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Family-based habit intervention to promote parent support for child physical activity; protocol for a randomized trial

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Running Head: PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 1

Family-based habit intervention to promote parent support for child physical activity;
protocol for a randomized trial

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Author Contributions

RER, MRB, CMB, VC, BG, and DERW all had input on conceptual model used and design of the study. ERM lead the writing of the protocol, and all authors approved the final manuscript. RER is responsible for project oversight.

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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 2

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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 3

Abstract

Introduction: Regular physical activity (PA) participation has many important physical and psychological health benefits, managing and preventing over 25 chronic conditions. Being more physically active as a child is associated with being more active as an adult, but less than 10% of Canadian children are achieving the recommended PA guidelines of 60 minutes per day of moderate to vigorous PA. Parental support is a predictor of child PA but parent intention to support child PA does not always predict enacted support. Targeting factors that assist in the sustainability of parent support behaviour of child PA may have an impact on child PA. The purpose of this study is to evaluate an intervention designed to promote habit formation of parental support (HABIT, independent variable) on child PA (dependant variable) compared to a planning and education group (PLANNING) and an education only group (EDUCATION).

Methods and analysis: The three conditions will be compared using a six-month longitudinal randomized trial. Eligible families have at least one child aged 6-12 years who is not meeting the 2011 Canadian PA Guidelines. Intervention materials are delivered to parents at baseline, with check-in sessions at 6 weeks and 3 months. Child moderate-to-vigorous PA, measured by accelerometry, is assessed at baseline, 6 weeks, 3 months, and 6 months as the primary outcome. At baseline and 6 months children perform fitness testing. So far, 123 families have been recruited from the Greater Victoria and surrounding area. Recruitment will be continuing through 2020 with a target of 240 families. **Ethics and Dissemination:** This protocol has been approved by the University of Victoria Human Research Ethics Board (Victoria, Canada). Results will be shared at conferences as presentations and as published manuscripts. Study findings will be made available to interested participants. **Registration details:** This trial is registered at clinicaltrials.gov # NCT03145688.

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 4

Article Summary**Strengths and Limitations of this study**

- This randomized trial will build on family-based PA research evaluating whether building parent support habit for child PA is an effective strategy to promote child PA
- The findings of this study can inform health policy and programs designed to improve health outcomes in children through increasing PA
- It is possible that results may be affected by participants in unconsciously adopting techniques from different conditions (e.g. the EDUCATION participant employs planning technique, PLANNING participant employs habit forming techniques)
- Inclusion of quantitative and qualitative manipulation checks will be useful for assessing intervention fidelity

Introduction

Physical activity (PA) has the potential to reduce the risk of at least 25 chronic medical conditions by 20-30% (Rhodes, Janssen, Bredin, Warburton, & Bauman, 2017), yet Canadian adults and children are not meeting recommended guidelines to optimize these benefits (Colley et al., 2012; Colley et al., 2011). Children are recommended to achieve 60 minutes per day of moderate to vigorous physical activity (MVPA) (Tremblay, Carson, & Chaput, 2016). For adults, 150 minutes of moderate to vigorous aerobic PA per week is recommended (Tremblay, Warburton, Janssen, Paterson, Latimer, Rhodes, Kho, Hicks, LeBlanc, et al., 2011). While many complications and diseases present in adulthood, there is compelling evidence showing the positive impact of increased PA among children on health, such as helping to guard against high blood pressure, high cholesterol, metabolic syndrome, low bone density, depression and obesity,

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 5

1
2
3 as well evidence demonstrating a relationship between increased MVPA and reduced
4
5 psychological distress, improved peer relations, and improved quality of life/well-being (Ahn,
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7 Sera, Cummins, & Flouri, 2018; Janssen & LeBlanc, 2010; Poitras et al., 2016). Unfortunately,
8
9 according to the Canadian Health Measures Survey, only 9% of boys and 4% of girls are
10
11 achieving the recommended amount of PA (Colley et al., 2017, 2011) Understanding the factors
12
13 that influence child PA is therefore important for promoting long-term population health.
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17
18 Parental influence is one such factor; a review of family based interventions to increase
19
20 physical activity found that parent support was a consistent determinant of child PA (Brown et
21
22 al., 2016). Parent support refers to the ways in which parents knowingly influence their child's
23
24 PA and includes both tangible (e.g. transportation) and intangible (e.g. encouragement)
25
26 behaviours (Beets, Cardinal, & Alderman, 2010). Interventions focused on parent support to
27
28 change child PA have been generally unsuccessful however, as reported in several reviews
29
30 (Kitzman-Ulrich et al., 2010; O'Connor et al., 2009; Salmon, Booth, Phongsavan, Murphy, &
31
32 Timperio, 2007; Sluijs, Kriemler, & Mcminn, 2011). More recent intervention research has
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34 shown some positive effects (O'Dwyer, Fairclough, Knowles, & Stratton, 2012; Morgan et al.,
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36 2011; Rhodes, Naylor, & McKay, 2010), but these are still balanced by several null results
37
38 (Backlund, Sundelin, & Larsson, 2011; Morrison et al., 2013; Olvera et al., 2008). A recent study
39
40 found that while most parents have positive intentions to support child health behaviours, few
41
42 substantively enact this support (Rhodes et al., 2018). Furthermore, this intention-behaviour gap
43
44 does not appear to be successfully bridged by current interventions targeting parents. For
45
46 example, a review by Brown (2016) found that the majority of interventions focus on educating
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48 parents on the benefits of PA, which does not appear to drive subsequent PA change (among
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50 parents and their children). This is likely because parents are already aware of the health benefits
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 6

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3 of PA for their children (Rhodes, Faulkner, et al., 2015; Rhodes et al., 2013; Rhodes, Spence, et
4 al., 2015) in addition to already having the intention to support behaviour (Rhodes et al., 2018).
5
6
7 Therefore, focusing on what parenting support can be harnessed (i.e., malleable through
8
9 intervention) to promote child PA represents an important avenue of enquiry.
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13 Several recent theoretical approaches have advanced beyond merely building intention to
14 perform behavior and suggest that building self-regulatory tactics such as planning is critical to
15 bridge the intention-behavior gap (Hagger & Chatzisarantis, 2014; Schwarzer, 2008; Sheeran &
16 Webb, 2016). This approach has been utilized in family interventions (Brown et al., 2016), yet it
17 may not be sufficient to sustain behavior changes over longer durations. For example, the Family
18 Physical Activity Planning study (Rhodes, Naylor, Blanchard, Quinlan, & Warburton, in press)
19 compared an intervention group focused on family physical activity planning (goal setting,
20 action planning, coping planning) to an education only group and found increased child PA at 3
21 months in the family planning group. This effect was not observed at 6 months however,
22 demonstrating a need to target behavioural strategies beyond mere planning for successful
23 maintenance of PA.
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39 The Multi-Process Action Control (M-PAC) Framework (Rhodes, 2017; Rhodes & De
40 Bruijn, 2013) may assist in sustaining health behaviors such as parental support of child physical
41 activity. This framework suggests that self-regulatory skills and tactics assist in translating
42 intentions into behavior during the initial adoption of PA, but sustainability is also determined by
43 the development of habit across time to ease the burden of continual volitional motivation and
44 self-regulation. Habits represent impulses to perform behaviour initiated via stimulus-response
45 bonds (Gardner, 2015) and contribute to physical activity largely via repeated consistency in
46 behavioural practices, salient cues associated with behavioural initiation, and affectively
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 7

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3 rewarding behaviour (Kaushal & Rhodes, 2015; Lally & Gardner, 2013; Rhodes & Rebar, 2018).
4
5 Consistent with M-PAC theory, habit formation has seen promising results in physical activity
6
7 research (Gardner, 2011, 2015; Kaushal, Rhodes, Meldrum, & Spence, 2017); habits may sustain
8
9 PA behaviour over time partially independent of goals (or intentions) (Deutsch & Strack, 2006;
10
11 Gardner, 2011) and through helping turn intentions into actual behaviour (Rhodes & De Bruijn,
12
13 2013). Of particular relevance to the current trial, a recent study evaluating parent support of
14
15 child physical activity with M-PAC found parent habit to be the largest independent correlate
16
17 with the translation of intention into behaviour compared to planning and motivational constructs
18
19 (Rhodes, Berry, et al., 2019).
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23

24 **Study Objectives and Hypotheses**

25
26
27 The primary objective of this study is to implement a theory-based intervention targeting
28
29 parental support of child MVPA comparing the effect of a PA habit formation + PA planning +
30
31 PA education (HABIT) condition to a PA planning + PA education (PLANNING) condition and
32
33 a PA education only group (EDUCATION) on child MVPA (dependant variable). The primary
34
35 end-point of this trial is six months, with additional secondary time points of 6 weeks and 3
36
37 months. Based on previous research (Brown, Hume, Pearson, & Salmon, 2013; Rhodes, Berry, et
38
39 al., 2019) it is hypothesized that children of families in the HABIT condition will demonstrate a
40
41 greater increase MVPA measured by accelerometry at 6 months compared to those in the
42
43 PLANNING group and the EDUCATION group. As per the results of Rhodes et al.'s family
44
45 physical activity planning intervention (Rhodes, Naylor, et al., 2019) we expect children of
46
47 families in the PLANNING group will demonstrate a greater increase in MVPA compared to the
48
49 EDUCATION group however this effect may diminish over time.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 8

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3 Secondary objectives include evaluating child fitness at baseline and 6 months. It is
4
5 hypothesized that child fitness will be greater for the HABIT condition compared to the
6
7 PLANNING and EDUCATION conditions at six months because of the resulting increased PA
8
9 hypothesized above. Tertiary objectives include evaluating parent physical activity and quality of
10
11 life. While parent and child co-participation in physical activity is not mandatory, parent support
12
13 of child physical activity may include co-participation (such as a family walk) and therefore it is
14
15 expected that parents in the HABIT condition will report higher physical activity via some
16
17 activities being performed with their children in comparison to the other conditions. Finally, no
18
19 differences in gender or season are hypothesized.
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22

Trial Design

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27 This study is a three-arm parallel design single blinded randomized trial. After baseline
28
29 assessment (MVPA, fitness testing, questionnaire), families are randomized to one of three
30
31 groups: 1) family physical activity habit formation + planning + education (HABIT); 2) family
32
33 physical activity planning + information/education (PLANNING); 3) standard physical activity
34
35 education (EDUCATION). The trial is testing the superiority of the HABIT condition.
36
37 Randomisation is performed by the Project Coordinator using Excel Sheet Randomization with
38
39 an allocation ratio of 1:1:1. Participants are blind to their condition until their participation in the
40
41 study is complete, at which point they are informed of their group by the Project Coordinator
42
43 and/or Research Assistant. Under no circumstance will participants be informed of their
44
45 condition while they are still enrolled in the study. Fitness testers are blind to each family's
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47 condition but the intervention delivery team is aware of the condition to allow for correct
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49 delivery of intervention materials.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 9

Methods

The study has been approved by the University of Victoria Human Research Ethics Board (HREB). The design, conduct, and reporting of the trial has and continues to follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (Chan et al., 2013). The trial is registered with the Clinical Trials Registry at the National Library of Medicine at the National Institutes of Health (ClinicalTrials.gov) Trial ID NCT03145688. See Table 1 for World Health Organization Trial Registration Data Set items.

In the case of protocol modifications or amendments, the Project Coordinator submits the appropriate documentation to the HREB at the University of Victoria. Once approved, the Project Coordinator then updates the trial information on the Clinical Trials Registry.

Patient and public involvement

No funds or time were allocated for patient and public involvement in this study. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients will not be invited to contribute to the writing or editing of this document for readability or accuracy. Participants are given the opportunity to share their experience in the wrap up interview providing information that will help inform future research.

Participants

Single or common law/married adult(s), with at least one child between the ages of six and twelve years, living in greater Victoria, (including the Capital Regional District, Westshore Communities, and Sooke) British Columbia, Canada are being recruited for this study. If more than one child is eligible in this range, one child is randomly (computer randomizer) designated

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 10

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2
3 as the target for analysis yet all willing children are included in the study. Families are included
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5 if the child participant is achieving less than the recommended 2011 Canadian physical activity
6
7 guidelines of 60 min of activity daily (Tremblay, Warburton, Janssen, Paterson, Latimer,
8
9 Rhodes, Kho, Hicks, Leblanc, et al., 2011).
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12
13 The age group of 6-12 was selected from our earlier pilot work (Rhodes et al., 2010) .
14
15 Specifically, children under six years of age engage in physical activity that is quite sporadic,
16
17 and thus very different than children six years and older (Temple, Naylor, Rhodes, & Wharf -
18
19 Higgins, 2009). Our decision to limit the age of children to 12 was more practical; 12-year-old
20
21 children represent the upper bound of the “tweens”, where parents are still very influential in
22
23 physical activity decisions and physical activity interventions at the level of the parent would be
24
25 still effective (O’Connor et al., 2009; Rhodes & Gustafson, 2016).
26
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29

30 **Recruitment**

31
32
33 Recruitment is being conducted by the Behavioural Medicine Lab at the University of
34
35 Victoria in British-Columbia, Canada. Parents with one or more children aged 6-12 are the
36
37 primary target for recruitment. Participants are being recruited primarily through the social
38
39 media platforms Facebook and Instagram. Facebook and Instagram posts are made bi-monthly
40
41 by the Behavioural Medicine Lab Recruitment Officer on the Behavioural Medicine Lab
42
43 Facebook page (<https://www.facebook.com/UVicBMED/>) and Instagram account (@uvicbmed)
44
45 which are linked, meaning a post made on Facebook is simultaneously shared on Instagram and
46
47 vice versa. Posts are limited to 100 words or less and briefly describe the intent of the study and
48
49 those eligible to partake, asking those interested to contact the Behavioural Medicine Lab
50
51 through email or phone information provided in the post. Facebook posts are also shared to
52
53 relevant Facebook groups (e.g. neighbourhood groups, young parent groups). Facebook posts are
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 11

1
2
3 “boosted” by paying a small fee to have the post appear as an ad in a target demographic’s news
4
5 feed. This increases the reach of the Facebook post with the goal of increasing recruitment. The
6
7 target demographic is specified by selecting variables of age, location of residence, and other
8
9 filters such as “parents”, and the ads typically run for 7 days. The Recruitment Officer also sets
10
11 up a recruitment booth twice per month at local markets and festival events during the summer,
12
13 and at community and recreation centers in the winter to engage with potential participants,
14
15 answer questions, and collect contact information for interested families. Posters are put up
16
17 every 3 – 4 months by a Research Assistant and/or Recruitment Officer in all major recreation
18
19 centers in the area, as well as shopping centers, health care centers, and schools. Word of mouth
20
21 is also used as a recruitment strategy.
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25

Enrolment

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30 When interested parents contact the lab, the Recruitment Officer(s) follows up with an
31
32 email to schedule a phone conversation. If initial contact is a message through Instagram or
33
34 Facebook, the Recruitment Officer replies asking the person to call/email or provide their contact
35
36 information to be contacted by phone or email. An initial recruitment phone interview is set up
37
38 with the Recruitment Officer. Participant families are screened by parent-report of average child
39
40 physical activity per day as well as the ParQ+ Health Screening Questionnaire (Warburton,
41
42 Jamnik, Bredin, & Gledhill, 2011). If screened in then the Recruitment Officer books the
43
44 baseline fitness test and advises the Project Coordinator who follows up with the family and
45
46 schedules a Fitness Tester for the baseline session. During the baseline session, the Fitness Tester
47
48 obtains written consent from parents and verbal consent from children (See appendix 1).
49
50
51 Participants are asked not to participate in any other research studies while enrolled in this one.
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55 After the baseline session, children wear an accelerometer for 7 days. The intervention delivery
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 12

1
2
3 session is scheduled after the week of accelerometer wear; once scheduled, the Research
4
5 Coordinator randomly assigns the family to one of the three conditions and prepares the
6
7 appropriate materials for the Research Assistant to take with them to the participants' home.
8
9

10 Participants receive an honorarium at baseline (\$25), 6 weeks (\$30), and 3 months (\$35),
11
12 and 6 months (\$40) for a total of \$130. Families only receive honorariums if they complete all
13
14 the measures for the check in (accelerometers, logbooks, questionnaires).
15
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17

Intervention

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21 The intervention is conducted in-person with a research assistant and the family at the
22
23 family home, and includes take away material for the families to use later on. Participants in all
24
25 three groups receive a specific physical activity workbook that serves as the template for a
26
27 dialogue with the research assistant during the intervention delivery. The workbook is designed
28
29 for families with information directed at the parent to review with the child, sections for parents
30
31 and children to complete together, and some sections for the parent to complete on their own.
32
33 The material incorporates established behaviour change techniques to promote child physical
34
35 activity. The full list of behaviour change techniques employed in each condition are
36
37 summarized in Table 2 as per Michie et al. Behaviour Change Taxonomy (BCT) (2013).
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43 The three intervention conditions follow and advance the prior work conducted in our
44
45 successful habit formation pilot trial (Kaushal & Rhodes, 2015) and feasibility study, but now
46
47 tested in comparison to our work on family physical activity planning (Quinlan, Rhodes,
48
49 Blanchard, Naylor, & Warburton, 2015; Rhodes, Naylor, et al., 2019; Rhodes et al., 2010). The
50
51 condition of key interest (HABIT) is focused on the behavior change technique of habit
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53 formation with the goal of impacting initiation of parental physical activity support and not the
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 13

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2
3 actual execution of child physical activity or execution of support behaviour, which may be quite
4
5 mindful (Verplanken & Melkevik, 2008). Contemporary research has shown that habits in the
6
7 physical activity domain can be discerned into habitual instigation – whereby, in this instance, a
8
9 parent non-consciously ‘decides’ to provide physical activity support – and habitual execution,
10
11 whereby a parent non-consciously performs the actions involved in providing physical activity
12
13 support (Gardner, Rebar, & Lally, 2019; Phillips & Gardner, 2016). The HABIT condition is
14
15 focused on encouraging the formation of instigation habits, such that parents are automatically
16
17 ‘reminded’ to select physical activity support (from available alternatives). We are not
18
19 attempting to promote non-conscious engagement in child physical activity support (i.e.
20
21 execution habit).
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26
27 Six week and three-month check-ins, or “booster” sessions, are scheduled by the Project
28
29 Coordinator with families in all conditions. This involves a house visit by a Research Assistant to
30
31 discuss the families’ experience so far. During the session the Research Assistant reviews the
32
33 relevant intervention condition with the family and supports family problem solving (BCT
34
35 construct 1.2) as needed to promote adherence to the intervention. For example, if a family
36
37 expresses difficulty with planning PA, the Research Assistant will go through the intervention
38
39 materials again to help the family identify what techniques they can focus on (such as rewards or
40
41 tracking) and help to brainstorm.
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44

Education condition (EDUCATION).

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48
49 The standard EDUCATION package consists of the Canadian 24 hour Movement
50
51 Guidelines for children recommending at least 60 minutes of MVPA per day and vigorous
52
53 intensity activities at least three times per week (Tremblay et al., 2016) (BCT construct 5.1). The
54
55 guide also contains information about the benefits of physical activity for children (BCT
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 14

1
2
3 construct 5.2, 5.3, 5.6), explanations of what moderate and vigorous intensity activities are, and
4 ideas for physical activities including structured (e.g. play a sport) and unstructured (e.g. go to
5 the playground) examples (BCT construct 4.1). The Research Assistant reviews this information
6
7
8
9
10 with families.

Planning + education group (PLANNING).

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15
16 Participants in the physical activity planning intervention condition receive the same
17 guidelines and information as the EDUCATION condition but are also provided with family
18 physical activity planning material for parents and children to complete together. Goal setting
19 and self monitoring are explained followed by a skill training component which is a workbook
20 on how to plan for family physical activity. The workbook includes a brainstorming exercise for
21 families where they list physical activities that they have found fun in the past, as well as
22 activities that they would find enjoyable to do as a family. This brainstormed list helps create the
23 template for physical activity planning by contextualizing what the participants would like to do
24 and the subsequent necessary support behaviours for parents (BCT construct 3.2, 3.3, 12.1, 12.2).
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37 The skill training material is based on our previous family-based physical activity
38 interventions which have demonstrated the effectiveness of targeting family based self-
39 regulatory processes such as planning, goal setting, problem solving, and self monitoring for
40 increasing physical activity outcomes in children (Quinlan et al., 2015; Rhodes, Naylor, et al.,
41 2019; Rhodes et al., 2010). The workbook facilitates goal setting and problem solving (1.1, 1.2).
42 Families are instructed to plan for “when,” “where,” “how,” and “what” physical activity will be
43 performed commensurate with the creation of action planning (BCT construct 1.4) and
44 implementation intentions [e.g., (Milne, 2002; Prestwich, Lawton, & Conner, 2003)]. This
45 section is followed by a page on rewards (BCT constructs 10.3, 10.7) with space for children to
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 15

1
2
3 brainstorm activities other than physical activity that they would like to do and which can
4
5 function as a reward for when children engage in their planned physical activity. The final page
6
7 is a journal and tracking sheet for families to log child physical activity (when, what, where, and
8
9 outcomes e.g. how the child felt, what happened right after) (BCT construct 2.3, 2.4). The design
10
11 of all material was created for prior research (Quinlan et al., 2015; Rhodes, Naylor, et al., 2019;
12
13 Rhodes et al., 2010) and features graphic design and colour images that represent family physical
14
15 activity. The Research Assistant reviews the worksheets with families, explains how to complete
16
17 them. The expectation that the workbook is completed is made clear.
18
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21

Habit + planning + education group (HABIT).

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23
24
25 Participants in the habit formation condition receive the same content as the
26
27 EDUCATION condition and PLANNING condition as well as additional material on creating
28
29 parent support habits for child physical activity. While parent support habit includes the child,
30
31 this section of the workbook is directed to the parent. The material is taken from research on
32
33 habit formation (Lally & Gardner, 2013) and our successful pilot study (Kaushal & Rhodes,
34
35 2015), but adapted in our feasibility study to the same colourful style and format as the other
36
37 information provided. The material includes a brief discussion of what habits are with some very
38
39 straightforward non-physical activity related examples such as preparing for sleep routines, or
40
41 selecting the car to commute to work. A key component of the habit section is based on planning
42
43 for context-dependent repetition (BCT constructs 8.1, 8.3), with pointers on how to maintain
44
45 repetition as habit forms. The use of script elicitation to understand/describe existing routines
46
47 and spot points at which physical activity support can be inserted follows. This involves parents
48
49 brainstorming existing routines in their child's life (for example, family brunch on Sundays) and
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51 then identifying what physical activities brainstormed in the planning section with the child that
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 16

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3 might be tagged on to the routine (for example, family walk after brunch every Sunday). This
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5 process has been successful in forming habits in other behavioural domains (Judah, Gardner, &
6
7 Aunger, 2013) as it helps identify reliable and consistent behaviour patterns into which new
8
9 behaviours may be inserted to optimise the likelihood of the context-dependent performance
10
11 required for habit to form. Cues are then introduced as factors to support habit formation (BCT
12
13 construct 7.1). Based on our previously successful trial (Kaushal & Rhodes, 2015), cues are
14
15 described as those factors that prompt a behaviour with a discussion of temporal, social, mood,
16
17 and visual cues to support physical activity (Short et al., 2015). Cues are considered factors that
18
19 a) can reliably precede the support activity but b) rarely be present when the activity is not to be
20
21 performed. Examples of cues are provided such as a soccer gear bag that is put out in the
22
23 morning before the family leaves for school and work, which prompts taking the child to soccer
24
25 when it's seen upon the family's return to the house (visual cue). The soccer gear bag is then
26
27 removed from sight until the next soccer day. Examples of temporal cues are also provided, such
28
29 taking the children on a walk with the family dog after dinner, where dinner occurs once a day
30
31 and can serve to pair well with the family's new plan to walk. We suggest that cues that are
32
33 repeatedly present during times when family physical activity is not performed – e.g., a sign on a
34
35 door that the family walks by all the time – should not be considered, as it reduces the salience of
36
37 the cue and so its potential for activating the desired action at opportune moments. Parents are
38
39 reminded of the importance of having consistent support practices for child physical activity. It is
40
41 made clear that this does not necessarily mean the same activity all the time, but it means
42
43 consistent protected time where support is performed so it links with support instigation habits.
44
45 This could mean child soccer practice every Tuesday night, family physical activity every
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47 Sunday after dinner, or encouraging the kids to play in the back yard each day after school.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 17

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3 Parents are then asked to brainstorm and create a plan of consistency and cues with the
4
5 workbooks provided. Parent support of child physical activity may include co-participation in
6
7 physical activity by the parent (such as the family walk after dinner) or not (such as driving the
8
9 child to sport practice). The final pages of the HABIT materials are titled “Ten tips for turning
10
11 exercise intentions into actions” and summarizes evidence-based physical activity promotion
12
13 practices, presenting the information in an accessible way. The expectation that the workbook is
14
15 completed is made clear.
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19
20 The intervention is discontinued if participants choose to withdraw from the study.
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23 **Outcome Measures**

24 **Primary outcome measure**

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29 Child MVPA is measured using seven-day accelerometry with the Actigraph wGT3X-
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31 BT Activity Monitor. Child MVPA will be evaluated as change from baseline at 6 weeks, 3
32
33 months, and 6 months. Child MVPA will be determined using the Evenson (2008) cutpoints
34
35 based off of recommendations from Trost et al. (2011). Evenson cutpoints define moderate
36
37 activity as 2296-4011 counts per minute (CPM) and vigorous activity as ≥ 4012 CPM. Therefore,
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39 MVPA will be any activity ≥ 2296 CPM.
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44 Children wear the accelerometer on an elastic belt secured snugly around the waist with
45
46 the device on their left hip for a minimum of 10 hours per day for 7 consecutive days.
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48 Participants are instructed to remove the accelerometers for water-based activities as they are not
49
50 waterproof. A logbook is provided for participants to note when accelerometers were removed
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52 for water-based activity or any other reason, provide other details of each day (e.g. if their
53
54 routine was changed for any reason), and record the details of their accelerometer wear days.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 18

ActiLife software version 6.11.9 (2015) is used to initialize accelerometers and download data and will be used to analyze the data. The accelerometers are initialized to collect pre-filtered data at a sample rate of 30 Hz for the children and are downloaded into 10-second epochs to capture the sporadic nature of child physical activity (Bailey et al., 1995; Cain, Sallis, Conway, Van Dyck, & Calhoun, 2013; Trost, McIver, & Pate, 2005). For determining valid wear time, the Troiano (2008) algorithm is used which defines non-wear time as a period of at least 60 consecutive minutes of zero counts, with an allowance for one to two minutes of counts between 0 and 100. A minimum of four days with at least 600 minutes per day including at least one weekend day of valid wear time will be included in our analyses based on recommended best practice (Trost et al., 2005; Ward, Evenson, Vaughn, Rodgers, & Troiano, 2005).

Secondary outcome measures**Self reported child physical activity.**

Children are asked to complete a modified version of the Physical Activity Questionnaire for Children (PAQ-C) (Crocker, Bailey, Faulkner, Kowalski, & McGrath, 1997) at baseline, 6 weeks, 3 months, and 6 months. The baseline and 6-month questionnaires are completed in the lab and the 6 week and 3 month questionnaires are sent as a link in an email to the parent and completed at the participant's home. These recall questionnaires were designed to assess regular moderate to vigorous physical activity in children and adolescents. Two physical activity variables are reported: general physical activity (minutes per day; question one) and load time (hours/week). The PAQ-C was validated against questionnaires, teacher rating, uni-axial accelerometer counts (Caltrac), fitness test (step test) and interview-assisted recall ($r = 0.39-0.63$) (Crocker et al., 1997). Questions on barriers to physical activity are also included in these questionnaires to determine physical activity capability.

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 19

Child health related fitness.

