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Active play in children with intellectual disabilities

Submission date
05/08/2020

Recruitment status
No longer recruiting

Registration date
14/08/2020

Overall study status
Completed

Last Edited
08/02/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Children with intellectual disabilities participate in low levels of physical activity. Previous research has demonstrated that children with intellectual disabilities face many barriers to physical activity, such as not having the skills or opportunity to be active. Active play is an approach to physical activity that involves outdoor play and is not skill-dependant or reliant on equipment. Therefore, active play could be an effective way to overcome the barriers to physical activity experienced by children with intellectual disabilities. The aim of this study is to investigate the feasibility of a school-based active play intervention for children with intellectual disabilities.

Who can participate?
The intervention will be delivered in two additional support needs schools in Greater Glasgow, Scotland. A convenience sample will be recruited from the two participating additional support needs schools, with two classes selected from each school to recruit from. Children are eligible to participate if they have intellectual disabilities [measured by the Child and Adolescent Intellectual Disability Screening Scale (CAIDS-Q)], are aged 7-12 years and are independently ambulatory. Children with additional support needs who did not have intellectual disabilities were not eligible. All parents and participants were required to provide informed consent prior to participation.

What does the study involve?
The Go2Play Active Play intervention was developed in partnership between Agile CIC social enterprise (www.agilecic.com) and Inspiring Scotland (https://www.inspiringscotland.org.uk) to encourage children to play physically active games in an outdoor environment. Children participate in 17 weekly 1-hour active play sessions during school. Sessions are facilitated by local play charities and are designed to develop fundamental movement skills and increase activity levels, but also to be fun and inclusive to foster positive experiences and perceptions of physical activity. Sessions consist of 30 minutes structured play, with each session focussing on developing different fundamental movement skills, e.g. throwing and catching games to develop object control. The second half of the session focusses on free play where children are encouraged to interact and to create and play their own games, with the aim of developing social skills.

What are the possible benefits and risks of participating?
It is expected that children's physical activity levels, fundamental movement skills, and social interactions will increase due to participating in this study, which could potentially benefit children's health and development. The sessions are also designed to be fun and enjoyable for participants. There are no major anticipated risks, except for minor injuries or ailments that are associated with physical activity.

Where is the study run from?
This study is run from The University of Glasgow, Scotland (UK)

When is the study starting and how long is it expected to run for?
This study started on 03/01/2019 for 8 months.

Who is funding the study?
This study is funded by The Chief Scientist Office, Scotland (UK)

Who is the main contact?
Dr Arlene McGarty (Arlene.McGarty@glasgow.ac.uk)

Contact information

Type(s)
Scientific

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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
Feasibility of the Go2Play active play intervention for increasing physical and social development in children with intellectual disabilities

Acronym
APID

Study objectives
Is it feasible to implement the Go2Play Active Play intervention in additional support needs schools for children with intellectual disabilities?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/09/2018, College of Medical Veterinary and Life Sciences ethics committee, University of Glasgow (120 University Place, Glasgow, G12 8TA, UK; no telephone number provided; mvls-ethics-admin@glasgow.ac.uk), ref: 200170188

Study design
Multicenter interventional single-arm feasibility trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Physical and social development in children with intellectual disabilities

Interventions
Single-group 17-week intervention implemented in two additional support needs schools (n=21 participants). The intervention consists of a weekly 1-hour active play session incorporating 30 minutes of structured games and 30 minutes of free play. Outcome measures are measured at baseline and immediately post-intervention.

Intervention Type
Behavioural

Primary outcome(s)
The primary outcome is feasibility. Specifically:
1. Recruitment measured prior to the intervention commencing by a member of the research team based on the number of children recruited out of the total number of eligible children who received an information pack

2. Retention measured weekly based on if/how many participants drop out of the trial. This is measured by the researcher team and based on feedback from teachers
3. Intervention adherence is measured as:
3.1. Attendance at each intervention activity session measured a member of the research team or teacher
3.2. Percentage of intervention session spent active at a moderate to vigorous intensity, measured using the ActiGraph GT3X+ accelerometer during 4 sample activity sessions at each school
4. Acceptability of different outcome measures:
4.1. School-based physical activity and sedentary behaviour are measured at baseline and post-intervention using the ActiGraph GT3X+ accelerometer, with feasibility assessed on the number of participants who meet the required wear time of four out of the five measurement days for at least 3 hours per day (which represents approximately 50% of the school day)
4.2. Fundamental movement skills were assessed at baseline and post-intervention using the Test of Gross Motor Development-2 (TGMD-2), with the percentage of participants completing this test, as well as reasons for non-compliance, recorded to assess feasibility
4.3. Social interactions are measured during the first and last intervention sessions using the Playground Observation of Peer Engagement (POPE) tool. Feasibility was assessed on whether this direct observation methodology and use of the POPE tool enabled all relevant social interactions to be recorded
4.4. Staff feedback relating to perceptions of feasibility, benefits/limitations, and effectiveness of delivery was collected via questionnaire from teachers (n = 3), whose students were involved in the intervention, and the lead facilitator of the intervention (n = 1).

Key secondary outcome(s))
1. School-based physical activity and sedentary behaviour are measured at baseline and post-intervention using the ActiGraph GT3X+ accelerometer, with potential intervention effects examined using paired samples t-tests
2. Fundamental movement skills were assessed at baseline and post-intervention using the Test of Gross Motor Development-2 (TGMD-2), with potential intervention effects examined using paired samples t-tests
3. Social interactions are measured during the first and last intervention sessions using the Playground Observation of Peer Engagement (POPE) tool, with potential intervention effects examined using paired samples t-tests

Completion date
30/08/2019

Eligibility

Key inclusion criteria
1. Have intellectual disabilities [measured by the Child and Adolescent Intellectual Disability Screening Scale (CAIDS-Q)]
2. Aged 7-12 years
3. Are independently ambulatory

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 years

Upper age limit
12 years

Sex
All

Total final enrolment
21

Key exclusion criteria
Children with additional support needs who do not have intellectual disabilities

Date of first enrolment
03/01/2019

Date of final enrolment
10/01/2019

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Glasgow
Mental Health & Wellbeing
1st floor Admin Building
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation

University of Glasgow

ROR
https://ror.org/00vtgdb53

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/02/2021	08/02/2021	Yes	No