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The Impact of the COVID-19 Pandemic on Physical, Social and Emotional Well-Being in a Cohort of Children With Disabilities in the United States

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ABSTRACT

Background: The COVID-19 pandemic has affected the daily lives of all individuals. Research is limited in how children with disabilities (CWD) in the United States (U.S.) have been affected by the pandemic socially or emotionally, or if they are obtaining the recommended 60 min of daily physical activity.

Objective: Evaluate (a) the social, behavioural and psychological changes of CWD during the pandemic, (b) whether CWD are reaching the recommended 60 min of daily physical activity and (c) how the social vulnerability index (SVI) impacts these variables.

Methods: This study was a cross-sectional survey study of parents of CWD at two rehabilitation hospitals.

Results: A total of 118 surveys were completed. Child's mean age was 9.5 ± 5.1 years; 49 (41.5%) were female; 67 (56.9%) were male. Seventy-one (60.2%) respondents agreed the pandemic has negatively affected their child's well-being, and 83 (70.3%) cited their child is more socially isolated. All respondents cited behavioural changes in their child. Eighty-seven (73.7%) children are leaving the house less, with 31 (26.3%) children completing 60 min of daily physical activity. The main barrier was concern for COVID transmission ($n = 76$, 64.4%). There were no differences between SVI risk groups for access to therapy at school ($p = 0.56$), therapy outside of school ($p = 0.44$), medical follow-up ($p = 0.91$), access to psychological services ($p = 0.21$), amount of physical activity ($p = 0.41$), well-being ($p = 0.89$), or social isolation ($p = 0.85$).

Conclusions: The COVID-19 pandemic has negatively impacted the social, emotional, and physical well-being of CWD, with the majority not reaching daily physical activity recommendations.

1 | Introduction

The COVID-19 pandemic has affected major aspects of daily life for individuals globally [1–3]. With sheltering in place, people were forced to alter their daily activities, thus impacting their physical and emotional health. Many studies in adults have reported the COVID-19 pandemic's negative impacts on physical and emotional well-being, with an increase in depression, anxiety, suicide and insomnia, and a decrease in physical activity [4–7].

The impact of the pandemic on children, however, is of particular interest. COVID-19 not only impacts the physical health of

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Summary

- It is known that the COVID-19 pandemic has impacted children with disabilities and their access to healthcare.
- This paper adds to the literature by examining the social, psychological and physical behaviours of children with disabilities in the U.S. during the COVID-19 pandemic.

children, but the ramifications of sheltering in place can affect children's social and emotional growth. In France, the lockdown negatively affected the morale and behaviour of children and their social interactions with others [8], and in the United States (U.S.), an increase in depression and anxiety was observed [9]. Furthermore, during the pandemic, many gyms and physical therapy offices ceased operations, forcing children to find unique ways to engage in physical activities. Although many children before the pandemic were not reaching daily physical activity recommendations, with studies finding anywhere from 4% to 40% [10], these numbers decreased to about 10% in European children during the height of the COVID pandemic [11].

Although research has emphasised the impact of the COVID-19 pandemic on children, minimal studies have examined the impact on children with disabilities (CWD). International studies have described increasing irritability [12], exacerbation of symptoms related to autism [13], and less physical activity for CWD during the pandemic [8, 11, 12, 14]. No studies have evaluated the full impact of COVID-19 on the social, mental and physical well-being of CWD in the U.S. Furthermore, no studies have examined if CWD in the U.S. are reaching the World Health Organization's (WHO) recommended 60 min of daily physical activity during the pandemic [15].

The objective of this study was to examine the social, psychological and physical behaviours of CWD in the U.S. during the COVID-19 pandemic by surveying parents. We specifically aimed to (a) describe the social, behavioural and psychological changes CWD experienced during the pandemic, (b) evaluate whether CWD were reaching the recommended 60 min of daily physical activity, (c) investigate barriers to pursuing this level of physical activity and (d) examine how the social vulnerability index (SVI) impacted these variables. We hypothesised that during the pandemic, CWD are experiencing more social isolation and behaviour changes, they are not reaching daily physical activity recommendations, and parents' concern for COVID-19 transmission is a predominant barrier. Furthermore, we hypothesised that those living in higher SVI areas had limited access to medical care and were exercising less than their low SVI area peers.

2 | Methods

2.1 | Ethical and Regulatory Considerations

This was a cross-sectional survey study approved by the Northwestern University Institutional Review Board (STU00215165). Surveys were administered through RedCap between October 21, 2021 and May 1, 2022. Informed consent was obtained.

2.2 | Inclusion Criteria

Participants were included in this study if they were the parent of a child being seen for outpatient therapy or for an appointment with an outpatient paediatric physiatrist, between the dates of October 21, 2021 and May 1, 2022.

2.3 | Exclusion Criteria

Participants were excluded from this study if they were unable to read in English or Spanish.

2.4 | Sample Size

Sample size was determined by the number of parents with children who presented to the clinic during the above dates.

2.5 | Participant Survey

The goal of the survey was to evaluate the parent's perception of the pandemic's social, psychological and physical impact on their child with a disability. An individual parent gave informed consent prior to completing the survey. The survey consisted of 38 questions and was administered in English or Spanish. Most questions had closed answers, either binary (yes/no) or multiple choice. A few questions were open-ended. To view the full survey, please see Appendices 1 and 2. The survey consisted of five sections related to the child:

1. Demographics
2. School
3. Medical visits and therapy
4. Emotional health
5. Physical activity

2.6 | Dissemination Strategy

The survey was disseminated in paediatric rehabilitation outpatient medical clinic offices and therapy clinics (physical therapy, occupational therapy and speech therapy) at two large freestanding rehabilitation hospitals in a large metropolitan city.

2.7 | Statistical Analysis

Parent-reported data was compiled and compared against daily physical activity recommendations and social vulnerability indices to conduct an overall assessment of the effect of the COVID-19 pandemic on physical activity and therapy programmes. There was no missing data. For certain analyses, the respondents were divided into three functional groups: (1)

wheelchair users, (2) users of other ambulatory devices (walker, frame, crutches, sticks) or independent on level surfaces and (3) independent ambulators on all surfaces. For other analyses, respondents were split into two groups: cerebral palsy and all other diagnoses.

All analyses were performed using SAS 9.4. Data were analysed based on the type of variables. Continuous variables were reported using mean and standard deviation with 95% confidence intervals, whereas categorical variables were reported using frequencies (*n*) and percentages. To find the association between categorical variables, chi squared analysis was performed, and *p* values were reported.

SVI was calculated using the Center for Disease Control and Prevention's (CDC) website. The SVI uses 16 U.S. census variables to help local officials identify certain communities that may need additional support in the face of disasters. Prior research supports the use of this tool in the context of the present study and is suitable for research on the paediatric population [16, 17]. Each parent's zip code was entered into the CDC database to determine the SVI. The SVI values range from 0 to 1, with 0 being the lowest SVI and 1 being the highest SVI. For statistical analysis, the SVIs were arbitrarily split into three groups: low (0–0.33), medium (0.34–0.66) and high (0.67–1.0) risk. Secondary analyses were performed to assess the impact of SVI risk on well-being and access to care using either the non-parametric Wilcoxon–Mann–Whitney test or Kruskal–Wallis test, as the underlying distribution was not normal.

Secondary analyses were also performed to assess the impact of functional level on access to care and the impact of diagnosis on well-being. These analyses were performed using either the non-parametric Wilcoxon–Mann–Whitney test or the Kruskal–Wallis test, due to non-normal distribution.

3 | Results

3.1 | Demographics

A total of 118 individuals completed the survey. Demographic information can be found in Table 1. The mean SVI was 0.50 ± 0.30 (95% CI: 0.0037, 0.9941 and median being 0.4504).

3.2 | School

Sixty-one (51.7%) children were attending school in person, and 57 (48.3%) were attending virtually at the end of the 2020–2021 academic year. Eighty-four (71.2%) children were attending school virtually for a period of time (Figure 1).

3.3 | Medical Visits and Therapy

Eighty-eight (74.6%) children received therapy services during the pandemic, and 66 (55.9%) received therapy at school. All respondents were receiving therapy outside of school. 105 (89.0%) received medical follow-up, with 78 (75.0%) respondents citing these appointments were in-person (Figure 1).

3.4 | Emotional Health

Seventy-one (60.2%) respondents agreed or strongly agreed that the pandemic has negatively affected their child's physical/emotional well-being, and 83 (70.3%) cited their child is more socially isolated during the pandemic than before the pandemic (Figure 1). All respondents cited behavioural changes in their child during the pandemic (Table 2). Fifty-eight (49.2%) cited more than one behavioural change in their child. Seventy-eight (66.1%) respondents reported no access to paediatric psychological services (Figure 1).

3.5 | Physical Activity

Seventeen (14.4%) parents were concerned about their child's weight gain during the pandemic. Eighty-seven (73.7%) children were leaving the house less during the pandemic than before the pandemic (Figure 1). Thirty-one (26.3%) children were doing 60 min or more of physical activity daily (Figure 2). The main barrier to physical activity was concern for COVID transmission ($n = 76$, 64.4%) (Table 3). If physical activity programmes were available during the pandemic, 92 (78.0%) parents said they would like their child to participate (Figure 1).

4 | Secondary Analyses

4.1 | Impact of SVI Risk on Well-Being and Access to Care

There were no differences between SVI risk groups for access to therapy at school ($p = 0.56$), therapy outside of school ($p = 0.44$), medical follow-up ($p = 0.91$), or access to psychological services ($p = 0.21$). SVI risk also did not correlate with the amount of physical activity ($p = 0.41$). Finally, the results of the Kruskal–Wallis test suggest that SVI risk did not correlate to well-being ($p = 0.89$) or social isolation ($p = 0.85$).

4.2 | Impact of Functional Level on Access to Care

Functional level (wheelchair user, independent on all surfaces in all environments, or other [cane, walker, sticks, or independent on flat surfaces]) did not affect participation in therapies ($p = 0.081$) or medical follow-up ($p = 0.34$). Functional level affected therapy at school, with wheelchair users and others receiving more therapies than those who were independent on all surfaces ($p = 0.0021$). All functional groups had a similar number of behavioural changes ($p = 0.96$), access to psychological services ($p = 0.15$) and amount of physical activity ($p = 0.64$).

4.3 | Impact of Diagnosis on Well-Being

Diagnosis of cerebral palsy versus all other diagnoses did not impact the amount of social isolation ($p = 0.66$) or the well-being of children ($p = 0.16$). Children with CP were not more likely to reach daily recommendations when compared to all other diagnoses ($p = 0.055$).

TABLE 1 | Characteristics of children whose parents completed the survey.

Demographic information	N (%)
Age	Mean = 9.5 ± 5.1 years, range = 10 months–18 years
0–4 years	27 (23.1)
5–8 years	31 (26.5)
9–13 years	26 (22.2)
14+ years	33 (28.2)
Gender	
Female	49 (41.5)
Male	67 (56.9)
Prefer not to answer	2 (1.7)
Language spoken at home	
Assyrian	1 (0.9)
Chinese	1 (0.9)
English	94 (79.7)
English/Spanish	3 (2.5)
Nepali	1 (0.9)
Spanish	16 (13.6)
Ukraine	1 (0.9)
Urdu	1 (0.9)
Diagnosis	
Cerebral palsy	44 (37.3)
Neuromuscular	3 (2.5)
Orthopaedic injury	2 (1.7)
Neurologic lesion	13 (11.0)
Genetic disease	11 (9.3)
Other[a]	45 (38.1)
Home functioning	
Wheelchair	34 (28.8)
Walker or frame	3 (3.4)
Crutches	1 (0.9)
Sticks (one or two)	4 (3.4)
Independent on level surfaces	17 (14.4)
Independent on all surfaces	58 (49.2)
School functioning	
Wheelchair	36 (30.5)
Walker or frame	9 (7.63)
Crutches	1 (0.9)
Sticks (one or two)	3 (2.5)
Independent on level surfaces	12 (10.2)
Independent on all surfaces	57 (48.3)
Mall functioning	
Wheelchair	42 (35.6)
Walker or frame	4 (3.4)
Crutches	2 (1.7)
Sticks (one or two)	3 (2.5)
Independent on level surfaces	13 (11.0)
Independent on all surfaces	54 (45.8)
Number of other children at home	
0	40 (33.9)
1	34 (28.8
2	31 (26.3)
3	8 (6.8)
4	4 (3.4)
5	1 (0.9)
SVI	Mean = 0.50 ± 0.30 (95% CI: 0.0037, 0.9941), median = 0.4504
Low = 0.00–0.33	41 (34.7)
Medium = 0.34–0.66	31 (26.3)
High = 0.67–1.00	46 (39.0)

Abbreviation: SVI, social vulnerability index.

[a] Free-text responses for 'other': autism, speech delays, stroke, cancer, hypotonia, postural orthostatic tachycardia syndrome, complex regional pain syndrome, attention deficit hyperactivity syndrome, Down syndrome and functional neurologic disorder.

5 | Discussion

The study objective was to evaluate the impact of the COVID-19 pandemic on the social, mental and physical well-being of CWD in the U.S. by surveying parents. Our results showed the pandemic negatively impacted CWD's well-being, with parents citing more social isolation and behavioural changes, and most children not reaching daily physical activity recommendations. Our hypothesis that the pandemic has led to increased social isolation and behavioural changes, with many children not reaching daily physical activity recommendations, was therefore supported.

Our results from the U.S. agree with international studies. Studies of Australian children with neurodevelopmental disorders have found children are more irritable since the COVID-19 outbreak, and children with autism in Germany and Austria have displayed exacerbation of symptoms [12, 13]. Such results

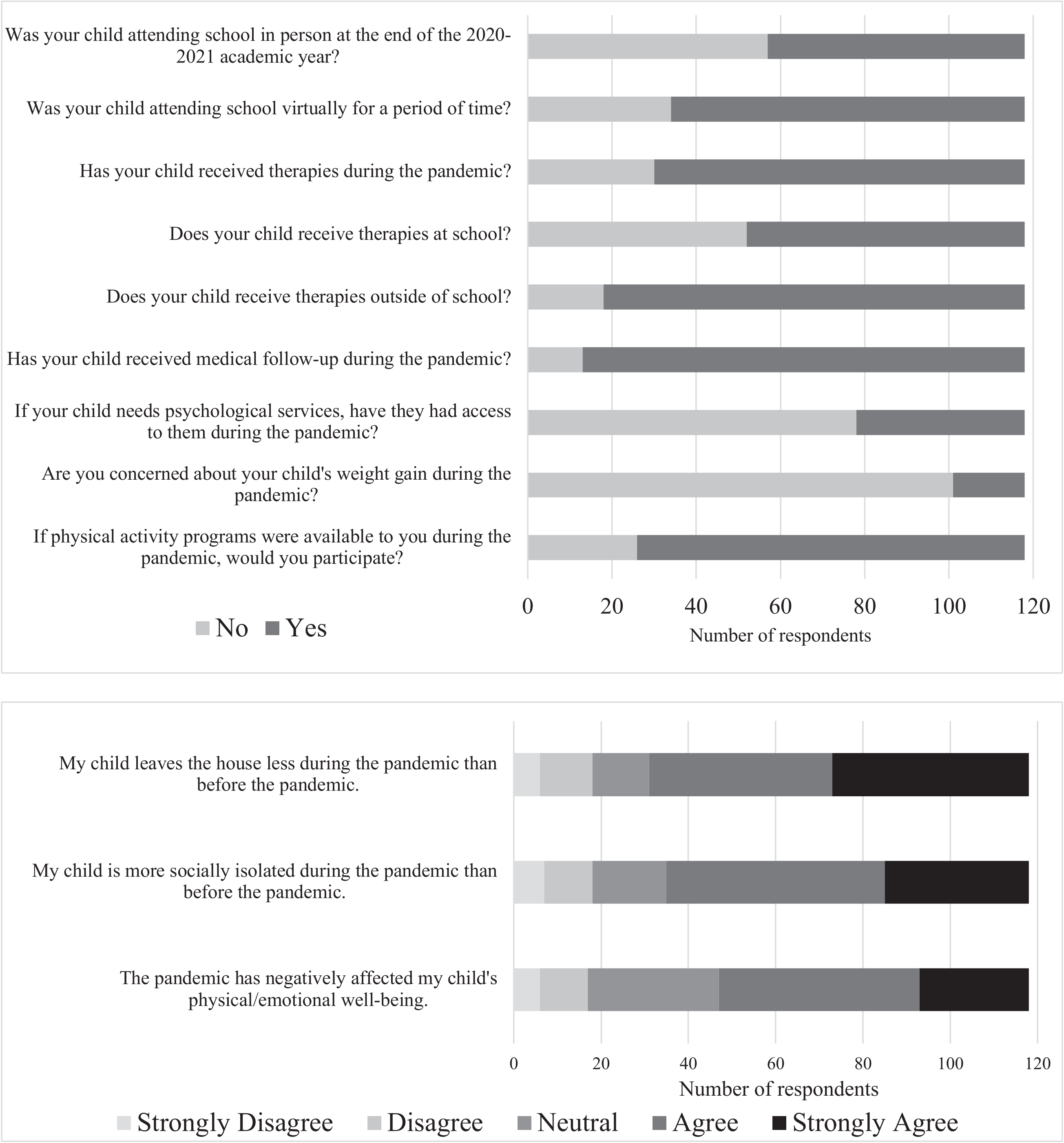

FIGURE 1 | Survey responses.

indicate the intersectional impact of the pandemic, visible in behavioural and social changes.

In addition to social and behavioural health, the physical health of CWD has also been impacted by the pandemic. Our results showed most children are leaving the house less during the pandemic and are not completing 60 min of daily physical activity. These findings agree with international studies. In France, 44% of children stopped all physical activities during the pandemic [8], and in the UK, 61% of children have shown a decrease in activity [14]. Interestingly, before the pandemic, only 23% of adolescents in the U.S. *without* disabilities, and 8%–40% of adolescents *with* disabilities in Europe were reaching the recommendations [18, 19]. Without pre-pandemic data for our study population, it is difficult to draw conclusions on whether their physical activity levels have changed. The fact that children in our study are leaving the house less during the pandemic suggests they are likely engaging in less physical activity. Additionally, the present data confirmed that concern regarding COVID-19 transmission was the largest barrier to children participating in more physical activity during the pandemic. Multiple qualitative studies in able-bodied adults and adolescents have confirmed concern for COVID-19 transmission as a barrier to physical activity [20–22]. However, no studies to date have quantified these barriers nor looked at concern for COVID-19

TABLE 2 | Parents' report of behavioural changes seen in their child during the pandemic.

Behavioural change	*N* (%)
Sleeping problems	33 (28.0)
Changes in appetite	21 (17.8)
Agitation	28 (23.7)
Anger	15 (12.7)
Regression	23 (19.5)
Sadness	32 (27.1)
Low energy	33 (28.0)
Lack of concentration	32 (27.1)
Worsening or new pain	9 (7.6)
Fidgeting and anxiety	34 (28.8)
Other[a]	34 (28.8)

[a] Free-text responses for 'other': pulling hair, biting for attention and increased shyness.

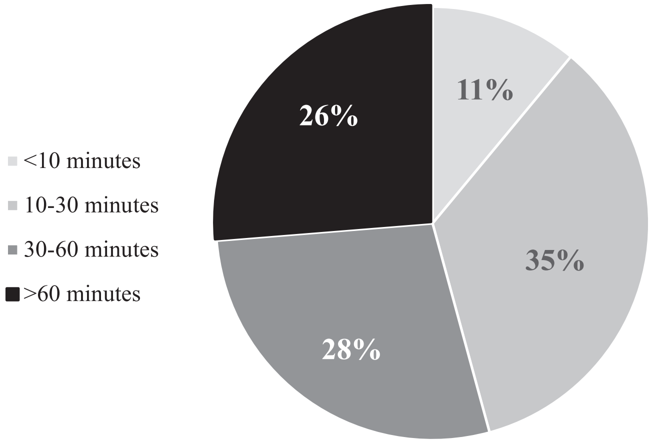

FIGURE 2 | Parents' report of how much daily physical activity their child was participating in during the pandemic.

TABLE 3 | Parental report of barriers affecting their child's access to physical activity.

Barrier	*N* (%)
Childcare	13 (11.0)
Concern for COVID transmission	76 (64.4)
Financial reasons	23 (19.5)
Transportation to physical activity	19 (16.1)
Other[a]	26 (22.0)

Note: Parents were able to select multiple answers.
[a] Free text responses for 'other': pain, fear and closed facilities.

transmission in a population with disabilities. Their concerns may be driven by the fact that people with disabilities have an increased risk of mortality from COVID-19 [23]. Due to this concern, in addition to access issues for CWD even before the pandemic [24], the findings of the present study support the need for virtual options for children that may be more accessible both with and without a lockdown in place.

Our secondary analyses included using the SVI risk tool, which utilises U.S. Census data to determine the social vulnerability of geographical areas to allocate resources during emergencies. Many factors contribute to an area's SVI risk, including poverty, access to medical care, vehicle access and crowded housing [25]. Our results indicate SVI risk did not correlate to access to care, amount of physical activity, well-being, or social isolation, thus disproving our hypothesis. To our knowledge, no studies to date have utilised the SVI risk tool to assess its correlation with mental and physical health during the pandemic. Although the SVI risk tool is a way to estimate risk based on geographical area, it is unable to assess each patient's *individual* risk. Certain patients living in a higher SVI risk area may not possess the same risk as the average individual in their geographical area. All patients in the present study had access to basic rehabilitation medical care, so even those living in higher SVI risk areas may have been lower SVI risk than the average individual in their geographical area. It is likely our study population does not represent the full spectrum of CWD of all SVI risks.

We anticipate the results of this study will provide pivotal insight into the challenges CWD and their parents have faced during the pandemic, allowing for inclusive planning for disabled populations during times of crisis. Studies conducted during the pandemic have examined a possible role for video games involving some level of activity and low-cost virtual reality as options for physical activity during the pandemic [26]. Future studies should examine the specific role of virtual physical fitness options for CWD while also searching for ways for children to maximise social interaction during a lockdown.

6 | Limitations

This study had a few notable limitations. This survey was given to parents and therefore represents the parent's perception of the pandemic on their children. There was also a selection bias, as our population was already receiving medical care (i.e., outpatient physical, occupational, or speech therapy, or visit with a physiatrist). We recognise there is a larger population of CWDs with limited access to medical care who we were unable to target with our survey. Additionally, there was a lack of pre-pandemic data with which to compare our patient population. We were therefore relying on a parent's recollection of their child prior to the pandemic, which can lead to recall bias. The study is also limited as no comparison is made to a cohort of non-disabled children; however, multiple prior studies have found significant impact on these children [8, 9, 11]. At last, this survey study was conducted partly during the winter season when outdoor physical activity options were limited.

7 | Conclusions

Overall, in our cohort of CWDs, the social, emotional and physical well-being of CWD has been negatively impacted by the

COVID-19 pandemic. The majority of these children are not reaching the recommended 60 min of daily physical activity during the pandemic. COVID transmission was cited as the main barrier to physical activity engagement. These findings support the need for virtual options or other novel strategies for children to optimise social interactions and physical activity during periods of mandated pandemic risk mitigation in particular. In addition, further assessment should be made of the impact of mitigation strategies and physical activity limitations during the pandemic on the longer term clinical and mental health outcomes of CWD.

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Disclosure

The authors have nothing to report.

Ethics Statement

This research involves human participants and was approved by the Institution Review Board.

Consent

All participants signed informed consent forms.

Conflicts of Interest

The authors declare no conflicts of interest.

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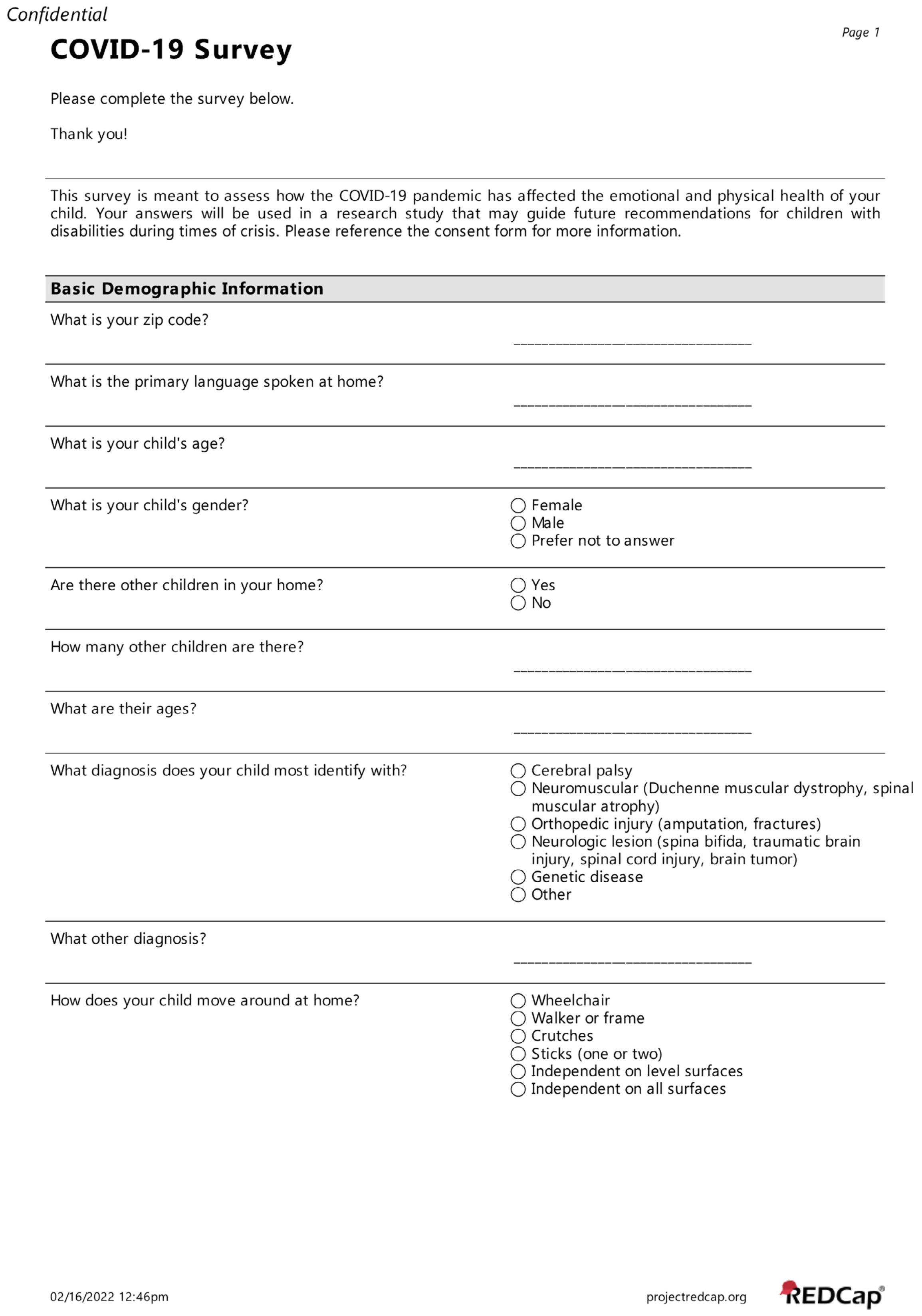
Appendix 1

COVID-19 Survey Administered to Study Participants



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Page 1

COVID-19 Survey

Please complete the survey below.

Thank you!

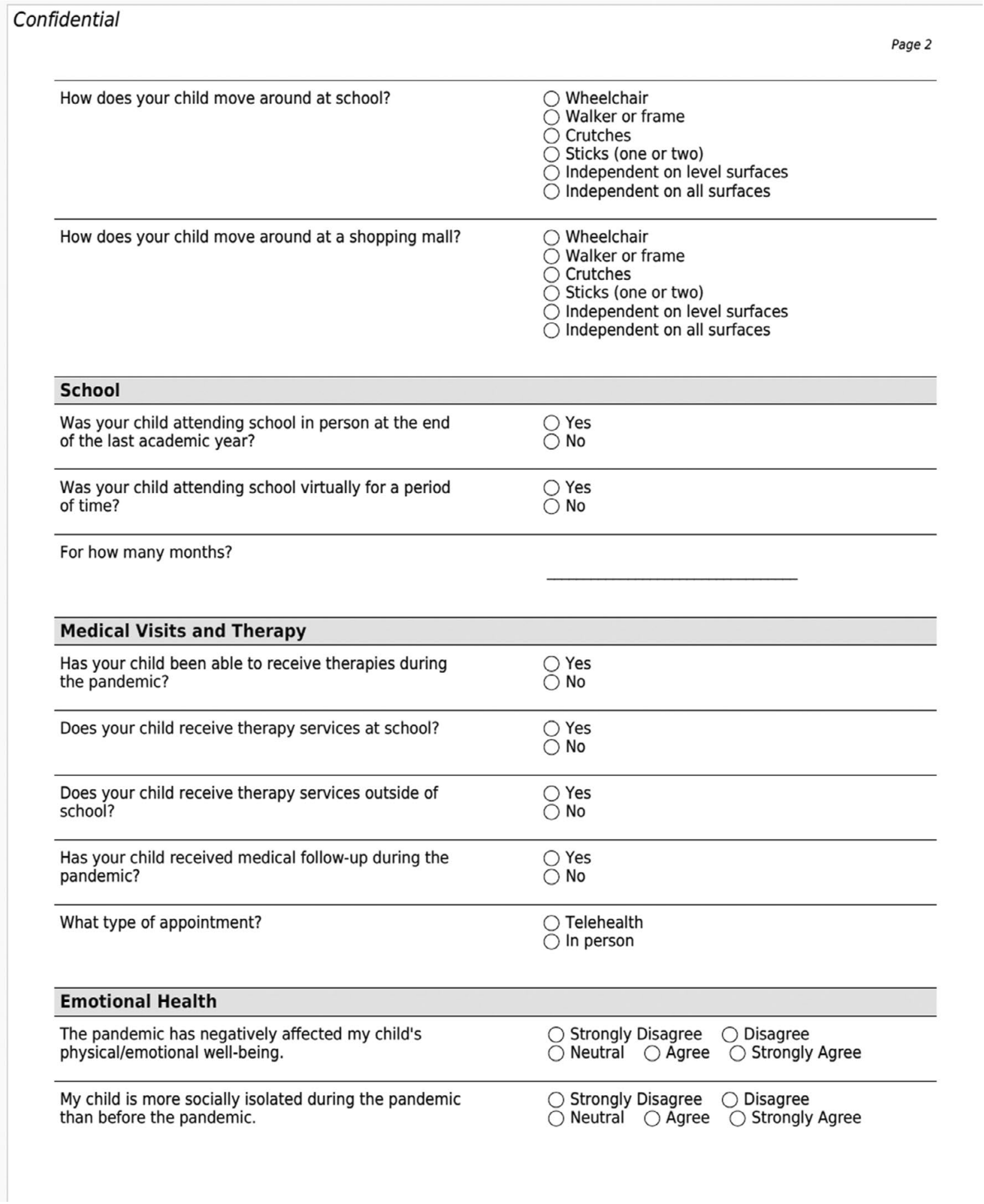
This survey is meant to assess how the COVID-19 pandemic has affected the emotional and physical health of your child. Your answers will be used in a research study that may guide future recommendations for children with disabilities during times of crisis. Please reference the consent form for more information.

Basic Demographic Information

What is your zip code?	________________________________
What is the primary language spoken at home?	________________________________
What is your child's age?	________________________________
What is your child's gender?	○ Female ○ Male ○ Prefer not to answer
Are there other children in your home?	○ Yes ○ No
How many other children are there?	________________________________
What are their ages?	________________________________
What diagnosis does your child most identify with?	○ Cerebral palsy ○ Neuromuscular (Duchenne muscular dystrophy, spinal muscular atrophy) ○ Orthopedic injury (amputation, fractures) ○ Neurologic lesion (spina bifida, traumatic brain injury, spinal cord injury, brain tumor) ○ Genetic disease ○ Other
What other diagnosis?	________________________________
How does your child move around at home?	○ Wheelchair ○ Walker or frame ○ Crutches ○ Sticks (one or two) ○ Independent on level surfaces ○ Independent on all surfaces

02/16/2022 12:46pm

projectredcap.org REDCap®



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Page 2

How does your child move around at school?	○ Wheelchair ○ Walker or frame ○ Crutches ○ Sticks (one or two) ○ Independent on level surfaces ○ Independent on all surfaces
How does your child move around at a shopping mall?	○ Wheelchair ○ Walker or frame ○ Crutches ○ Sticks (one or two) ○ Independent on level surfaces ○ Independent on all surfaces

School

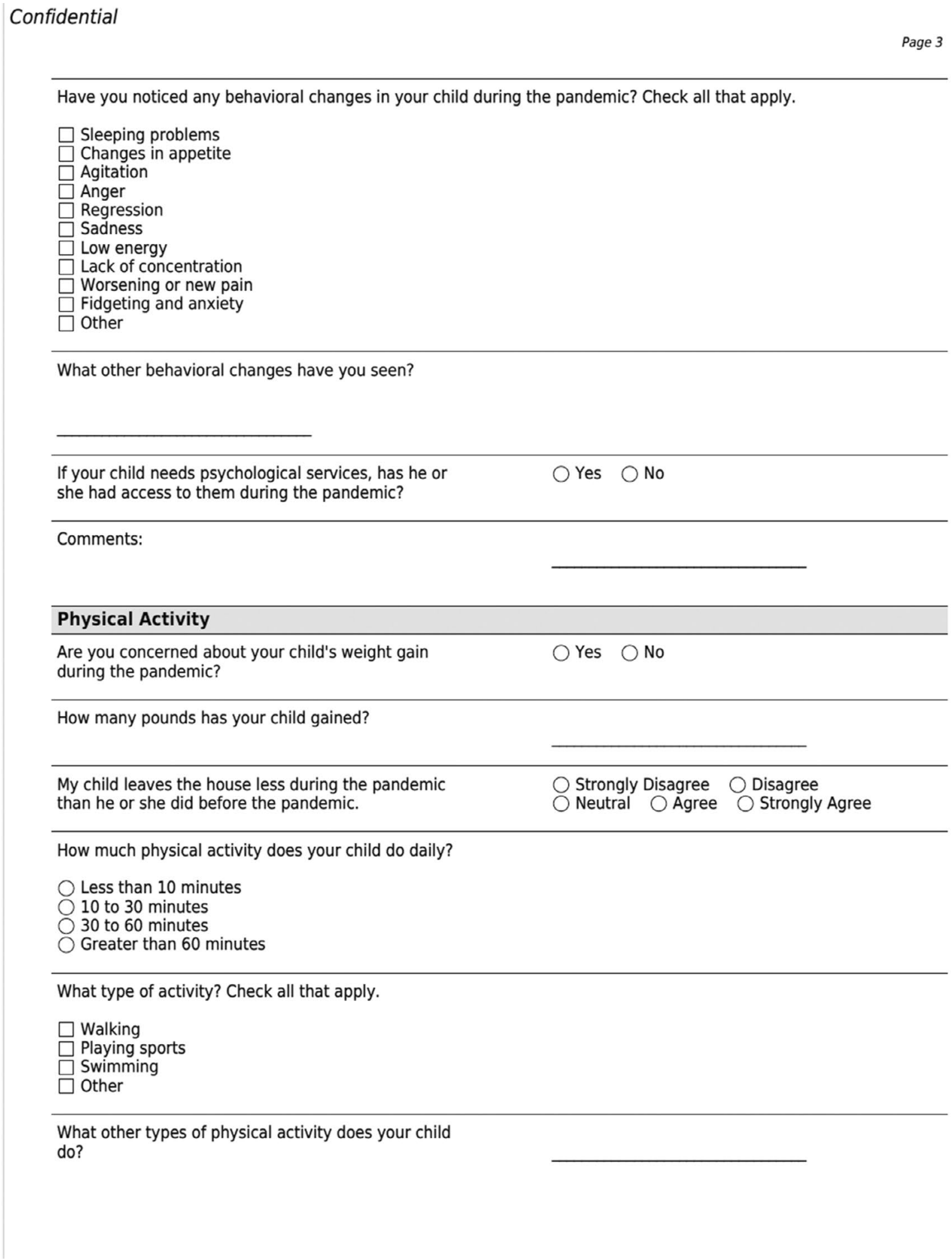
Was your child attending school in person at the end of the last academic year?	○ Yes ○ No
Was your child attending school virtually for a period of time?	○ Yes ○ No
For how many months?	______________________________

Medical Visits and Therapy

Has your child been able to receive therapies during the pandemic?	○ Yes ○ No
Does your child receive therapy services at school?	○ Yes ○ No
Does your child receive therapy services outside of school?	○ Yes ○ No
Has your child received medical follow-up during the pandemic?	○ Yes ○ No
What type of appointment?	○ Telehealth ○ In person

Emotional Health

The pandemic has negatively affected my child's physical/emotional well-being.	○ Strongly Disagree ○ Disagree ○ Neutral ○ Agree ○ Strongly Agree
My child is more socially isolated during the pandemic than before the pandemic.	○ Strongly Disagree ○ Disagree ○ Neutral ○ Agree ○ Strongly Agree



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Page 3

Have you noticed any behavioral changes in your child during the pandemic? Check all that apply.

☐ Sleeping problems
☐ Changes in appetite
☐ Agitation
☐ Anger
☐ Regression
☐ Sadness
☐ Low energy
☐ Lack of concentration
☐ Worsening or new pain
☐ Fidgeting and anxiety
☐ Other

What other behavioral changes have you seen?

____

If your child needs psychological services, has he or she had access to them during the pandemic? ○ Yes ○ No

Comments: __________________________________

Physical Activity

Are you concerned about your child's weight gain during the pandemic? ○ Yes ○ No

How many pounds has your child gained? __________________________________

My child leaves the house less during the pandemic than he or she did before the pandemic. ○ Strongly Disagree ○ Disagree ○ Neutral ○ Agree ○ Strongly Agree

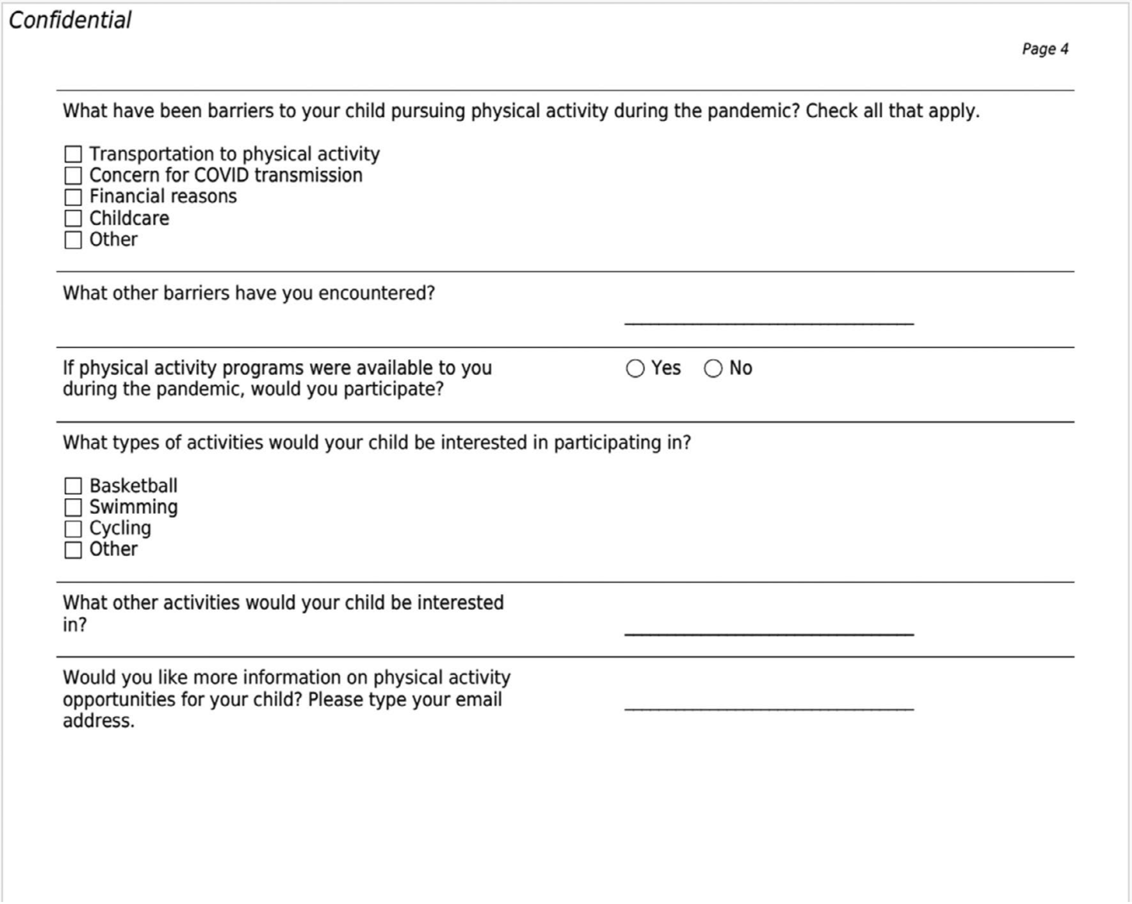
How much physical activity does your child do daily?

○ Less than 10 minutes
○ 10 to 30 minutes
○ 30 to 60 minutes
○ Greater than 60 minutes

What type of activity? Check all that apply.

☐ Walking
☐ Playing sports
☐ Swimming
☐ Other

What other types of physical activity does your child do? __________________________________



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Page 4

What have been barriers to your child pursuing physical activity during the pandemic? Check all that apply.

☐ Transportation to physical activity
☐ Concern for COVID transmission
☐ Financial reasons
☐ Childcare
☐ Other

What other barriers have you encountered? ________________________________

If physical activity programs were available to you during the pandemic, would you participate? ○ Yes ○ No

What types of activities would your child be interested in participating in?

☐ Basketball
☐ Swimming
☐ Cycling
☐ Other

What other activities would your child be interested in? ________________________________

Would you like more information on physical activity opportunities for your child? Please type your email address. ________________________________

Appendix 2

STROBE Statement—Checklist of Items That Should Be Included in Reports of Cross-Sectional Studies

	Item no.	Recommendation	Page no.
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2–3
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	4–5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up and data collection	4–5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	4

	Item no.	Recommendation	Page no.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5*
Bias	9	Describe any efforts to address potential sources of bias	11
Study size	10	Explain how the study size was arrived at	4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5–6
		(b) Describe any methods used to examine subgroups and interactions	5–6
		(c) Explain how missing data were addressed	5
		(d) If applicable, describe analytical methods taking account of sampling strategy	n/a
		(e) Describe any sensitivity analyses	5–6
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—for example, numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders	7
		(b) Indicate number of participants with missing data for each variable of interest	n/a
Outcome data	15*	Report numbers of outcome events or summary measures	7–8
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7–8
		(b) Report category boundaries when continuous variables were categorized	7–8
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—for example, analyses of subgroups and interactions, and sensitivity analyses	7–8

	Item no.	Recommendation	Page no.
Discussion			
Key results	18	Summarise key results with reference to study objectives	9–10
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11–12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	9–11
Generalisability	21	Discuss the generalisability (external validity) of the study results	11
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	n/a

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of *PLoS Medicine* at http://www.plosmedicine.org/, *Annals of Internal Medicine* at http://www.annals.org/, and *Epidemiology* at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

*Give information separately for exposed and unexposed groups.