for ways to make RIPPLE quicker to complete?
3b. Were there too many questions, not enough questions, or the right amount of questions?	Probe for specific factors (*e.g.*): • Which questions do you recommend we remove or add?
II. Acceptability	
4. Do you think the program will be easy for parents to use?	Probe for specific factors (*e.g.*): • Navigation
5. Do you think parents will be able to understand the program? Were there any parts of the program that you felt were difficult to understand?	Probe for specific factors (*e.g.*): • Comprehensibility of questions • Information • Medical terminology • Reading level
6. What are your thoughts about the personalized feedback that parents receive about their child's weight status (*Weight a Second!*) prior to answering the intervention questions?	Probe for specific factors (*e.g.*): • Feedback helpful to parents? • How will parents react; positive *vs.* negative?
7a. At the end of RIPPLE, parents are given the option to select information about resources regarding children's healthy lifestyle behaviors. Do you think this information will be helpful to parents?	Probe for specific factors (*e.g.*): • Online handouts • Services
7b. Are there other online handouts/services you suggest adding?	Probe for specific factors (*e.g.*): • List of resources (handouts and services) – adequate or more to add?
III. Satisfaction	
8. Overall, how satisfied were you with the program?	Probe for specific factors (*e.g.*): • Qualitative or quantitative indicators

IV. Feasibility (context)	
9. How do you think this online, parent-based tool will fit into current primary care practice?	Probe for specific factors (*e.g.*): • Will this tool conflict with current physician practices? • Is it appropriate to provide such information and resources to families through the use of technology?
V. Academic Inquiries	
10. Many health care providers in primary care report a variety of barriers to preventing and managing childhood obesity (*e.g.,* lack of time, patient resources, professional training, family motivation). Will RIPPLE impact these barriers reported by **providers**? If so, how?	Probe for specific factors (*e.g.*): • Efficiency in screening • Facilitate discussion with families on obesity prevention • Overcome lack of resources
11. Families experience a number of challenges to preventing and managing childhood obesity (*e.g.,* lack of motivation to make changes, inadequate time to plan). Will RIPPLE impact these barriers reported by **families?** If so, how?	Probe for specific factors (*e.g.*): • Enhance parent awareness about children's weight • Motivate parents to sustain healthy lifestyle behaviors
12. This program is designed for parents of 5 – 17 year old children. If this program shows promise in this age group, what are your thoughts about using this program with parents of younger children? What, if any, modifications should be made?	Probe for specific factors (*e.g.*): • Parents of children less than 5 be more or less receptive to this program than parents of children 5 years and older? • What are some +/- of this program for families with young children? • Would this modified program support or conflict current physician practices for families with young kids? • Should the modified program focus on pre-school children (aged 3-4 years) or infants and toddlers as well?

VI. Summary	
13. [Interviewer to summarize key points]. Is there anything I missed? 14. Is there anything we didn't talk about that you think we should know as we modify the program for use with parents?	

[At this point, the moderator will conclude the focus group, and thank participants for their feedback and participation].

Appendix N. Consolidated criteria for reporting qualitative studies: a checklist

No.	Item	Question	Description
Domain 1: Research Team and Reflexivity			
Personal Characteristics			
1.	Interviewer/facilitator	Which author conducted the focus group?	First author (JA) and last author (GB)
2.	Credentials	What were the researchers' credentials?	JA: BA, PhD Candidate GB: PhD, RD
3.	Occupation	What was their occupation at the time of the study?	JA: Graduate student GB: Associate Professor
4.	Gender	Was the researcher male or female?	JA: Female GB: Male
5.	Experience and training	What experience or training did the researcher have?	JA: Formal training in qualitative methods, participated in previous qualitative studies, attended qualitative workshops. GB: Principal investigator on several qualitative projects.
Relationship with Participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Relationships were present with >75% of participants.
7.	Participant knowledge of the interviewer	What did the participants know about the researcher?	Personal interest in the research and reasons for doing it were described prior to the focus groups verbally and in writing.
8.	Interviewer characteristics	What characteristics were reported about the facilitator?	None

Domain 2: Study Design			
Theoretical Framework			
9.	Methodological orientation	What methodological orientation was stated to underpin the study?	Thematic analysis
Participant Selection			
10.	Sampling	How were participants selected?	Purposive sampling
11.	Method of approach	How were participants approached?	Face-to-face and email
12.	Sample size	How many participants were in the study?	38
13.	Non-participation	How many people refused to participant or dropped out? Reasons?	Six participants declined the invitation to participate. Reasons were not explored. None of the participants dropped out.
Setting			
14.	Setting of data collection	Where was the data collected?	Clinic and university setting.
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	One court reporter.
16.	Description of sample	What are the important characteristics of the sample?	Parents of children aged 5 – 17 years, or pediatric-focused health care professionals, researchers, trainees, and health care system administrators.
Data Collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Yes. The guide was reviewed by our research team and revised accordingly. During data collection, minor

			modifications were made accordingly.
18.	Repeat interviews	Were repeat interviews carried out?	No
19.	Audio/visual recording	Did the researcher use audio or visual recording to collect the data?	No, a court reporter was used. See the methods section for description.
20.	Field notes	Were field notes made during and/or after the focus group?	Some notes during the focus group.
21.	Duration	What was the duration of the focus groups?	All focus groups were ~90 minutes.
22.	Data saturation	Was data saturation discussed?	Yes
23.	Transcripts returned	Were transcripts returned to participants for comment or correction?	No
Domain 3: Analysis and Findings			
Data Analysis			
24.	Number of data coders	How many coders coded the data?	One (JA). Fellow trainees and research members participated in several individual and group discussions about emerging themes.
25.	Description of the coding tree	Did authors provide a description of the coding tree?	No
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Derived from the data.
27.	Software	What software, if applicable, was used to manage the data?	*NVivo 10*

28.	Participant checking	Did participants provide feedback on the findings?	No
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified?	Yes (Table 4.1). Quotations were identified by participant group (*e.g.,* parent, health care professional).
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Yes
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Yes
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes, these are marked as *negative cases* in Table 4.1.

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