Health-related fitness is assessed in the lab at baseline and 6 months as per the Canadian Assessment of Physical Literacy physical fitness testing protocol (Longmuir et al., 2015). The key components of body composition, cardiovascular fitness and musculoskeletal fitness are tested. Body mass (kg), height (cm), body mass index, and waist circumference (cm) are measured according to standard procedures. Cardiovascular fitness is assessed by performance on the Leger 20 meter Shuttle run. Musculoskeletal fitness involves a test of grip strength, the sit and reach test, and the plank hold test. All tests are conducted by qualified exercise professionals and specialized equipment. The total time required for the health-related physical fitness measurements is approximately 30 minutes per person.

Parental support habit.

At all time points (baseline, 6 weeks, 3 months, 6 months) parental support habit for child physical activity is measured with an adapted Self-Reported Habit Strength Index (Verplanken & Orbell, 2003), which provides the opportunity to use the self-reported behavioural automaticity index subscale (Gardner, Abraham, Lally, & de Bruijn, 2012) as well. Parents respond on a five-point scale to questions in the following format: “Regular support of my child’s PA is something I do.... automatically, frequently, etc.”. The Self Report Habit Strength Index has been shown to map well to measuring instigation habit (Benjamin Gardner, Phillips, & Judah, 2016). Both measures show excellent reliability and validity in self-reported and objective physical activity assessment (Thurn, Finne, Brandes, & Bucksch, 2014). These measures evaluate the construct of habit which is a component of the M-PAC framework and have been adapted to parental support habits (Rhodes et al., 2018).

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 20

Tertiary outcome measures**Parental physical activity.**

Parents self-report physical activity using the Godin Leisure-Time Exercise Questionnaire (Godin & Shephard, 1985; Godin, Jobin, & Bouillon, 1986) at all time points. This questionnaire assesses the frequency of mild, moderate, and strenuous activity performed for at least 15 minutes during free time in a typical week.

Other parental factors.

The Satisfaction with Life Scale (Diener, Emmons, Larsen, & Griffin, 1985) is used to determine parental quality of life, the parenting sense of competence scale (Gibaud-Wallston & Wandersman, 2001) is used to assess parent sense of competence, and the Family Environment Scale (Moos & Moos, 1994) is used to assess family functioning. All measures are assessed at baseline, 6 weeks, 3 months, and 6 months.

M-PAC constructs for parental support of physical activity.

In addition to habit, other M-PAC constructs of affective attitude, instrumental attitude and perceived behavioural control are assessed using the constructs of the theory of planned behaviour (Ajzen, 1991). Behavioural regulation is measured via the instrument from Sniehotta and colleagues (2005) and parent support identity (whether parents identify as being a supportive of their child's physical activity) is measured via a modified exercise identity scale from Anderson and colleagues (1994, 1995, 1998). Measures from these instruments have demonstrated excellent predictive validity and internal consistency in adult (Rhodes & Lim, 2016; Rhodes & Plotnikoff, 2005; Rhodes, Warburton, & Bredin, 2009), parental physical activity support (Rhodes & Gustafson, 2016) and child/adolescent (Rhodes, Macdonald, &

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 21

McKay, 2006) populations. The instruments have displayed validity for both personal and family-based (i.e., activities as a family collective) physical activity (Casiro, Rhodes, Naylor, & McKay, 2011; Rhodes, Berry, et al., 2019).

Demographics

The baseline questionnaire includes questions to assess characteristics including age, gender, marital status, number of children and ages, ethnicity, level of education, and employment information.

Manipulation check outcomes

The manipulation check outcomes of the study are examined via parent self-report of cue use and consistency on the questionnaires at 6 weeks, 3 months, and 6 months (Kaushal & Rhodes, 2015) as well as a short process evaluation of the intervention at six-months. The consistency item asks parents “over the past 6 weeks/3 months, how consistently did you support your child to be physically active at the same time each day?” on a 5 point scale from not consistent (random) to very consistent. For cue consistency, parents rank statements from “Not true at all” to “very true” on a 7 point scale related to the question “over the last 6 weeks/3 months each time I supported my child to be physically active...”. Statements refer to different types of cues such as temporal (“it was the same time of day, I was doing the same type of activity”), visual (“I was in the same place”), social (“I was around the same people”), and mood (“I was in the same mood”).

The process evaluation procedures involve a brief quantitative questionnaire to assess use of the intervention material and overall satisfaction of the study (Carroll et al., 2007). Second, semi-structured interviews are conducted, allowing for examination of intervention material use

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 22

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3 and satisfaction of study. Some straightforward quantitative questions (e.g., did you use the
4 intervention materials, how often, was it easy to read) questions are also be included in this
5 interview. These have proved useful in our prior evaluations (Rhodes, Naylor, et al., 2019).
6
7 Interviews are conducted with parents and children (individually) by Research Assistants.
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10 11 12 13 **Statistical power and sample size**

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15
16 Given the hierarchical nature of the data (i.e., the 4 measurement occasions at Level-1
17 were considered to be nested within the participant at Level-2), the OpDes Program for power
18 estimation of hierarchical linear models (HLM) (Raudenbush & Bryk, 2002) was used. With a
19 frequency of 4 measurement occasions, three conditions, a duration of 6 months as the primary
20 end-point, within-person variance of 1.0, a growth rate of 1.0, and a small effect size ($d = 0.30$ -
21 0.40), a minimum of 150 families with a goal of 240 families (i.e., 50-80 children per condition)
22 are needed to show significant difference in physical activity accelerometry (minutes of MVPA
23 primary outcome) by condition over time. The effect size represents the findings from our prior
24 intervention research with this demographic (Rhodes, Naylor, et al., 2019; Rhodes et al., 2010)
25 and considering our pilot study on habit formation (Kaushal et al., 2017), yet it is clearly in the
26 range for the detection of differences between the PLANNING and HABIT conditions (Cohen,
27 1992; Ferguson, 2009).
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44 **Data management**

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47 Confidentiality procedures are outlined on the consent form. Each participant is given an
48 ID#, all hard copy data (fitness test records, accelerometer logbooks) is kept in locked cabinets in
49 a locked lab at the University of Victoria, data entered on the computer (accelerometer data,
50 fitness test data) is stored on secure servers. Questionnaire data is stored on SurveyMonkey
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 23

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3 servers in Canada. Only the Research Team has access to the data. The details of data
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5 confidentiality and storage are included in the consent form and explained to participants by the
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7 Research Assistant during the baseline lab session. If a participant chooses to withdraw from the
8
9 study, they are asked by the Project Coordinator if they would like their data to be destroyed or if
10
11 the data that has been collected to that point can be used in the study. Participants receive a
12
13 report of their data when they are complete with participation. A formal data monitoring
14
15 committee has not been created for this intervention however the Project Coordinator provides
16
17 monthly reports on participant numbers and trial progress to the Principal Investigator. The trial
18
19 will be stopped when target participant numbers are achieved and/or at the grant deadline of June
20
21 2020. The final decision will be made by the Principal Investigator. The research team (including
22
23 Project Coordinator, Assistants, and Fitness testers) are trained to document and report any
24
25 adverse events to the Project Coordinator and Principal Investigator. Depending on the nature of
26
27 the event, action will be taken to ensure safety of all parties involved.
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Analysis strategy

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37 Missing data will be evaluated for pattern of missingness for each outcome at all time
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39 points using the dummy coding procedures of Allison (2002). Depending on the outcome of
40
41 these tests (e.g., missing at random, missing completely at random, etc.) we will initiate the
42
43 appropriate missing data handling strategy. ITT analyses will also be performed in addition to
44
45 sensitivity analysis procedures. The first set of analyses will make preliminary demographic
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47 comparisons among adherers to the study versus drop-outs. These analyses will allow us to
48
49 determine the representativeness of the sample. To determine whether minutes / day of MVPA
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51 change over time similarly for all 3 conditions, a Level-1 model will be specified wherein the
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53 intercept (i.e., minutes / day of MVPA at baseline) will be allowed to vary randomly (i.e., vary
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 24

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3 across participants) and the slope for the linear trend will be constrained to be fixed (i.e., the
4 same across participants) controlling for important covariates (i.e., demographics) at Level-2.
5
6 Additionally, dummy variables will be created for condition (HABIT: 1= yes or 2 = no;
7
8 PLANNING: 1 = yes or 2 = no; EDUCATION: 1= yes or 2 = No) at Level-2 with the HABIT
9
10 and PLANNING condition variables being added to the model to predict the intercept and slope
11
12 at Level-1. In doing so, the EDUCATION group is compared against the other two groups to
13
14 determine if baseline MVPA is similar across conditions and whether the change in MVPA is
15
16 similar across conditions. Follow-up analyses will be conducted for the HABIT vs. PLANNING
17
18 condition comparison. The same analytical approach will be used to determine whether there are
19
20 group differences in the health-related quality of life, and the health-related fitness outcomes and
21
22 tertiary outcomes of parent physical activity and health-related quality of life. To determine
23
24 whether the change in the underlying motives explain the potential change in MVPA during the
25
26 intervention similarly for all 3 groups, a time varying covariate mediation analysis approach will
27
28 be utilized following the procedure outlined by Krull and MacKinnon (2001) for Level-1
29
30 Mediation. Briefly, the analyses needed to establish mediation will treat the underlying motives
31
32 as time varying covariates at Level-1 of the model. Then, the dummy coded condition variables
33
34 will be entered at Level-2 to determine if the mediation relationships are similar across groups.
35
36 Finally, to determine whether there is a seasonal, intergenerational, or gender difference across
37
38 the primary and secondary outcomes, each variable will be entered into the various models at
39
40 Level-2 to predict the intercepts and slopes at Level-1. Doing so will determine if they impact
41
42 the change in the various outcomes across time.
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52 The end of study process evaluation questions will be analyzed using descriptive
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54 statistics. Qualitative data analysis will be overseen by the Principal Investigator but conducted
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 25

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2
3 by Research Assistants unconnected with the intervention activities (Merrick, 1999). The
4
5 responses to open-ended questions will be categorized and coded into common themes (Patton,
6
7 1990).
8
9

10 **Results**

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13 At time of submission (August 2019), we have obtained ethical approval, registered the
14
15 trial, and recruited 123 families. Recruitment is expected to be complete in June 2020. From the
16
17 123 families recruited, 22 have completed baseline measures, 19 have completed the six-week
18
19 measures, 12 have completed the three-month measures, 52 have completed the study, and 18
20
21 have dropped out. See Figure 1 for the study procedures and participant flow chart.
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26 **Discussion**

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29 This protocol paper outlines the implementation of a randomized trial employing parent
30
31 supported physical activity habit formation strategies with their children. The guiding conceptual
32
33 model is the M-PAC framework and the overall goal is increased physical activity behaviour in
34
35 children.
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39 **Ethics and Dissemination**

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41
42 This protocol has been approved by the University of Victoria Human Research Ethics
43
44 Board (Victoria, Canada). Details on obtaining consent from participants and confidentiality is
45
46 outlined in the Methods section. No harms are expected as a result of participation in this study
47
48 however participants are provided with contact information for the Project Coordinator, Principal
49
50 Investigator, and Human Research Ethics Board in the case they have something to report. Results
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52 from this trial will be shared at conferences as presentations and in scientific journals as published
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54 manuscripts. Participants who express interest in study results will be made aware of any relevant
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 26

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3 publications. Public access to the participant level dataset will not be granted. There are no current
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5 plans to grant public access to the full protocol or statistical code. All authors who have contributed
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7 to the protocol design are eligible for authorship on subsequent publications.
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For peer review only

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Tables

Table 1

World Health Organization trial registration data set items

Data Category	Information
Primary registry and trial identifying number	ClinicalTrials.gov # NCT03145688
Date of registration in primary registry	Submitted January 27 2017, version 1 finalized and released May 4 2017
Secondary identifying numbers	Unique Protocol ID: 35941 51350
Source(s) of monetary or material support	Heart and Stroke Foundation of Canada
Primary sponsor	Heart and Stroke Foundation of Canada
Secondary sponsor(s)	n/a
Contact for public queries	<i>EM</i> , MSc. ermedd@uvic.ca, 250-721-8384
Contact for scientific queries	<i>EM</i> , MSc. Behavioural Medicine Lab, Victoria, Canada
Public title	Family habit physical activity study
Scientific title	Promoting habit formation in family physical activity
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Child physical activity
Intervention(s)	Family based education, planning, and habit formation
Key inclusion and exclusion criteria	Ages eligible for study: families with children 6-12 years Accepts healthy volunteers: yes Inclusion criteria: child achieving less than 60 minutes of moderate to vigorous physical activity per day Exclusion criteria: Child achieving more than 60 minutes of moderate to vigorous physical activity per day
Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: single blind (participants) Primary purpose: evaluate intervention designed to improve child physical activity through promoting parent support habit
Date of first enrolment	February 2017
Target sample size	240 families
Recruitment status	Recruiting
Primary outcome(s)	Child moderate to vigorous physical activity
Key secondary outcomes	Child fitness, parent support habit

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Table 2

Description of intervention components and associated behaviour change techniques

Intervention Condition	Resources included in Booklet	Physical activity behaviour change techniques	BCT Taxonomy construct
Education	Canadian 24 hour Movement Guidelines: Included list of benefits of physical activity.	Instruction on how to perform a behaviour	4.1
		Information about health consequences	5.1
		Salience of consequences	5.2
		Information about social and environmental consequences	5.3
		Information about emotional consequences	5.6
Planning (Includes Education condition resources)	Goal setting materials Explanation of SMART goals, self-monitoring Family physical activity planning worksheets: Included brainstorming worksheets for where to be active, new modes for being active, how to plan activity, how to incorporate rewards, and journaling and tracking worksheets.	Goal setting (behaviour)	1.1
		Problem solving	1.2
		Action planning	1.4
		Self-monitoring of behaviour	2.3
		Self-monitoring of outcome(s) of behaviour	2.4
		Social support (practical)	3.2
		Social support (emotional)	3.3
		Non-specific reward	10.3
		Self-incentive	10.7
		Restructure physical environment	12.1
Restructure social environment	12.2		
Habit (Includes Education and Planning group resources)	Habit Building Resources Explanation and examples of habits, introduction to cues and anchoring, brainstorming and planning worksheets	Prompts/Cues	7.1
		Behavioural practice/rehearsal	8.1
		Habit formation	8.3

Behaviour change techniques are coded as outlined by The Behaviour Change Technique Taxonomy Version 1 (Michie et al., 2013)

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Figure Legend

Figure 1. Study procedures and participant flow chart. PA = physical activity.

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Appendix 1



CONSENT FORM - PARENTS

“Family physical activity study: A randomized controlled trial”

You are being asked to take part in a study titled “A Family Physical Activity Study”. We are inviting any parent(s) who currently have at least one child between the ages of 6 and 12 years, to participate in this study. **Specifically, we are seeking families in which at least one child is struggling to meet physical activity guidelines.** This study has been reviewed by the University of Victoria Ethics Committee and has met the rigorous requirements for ethical approval.

Although regular physical activity is essential for healthy development in children and numerous benefits of an active lifestyle have been reported, less than one third of Canadian children are meeting physical activity guidelines. Furthermore, children who are overweight as youth are twice as likely to remain overweight into adulthood. Child health is influenced by parental health practices; however, many parents have difficulty maintaining a regular physical activity program due to family obligations. As a result, the promotion of regular activity is paramount in alleviating the potential health implications that may arise for the entire family. We hope that you will help us learn more about factors influencing physical activity in families by participating in the study.

Purpose of this Project

In this study, we will be examining whether different strategies help to promote family-based physical activity.

What do I have to do to participate?

- 1) First we ask that you sign this consent form.
- 2) We will then conduct a **fitness test for your child** at the Behavioural Medicine Lab at the University of Victoria, on a date that is convenient for you.

The tests include blood pressure, body composition (height, weight, girth measurements), a Leger shuttle run test, some strength tests (grip strength, push ups, sit ups, plank test) and a sit & reach flexibility test. This will take approximately 45 minutes. Prior to conducting the fitness test we will administer a questionnaire to ensure that it is safe for your child to undergo fitness testing and partake in physical activity. (Physical Activity Readiness Questionnaire that is administered over the phone).

- 3) We will ask you to complete a **Baseline online questionnaire (should take approx. 20-30 minutes of your time)** while your child is doing their fitness test (**fitness test takes approx.. 1 hour**).

- 4) After the fitness test, we will send your child home with an accelerometer which we will ask him or her to wear for one week. We will ask your child to wear an accelerometer at **four times for seven consecutive days throughout the study**. We will also provide a logbook to write down some information about when your child put the accelerometer on and took it off, and what activities they were doing during the day. You will get the accelerometer information back at the end of the study.

- 5) Once the accelerometer has been worn for one week, we will contact you to pick up the accelerometer and accelerometer log book. At this time we will go through some materials to help increase your child's physical activity. You will be randomized to one of three conditions. Each condition is aimed at increasing

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physical activity for your child but the materials differ. At the end of the study you will find out what the other conditions received for materials and have the option to receive these materials as well. The study materials will include information and strategies for how you can help increase the physical activity of your child. **This will take about 30 minutes to work through.** The materials are print copy and outline benefits of physical activity, information about activities, brainstorming about barriers and some other strategies for how to increase physical activity for your child. **We will ask you to keep and refer to these materials over the course of the study.**

6) **After six weeks**, we will contact you about a **second questionnaire** that we will email to you and ask your **child to wear an accelerometer for another week.** We will also provide an information ‘booster’ session and check in to see how things are going with your child’s physical activity.

7) **At 3 months’ time**, we will ask you to complete **another questionnaire online** and ask your child to **wear an accelerometer for a third time.**

8) **After 6 months**, we will set up a time for **final fitness testing at our lab for your child**, ask you to complete the **last questionnaire**, and ask your child to **wear accelerometers for one week.** At the end of the last week we will setup a time to pick up the accelerometer and **ask you a few wrap up interview questions which should take approximately ten minutes.** This will be tape recorded.

In the questionnaires, you will be asked about demographic information (such as ethnicity, employment and education), questions about your physical activity and your child’s physical activity, and some questions on quality of life. Your child will also be asked about their activities and a child-adapted quality of life scale.

Inconvenience, Risks, and Benefits

There are minimal risks associated with the study but it is **important for you to be aware that you may be asked about some sensitive topics such as demographic information (ethnicity, employment, health) or about your quality of life, or stress.** These questions can make some people uncomfortable and you do not have to answer them if you do not want to. **Also your child will be asked about their activities and some questions about their life. If these questions make your child uncomfortable they do not have to answer them. You also may be inconvenienced by time to participate in the study. Each questionnaire takes approximately 20-30 minutes to complete. Your child’s fitness test may take around 45 minutes each time to complete. The fitness test can make some kids nervous but our trained fitness testers are very careful and will not force your child to do anything they do not want to.** Your child will be shown all the tests and explained in detail what they require. These are standardized tests which are used with kids all across Canada. Any contraindication to exercise or fitness testing would come up through administration of the Physical Activity Readiness Questionnaire. If it is noted that there may be a contraindication to increasing yours or your child’s level of activity, then we will require medical screening prior to participation in the study and in the fitness testing.

The potential benefits of your participation in this research include increasing your child’s level of physical activity participation, which comes with associated health benefits. **Additionally you and your child will earn an honorarium after every assessment point increasing by \$5 at each time point (i.e. families will receive \$25 after the baseline assessment, \$30 after the 6-week assessment, \$35 after the 3 month assessment and \$40 after the 6 month assessment).** If you withdraw from the study you will be paid up to your completed measure (i.e. if you complete six weeks and then withdraw you will receive \$30). You will also get all of your child’s fitness testing and accelerometer information back at the end of the study. Furthermore, you will be providing much needed information on the current health behaviours of parents and their families and the barriers which prevent regular family physical activity involvement. This information will be very helpful to us in designing intervention programs catered to families. As well, if

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requested, you can obtain feedback of the results of this study. The results of the study will be presented at scholarly meetings and published as an article in an academic journal.

Anonymity and Confidentiality

The information from the questionnaires, accelerometers, fitness tests, and interviews will be anonymous during data analysis and publication of study results. All data will be published as group data, and any data kept separate will be identified by ID-number (no name). We will need your contact information in order to provide you with materials and collect materials. However, we can assure you that your confidentiality will be completely protected and only the research team will have access to your contact information. In terms of protecting the confidentiality of your data, the data file and completed questionnaires will be kept in a locked and secure environment on the University of Victoria campus at all times. Only the investigators will have access to the data. The original questionnaires will be shredded after 5 years.

Do I have to participate?

No, your participation in this study is completely voluntary and you have the right to withdraw at any time without consequence. As well, if you choose to withdraw before the six-month follow up, it is up to you whether or not we use that data that we will have collected from you up until that point. It is only through voluntary participation in research projects that we increase our knowledge about issues that are important to health. If one family member chooses to withdraw, the rest of the family can complete the study. If your child decides they do not want to participate, you both may withdraw with no questions asked. If there is only one child participating and they wish to withdraw, the family will be removed from the study. If there are two children within the ages of 6-12 and one child wishes to withdraw but the other would like to remain, the family may continue on. If there is only one parent and they wish to withdraw they will be removed from the study. If there are two parents and only one wishes to withdraw the other family members can continue on. The participant who withdraws will be asked if their data can still be used in the study.

If you have any questions or concern about this study please do not hesitate to contact either Sandy Courtnall (Research Coordinator) or Dr. Ryan Rhodes (Primary Investigator). In addition, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria (250-472-4545 or ethics@uvic.ca).

Other co-investigators of the study:

Dr. Mark Beauchamp, Dr. Chris Blanchard, Dr. Valerie Carson, Dr. Benjamin Gardner, Dr. Darren Warburton

Your signature below indicates that you understand the above conditions of participation in this study, and that you have had the opportunity to have your questions answered by the researchers. Your signature indicates that you consent to both yourself participating in the study and your child to participate in the study.

<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
Please sign one copy for the researchers and sign and keep one copy for your records		
Ryan E. Rhodes, Ph.D., Professor (250) 721-8384 rhodes@uvic.ca	Sandy Courtnall, Project Coordinator (250) 472-5288 scourtna@uvic.ca	

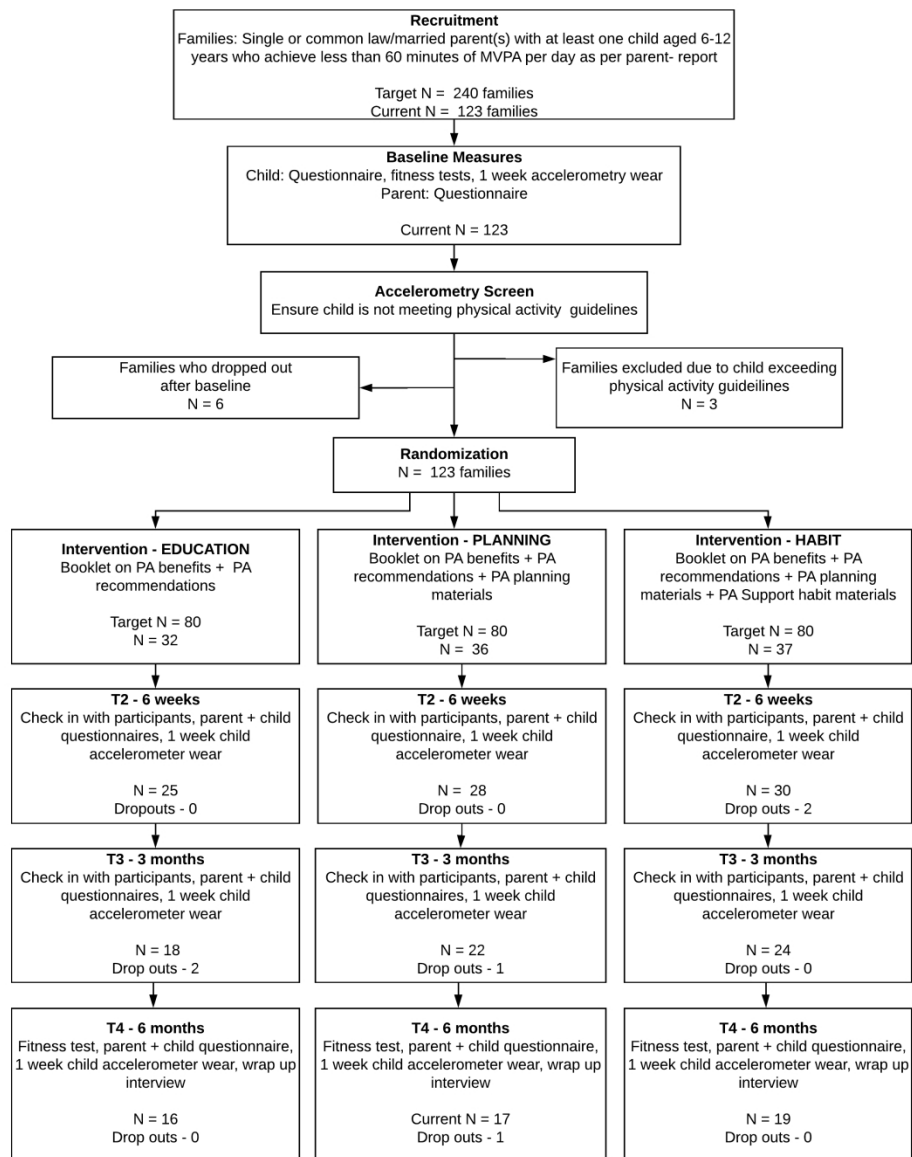


Figure 1. Study procedures and participant flow chart. PA = physical activity.



STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1___
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___1___
	2b	All items from the World Health Organization Trial Registration Data Set	_37 (table 1)_
Protocol version	3	Date and version identifier	___2___
Funding	4	Sources and types of financial, material, and other support	___1___
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___1___
	5b	Name and contact information for the trial sponsor	___1___
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___1___
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___n/a___

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____ 4-6 _____

4

5

6 6b Explanation for choice of comparators _____ 5-7 _____

7

8 Objectives 7 Specific objectives or hypotheses _____ 7-8 _____

9

10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____ 8 _____

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14 **Methods: Participants, interventions, and outcomes**

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16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____ 9-11 _____

17

18

19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____ 9-10 _____

20

21

22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____ 12-17 _____

23

24

25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____ 17 _____

26

27 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) _____ 12 _____

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29 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial _____ 11 _____

30

31

32 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended _____ 17-20 _____

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40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) __Figure 1__

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1 Sample size 14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations 22

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4 Recruitment 15 Strategies for achieving adequate participant enrolment to reach target sample size 10-11

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6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

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10 Sequence generation 16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions 8

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16 Allocation concealment mechanism 16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned 8

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20 Implementation 16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions 8, 10-12

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24 Blinding (masking) 17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how 8

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27 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial 8

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31 **Methods: Data collection, management, and analysis**

32

33 Data collection methods 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol 17-22

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39 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols 12-13

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1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___22-24___
2				
3				
4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___22-24___
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___22-24___
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___22-24___
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___23___
17				
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22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___23___
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___23___
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___23___
29				
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31				
32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___9___
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___9___
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____11_____
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3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____n/a_____
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6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____23_____
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____1_____
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____23_____
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____25_____
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____25-26_____
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	_____26_____
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____25-26_____
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____40-42_____
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____
35				
36				

37 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
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BMJ Open

Family-based habit intervention to promote parent support for child physical activity in Canada; protocol for a randomized trial

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-033732.R1
Article Type:	Protocol
Date Submitted by the Author:	06-Feb-2020
Complete List of Authors:	Medd, Emily; University of Victoria, School of Exercise Science, Physical and Health Education Beauchamp, Mark; The University of British Columbia, School of Kinesiology Blanchard, Chris; Dalhousie University, School of Health and Human Performance Carson, Valerie; University of Alberta, Faculty of Kinesiology, Sport, and Recreation Gardner, Benjamin; King's College, Faculty of Psychology Warburton, Darren; University of British Columbia, School of Kinesiology Rhodes, Ryan; University of Victoria, School of Exercise Science, Physical and Health Education
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Public health
Keywords:	PUBLIC HEALTH, PREVENTIVE MEDICINE, SPORTS MEDICINE

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Running Head: PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 1

Family-based habit intervention to promote parent support for child physical activity in Canada;
protocol for a randomized trial

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Gardner⁵, Darren E.R. Warburton², & Ryan E. Rhodes¹

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Author Contributions

RER, MRB, CMB, VC, BG, and DERW all had input on conceptual model used and design of the study. ERM lead the writing of the protocol, and all authors approved the final manuscript. RER is responsible for project oversight.

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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 2

Registered Trial: clinicaltrials.gov # NCT03145688, Version 2, June 6 2019
Version 1 released May 4 2017, Version 2 sample size number edited to reflect minimum participant number required for statistical significance.

Word Count: 6,602 words

Keywords: Family physical activity, habit formation, health promotion, exercise, parenting

For peer review only

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 3

Abstract

Introduction: Regular physical activity (PA) participation has many important physical and psychological health benefits, managing and preventing over 25 chronic conditions. Being more physically active as a child is associated with being more active as an adult, but less than 10% of Canadian children are achieving the recommended PA guidelines of 60 minutes per day of moderate to vigorous PA. Parental support is a predictor of child PA but parent intention to support child PA does not always predict enacted support. Targeting factors that assist in the sustainability of parent support behaviour of child PA may have an impact on child PA. The purpose of this study is to evaluate an intervention designed to promote habit formation of parental support (HABIT, independent variable) on child PA (dependant variable) compared to a planning and education group (PLANNING) and an education only group (EDUCATION).

Methods and analysis: The three conditions will be compared using a six-month longitudinal randomized trial. Eligible families have at least one child aged 6-12 years who is not meeting the 2011 Canadian PA Guidelines. Intervention materials are delivered to parents at baseline, with check-in sessions at 6 weeks and 3 months. Child moderate-to-vigorous PA, measured by accelerometry, is assessed at baseline, 6 weeks, 3 months, and 6 months as the primary outcome. At baseline and 6 months children perform fitness testing. So far, 123 families have been recruited from the Greater Victoria and surrounding area. Recruitment will be continuing through 2020 with a target of 240 families. **Ethics and Dissemination:** This protocol has been approved by the University of Victoria Human Research Ethics Board (Victoria, Canada). Results will be shared at conferences as presentations and as published manuscripts. Study findings will be made available to interested participants. **Registration details:** This trial is registered at clinicaltrials.gov # NCT03145688.

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 4

Article Summary**Strengths and Limitations of this study**

- This randomized trial will build on family-based PA research evaluating whether building parent support habit for child PA is an effective strategy to promote child PA
- The findings of this study can inform health policy and programs designed to improve health outcomes in children through increasing PA
- It is possible that results may be affected by participants unconsciously adopting techniques from different conditions (e.g. the EDUCATION participant employs planning technique, PLANNING participant employs habit forming techniques)
- Inclusion of quantitative and qualitative manipulation checks will be useful for assessing intervention fidelity

Introduction

Physical activity (PA) has the potential to reduce the risk of at least 25 chronic medical conditions by 20-30%,[1] yet Canadian adults and children are not meeting recommended guidelines to optimize these benefits.[2,3] Children are recommended to achieve 60 minutes per day of moderate to vigorous physical activity (MVPA).[4] For adults, 150 minutes of MVPA per week is recommended.[5] While many complications and diseases present in adulthood, there is compelling evidence showing the positive impact of increased physical activity among children on health. Physical activity can help to guard against high blood pressure, high cholesterol, metabolic syndrome, low bone density, depression and obesity, As well, there is evidence demonstrating a relationship between increased MVPA and reduced psychological distress, improved peer relations, and improved quality of life/well-being.[6–8] Unfortunately, according

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 5

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3 to the Canadian Health Measures Survey, only 9% of boys and 4% of girls are achieving the
4 recommended amount of physical activity.[3,9] Understanding the factors that influence child
5
6 PA is therefore important for promoting long-term population health.
7
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9

10 Parental influence is one such factor; a review of family based interventions to increase
11 physical activity found that parent support was a consistent determinant of child physical
12 activity.[10] Parent support refers to the ways in which parents knowingly influence their child's
13 physical activity and includes both tangible (e.g. transportation) and intangible (e.g.
14 encouragement) behaviours.[11] Interventions focused on parent support to change child
15 physical activity have been generally unsuccessful however, as reported in several reviews. [12–
16 15] More recent intervention research has shown some positive effects,[16–18] but these are still
17 balanced by several null results.[19–21] A recent study found that while most parents have
18 positive intentions to support child health behaviours, few substantively enact this support.[22]
19 Furthermore, this intention-behaviour gap does not appear to be successfully bridged by current
20 interventions targeting parents. For example, a review[10] found that the majority of
21 interventions focus on educating parents on the benefits of physical activity, which does not
22 appear to drive subsequent physical activity change (among parents and their children). This is
23 likely because parents are already aware of the health benefits of physical activity for their
24 children,[23–25] in addition to already having the intention to support behaviour.[22] Therefore,
25 focusing on what parenting support can be harnessed (i.e., malleable through intervention) to
26 promote child physical activity represents an important avenue of enquiry.
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50 Several recent theoretical approaches have advanced beyond merely building intention to
51 perform behavior and suggest that building self-regulatory tactics such as planning is critical to
52 bridge the intention-behavior gap.[26–28] This approach has been utilized in family
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 6

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3 interventions,[10] yet it may not be sufficient to sustain behavior changes over longer durations.
4
5 For example, the Family Physical Activity Planning study[22] compared an intervention group
6
7 focused on family physical activity planning (goal setting, action planning, coping planning) to
8
9 an education only group and found increased child physical activity at 3 months in the family
10
11 planning group. This effect was not observed at 6 months however, demonstrating a need to
12
13 target behavioural strategies beyond mere planning for successful maintenance of physical
14
15 activity.
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19

20 The Multi-Process Action Control (M-PAC) Framework[29,30] may assist in sustaining
21
22 health behaviors such as parental support of child physical activity. This framework suggests that
23
24 self-regulatory skills and tactics assist in translating intentions into behavior during the initial
25
26 adoption of physical activity, but sustainability is also determined by the development of habit
27
28 across time to ease the burden of continual volitional motivation and self-regulation. Habits
29
30 represent impulses to perform behaviour initiated via stimulus-response bonds,[31] and
31
32 contribute to physical activity largely via repeated consistency in behavioural practices, salient
33
34 cues associated with behavioural initiation, and affectively rewarding behaviour.[32–34]
35
36 Consistent with M-PAC theory, habit formation has seen promising results in physical activity
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38 research;[31,35,36] habits may sustain physical activity behaviour over time partially
39
40 independent of goals (or intentions),[35,37] and through helping turn intentions into actual
41
42 behaviour.[30] Of particular relevance to the current trial, a recent study evaluating parent
43
44 support of child physical activity with M-PAC found parent habit to be the largest independent
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46 correlate with the translation of intention into behaviour compared to planning and motivational
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48 constructs.[38]
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 7

Study Objectives and Hypotheses

The primary objective of this study is to implement a theory-based intervention targeting parental support of child MVPA comparing the effect of a PA habit formation + PA planning + PA education (HABIT) condition to a PA planning + PA education (PLANNING) condition and a PA education only group (EDUCATION) on child MVPA (dependant variable). The primary end-point of this trial is six months, with additional secondary time points of 6 weeks and 3 months. Based on previous research,[38, 39] it is hypothesized that children of families in the HABIT condition will demonstrate a greater increase MVPA measured by accelerometry at 6 months compared to those in the PLANNING group and the EDUCATION group. As per the results of Rhodes et al.'s family physical activity planning intervention[22] we expect children of families in the PLANNING group will demonstrate a greater increase in MVPA compared to the EDUCATION group however this effect may diminish over time.

Secondary objectives include evaluating child fitness at baseline and 6 months. It is hypothesized that child fitness will be greater for the HABIT condition compared to the PLANNING and EDUCATION conditions at six months because of the resulting increased physical activity hypothesized above. Tertiary objectives include evaluating parent physical activity and quality of life. While parent and child co-participation in physical activity is not mandatory, parent support of child physical activity may include co-participation (such as a family walk) and therefore it is expected that parents in the HABIT condition will report higher physical activity via some activities being performed with their children in comparison to the other conditions. Finally, no differences in gender or season are hypothesized. The climate in Victoria is relatively mild and outdoor activities continue throughout the year. Seasonal effects (for example, potentially less outdoor physical activity participation during winter months or less

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 8

1
2
3 structured sport participation during summer months) are also expected to be balanced to a
4
5 certain extent by the selected recruitment method. Rolling recruitment ensures that participants
6
7 are at all stages of participation during all seasons. Finally, there is not sufficient evidence at this
8
9 point to support that boys and girls will respond differently to a habit-based physical activity
10
11 intervention.
12
13

14 15 **Trial Design**

16
17
18 This study is a three-arm parallel design single blinded randomized trial. After baseline
19
20 assessment (MVPA, fitness testing, questionnaire), families are randomized to one of three
21
22 groups: 1) family physical activity habit formation + planning + education (HABIT); 2) family
23
24 physical activity planning + information/education (PLANNING); 3) standard physical activity
25
26 education (EDUCATION). The trial is testing the superiority of the HABIT condition.
27
28 Randomisation is performed by the Project Coordinator using Excel Sheet Randomization with
29
30 an allocation ratio of 1:1:1. Participants are blind to their condition until their participation in the
31
32 study is complete, at which point they are informed of their group by the Project Coordinator
33
34 and/or Research Assistant. Under no circumstance will participants be informed of their
35
36 condition while they are still enrolled in the study. Fitness testers are blind to each family's
37
38 condition but the intervention delivery team is aware of the condition to allow for correct
39
40 delivery of intervention materials.
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46 47 **Methods**

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49 The study has been approved by the University of Victoria Human Research Ethics
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51 Board (HREB). The design, conduct, and reporting of the trial has and continues to follow the
52
53 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[40]
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 9

1
2
3 The trial is registered with the Clinical Trials Registry at the National Library of Medicine at the
4
5 National Institutes of Health (ClinicalTrials.gov) Trial ID NCT03145688. See Table 1 for World
6
7 Health Organization Trial Registration Data Set items.
8
9

10 In the case of protocol modifications or amendments, the Project Coordinator submits the
11
12 appropriate documentation to the HREB at the University of Victoria. Once approved, the
13
14 Project Coordinator then updates the trial information on the Clinical Trials Registry.
15
16

17 18 **Patient and public involvement** 19

20
21 No funds or time were allocated for patient (participant) and public involvement in this
22
23 study. Participants were not invited to comment on the study design and were not consulted to
24
25 develop participant relevant outcomes or interpret the results. Participants will not be invited to
26
27 contribute to the writing or editing of this document for readability or accuracy. Participants are
28
29 given the opportunity to share their experience in the wrap up interview providing information
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31 that will help inform future research.
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36 **Participants** 37

38
39 Single or common law/married adult(s), with at least one child between the ages of six
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41 and twelve years, living in greater Victoria, (including the Capital Regional District, Westshore
42
43 Communities, and Sooke) British Columbia, Canada are being recruited for this study. If more
44
45 than one child is eligible in this range, one child is randomly (computer randomizer) designated
46
47 as the target for analysis yet all willing children are included in the study. Families are included
48
49 if the child participant is achieving less than the recommended 2011 Canadian physical activity
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51 guidelines of 60 min of MVPA daily.[41]
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 10

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3 The age group of 6-12 was selected from our earlier pilot work.[18] Specifically, children
4 under six years of age engage in physical activity that is quite sporadic, and thus very different
5 than children six years and older.[42] Our decision to limit the age of children to 12 was more
6 practical; 12-year-old children represent the upper bound of the “twens”, where parents are still
7 very influential in physical activity decisions and physical activity interventions at the level of
8 the parent would be still effective.[12,43]
9

Recruitment

10
11
12 Recruitment is being conducted by the Behavioural Medicine Lab at the University of
13 Victoria in British-Columbia, Canada. Parents with one or more children aged 6-12 are the
14 primary target for recruitment. Victoria’s population is representative of Canada: according to
15 data from the 2016 Canadian census, the age distribution, family structure, and income of
16 Victoria residents are similar to those of Canada.[44]
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20 Participants are being recruited through the social media platforms Facebook and
21 Instagram, posters at community facilities, in person at local markets and festivals, and through
22 word of mouth. Facebook and Instagram posts are made bi-monthly by the Behavioural
23 Medicine Lab Recruitment Officer on the Behavioural Medicine Lab Facebook page
24 (<https://www.facebook.com/UVicBMED/>) and Instagram account (@uvicbmed) which are
25 linked, meaning a post made on Facebook is simultaneously shared on Instagram and vice versa.
26 Posts are limited to 100 words or less and briefly describe the intent of the study and those
27 eligible to partake, asking those interested to contact the Behavioural Medicine Lab through
28 email or phone information provided in the post. Facebook posts are also shared to relevant
29 Facebook groups (e.g. neighbourhood groups, young parent groups). Facebook posts are
30 “boosted” by paying a small fee to have the post appear as an ad in a target demographic’s news
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 11

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3 feed. This increases the reach of the Facebook post with the goal of increasing recruitment. The
4 target demographic is specified by selecting variables of age, location of residence, and other
5 filters such as “parents”, and the ads typically run for 7 days. The Recruitment Officer also sets
6 up a recruitment booth twice per month at local markets and festival events during the summer,
7 and at community and recreation centers in the winter to engage with potential participants,
8 answer questions, and collect contact information for interested families. Posters are put up
9 every 3 – 4 months by a Research Assistant and/or Recruitment Officer in all major recreation
10 centers in the area, as well as shopping centers, health care centers, and schools. Word of mouth
11 is also used as a recruitment strategy by asking participants to share information about the study
12 with acquaintances. Since participants self-select, application of the results will be limited to
13 families already interested in supporting their child’s physical activity.
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29 **Enrolment**

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32 When interested parents contact the lab, the Recruitment Officer(s) follows up with an
33 email to schedule a phone conversation. If initial contact is a message through Instagram or
34 Facebook, the Recruitment Officer replies asking the person to call/email or provide their contact
35 information to be contacted by phone or email. An initial recruitment phone interview is set up
36 with the Recruitment Officer. Participant families are screened by parent-report of average child
37 physical activity per day as well as the ParQ+ Health Screening Questionnaire.[45] If screened in
38 then the Recruitment Officer books the baseline fitness test and advises the Project Coordinator
39 who follows up with the family and schedules a Fitness Tester for the baseline session. Fitness
40 Testers are all Certified Personal Trainers or Clinical Exercise Physiologists registered with the
41 Canadian Society for Exercise Physiology.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 12

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3 During the baseline session, the Fitness Tester obtains written consent from parents and
4 verbal consent from children (See Appendix 1). Participants are asked not to participate in any
5 other research studies while enrolled in the present study. After the baseline session, children
6 wear an accelerometer for 7 days. The intervention delivery session is scheduled after the week
7 of accelerometer wear; once scheduled, the Research Coordinator randomly assigns the family to
8 one of the three conditions and prepares the appropriate materials for the Research Assistant to
9 take with them to the participants' home. The Research Assistants are Kinesiology and
10 Psychology undergraduate and graduate students. These are paid positions that involve thorough
11 training in the lab and in the field. Training involves review of a training manual, study
12 materials, shadowing sessions with experienced Research Assistants, practicing sessions and
13 successfully demonstrating participant appointments to the Project Coordinator to confirm that
14 they are ready to take the lead on these deliveries and check in's w/participants on their own.
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31 Participants receive an honorarium at baseline (\$25), 6 weeks (\$30), 3 months (\$35), and
32 6 months (\$40) for a total of \$130. Families only receive honorariums if they complete all the
33 measures for the check in (accelerometers, logbooks, questionnaires).
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Intervention

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42 The intervention is conducted in-person with a Research Assistant and the family at the
43 family home, and includes take away material for the families to use later on. The material is a
44 condition specific physical activity workbook and serves as a template for the dialogue between
45 the Research Assistant and families during the intervention delivery. The Research Assistant
46 explains each section of the book to families as per the intervention delivery script from the
47 training manual, answering questions as needed and ensuring that families are comfortable to
48 complete the workbook in the coming weeks. Families are asked not to share any information
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 13

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3 with any acquaintances who happen to be participating in the same study. Intervention delivery
4 sessions range from 25-40 minutes in length depending on the condition and the family.
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8 The workbook is designed for families with information directed at the parent to review
9 with the child, sections for parents and children to complete together, and some sections for the
10 parent to complete on their own. The material incorporates established behaviour change
11 techniques to promote child physical activity. The full list of behaviour change techniques
12 employed in each condition are summarized in Table 2 as per Michie et al. Behaviour Change
13 Taxonomy (BCT).[46] These techniques are incorporated in the workbook and reinforced by the
14 discussion between the Research Assistant and the family.
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25 The three intervention conditions follow and advance the prior work conducted in our
26 successful habit formation pilot trial[32] and feasibility study, but now tested in comparison to
27 our work on family physical activity planning.[18,22,47] The condition of key interest (HABIT)
28 is focused on the behavior change technique of habit formation with the goal of impacting
29 initiation of parental physical activity support and not the actual execution of child physical
30 activity or execution of support behaviour, which may be quite mindful (Verplanken &
31 Melkevik, 2008).[48] Contemporary research has shown that habits in the physical activity
32 domain can be discerned into habitual instigation – whereby, in this instance, a parent non-
33 consciously ‘decides’ to provide physical activity support – and habitual execution, whereby a
34 parent non-consciously performs the actions involved in providing physical activity
35 support.[49,50] The HABIT condition is focused on encouraging the formation of instigation
36 habits, such that parents are automatically ‘reminded’ to select physical activity support (from
37 available alternatives). We are not attempting to promote non-conscious engagement in child
38 physical activity support (i.e. execution habit).
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 14

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3 Six week and three-month check-ins, or “booster” sessions, are scheduled by the Project
4
5 Coordinator with families in all conditions. This involves a 10-15 minute house visit by a
6
7 Research Assistant to discuss the families’ experience so far. Research Assistants follow a check
8
9 in script included in the training manual and review the intervention delivery materials as needed
10
11 to support family problem solving (BCT construct 1.2) and promote adherence to the
12
13 intervention. Based on what the family expresses as personal challenges or barriers, the Research
14
15 Assistant will re-emphasize strategies in the workbook that address that concern. For example, if
16
17 a family expresses difficulty with planning physical activity, the Research Assistant will go
18
19 through the intervention materials again to help the family identify what techniques they can
20
21 focus on (such as rewards or tracking) and help to brainstorm strategies.
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Education condition (EDUCATION).

26
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29 The standard EDUCATION package consists of the Canadian 24 hour Movement
30
31 Guidelines for children recommending at least 60 minutes of MVPA per day and vigorous
32
33 intensity activities at least three times per week (BCT construct 5.1).[4] The guide also contains
34
35 information about the benefits of physical activity for children (BCT construct 5.2, 5.3, 5.6),
36
37 explanations of what moderate and vigorous intensity activities are, and ideas for physical
38
39 activities including structured (e.g. play a sport) and unstructured (e.g. go to the playground)
40
41 examples (BCT construct 4.1). The Research Assistant reviews this information with families.
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Planning + education group (PLANNING).

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49 Participants in the physical activity planning intervention condition receive the same
50
51 guidelines and information as the EDUCATION condition but are also provided with family
52
53 physical activity planning material for parents and children to complete together. Goal setting
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 15

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2
3 and self monitoring are explained by the Research Assistant followed by a skill training
4
5 component which is a section on how to plan for family physical activity. The workbook
6
7 includes a brainstorming exercise for families where they list physical activities that they have
8
9 found fun in the past, as well as activities that they would find enjoyable to do as a family. This
10
11 brainstormed list helps create the template for physical activity planning by contextualizing what
12
13 the participants would like to do and the subsequent necessary support behaviours for parents
14
15 (BCT construct 3.2, 3.3, 12.1, 12.2). Research Assistants explain the exercise and support
16
17 brainstorming with families as needed.
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22 The skill training material is based on our previous family-based physical activity
23
24 interventions which have demonstrated the effectiveness of targeting family based self-
25
26 regulatory processes such as planning, goal setting, problem solving, and self monitoring for
27
28 increasing physical activity outcomes in children.[18,22,47] The workbook facilitates goal
29
30 setting and problem solving (1.1, 1.2). Families are instructed to plan for “when,” “where,”
31
32 “how,” and “what” physical activity will be performed commensurate with the creation of action
33
34 planning (BCT construct 1.4) and implementation intentions (e.g.,[51,52]). This section is
35
36 followed by a page on rewards (BCT constructs 10.3, 10.7) with space for children to brainstorm
37
38 activities other than physical activity that they would like to do and which can function as a
39
40 reward for when children engage in their planned physical activity. The final page is a journal
41
42 and tracking sheet for families to log child physical activity (when, what, where, and outcomes
43
44 e.g. how the child felt, what happened right after) (BCT construct 2.3, 2.4). The design of all
45
46 material was created for prior research[18,22,47] and features graphic design and colour images
47
48 that represent family physical activity. The Research Assistant reviews each section with
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 16

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3 families, explains how to complete them, and informs them that their participation in the study
4
5 includes completing the workbook.
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7

8 **Habit + planning + education group (HABIT).**
9

10
11 Participants in the habit formation condition receive the same content as the
12
13 EDUCATION condition and PLANNING condition as well as additional material on creating
14
15 parent support habits for child physical activity. As with the other conditions, the Research
16
17 Assistant reviews the workbook with families and answers questions as needed. While parent
18
19 support habit includes the child, this section of the workbook is directed more to the parent as the
20
21 habit of interest is parental support of child physical activity. The material is taken from research
22
23 on habit formation[33] and our successful pilot study,[32] but adapted in our feasibility study to
24
25 the same colourful style and format as the other information provided. The material includes a
26
27 brief discussion of what habits are with some very straightforward non-physical activity related
28
29 examples such as preparing for sleep routines, or selecting the car to commute to work. A key
30
31 component of the habit section is based on planning for context-dependent repetition (BCT
32
33 constructs 8.1, 8.3), with pointers on how to maintain repetition as habit forms. The use of script
34
35 elicitation to understand/describe existing routines and spot points at which physical activity
36
37 support can be inserted follows. This involves a worksheet for parents to brainstorm existing
38
39 routines in their child's life (for example, family brunch on Sundays) and then identify what
40
41 physical activities brainstormed in the planning section with the child that might be tagged on to
42
43 the routine (for example, family walk after brunch every Sunday). This process has been
44
45 successful in forming habits in other behavioural domains[53] as it helps identify reliable and
46
47 consistent behaviour patterns into which new behaviours may be inserted to optimise the
48
49 likelihood of the context-dependent performance required for habit to form. Cues are then
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 17

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3 introduced as factors to support habit formation (BCT construct 7.1). Based on our previously
4 successful trial,[32] cues are described as those factors that prompt a behaviour with a discussion
5 of temporal, social, mood, and visual cues to support physical activity.[54] Cues are considered
6 factors that a) can reliably precede the support activity but b) rarely be present when the activity
7 is not to be performed. Examples of cues are provided such as a soccer gear bag that is put out in
8 the morning before the family leaves for school and work, which prompts taking the child to
9 soccer when it's seen upon the family's return to the house (visual cue). The soccer gear bag is
10 then removed from sight until the next soccer day. Examples of temporal cues are also provided,
11 such taking the children on a walk with the family dog after dinner, where dinner occurs once a
12 day and can serve to pair well with the family's new plan to walk. We suggest that cues that are
13 repeatedly present during times when family physical activity is not performed – e.g., a sign on a
14 door that the family walks by all the time – should not be considered, as it reduces the salience of
15 the cue and so its potential for activating the desired action at opportune moments. Parents are
16 reminded of the importance of having consistent support practices for child physical activity. It is
17 made clear that this does not necessarily mean the same activity all the time, but it means
18 consistent protected time where support is performed so it links with support instigation habits.
19 This could mean child soccer practice every Tuesday night, family physical activity every
20 Sunday after dinner, or encouraging the kids to play in the back yard each day after school.
21 Parents are then asked to brainstorm and create a plan of consistency and cues with the
22 workbooks provided. Parent support of child physical activity may include co-participation in
23 physical activity by the parent (such as the family walk after dinner) or not (such as driving the
24 child to sport practice). The final pages of the HABIT materials are titled “Ten tips for turning
25 exercise intentions into actions” and summarizes evidence-based physical activity promotion
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 18

practices, presenting the information in an accessible way. The Research Assistant reviews all sections and worksheets with families, explains how to complete them, and informs them that participation in the study includes completing the workbook.

The intervention is discontinued if participants choose to withdraw from the study.

Outcome Measures

Differences between the HABIT condition are being tested relative to the PLANNING and EDUCATION conditions.

Primary outcome measure

Child MVPA is measured using seven-day accelerometry with the Actigraph wGT3X-BT Activity Monitor. Child MVPA will be evaluated as change from baseline at 6 weeks, 3 months, and 6 months. Child MVPA will be determined using the Evenson[55] cutpoints based off of recommendations from Trost et al.[56]. Evenson cutpoints define moderate activity as 2296-4011 counts per minute (CPM) and vigorous activity as ≥ 4012 CPM. Therefore, MVPA will be any activity ≥ 2296 CPM.

Children wear the accelerometer on an elastic belt secured snugly around the waist with the device on their left hip for a minimum of 10 hours per day for 7 consecutive days. Participants are instructed to remove the accelerometers for water-based activities as they are not waterproof. A logbook is provided for participants to note when accelerometers were removed for water-based activity or any other reason, provide other details of each day (e.g. if their routine was changed for any reason), and record the details of their accelerometer wear days. ActiLife software version 6.11.9[57] is used to initialize accelerometers and download data and will be used to analyze the data. The accelerometers are initialized to collect pre-filtered data at a

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 19

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3 sample rate of 30 Hz for the children and are downloaded into 10-second epochs to capture the
4 sporadic nature of child physical activity.[58–60] For determining valid wear time, the Troiano
5 algorithm is used which defines non-wear time as a period of at least 60 consecutive minutes of
6 zero counts, with an allowance for one to two minutes of counts between 0 and 100.[61] A
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8 minimum of four days with at least 600 minutes per day including at least one weekend day of
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10 valid wear time will be included in our analyses based on recommended best practice[60,62].
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Secondary outcome measures**Child physical activity measures.**

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24 Children are asked to complete a modified version of the Physical Activity Questionnaire
25 for Children (PAQ-C)[63] at baseline, 6 weeks, 3 months, and 6 months. This measure is
26 included in addition to accelerometry measured PA as they are not identical measures: including
27 self-report PA will allow for assessment of volitional physical activity.[64] These recall
28 questionnaires were designed to assess regular moderate to vigorous physical activity in children
29 and adolescents. Frequency of different types of activity as well as intensity are assessed. The
30 PAQ-C was validated against questionnaires, teacher rating, uni-axial accelerometer counts
31 (Caltrac), fitness test (step test) and interview-assisted recall ($r = 0.39-0.63$) [63]. Questions on
32 barriers to physical activity are also included in these questionnaires to determine physical
33 activity capability.
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47 Parent report of child PA and family PA are also assessed using modified Godin Leisure-
48 Time Exercise Questionnaire[65] asking frequency and duration of structured vs. unstructured
49 physical activity performed individually (child) and as a family (family).
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 20

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3 The baseline and 6-month questionnaires are completed in the lab and the 6 week and 3-
4 month questionnaires are sent as a link in an email to the parent and completed at the
5
6 participant's home.
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Child health related fitness.

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14 Health-related fitness is assessed in the lab at baseline and 6 months as per the Canadian
15
16 Assessment of Physical Literacy physical fitness testing protocol.[66] The key components of
17
18 body composition, cardiovascular fitness and musculoskeletal fitness are tested. Body mass (kg),
19
20 height (cm), body mass index, and waist circumference (cm) are measured according to standard
21
22 procedures. Cardiovascular fitness is assessed by performance on the Leger 20-meter Shuttle run.
23
24 Musculoskeletal fitness involves a test of grip strength, the sit and reach test, and the plank hold
25
26 test. All tests are conducted by qualified exercise professionals and specialized equipment. The
27
28 total time required for the health-related physical fitness measurements is approximately 30
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30 minutes per person.
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Parent support and support habit.

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38 The Activity Support Scale for Multiple Groups (ACTS-MG)[67] is used to measure
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40 parent support of child physical activity.
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44 Parental support habit for child physical activity is measured with an adapted Self-
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46 Reported Habit Strength Index,[68] which provides the opportunity to use the self-reported
47
48 behavioural automaticity index subscale[69] as well. Parents respond on a five-point scale to
49
50 questions in the following format: "Regular support of my child's PA is something I do....
51
52 automatically, frequently, etc.". The Self Report Habit Strength Index has been shown to map
53
54 well to measuring instigation habit.[70] Both measures show excellent reliability and validity in
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 21

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3 self-reported and objective physical activity assessment.[71] These measures evaluate the
4
5 construct of habit which is a component of the M-PAC framework and have been adapted to
6
7 parental support habits.[38] All measures are examined at all time points (baseline, 6 weeks, 3
8
9 months, 6 months).

Tertiary outcome measures**Parent physical activity.**

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19 Parents self-report physical activity using the Godin Leisure-Time Exercise
20
21 Questionnaire[65,72] at all time points. This questionnaire assesses the frequency of mild,
22
23 moderate, and strenuous activity performed during free time in a typical week.

Other parent factors.

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29 The 12-Item Short-Form Health Survey[73] is used to determine parental quality of life,
30
31 and the Family Environment Scale[74] is used to assess and family functioning at baseline, 6
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33 weeks, 3 months, and 6 months. At one time point during the study, personality (Revised NEO
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35 Personality Inventory[75]), parenting sense of competence (the Parenting Sense of Competence
36
37 scale[76]) and physical activity availability (from the Home Environment Survey[77]) are
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39 assessed.
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M-PAC constructs for parental support of physical activity.

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47 In addition to habit, other M-PAC constructs of affective attitude, instrumental attitude
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49 and perceived behavioural control are assessed using the constructs of the theory of planned
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51 behaviour.[78] Intention was measured using two questions employed in previous work with the
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53 Theory of Planned Behavior,[79,80] asking about commitment and intention to support child
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 22

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3 physical activity. Behavioural regulation is measured via the instrument from Sniehotta and
4 colleagues[81] and parent support identity (whether parents identify as being a supportive of
5 their child's physical activity) is measured via a modified exercise identity scale from Anderson
6 and colleagues.[82–84] Measures from these instruments have demonstrated excellent predictive
7 validity and internal consistency in adults,[85–87] parental physical activity support,[43] and
8 child/adolescent populations.[88] The instruments have displayed validity for both personal and
9 family-based (i.e., activities as a family collective) physical activity.[38,89]

20 **Demographics**

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23 The baseline questionnaire includes questions to assess characteristics including age,
24 gender, marital status, ethnicity, level of education, income level, number, gender, and age of
25 children, and employment information.

30 **Manipulation check outcomes**

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32
33 The manipulation check outcomes of the study are examined via parent self-report of cue
34 use and consistency on the questionnaires at 6 weeks, 3 months, and 6 months,[32] as well as a
35 short process evaluation of the intervention at six-months. The consistency item asks parents
36 “over the past 6 weeks/3 months, how consistently did you support your child to be physically
37 active at the same time each day?” on a 5-point scale from not consistent (random) to very
38 consistent. For cue consistency, parents rank statements from “Not true at all” to “very true” on a
39 7-point scale related to the question “over the last 6 weeks/3 months each time I supported my
40 child to be physically active...”. Statements refer to different types of cues such as temporal (“it
41 was the same time of day, I was doing the same type of activity”), visual (“I was in the same
42 place”), social (“I was around the same people”), and mood (“I was in the same mood”).

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 23

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3 The process evaluation procedures involve a brief quantitative questionnaire included on
4 the final 6 month parent questionnaire to assess use of the intervention material and overall
5 satisfaction of the study.[90] Second, semi-structured interviews are conducted with families
6 during the 6 month lab session, allowing for more in depth examination of intervention material
7 use and satisfaction of the study. All parents complete the interview and children have the option
8 to participate alongside their parent. Some straightforward quantitative questions (e.g., did you
9 use the intervention materials, how often) questions are included in this interview as these have
10 proved useful in our prior evaluations.[22] Participants have the opportunity to elaborate on their
11 response to each question, providing more context. Key open-ended questions include family
12 physical activity type and frequency, barriers, and changes. The PLANNING and HABIT group
13 participants are also asked if they used the material, found it useful in promoting physical
14 activity, and why/why not. All participants have the opportunity to provide any other feedback as
15 well.
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Statistical power and sample size

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36 Given the hierarchical nature of the data (i.e., the 4 measurement occasions at Level-1
37 were considered to be nested within the participant at Level-2), the OpDes Program for power
38 estimation of hierarchical linear models (HLM)[91] was used. With a frequency of 4
39 measurement occasions, three conditions, a duration of 6 months as the primary end-point,
40 within-person variance of 1.0, a growth rate of 1.0, and a small effect size ($d = 0.30-0.40$), a
41 minimum of 150 families with a goal of 240 families (i.e., 50-80 children per condition) are
42 needed to show significant difference in physical activity accelerometry (minutes of MVPA
43 primary outcome) by condition over time. The effect size represents the findings from our prior
44 intervention research with this demographic[18,22] and considering our pilot study on habit
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 24

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3 formation,[36] yet it is clearly in the range for the detection of differences between the
4
5 PLANNING and HABIT conditions.[92,93]
6
7

Data management
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9

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11 Confidentiality procedures are outlined on the consent form. Each participant is given an
12
13 ID#, all hard copy data (fitness test records, accelerometer logbooks) is kept in locked cabinets in
14
15 a locked lab at the University of Victoria, data entered on the computer (accelerometer data,
16
17 fitness test data) is stored on secure servers. Questionnaire data is stored on SurveyMonkey
18
19 servers in Canada. Only the Research Team has access to the data. The details of data
20
21 confidentiality and storage are included in the consent form and explained to participants by the
22
23 Research Assistant during the baseline lab session. If a participant chooses to withdraw from the
24
25 study, they are asked by the Project Coordinator if they would like their data to be destroyed or if
26
27 the data that has been collected to that point can be used in the study. Participants receive a
28
29 report of their data when they are complete with participation. A formal data monitoring
30
31 committee has not been created for this intervention however the Project Coordinator provides
32
33 monthly reports on participant numbers and trial progress to the Principal Investigator. The trial
34
35 will be stopped when target participant numbers are achieved and/or at the grant deadline of June
36
37 2020. The final decision will be made by the Principal Investigator. The research team (including
38
39 Project Coordinator, Assistants, and Fitness testers) are trained to document and report any
40
41 adverse events to the Project Coordinator and Principal Investigator. Depending on the nature of
42
43 the event, action will be taken to ensure safety of all parties involved.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 25

Analysis strategy

Missing data will be evaluated for pattern of missingness for each outcome at all time points using the dummy coding procedures of Allison.[94] Depending on the outcome of these tests (e.g., missing at random, missing completely at random, etc.) we will initiate the appropriate missing data handling strategy. ITT analyses will also be performed in addition to sensitivity analysis procedures. The first set of analyses will make preliminary demographic comparisons among adherers to the study versus drop-outs. These analyses will allow us to determine the representativeness of the sample. To determine whether minutes / day of MVPA change over time similarly for all 3 conditions, a Level-1 model will be specified wherein the intercept (i.e., minutes / day of MVPA at baseline) will be allowed to vary randomly (i.e., vary across participants) and the slope for the linear trend will be constrained to be fixed (i.e., the same across participants) controlling for important covariates (i.e., demographics) at Level-2. Additionally, dummy variables will be created for condition (HABIT: 1= yes or 2 = no; PLANNING: 1 = yes or 2 = no; EDUCATION: 1= yes or 2 = No) at Level-2 with the HABIT and PLANNING condition variables being added to the model to predict the intercept and slope at Level-1. In doing so, the EDUCATION group is compared against the other two groups to determine if baseline MVPA is similar across conditions and whether the change in MVPA is similar across conditions. Follow-up analyses will be conducted for the HABIT vs. PLANNING condition comparison. The same analytical approach will be used to determine whether there are group differences in the health-related quality of life, and the health-related fitness outcomes and tertiary outcomes of parent physical activity and health-related quality of life. To determine whether the change in the underlying motives explain the potential change in MVPA during the intervention similarly for all 3 groups, a time varying covariate mediation analysis approach will

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3 be utilized following the procedure outlined by Krull and MacKinnon[95] for Level-1 Mediation.
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5 Briefly, the analyses needed to establish mediation will treat the underlying motives as time
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7 varying covariates at Level-1 of the model. Then, the dummy coded condition variables will be
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9 entered at Level-2 to determine if the mediation relationships are similar across groups. Finally,
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11 to determine whether there is a seasonal, intergenerational, or gender difference across the
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13 primary and secondary outcomes, each variable will be entered into the various models at Level-
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15 2 to predict the intercepts and slopes at Level-1. Doing so will determine if they impact the
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17 change in the various outcomes across time.
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22 The end of study process evaluation questions will be analyzed using descriptive
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24 statistics. Qualitative data analysis will be overseen by the Principal Investigator but conducted
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26 by Research Assistants unconnected with the intervention activities.[96] The responses to open-
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28 ended questions will be categorized and coded into common themes.[97]
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32 Results

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35 At time of submission (August 2019), we have obtained ethical approval, registered the
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37 trial, and recruited 123 families. Recruitment is expected to be complete in December 2020.
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39 From the 123 families recruited, 22 have completed baseline measures, 19 have completed the
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41 six-week measures, 12 have completed the three-month measures, 52 have completed the study,
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43 and 18 have dropped out. See Figure 1 for the study procedures and participant flow chart.
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47 Discussion

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50 This protocol paper outlines the implementation of a randomized trial employing parent
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52 supported physical activity habit formation strategies with their children. The guiding conceptual
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3 model is the M-PAC framework and the overall goal is increased physical activity behaviour in
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5 children.
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8 **Ethics and Dissemination**

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11 This protocol has been approved by the University of Victoria Human Research Ethics
12 Board (Victoria, Canada). Details on obtaining consent from participants and confidentiality is
13 outlined in the Methods section. No harms are expected as a result of participation in this study
14 however participants are provided with contact information for the Project Coordinator, Principal
15 Investigator, and Human Research Ethics Board in the case they have something to report. Results
16 from this trial will be shared at conferences as presentations and in scientific journals as published
17 manuscripts. Participants who express interest in study results will be made aware of any relevant
18 publications. Public access to the participant level dataset will not be granted. There are no current
19 plans to grant public access to the full protocol or statistical code. All authors who have contributed
20 to the protocol design are eligible for authorship on subsequent publications.
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PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 38

Tables

Table 1

World Health Organization trial registration data set items

Data Category	Information
Primary registry and trial identifying number	ClinicalTrials.gov # NCT03145688
Date of registration in primary registry	Submitted January 27 2017, version 1 finalized and released May 4 2017
Secondary identifying numbers	Unique Protocol ID: 35941 51350
Source(s) of monetary or material support	Heart and Stroke Foundation of Canada
Primary sponsor	Heart and Stroke Foundation of Canada
Secondary sponsor(s)	n/a
Contact for public queries	EM, MSc. ermedd@uvic.ca, 250-721-8384
Contact for scientific queries	EM, MSc. Behavioural Medicine Lab, Victoria, Canada
Public title	Family habit physical activity study
Scientific title	Promoting habit formation in family physical activity
Countries of recruitment	Canada
Health condition(s) or problem(s) studied	Child physical activity
Intervention(s)	Family based education, planning, and habit formation
Key inclusion and exclusion criteria	Ages eligible for study: families with children 6-12 years Accepts healthy volunteers: yes Inclusion criteria: child achieving less than 60 minutes of moderate to vigorous physical activity per day Exclusion criteria: Child achieving more than 60 minutes of moderate to vigorous physical activity per day

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 39

Study type	Interventional Allocation: randomized Intervention model: parallel assignment Masking: single blind (participants) Primary purpose: evaluate intervention designed to improve child physical activity through promoting parent support habit
Date of first enrolment	February 2017
Target sample size	240 families
Recruitment status	Recruiting
Primary outcome(s)	Child moderate to vigorous physical activity
Key secondary outcomes	Child fitness, parent support habit

Table 2

Description of intervention components and associated behaviour change techniques

Intervention Condition	Resources included in Booklet	Physical activity behaviour change techniques	BCT Taxonomy construct
Education	Canadian 24-hour Movement Guidelines: Included list of benefits of physical activity.	Instruction on how to perform a behaviour	4.1
		Information about health consequences	5.1
		Salience of consequences	5.2
		Information about social and environmental consequences	5.3
		Information about emotional consequences	5.6
Planning (Includes Education condition resources)	Goal setting materials Explanation of SMART goals, self-monitoring Family physical activity planning worksheets: Included brainstorming worksheets for where to be active, new modes for being active, how to plan activity, how to incorporate rewards,	Goal setting (behaviour)	1.1
		Problem solving	1.2
		Action planning	1.4
		Self-monitoring of behaviour	2.3
		Self-monitoring of outcome(s) of behaviour	2.4
		Social support (practical)	3.2
		Social support (emotional)	3.3
		Non-specific reward	10.3

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 40

		and journaling and tracking worksheets.	Self-incentive	10.7
			Restructure physical environment	12.1
			Restructure social environment	12.2
	Habit (Includes Education and Planning group resources)	Habit Building Resources Explanation and examples of habits, introduction to cues and anchoring, brainstorming and planning worksheets	Prompts/Cues	7.1
			Behavioural practice/rehearsal	8.1
			Habit formation	8.3

Behaviour change techniques are coded as outlined by The Behaviour Change Technique Taxonomy Version 1 [46]

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Figure Legend

Figure 1. Study procedures and participant flow chart. PA = physical activity.

