

**‘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**

**Short running title:** ‘Walk Buds’: A walking protocol for 9-13yr old children with intellectual disability. A study protocol.

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# **‘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.**

## **Abstract**

**Background:** Young people with intellectual disabilities are traditionally less physically fit compared to their non-disabled peers. While the health benefits of increasing physical activity are evident, there remains a lack of evidence on how to increase physical activity and reduce sedentary behaviour in young people with intellectual disabilities. Walking interventions, including those delivered in school settings, have been found to significantly increase physical activity levels of young people without disabilities. However, to date there has been a paucity of studies testing walking interventions for young people with intellectual disabilities in school settings. In an earlier study we developed the Walk Buds school-based walking programme for children with intellectual disability (aged 9-13yrs), which incorporated a paired buddy component.

**Aim:** We plan to conduct a clustered feasibility RCT that will enable us to examine the acceptability of the Walk Buds programme, randomisation, and outcome measures, check the fidelity programme delivery, and identify the facilitators and barriers to the implementation of the programme.

**Methods:** This study is a two-arm, cRCT feasibility trial where eight schools will be randomised into either an intervention arm (Walk Buds) or an ‘exercise as usual’ arm. We are aiming to recruit between 130-160 young people with intellectual disabilities. Outcome measures will be recorded at baseline and three-months post-intervention. 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.

**Discussion:** Walk Buds is the first theoretically underpinned, peer-led, multi-component, manualised school-based walking programme that aims to increase physical activity, physical fitness, and emotional wellbeing in 9-13yr old children with intellectual disabilities.

## **Trail registration:**

**Key words:** intellectual disability, school-based, walking programme, physical activity, feasibility

## **Background**

People with intellectual disabilities are more likely to have significantly poorer health, and consistently demonstrate lower levels of cardiovascular fitness when compared to their non-disabled peers (O'Leary et al. 2018). Risk factors include poor diet, a lack of physical activity and sedentary behaviour (Taggart & Cousins 2014). Young people with intellectual disabilities are traditionally less physically fit and engage in levels of activity below the recommended level of 60 minutes of moderate to vigorous physical activity (MVPA) per day compared to their non-disabled peers (Einarsson et al. 2015).

There are many health benefits associated with increased physical activity (cardiovascular & musculoskeletal, maintenance of healthy weight, improved mental health and quality of life) (Janssen & LeBlanc 2010). While the health benefits of increasing physical activity for young people are evident, there remains a lack of evidence on how to increase physical activity and reduce sedentary behaviour in children and young people with intellectual disabilities.

## **Benefits of school-based interventions**

School settings are regularly used for physical activity interventions (Kriemler et al. 2011), as time spent in school is often the most active time for many adolescents (Fairclough et al. 2012). School-based interventions may help negate social or cultural factors by encouraging participation by children who may not otherwise get the encouragement or opportunity to participate outside the school setting (Love et al. 2019; Cox et al 2020; Golubovic et al. 2012). Walking is one form of school-based physical activity which is convenient, accessible, and free, that can be easily incorporated into daily life and sustained into adulthood (Ogilvie et al. 2007).

Walking interventions, including those delivered in mainstream school settings, have been found to significantly increase physical activity levels and the health of young people without intellectual disabilities (5-18yrs) (Mendoza et al. 2011; Carlin et al. 2016, 2018). Walking requires little skill and can be accumulated in short bouts throughout the day, which may then suit the sporadic nature of children with intellectual disability activities (Downs et al., 2016). Successful physical activity interventions often include key components, such as peer support and pedometers which have both been found to be effective in increasing physical activity in adolescents with intellectual disability (Shields et al. 2012; Melville et al. 2015). As children with intellectual disabilities have higher levels of sedentary behaviour compared to their non-disabled peers (Downs et al., 2016), a walking intervention may be successful in increasing light to moderate physical activity in this population. However, to date there has been a paucity of studies testing walking interventions for children with intellectual disabilities, targeting physical activity in school settings (Bellamy et al.2020), and non which have incorporated a buddy system using older peers as motivating peers.

## **Development of the Walk Buds programme**

In an earlier study we co-produced, co-created and field-tested a school-based, theoretically underpinned, multicomponent walking programme for children with intellectual disability (aged 9-13yrs) targeting physical activity (Johnston, 2018). We named this programme 'Walk Buds'. The Walk Buds programme was underpinned

by the COM-B (capability, opportunity, motivation, and behaviour) (Michie et al. 2014) and socio-ecological models (LeRoy et al. 1989). The core components of the Walk Buds programme are: it is a manualised intervention, it is based upon an incremental walking programme, it has a peer buddy system where older pupils (aged 16-19yrs) in the same school walk with the younger pupil, uses pedometers to record steps and as a motivational tool, provides weekly incentives for participation, the use of walk diaries to collate data on participation; and clear walk routes within or nearby school grounds.

From the field testing, the teachers reported that: a) the Walk Buds programme could be successfully implemented in a school setting; b) the younger children and peer buddies enjoyed walking together; and c) they developed friendships that otherwise may not have been formed (Johnston, 2018).

### **Aim & objectives of the study**

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 feasibility 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.

## **Methods**

### **Study design**

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.

### **Study settings and recruitment**

The study will take place in eight schools for children with intellectual disabilities across N Ireland providing education for children aged 5-19 years. Schools will be selected if they meet the following criteria:

1. Schools providing education for children with intellectual disabilities from age 5-19 years
2. Schools will refer 10 children (9-13yrs) and between 5-10 peer buddies or role models (16-19yrs) to the research team.
3. Schools are prepared to deliver the Walk Buds programme for 12 weeks.

### **Participant selection**

As this is a feasibility study, and the purpose is to explore the acceptability of the intervention and outcome measures, a formal a priori power calculation has not been conducted (Arain et al. 2010). At the cluster level, eight schools will be recruited: four schools randomised to Walk Buds and four schools randomised to the control/comparator arm.

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. Teachers and parents/guardians will then be provided with a participant information sheet and consent form, and the younger children and peer buddies will be provided with a user-friendly information sheet and assent form. The teachers will collate the parental/guardian consent and young person assent forms within each school.

The Research Associates will receive training from the first author (LT) in how to assess capacity to consent and ensure informed consent is maintained throughout the project on a case-by-case basis. All children and young people will receive an easy read participant information (PIS) sheet and assent form with pictures / symbols to explain the purpose of the study and what is involved. The PIS and assent form have been prepared in collaboration with our partner representatives. The Research Associates will clearly explain the decisions to be made about joining the Walk Buds Study, wearing the Actigraphs and completing the physical activity tasks at the two time points, and then the school being randomised to either the intervention or control arm. The Research Associates will explain what is involved in participating in the Walk Buds programme (time commitments).

### **Inclusion Criterion**

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

- Younger children with mild/moderate intellectual disabilities aged 9-13yrs
- Peer buddies will need to have a mild intellectual disability and be aged 16-19yrs
- Both groups of young people will need to have sufficient mobility to participate in the walking programme (i.e. initially able to walk for 15 minutes)
- Teachers will assess the level of intellectual disability and
- Parent consent, child assent and teacher consent will be required.

## **Exclusion Criterion**

Potential participants will be excluded if they:

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

## **Randomisation and Blinding**

As in most school-based physical activity interventions, blinding of the teachers, children with intellectual disabilities, peer buddies and parents to the schools' allocation will not be possible, however the statistician conducting the randomisation will be blind.

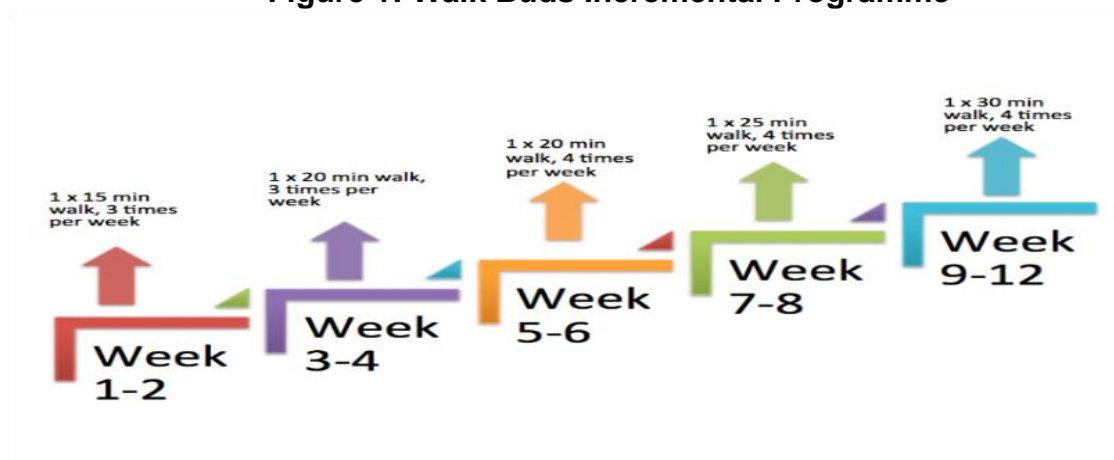
## **Walk Buds Intervention**

Earlier triangulation of theory and research evidence has resulted in the development and co-creation of the Walk Buds walking programme (see Johnston, 2018). The core components of the Walk Buds programme 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' 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:* The younger pupils and peer buddies will 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 will 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 week number, walk number, the pupils who participated, whether pedometers were worn, step count, the route used, the duration of the walk, reasons for non-participation, and general comments 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.

**Figure 1: Walk Buds Incremental Programme**



### **Control/Comparator Group**

The four schools assigned to this arm will not receive the walking programme; They will continue to participate in their school's normal activity programme during the trial period. When the trial is completed, the schools in the control arm will be offered all the Walk Buds training resources and will be supported to run the programme. None of the schools currently operate walking activities with an age-differed buddy system.

### **Compliance and fidelity**

To monitor compliance with the intervention delivery, teachers will be asked to keep a log of their implementation (how often they delivered the intervention, recruitment of peer buddies, number of walks). To monitor fidelity, 5 walking sessions in each school will be observed by a member of the research team. The researchers will use an observation tool informed by Carroll et al.'s (2007) conceptual framework for

exploring implementation, content, coverage, frequency, duration, and moderating variables (intervention complexity, facilitation strategies, quality of delivery & participant responsiveness).

### **Data collection**

Testing the feasibility of the individual outcome measures of the children's physical activity (both the 9–13-year-olds and the peer buddies), physical fitness, and emotional wellbeing will occur at baseline and three-months post intervention. After the baseline measures have been collected, schools will be randomised to either Walk Buds or the control group. Acceptability and feasibility data will be gathered throughout the study and during the process evaluation.

*Demographic and anthropometric measures:* We will collect anthropometric measures (gender, age, weight, and height) from each younger pupil and peer buddy at baseline and three-months post intervention.

*Objectively measured physical activity:* The primary outcome measure will be PA, objectively measured by the use of Actigraph GT3X accelerometers. Younger pupils (9-13yrs) and peer buddies (15-19yrs) will wear an Actigraph accelerometer at baseline and three-months post intervention for a period of seven-days (including over the weekend).

We are aware that there may be compliance issues with the wear time of these Actigraph accelerometers, therefore, to enhance wear time the younger pupils and peer buddies will be offered a £10 shopping voucher at the two time points on their return. In addition, reminder posters and information leaflets will be given to parents and teachers.

*Physical activity:* The 6-minute walk test (6-MWT) will be used to measure physical fitness by distance walked. The 6-MWT involves walking back and forth along a set path as quickly as possible to ascertain how many metres a participant can walk in 6 minutes. The 6-MWT has been shown to be a valid and reliable measure of physical fitness for young people with intellectual disability (Elmaghoub et al. 2011; Bellamy et al. 2020). We will conduct the 6-MWT with all younger pupils and the buddies in both trial arms, at baseline and three-months post intervention.

*Teacher and parent/guardian-reported well-being:* At baseline and three-months post intervention, teachers and parents will complete a Strengths and Difficulties Questionnaire (SDQ) for each child. The SDQ is a 25-item behavioural screening questionnaire for 3–19yr olds (it has 5 sub-scales relating to emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and prosocial behaviour) and has been used in other adolescent intellectual disability studies.

### **Process evaluation**

A process evaluation will assess whether Walk Buds was delivered and received as intended, and provide an understanding of how the trial processes relate to the context within which the intervention was implemented (Grant et al. 2012).



Within each of the four schools in the intervention arm, separate focus groups will be held with approximately five younger pupils, five of the older Buddies, six to eight parents, and 2-3 teaching staff. The younger pupils and peer buddies will be supported by a teacher/classroom assistant during each focus group. Each focus group will be audio recorded, transcribed and then analysed using a Thematic Content Analysis approach (Braun & Clarke, 1997).

The data on the acceptability and feasibility of the intervention will be integrated with the qualitative findings from the focus groups, and from observations of school characteristics using the model proposed by Grant et al. (2012). Through this, the barriers and facilitators to implementation will be explored and the intervention logic model will be refined.

### **Data analysis**

A CONSORT flow diagram will report recruitment, attrition, and retention rate. Reasons for attrition and loss to follow-up will be reported. Given that this is a feasibility study and likely to be under-powered, statistical significance of treatment effects will not be analysed (Arain et al. 2010). However, between group comparisons will be conducted to inform the statistical model for the future trial. This will include two elements 1) a series of ANOVAs of the baseline data of children's standardised scores on physical activity, physical fitness, and emotional wellbeing to investigate pre-intervention group differences and temporal differences; and 2) a series of ANCOVAs to investigate post-intervention group differences. Qualitative analysis of the data gathered in the semi-structured interviews will be carried out using Braun & Clarke's (2006) thematic analysis.

The researchers will be trained to enter quantitative data into the study database and will liaise with the study statistician to export the data for analysis. For qualitative data, and fidelity assessment, the researchers will be trained in GDPR and register with Data Safe Haven, a secure platform recommended for research at UCL so that participant data, such as audio recordings, can be uploaded and downloaded without compromising confidentiality and breaches in personal information handling.

### **Progression Criterion for Proceeding to a full definitive trial**

The primary factor for consideration as to whether to proceed to a full definitive trial will be the feasibility data pertaining to recruitment, retention, and the completion of outcome measures. However, strict thresholds for progression have not been set as these factors can be influenced by contextual variations that may not impact on a future trial. Rather, the decision to proceed to a main trial will be made along by the research team in collaboration with the Trial Steering Committee. Solutions to any problems observed in the trial will be sought through four potential options suggested by Bugge et al. (2013): 1) adapt Walk Buds 2) adjust the context within which the intervention would be delivered 3) amend elements of the trial design or 4) implement a combination of all of these actions.

### **Trial steering committee**

Our Walk Buds study will be overseen by a Trial Steering Committee (TSC) comprising of experienced researchers within intellectual disabilities, methodology and statistics, as well as independent members with experience working in special schools across Northern Ireland. We will not require a Data Management & Ethics

Committee (DMEC) to meet as this is only a feasibility study, but this will be established within the definitive RCT trial.

### **Ethical considerations**

As noted, this is a low-risk study in that no additional potential harm is associated with the research compared to everyday walking. The main ethical considerations relate to the welfare of the young people, parental consent and the children's capacity to assent, the maintenance of confidentiality, and health and safety while conducting the Walk Buds programme. The programme will be delivered in line with each schools' health and safety and child protection policies.

Consent will be obtained from parents, and assent from each young pupil and peer buddy prior to the Walk Buds programme and commencing the focus groups. Participants (pupils, parents, and teachers) will have the opportunity to opt out of the study at any point of data collection and analysis. Participants will be assured that their data will be anonymised and that their contributions are confidential.

All the focus groups with the younger pupils and peer buddies will be supervised by a teacher/classroom assistant in their own school. In the unlikely event a younger pupil, peer buddy, parent and/or teacher becomes distressed, we will follow both the university's and each school's safety protocol. The limits of confidentiality will be addressed from the outset of each semi-structured interview, i.e., that if anyone discloses information that would be considered harmful towards themselves or others that this would need to be passed on to the appropriate line manager to explore further. Participants will also be reminded to be discreet, not to name others and to disclose as little as possible of a personal, confidential, or sensitive nature.

This is a low-risk study in relation to health and safety of all participants, but it will be acknowledged that discussing walking and physical activity, may cause some distress for participants if they found the walking programme difficult to complete. Participant information sheets will state this clearly and will inform participants what to do if they experience distress as a result of participation

### **Adverse event reporting**

Any adverse events occurring during this feasibility study will be recorded and promptly reported to the TSC. However, as this is a low-risk study it is not anticipated there will be adverse events. In the likelihood there are adverse events, the TSC will be contacted, the situation discussed, and the trial may be suspended or discontinued. The schools, teachers, all the young people with intellectual disability in both arms and parents/guardian will be informed in such an event.

### **Dissemination**

We aim to publish the results of our feasibility study and process evaluation to all of our participants using a user-friendly version. We also intend to disseminate our learning from this feasibility trial through national and international conferences and peer-reviewed journals.

### **Discussion**

This programme to be tested is the first theoretically underpinned, peer-led, multi-component, manualised school-based walking intervention that aims to

increase physical activity, physical fitness, and emotional wellbeing in 9-13yr old children with intellectual disabilities. This study has a number of strengths. The recognition of the complexity at both the individual (children) and system (teacher and school) levels, and the use of intervention logic modelling (Kellogg Foundation 2004), enhances uniqueness and ecological validity of the Walk Buds intervention. The inclusion of qualitative data in the process evaluation will allow detailed exploration of the acceptability of the intervention and the trial processes. Thus, we will be able to identify issues that may impact on the external and internal validity of a large-scale cRCT.

**Study status**

Current study protocol: Version 1.2 (21/09/2021). The trial has been submitted to the ISRCTN register (no. ISRCTN34281561).

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