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Health and physical activity among children with intellectual disabilities

Submission date
06/01/2020

Recruitment status
No longer recruiting

Registration date
29/01/2020

Overall study status
Completed

Last Edited
13/12/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Physical activity can have tremendous benefits to a child's overall wellbeing. However, children's physical activity engagement and participation is quite low. Parents can play a key role in improving their child's level of physical activity. Research suggests that parental behaviors (e.g., encouragement, providing transportation, facilitating enrolment) are strong correlates of child physical activity. These findings are especially true among parents of children with intellectual disabilities. Messages targeting parents have been proposed as a strategy to increase parent support. Although persuasive messaging has been shown to positively influence parent support for physical activity among children without disabilities, there is limited research to guide the development of messages targeting parents of children with intellectual disabilities. Therefore, this study aimed to explore the effects of an online messaging intervention on physical activity support behaviours for parents of children with intellectual disabilities.

Who can participate?
Parents, legal guardians, or primary caregivers of a child, youth, or young adult with an intellectual disability (e.g., Down syndrome, fetal alcohol spectrum disorder, or cerebral palsy) or autism were eligible to participate. Additionally, participants must have been fluent in English and resided in Canada.

What does the study involve?
Participants were be randomly assigned to receive a newsletter containing varying combinations of risk information (demonstrating that children with intellectual disabilities are more likely to experience certain health issues) and gain- or loss-framed messages. Gain-framed messages highlight the benefits of engaging in physical activity whereas loss-framed messages highlight the risks of not participating. Online surveys were completed to examine changes in parents' physical activity support behaviours following message exposure.

What are the possible benefits and risks of participating?
No direct benefits were anticipated for the participants. Findings from this study have the potential to benefit the population of parents of children with intellectual disabilities more wholly. That is, information gained in this study will advance understanding of how to optimize messages to increase physical activity engagement among children with intellectual disabilities.

Further, to minimize the psychological and emotional distress experienced by participants due to the potentially stressful nature of the research questions, various provisions were put in place. Participants were able to opt-out of the study at any time, researchers monitored responses, and necessary supports were available should research questions lead to distress. Additionally, an information sheet of physical activity and support resources was accessible to participants.

Where is the study run from?
This study ran from York University (Canada). Participants were recruited through partnerships with community-based organizations (e.g., Special Olympics), social media advertisements, emails to participants from previous studies, and word of mouth. Due to the nature of the intervention, participants were not limited by their geographical location as questionnaires were completed online with SurveyMonkey.

When is the study starting and how long is it expected to run for?
July 2019 to December 2021

Who is funding the study?
York University (Canada)

Who is the main contact?
Rebecca Bassett-Gunter, rgunter@yorku.ca

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Physical activity support behaviours among parents of children with intellectual disabilities: Evaluating an online messaging intervention

Study objectives
Current study hypothesis as of 18/08/2023:

Due to conflicting findings in the existing literature and the novel implementation of this messaging approach among parents of children and youth with intellectual disabilities, a priori hypotheses were not generated regarding effects of the messaging intervention on message perceptions, extended parallel process model constructs, and parental support for physical activity.

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Previous study hypothesis:

We have not developed a priori hypothesis because of conflicting predictions. According to the Extended Parallel Process Model, we would hypothesize that the risk information + gain-framed messages would be most effective for increasing parent support behaviours. However, the congruency effect would suggest that risk information + loss-framed messages would be most effective. Previous research has resulted in mixed findings. Accordingly, we have not made an a priori hypothesis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 04/02/2020, York University Office of Research Ethics (Office of Research Ethics, 309 York Lanes, York University, 4700 Keele Street, North York, Ontario, M3J 1P3, Canada; +1 416 736 5914; ore@yorku.ca), ref: e2020-028

Study design
Current study design as of 18/08/2023:

A four (time) x three (risk) x three (frame) repeated measures experimental design was employed

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Previous study design:

The study will use a 5 (messaging condition) x 4 (time) experimental design

Primary study design

Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Current condition as of 18/08/2023:

Parents of children and youth with intellectual disabilities

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Previous condition:

Parents of children with intellectual disability

Interventions
Current interventions as of 18/08/2023:

In the screening stage, participants completed an eligibility assessment and a demographics questionnaire. Participants self-identified their children's primary disability in the eligibility assessment. Follow-up phone calls were performed to confirm eligibility. Eligible participants were assigned to one of five conditions: 1) risk information + gain-framed messages, 2) risk information + loss-framed messages, 3) no risk information + gain-framed messages, 4) no risk information + loss-framed messages, or 5) control. Assignment of participants to each condition was performed randomly and in a single-blind manner.