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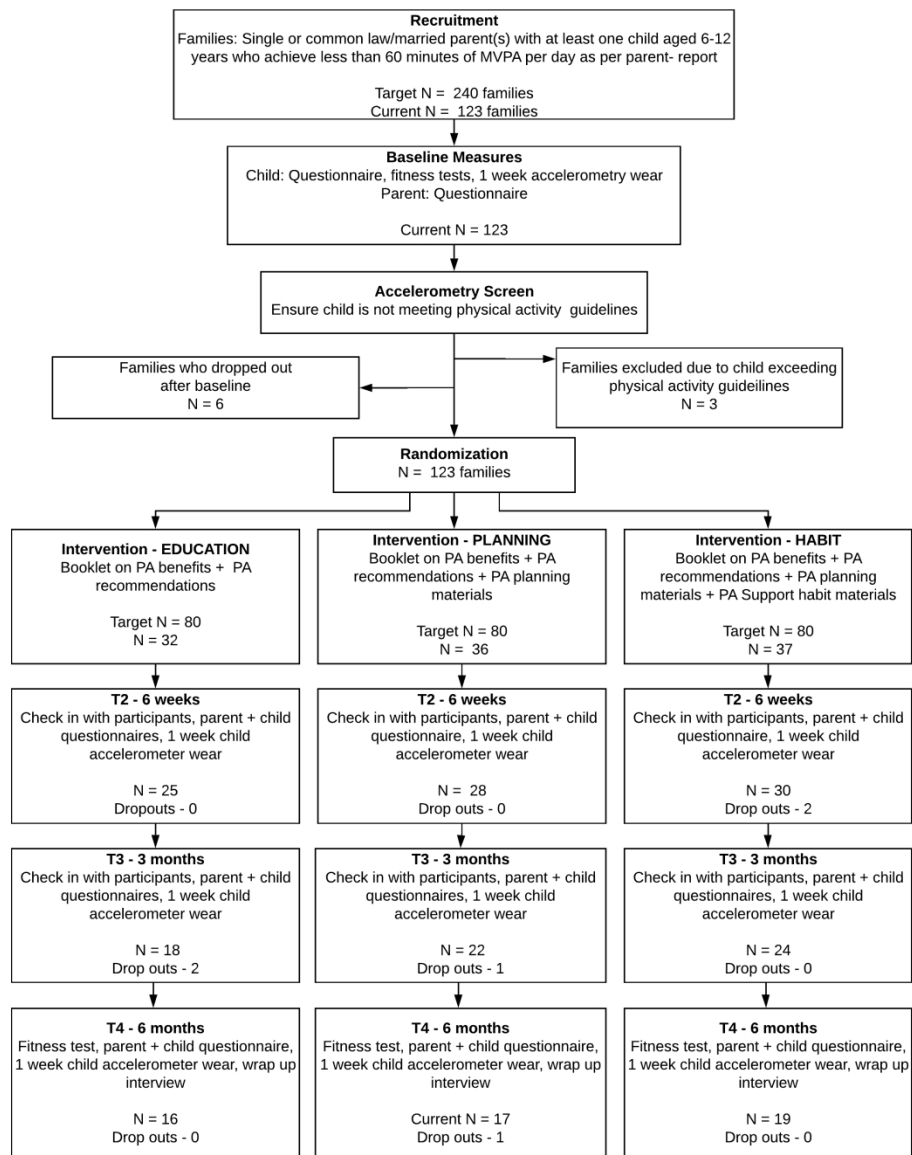


Figure 1. Study procedures and participant flow chart. PA = physical activity.

Appendix 1



CONSENT FORM - PARENTS

“Family physical activity study: A randomized controlled trial”

You are being asked to take part in a study titled “A Family Physical Activity Study”. We are inviting any parent(s) who currently have at least one child between the ages of 6 and 12 years, to participate in this study. **Specifically, we are seeking families in which at least one child is struggling to meet physical activity guidelines.** This study has been reviewed by the University of Victoria Ethics Committee and has met the rigorous requirements for ethical approval.

Although regular physical activity is essential for healthy development in children and numerous benefits of an active lifestyle have been reported, less than one third of Canadian children are meeting physical activity guidelines. Furthermore, children who are overweight as youth are twice as likely to remain overweight into adulthood. Child health is influenced by parental health practices; however, many parents have difficulty maintaining a regular physical activity program due to family obligations. As a result, the promotion of regular activity is paramount in alleviating the potential health implications that may arise for the entire family. We hope that you will help us learn more about factors influencing physical activity in families by participating in the study.

Purpose of this Project

In this study, we will be examining whether different strategies help to promote family-based physical activity.

What do I have to do to participate?

- 1) First we ask that you sign this consent form.
- 2) We will then conduct a **fitness test for your child** at the Behavioural Medicine Lab at the University of Victoria, on a date that is convenient for you.

The tests include blood pressure, body composition (height, weight, girth measurements), a Leger shuttle run test, some strength tests (grip strength, push ups, sit ups, plank test) and a sit & reach flexibility test. This will take approximately 45 minutes. Prior to conducting the fitness test we will administer a questionnaire to ensure that it is safe for your child to undergo fitness testing and partake in physical activity. (Physical Activity Readiness Questionnaire that is administered over the phone).

- 3) We will ask you to complete a **Baseline online questionnaire (should take approx. 20-30 minutes of your time)** while your child is doing their fitness test (**fitness test takes approx.. 1 hour**).

- 4) After the fitness test, we will send your child home with an accelerometer which we will ask him or her to wear for one week. We will ask your child to wear an accelerometer at **four times for seven consecutive days throughout the study**. We will also provide a logbook to write down some information about when your child put the accelerometer on and took it off, and what activities they were doing during the day. You will get the accelerometer information back at the end of the study.

- 5) Once the accelerometer has been worn for one week, we will contact you to pick up the accelerometer and accelerometer log book. At this time we will go through some materials to help increase your child's physical activity. You will be randomized to one of three conditions. Each condition is aimed at increasing

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 2

physical activity for your child but the materials differ. At the end of the study you will find out what the other conditions received for materials and have the option to receive these materials as well. The study materials will include information and strategies for how you can help increase the physical activity of your child. **This will take about 30 minutes to work through.** The materials are print copy and outline benefits of physical activity, information about activities, brainstorming about barriers and some other strategies for how to increase physical activity for your child. **We will ask you to keep and refer to these materials over the course of the study.**

6) **After six weeks**, we will contact you about a **second questionnaire** that we will email to you and ask your **child to wear an accelerometer for another week.** We will also provide an information ‘booster’ session and check in to see how things are going with your child’s physical activity.

7) **At 3 months’ time**, we will ask you to complete **another questionnaire online** and ask your child to **wear an accelerometer for a third time.**

8) **After 6 months**, we will set up a time for **final fitness testing at our lab for your child**, ask you to complete the **last questionnaire**, and ask your child to **wear accelerometers for one week.** At the end of the last week we will setup a time to pick up the accelerometer and **ask you a few wrap up interview questions which should take approximately ten minutes.** This will be tape recorded.

In the questionnaires, you will be asked about demographic information (such as ethnicity, employment and education), questions about your physical activity and your child’s physical activity, and some questions on quality of life. Your child will also be asked about their activities and a child-adapted quality of life scale.

Inconvenience, Risks, and Benefits

There are minimal risks associated with the study but it is **important for you to be aware that you may be asked about some sensitive topics such as demographic information (ethnicity, employment, health) or about your quality of life, or stress.** These questions can make some people uncomfortable and you do not have to answer them if you do not want to. Also your child will be asked about their activities and some questions about their life. **If these questions make your child uncomfortable they do not have to answer them.** You also may be inconvenienced by time to participate in the study. **Each questionnaire takes approximately 20-30 minutes to complete. Your child’s fitness test may take around 45 minutes each time to complete. The fitness test can make some kids nervous but our trained fitness testers are very careful and will not force your child to do anything they do not want to.** Your child will be shown all the tests and explained in detail what they require. These are standardized tests which are used with kids all across Canada. Any contraindication to exercise or fitness testing would come up through administration of the Physical Activity Readiness Questionnaire. If it is noted that there may be a contraindication to increasing yours or your child’s level of activity, then we will require medical screening prior to participation in the study and in the fitness testing.

The potential benefits of your participation in this research include increasing your child’s level of physical activity participation, which comes with associated health benefits. **Additionally you and your child will earn an honorarium after every assessment point increasing by \$5 at each time point (i.e. families will receive \$25 after the baseline assessment, \$30 after the 6-week assessment, \$35 after the 3 month assessment and \$40 after the 6 month assessment).** If you withdraw from the study you will be paid up to your completed measure (i.e. if you complete six weeks and then withdraw you will receive \$30). You will also get all of your child’s fitness testing and accelerometer information back at the end of the study. Furthermore, you will be providing much needed information on the current health behaviours of parents and their families and the barriers which prevent regular family physical activity involvement. This information will be very helpful to us in designing intervention programs catered to families. As well, if

PARENT SUPPORT HABIT FOR CHILD PHYSICAL ACTIVITY 3

requested, you can obtain feedback of the results of this study. The results of the study will be presented at scholarly meetings and published as an article in an academic journal.

Anonymity and Confidentiality

The information from the questionnaires, accelerometers, fitness tests, and interviews will be anonymous during data analysis and publication of study results. All data will be published as group data, and any data kept separate will be identified by ID-number (no name). We will need your contact information in order to provide you with materials and collect materials. However, we can assure you that your confidentiality will be completely protected and only the research team will have access to your contact information. In terms of protecting the confidentiality of your data, the data file and completed questionnaires will be kept in a locked and secure environment on the University of Victoria campus at all times. Only the investigators will have access to the data. The original questionnaires will be shredded after 5 years.

Do I have to participate?

No, your participation in this study is completely voluntary and you have the right to withdraw at any time without consequence. As well, if you choose to withdraw before the six-month follow up, it is up to you whether or not we use that data that we will have collected from you up until that point. It is only through voluntary participation in research projects that we increase our knowledge about issues that are important to health. If one family member chooses to withdraw, the rest of the family can complete the study. If your child decides they do not want to participate, you both may withdraw with no questions asked. If there is only one child participating and they wish to withdraw, the family will be removed from the study. If there are two children within the ages of 6-12 and one child wishes to withdraw but the other would like to remain, the family may continue on. If there is only one parent and they wish to withdraw they will be removed from the study. If there are two parents and only one wishes to withdraw the other family members can continue on. The participant who withdraws will be asked if their data can still be used in the study.

If you have any questions or concern about this study please do not hesitate to contact either Sandy Courtnall (Research Coordinator) or Dr. Ryan Rhodes (Primary Investigator). In addition, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria (250-472-4545 or ethics@uvic.ca).

Other co-investigators of the study:

Dr. Mark Beauchamp, Dr. Chris Blanchard, Dr. Valerie Carson, Dr. Benjamin Gardner, Dr. Darren Warburton

Your signature below indicates that you understand the above conditions of participation in this study, and that you have had the opportunity to have your questions answered by the researchers. Your signature indicates that you consent to both yourself participating in the study and your child to participate in the study.

<i>Name of Participant</i>	<i>Signature</i>	<i>Date</i>
Please sign one copy for the researchers and sign and keep one copy for your records		
Ryan E. Rhodes, Ph.D., Professor (250) 721-8384 rhodes@uvic.ca	Sandy Courtnall, Project Coordinator (250) 472-5288 scourtna@uvic.ca	



SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1___
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	___1___
	2b	All items from the World Health Organization Trial Registration Data Set	_37 (table 1)_
Protocol version	3	Date and version identifier	___2___
Funding	4	Sources and types of financial, material, and other support	___1___
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	___1___
	5b	Name and contact information for the trial sponsor	___1___
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	___1___
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	___n/a___

1 **Introduction**

2

3 Background and rationale 6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention _____ 4-6 _____

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6 6b Explanation for choice of comparators _____ 5-7 _____

7

8 Objectives 7 Specific objectives or hypotheses _____ 7-8 _____

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10 Trial design 8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory) _____ 8 _____

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14 **Methods: Participants, interventions, and outcomes**

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16 Study setting 9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained _____ 9-11 _____

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19 Eligibility criteria 10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) _____ 9-10 _____

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22 Interventions 11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered _____ 12-17 _____

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25 11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease) _____ 17 _____

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28 11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests) _____ 12 _____

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31 11d Relevant concomitant care and interventions that are permitted or prohibited during the trial _____ 11 _____

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34 Outcomes 12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended _____ 17-20 _____

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40 Participant timeline 13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) ___Figure 1_____

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1	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	___22___
2				
3				
4	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	___10-11___
5				

6 **Methods: Assignment of interventions (for controlled trials)**

7 Allocation:

8				
9				
10	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	___8___
11				
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16	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___8___
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20	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	___8, 10-12___
21				
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24	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	___8___
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27		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	___8___
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31 **Methods: Data collection, management, and analysis**

32				
33	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	___17-22___
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39		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	___12-13___
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1	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	___22-24___
2				
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4				
5	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___22-24___
6				
7				
8		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___22-24___
9				
10		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	___22-24___
11				
12				
13				
14	Methods: Monitoring			
15				
16	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	___23___
17				
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22		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	___23___
23				
24				
25	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___23___
26				
27				
28	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	___23___
29				
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32	Ethics and dissemination			
33				
34	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	___9___
35				
36				
37	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	___9___
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1	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____11_____
2				
3				
4		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____n/a_____
5				
6				
7	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____23_____
8				
9				
10	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____1_____
11				
12				
13	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____23_____
14				
15				
16	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____25_____
17				
18				
19				
20	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____25-26_____
21				
22				
23				
24		31b	Authorship eligibility guidelines and any intended use of professional writers	_____26_____
25				
26		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____25-26_____
27				
28				
29	Appendices			
30				
31	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____40-42_____
32				
33				
34	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____n/a_____
35				
36				

37 *It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items.
 38 Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons
 39 "[Attribution-NonCommercial-NoDerivs 3.0 Unported](https://creativecommons.org/licenses/by-nc-nd/3.0/)" license.
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