'Walk Buds': A walking programme to increase physical activity, physical fitness and emotional wellbeing, in children aged 9-13 years with intellectual disability

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/02/2022		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
21/02/2022		☐ Results		
Last Edited	Condition category	Individual participant data		
11/03/2025	Mental and Behavioural Disorders	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

'Walk Buds' is a school walking intervention that promotes physical activity in children with intellectual disabilities (9-13 years); and was co-produced with the teachers, parents and children. Promoting activity levels in children is important for their health. We think that if children have an older peer to motivate and support them that this may promote activity. We want to test whether Walk Buds works in schools, that is can be supported by the teachers and are parents willing to have their child participate in the intervention.

Who can participate?

Schools for children with intellectual disabilities, containing children aged 9 – 19 years.

What does the study involve?

Participating schools will be randomly allocated to the Walk Buds programme or to 'exercise as usual'.

We will collect measures on physical activity and wellbeing to find out if the early findings indicate whether a larger trial can be undertaken.

What are the possible benefits and risks of participating?

Benefits include an increase in physical activity, a reduction in sedentary behaviour and emotional wellbeing. This is a low risk study with limited risks for participating as teachers will be supervising the children with intellectual disabilities at all times.

Where is the study run from? Ulster University (UK)

When is the study starting and how long is it expected to run for? May 2021 to February 2023

Who is funding the study? Baily Thomas Charity (UK)

Who is the main contact? Prof Laurence Taggart, laurence.taggart@qub.ac.uk

Study website

https://www.ulster.ac.uk/research/topic/nursing-and-health/caring-for-people-with-complex-needs/research-themes/neurodevelopmental

Contact information

Type(s)

Principal Investigator

Contact name

Prof Laurence Taggart

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

'Walk Buds': A walking programme to increase physical activity, physical fitness and emotional wellbeing, in 9-13yr old children with intellectual disability. A study protocol for a clustered RCT

Acronym

WALK BUDS

Study objectives

The research question is whether it is possible to conduct a clustered Randomised Controlled Trial (cRCT) to evaluate the effectiveness of a walking programme (Walk Buds) to increase physical activity, physical fitness, and emotional wellbeing in 9-13yr old children with intellectual disabilities.

We will conduct a clustered RCT that will enable us to:

- 1. Examine the acceptability of the innovative Walk Buds programme, the acceptability of the measurement devices, and the accompanying training materials, by both the pupils who receive it, and the teachers who deliver the programme
- 2. Measure the implementation of the Walk Buds programme by teachers including compliance and fidelity of delivery
- 3. Determine the acceptability of randomisation to the schools
- 4. Determine the appropriateness and acceptability of the outcome measures for the children, teachers, and parents
- 5. Identify the facilitators and barriers to the implementation of the Walk Buds intervention (including recruitment, consent, sampling procedures, attendance level, loss to follow-up) and refine the intervention's logic model.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/09/2021, Ulster University Research Ethics Committee (Ulster University, Shore Road, Newtownabbey, Co Antrim, BT37 0WB, UK; +44 2890365131; n.curry@ulster.ac.uk), ref: REC/21/0039

Study design

Interventional feasibility cluster randomized trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Treatment

Participant information sheet

See additional files

Health condition(s) or problem(s) studied

Children with intellectual disabilities

Interventions

This study is a two-arm, cRCT feasibility trial where schools are randomised into either an intervention arm (Walk Buds) or an 'exercise as usual' arm. We are aiming to recruit eight schools, each with twenty pupils. The Walk Buds programme will be delivered by teaching staff. Outcome measures will be recorded at baseline and three-months post-intervention. The protocol has been developed according to the SPIRIT 2013 Statement (Chan et al. 2013), recommendations for protocol items for clinical trials and the CONSORT 2010 guidelines for feasibility trials (Eldridge et al. 2016). A process evaluation will explore the factors that could impact on the internal and external validity of a future cRCT and the intervention's logic model.

Earlier triangulation of theory and research evidence has resulted in the development and cocreation of the Walk Buds walking programme (see Johnston, 2018). The core components of the Walk Buds intervention are:

- Theoretical underpinning: Walk Buds is theoretically underpinned by the COM-B (capability, opportunity, motivation, and behaviour) (Michie et al. 2014) and socio-ecological models (LeRoy et al. 1989).
- Peer buddy system: Younger pupils with intellectual disabilities (aged 9-13yrs) are matched on ability/interests by teachers to walk with adolescents with intellectual disabilities (aged 16-19yrs) or 'peer buddies' the for the 12 weeks from the same school. One or two younger children with intellectual disabilities can be matched with one peer buddy.
- Incremental programme: Theyounger pupils and peer buddieswill walk together initially for 15 mins three times per week, increasing to 30 minutes four-times per week in the last four weeks, over a 12-week period (see Figure 1).
- Peer buddy training: The peer buddy training involves an interactive presentation delivered by the researcher during the school day on aspects including benefits of walking, duration of walks, the walking programme, data collection and measurement tools, safety, and appropriate clothing. The presentation will be followed by a question-and-answer session where the peer buddies can ask the researcher any questions they might have.
- Walk supervisor training: Teachers or classroom assistants can be walk supervisors. The researcher will deliver training to walk supervisors during the school day prior to the commencement of the walking programme. Walk supervisor training will include how to implement the walking programme how to complete the walk diary, how to use the pedometers, and when to offer the rewards.
- Use of walk routes: Walk routes within or nearby school grounds will be developed by schools in conjunction with the researcher.
- Use of walk diaries: Schools will be provided with a walk diary to log the details of each walk. Walk diaries will help the younger pupils, peer buddies and teachers to reflect on the participants motivation to engage in the Walk Buds programme. Details such as the staff member who supervised the walk, the duration of the walk, general feelings of participants after the walk and step count of each participant will be recorded.
- Use of pedometers: Pedometers will be used as a motivational tool for goal setting and so children and their peer buddies can see their step count at the end of each walk.
- Incentives: Each younger pupil and peer buddy will receive a small prize on a fortnightly basis (e. g., water bottle, wrist band, certificate of achievement, etc), as these incentives will help encourage and maintain participation in the walking programme.

Intervention Type

Behavioural

Primary outcome measure

Physical activity as measured by Actigraph at baseline and 3 months post intervention.

Secondary outcome measures

- 1. Recruitment rate recorded as the number of children with intellectual disability who consent to participate in the study the by baseline data collection point by the end of Jan 22.
- 2. Attrition rate recorded as the number of children with intellectual disabilities who consent to participate that remain in the study until the end of follow up at 3 months post data collection.

Overall study start date

01/05/2021

Completion date

28/02/2023

Eligibility

Key inclusion criteria

Clusters will be schools for children with intellectual disabilities. The identified children must meet the following inclusion criteria:

- 1. Younger children with mild/moderate intellectual disabilities aged 9 13 yrs
- 2. Peer buddies will need to have a mild intellectual disability and be aged 16 19 yrs
- 3. Both groups of young people will need to have sufficient mobility to participate in the walking programme
- 4. Teachers will assess the level of intellectual disability and
- 5. Parent consent, child assent and teacher consent will be required.

Participant type(s)

Other

Age group

Child

Lower age limit

9 Years

Upper age limit

19 Years

Sex

Both

Target number of participants

Schools will be approached and consented to participate in the study by the first author (LT). Teachers will identify 10 younger children (aged 9-13yrs) and between 5-10 peer buddies (aged 16-19yrs) based upon the specific criterion below. In total we are planning to recruit between 130-160 young people with intellectual disability.

Key exclusion criteria

- 1. Have very limited mobility and communication
- 2. Present with severe behaviours that challenge
- 3. Parent/quardian does not consent, and young person does not provide assent/consent

Date of first enrolment 01/10/2021

Date of final enrolment 28/01/2022

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre Ulster University Shore Road Newtownabbey United Kingdom

Sponsor information

Organisation

BT37 0WB

University of Ulster

Sponsor details

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Sponsor type

University/education

Website

https://www.ulster.ac.uk/

ROR

https://ror.org/01yp9g959

Funder(s)

Funder type

Charity

Funder Name

Baily Thomas Charity

Results and Publications

Publication and dissemination plan

One paper will be published on the results and another paper published on the process evaluation of the feasibility clustered RC

Intention to publish date

28/02/2023

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?
Participant information sheet	version 2, Gary	01/09/2021	21/02/2022	No	Yes
Participant information sheet	version 2, Peter	01/09/2021	21/02/2022	No	Yes
Protocol article		18/07/2022	05/06/2024	Yes	No