Next, participants completed a series of questionnaires to assess a variety of theoretical predictors of parent physical activity support behaviour and child physical activity participation. Participants completed a child characteristics questionnaire, followed by a baseline questionnaire measuring extended parallel process model constructs and parental support for physical activity. Participants then read an online newsletter that corresponded with their assigned condition. Immediately after reading the newsletter, participants completed follow-up questionnaire one. This questionnaire was similar to the baseline, with the addition of manipulation checks and measures pertaining to message perceptions. Two weeks following the baseline questionnaire, participants completed follow-up questionnaire two, which contained measures of extended parallel process model constructs and parental support for physical activity. Lastly, two months post-baseline, participants completed follow-up questionnaire three, which was identical to follow-up questionnaire two.

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Previous interventions:

Using a random numbers table, participants will be randomly assigned to one of five conditions: 1) no risk information + loss-framed messages, 2) no risk information + gain-framed messages, 3) risk information + loss-framed messages, 4) risk information + gain-framed messages, 5) control. Parents will receive information and PA messages unique to their condition.
Following randomization, participants will complete a series of questionnaires to assess a variety of theoretical predictors of parent physical activity support behaviour and child physical activity participation.
Each participant will receive then receive an e-newsletter specific to their condition.

Immediately after receiving the e-newsletter, participants will be asked to complete a follow-up questionnaire (FQ1)
Two weeks following the completion of FQ1, participants will receive a link to complete a second follow up questionnaire (FQ2)
Two months following the completion of the baseline questionnaire, participants will receive a link to complete the final follow up questionnaire (FQ3)

All questionnaires and messaging material will be administered online.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 18/08/2023:

Parental support behaviours assessed by parental responses to online questionnaires at baseline, immediately post-intervention, two weeks and two months

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Previous primary outcome measure:

Parental physical activity support behaviours assessed by parental responses to online questionnaires at baseline, immediately post-intervention, 2 weeks and 2 months

Key secondary outcome(s))
Current secondary outcome measures as of 18/08/2023:

1. Messaging manipulations measured immediately post-intervention
2. Message perceptions measured immediately post-intervention
3. Extended parallel process model constructs measured at baseline, immediately post-intervention, two weeks and two months

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Previous secondary outcome measures:

1. Feasibility of the experimental design through whether it is possible to randomize parents to particular conditions and to assess the potential effects of message exposure throughout the study and after data collection
2. Acceptability of the intervention assessed by parental responses to online questionnaires at baseline, immediately post-intervention, 2 weeks and 2 months
3. Participant retention measured by withdrawal from the study at 2 months

Completion date
01/12/2021

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/08/2023:

1. Parents, legal guardians, or primary caregivers of a child, youth, or young adult with an intellectual disability (e.g., Down syndrome, fetal alcohol spectrum disorder, or cerebral palsy) or autism
2. Fluency in English
3. Residence in Canada

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Previous inclusion criteria:

1. Primary guardian of a child(ren) with an intellectual disability (disabilities including but not limited to; Down syndrome, autism, and Fragile X syndrome)
2. Primary guardian of a child(ren) between 5 and 17 years
3. English as first or primary language

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
80

Key exclusion criteria
None

Date of first enrolment
01/05/2020

Date of final enrolment
01/12/2021

Locations

Countries of recruitment
Canada

Study participating centre
York University
4700 Keele St.
Toronto

Canada
M3J 1P3

Sponsor information

Organisation
York University Office of Research Ethics

Funder(s)

Funder type
University/education

Funder Name
York University (Canada)

Alternative Name(s)
York University (Toronto), Université York, York University | Toronto ON, YU, YorkU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Rebecca Bassett-Gunter (rgunter@yorku.ca)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V1.0	28/01/2020	05/02/2020	No	Yes
Participant information sheet	version 2.0		18/08/2023	No	Yes

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes