

Improving physical activity in children with autism and their parents

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		<input type="checkbox"/> Protocol
Registration date 19/08/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 29/08/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Participation in regular physical activity is a critical component of overall well-being. However, opportunities for families who have a child on the autism spectrum to engage in health enhancing physical activity are relatively obsolete. A virtual physical activity intervention has the potential to address many participation barriers, and represents a timely opportunity to promote positive trajectories of physical activity among vulnerable populations.

The first objective of this study is to examine PA trajectories during a yearlong virtual PA intervention for children on the autism spectrum and their primary caregiver.

The secondary objective is to explore relationships in PA participation between caregiver and child dyads (pairs).

Who can participate?

Children on the autism spectrum and their primary caregiver can participate in this one-year virtual intervention. Participants have to reside within the city limits of the Midwestern large and urban city where the study took place.

What does the study involve?

Multiple virtual physical activity participation sessions for children on the autism spectrum and their caregivers over a 12-month period.

What are the possible benefits and risks of participating?

Benefits: Improved health

Risks: No known risks

Where is the study run from?

Wayne State University (USA)

When is the study starting and how long is it expected to run for?

December 2020 to March 2023

Who is funding the study?

Michigan Health Endowment Fund (USA); Grant number G-2004-146232

Who is the main contact?

Dr Leah Ketcheson, leah.ketcheson@wayne.edu

Contact information

Type(s)

Principal investigator

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 Literacy And Nutrition Education: Trajectories of physical activity among children on the autism spectrum and their caregivers: Outcomes of a virtual 1-year longitudinal intervention

Acronym

PLANE

Study objectives

1. Children who participate in PLANE will increase their physical activity participation throughout the year long intervention.
2. Parents of children who participated in PLANE will increase their PA participation throughout the year long intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 08/09/2020, Wayne State University Institutional Review Board (87 Canfield Street, 2nd Floor, Detroit, MI 48201, USA; +1 313-577-1628; IRBquestions@wayne.edu), ref: 20-05-2245

Study design

Single center interventional non-randomized longitudinal study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Health promotion for children on the autism spectrum as well as their primary careprovider

Interventions

All participating families were enrolled in a virtual format of the longitudinal Physical Literacy and Nutrition Education (PLANE) intervention (see framework: Ketcheson & Pitchford, 2021). Families were enrolled in the program and then were sent a Qualtrics link with directions to complete baseline measures. Within one week of online link completion, families were instructed to come to a designated location on the university campus for an opportunity to pick up their PA intervention equipment. Physical activity intervention materials for children included sports equipment meant to promote physical literacy including a variety of sports balls, baseball bat and tee, hockey stick, jump rope, hula hoop, small weights, and resistance bands. Caregiver supplies included equipment meant to promote general fitness such as balance and yoga balls, weight bars, core sliders, weighted medicine ball, dumbbells, and loop bands. All equipment was received by contactless delivery to the participant's vehicle trunk. . While a complete review of intervention components can be found in Ketcheson & Pitchford 2021, a brief outline will be shared below. With exception to the goal-setting survey that was administered every week, all other online evaluation measures administered at pre-intervention (baseline) were administered again at four-, eight-, and twelve months.

PA Intervention - Child

For children on the autism spectrum, three separate groups were created. The youngest group age range included children between 2 - 5, the middle group were between 6 –12 years, and the oldest group were between 13 – 18 years. All PA sessions were designed to simultaneously help participants acquire physical literacy skills and contribute to meeting PAG recommendations (2018). For example, the youngest group focused on activities to promote fundamental motor skills (e.g., hopping, kicking, running), the middle group focused on team sports (e.g., hockey, basketball, baseball), while the oldest group focused on promoting physical fitness (e.g., muscular strength and endurance activities). Each group met in synchronous weekly sessions with a consistent lead coach who delivered the intervention for the duration of the year. All coaches had certified credentials as behavioral analysts with ample prior experience coaching disability sport or adapted physical activity. In addition to the weekly zoom session, all children were provided with weekly asynchronous material, including an interactive online worksheet with additional resources to practice skills and engage in physical activities.

PA Intervention - Caregiver

Caregivers were encouraged to participate in the synchronous weekly sessions with their child, to provide support and engage in the activities. In addition to child-focused activities, caregivers were also provided weekly adult-focused PA sessions in a synchronous format. The adult PA sessions were designed to adhere to PAG recommendations (2018) for adults and included lesson engagement in multicomponent PA (e.g., strength training, yoga, cardiovascular activity). Caregivers were also provided asynchronous material including their own interactive online worksheet with additional opportunities to engage in a variety of PA.

Intervention fidelity

While the primary learning activities for each of the age groups varied, a similar structure in routine was operationalized. Lead instructors began each synchronous virtual session with an opportunity to move to music, followed by a social greeting, an introduction to the new skill, an opportunity to practice the targeted skill (first without then with equipment), followed by small-group and large-group activities, a review of the asynchronous learning material for the week, a check for understanding, the delivery of yoga and breathing exercises, and an opportunity to complete goal setting link. Asynchronous material and worksheets for both children and caregivers were sent out through a texting app and email each week. Family engagement in the program was calculated based on whether the family participated in the child, adult, or goal-setting activities for a given week.

Intervention Type

Behavioural

Primary outcome(s)

Physical activity trajectories of both children and primary caregiver during a yearlong virtual physical activity intervention for children on the autism spectrum and their primary caregiver. Measurements were evaluated at baseline, 4, 8 and 12 months. Physical activity was measured based questions adapted from the 2018 version of the 2018 U.S. Report Card on Physical Activity.

Key secondary outcome(s)

Relationships in physical activity participation between caregiver and child dyads. Physical activity results from the primary outcome measure were evaluated for associations between parent and caregivers at baseline, 4, 8 and 12 months.

Completion date

01/03/2023

Eligibility

Key inclusion criteria

All child participants aged 2 - 18 years had a caregiver-reported diagnosis of autism spectrum disorder (ASD) from a certified medical or educational provider. Caregivers self identified as primary carer.

Participants had to reside within the city limits of the Midwestern large and urban city where the study took place.

Participant type(s)

Mixed

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

2 years

Upper age limit

18 years

Sex

All

Total final enrolment

70

Key exclusion criteria

1. No confirmed diagnosis of autism in child
2. No identification of child with autism as biological or legal child

Date of first enrolment

01/11/2020

Date of final enrolment

01/12/2020

Locations

Countries of recruitment

United States of America

Study participating centre

Wayne State University

5101 John C Lodge Fwy

Detroit

United States of America

48202

Sponsor information

Organisation

Wayne State University

ROR

<https://ror.org/01070mq45>

Funder(s)

Funder type

Charity

Funder Name

Michigan Health Endowment Fund

Alternative Name(s)

Health Fund, MHEF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication