The walking in schools (WISH) trial

Submission date	Recruitment status	[X] Prospectively registered		
26/06/2019	No longer recruiting	[X] Protocol		
Registration date	Overall study status	[X] Statistical analysis plan		
02/07/2019	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/02/2024	Other			

Plain English summary of protocol

Background and study aims

The immediate and future health benefits of regular physical activity (PA) are well established. Despite this, many children and adolescents on the island of Ireland fail to meet current PA recommendations. The transition from primary to second-level education represents a time when physical activity decreases, especially in adolescent girls. School-based activities that increase opportunities for PA are needed, particularly for those left out of other sporting activities because of the competitive selection process for school teams, and for types of activity that can be easily maintained into adulthood, such as walking.

Walking is a low-cost, effective means of increasing PA in adults and, after active play, is the greatest contributor to PA in children. It is the most prevalent PA among active adults. The potential of walking to promote PA in low-active adolescent girls encouraging a lifelong walking habit has not been explored. In addition, the school environment is an important health-promoting setting, overcoming many of the health inequalities found in other settings.

The study aims to assess the effectiveness of a low-cost school-based, peer-led brisk walking intervention in increasing PA in adolescent girls when delivered across the school year in a fully-powered trial in schools across Northern Ireland and the Border region of Ireland.

Who can participate?

All female pupils who attend a school selected to take part in the study and are aged 12-14 years (i.e. in Year 9 or 10 (NI) / First Year or Second Year (ROI) of post-primary education) will be invited to take part in this study. As this study aims to increase the amount of physical activity, only pupils who are healthy and free from any medical condition that may limit their ability to take part in a brisk walking programme will be eligible to take part in the study.

What does the study involve?

To assess the impact of this walking programme on physical activity and other factors, we would like to carry out a number of measurements at different time points throughout the study.

At baseline (week 0) we will take the first set of measurements in a semi-screened area. We will firstly measure height and weight, and then take measurements of waist and hip circumference. We will also ask participants to complete a series of questionnaires which will involve general questions about physical activity, as well as some scales to assess attitudes towards physical

activity and walking. We will also collect some information on wellbeing, sleep and social media usage.

In the week before these measurements, we would like to collect some information about physical activity levels using a device known as an accelerometer. An accelerometer is a device that measures the amount and the direction of any activity that someone does. We will ask participants to wear this device for one week; it is small in size (about the size of a matchbox) and we will provide pupils with an information sheet on how to correctly wear the device. Participants will be asked to remove the accelerometer when bathing, taking part in water-based activities such as swimming and when asleep. This measurement of physical activity is non-invasive and will not impede on participants' daily routine in any way.

Once our first set of measurements are complete, schools will be randomly allocated to either 1) the walking programme (intervention), or 2) continue with usual physical activity habits (control). Added 11/11/2021: Schools will be randomised using computer software (i.e. randomization.com). Randomisation will be stratified by country and random allocation will be performed by faculty staff who will be blind to school identity and independent of the study team.

- 1. Walking intervention: If a school is randomly selected to take part in the walking programme, participants will have the opportunity to attend a number of group-led walks throughout the school week. These walks will be led by older students who have been trained as walk leaders and these older students will be under the supervision of a member of school staff. During the programme, participants will be encouraged to attend as many walking sessions as possible. The actual walking intervention will last a minimum of 20 and a maximum of 22 weeks. If schools close for face-to-face teaching (national lockdowns), walks will occur outside of the school grounds, on a route decided by the pupils. Pupils will be provided with an infographic to help them choose a safe walking route
- 2. Control group: If a school is randomly selected not to take part in the walking programme, pupils will not have to take part in any further physical activity as a result of this study. Although pupils will not take part in the walking programme, we will still collect take measurements at the time points outlined below.

Regardless of being assigned to either the intervention or control group, all participants will be involved in the study for approximately 1 year (to allow for follow up measurements), which will be conducted at a number of time points throughout the study.

Participants may be selected to take part in some evaluation work about the study. This is in the form of a focus group, which is an informal group discussion, where we would ask your participants to share their experiences of taking part in the walking programme. Participants will be randomly selected and asked to take part in the focus groups at the beginning and/or end of the intervention. The focus groups will discuss topics including physical activity, breaktime activities and social media.

What are the possible benefits and risks of participating?

We would hope that participants will enjoy taking part in this research study and find it a fun and enjoyable activity. Although participation in the study may not bring direct benefits to participants, the results of this study will help researchers further understand what approaches are useful when trying to encourage this age group to take part in more physical activity.

As with all physical activity, there is a minimal risk of injury or discomfort however walking is a very safe form of physical activity, and the walks not be performed at a high intensity. Risk assessments will be conducted at each school before the study takes place.

Where is the study run from?

- 1. Ulster University, UK
- 2. Letterkenny Institute of Technology (LYIT), Ireland
- 3. University of Bristol, UK
- 4. University of Wolverhampton, UK

When is the study starting and how long is it expected to run for? Participant recruitment is due to begin in September 2019 and the study is expected to run until 31/05/2023

Added 19/10/2021: Due to school closures during phase 1 of the WISH trial (September 2019 – November 2020), the WISH trial was paused. Recruitment was restarted for phase 2 in August 2020.

Again, due to school closures, phase 2 of the WISH Trial (September 2020 – November 2021) was paused (1st February 2021 – 31st July 2021). Recruitment to the WISH Trial restarted in August 2021. Added 11/11/2021: Therefore, no data collected during phases 1 or 2 will contribute to the overall trial.

Who is funding the study?

The WISH Study is funded by the CHITIN project. The CHITIN project has received funding from the Department of Health NI and the Health Service Executive (ROI)) from the EU's INTERREG VA Programme, which is managed by the Special EU Programmes Body (SEUPB).

Who is the main contact?

Public: Dr Maria O'Kane (m.okane@ulster.ac.uk)

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

REC/19/0020

Study information

Scientific Title

The Walking In ScHools (WISH) Trial: a cross-border trial to evaluate a walking intervention in adolescent girls.

Acronym

WISH

Study objectives

To conduct a fully-powered clustered randomised controlled trial to evaluate the effectiveness of a novel, low-cost, peer-led school-based walking intervention, delivered across the school year, at increasing objectively measured PA levels of adolescent girls in schools within NI and the border counties of Ireland.

It is hypothesised that intervention participants will increase daily physical activity and reduce time spent sedentary by replacing sedentary behaviour with walking.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Aproved 20/06/2019, Ulster University Research Ethics Committee (Research Governance, Room 26A20, Ulster University, Shore Road, Newtownabbey, Co Antrim, BT37 OQB; +44 28 9036 6629), ref: REC/19/0020.

Study design

Clustered randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Physical activity

Interventions

Current intervention as of 13/09/2021:

Schools will be randomised to either receive the walking intervention, or to act as controls. Following baseline measurements, the intervention will be delivered for the whole school year. Allowing for holidays, exams, educational trips and other school events this will vary from one school to another however the minimum intervention will be a minimum 20 and a maximum of 22 weeks.

INTERVENTION: In intervention schools, female pupils (identified by school staff) aged 15-18 years (peer role models) will be trained as walk leaders to lead younger pupils (aged 12-14 years) in 10-15 min walks before school and at break and lunch recess. When girls are in school, walks will occur in school grounds and pupils will be encouraged to participate in as many walks as possible each week. If schools close for face-to-face teaching (national lockdowns), walks will occur outside of the school grounds, on a route pre-determined by the pupils. Pupils will be provided with a risk assessment infographic to help them choose a safe walking route. Reward cards, stamped for each walk completed and exchanged for small rewards with low monetary value will be used for self-monitoring. Walking routes will be pre-determined and a risk assessment will be completed for each school site. Peer walk leaders will be trained to ensure they consider safety concerns of facilitating the walks and the training programme will emphasize the importance of the walks being performed at a brisk pace, i.e. at a pace sufficient to elicit moderate intensity PA in participants. Training will also include information on providing and encouraging social support amongst participants to align with Self Determination Theory (SDT). Two walk leaders will accompany each walk, one at the front and one at the back of the group. Leaders will set the pace of the walk and ensure the safety of pupils. Walks will take place in a one of the pre-planned routes around the school grounds. At the end of each walk, walk leaders will stamp each participants' card and note attendees to monitor compliance with the intervention.

As part of the social support component of the intervention, participants and walk leaders will be invited to be part of separate closed social media groups designed to include opportunities for social support in the form of capabilities to share progress with friends. In addition, social support and encouragement to continue to participate will be provided to participants via weekly updates which will include: strategies to address barriers and recognize progress; links to websites and resources; and vignettes of support and advice from others who have successfully increased their physical activity levels. These pages will only be accessible to those in the intervention and will be moderated by named members of the research team to ensure data protection.

CONTROL: During the intervention period, schools (and participants) in the control group will be instructed to continue with their normal PA habits.

Previous intervention:

Schools will be randomised to either receive the walking intervention, or to act as controls. Following baseline measurements, the intervention will be delivered for the whole school year.

Allowing for holidays, exams, educational trips and other school events this will vary from one school to another however the minimum intervention will be a minimum 20 and a maximum of 22 weeks.

INTERVENTION: In intervention schools, female pupils (identified by school staff) aged 16-18yrs (peer role models) will be trained as walk leaders to lead younger pupils (aged 12-14rs) in 10-15 min walks before school and at break and lunch recess. All walks will occur in school grounds and pupils will be encouraged to participate in many walks as possible each week. Reward cards, stamped for each walk completed and exchanged for small rewards with low monetary value will be used for self-monitoring. Walking routes will be pre-determined and a risk assessment will be completed for each school site. Peer walk leaders will be trained to ensure they consider safety concerns of facilitating the walks and the training programme will emphasize the importance of the walks being performed at a brisk pace, i.e. at a pace sufficient to elicit moderate intensity PA in participants. Training will also include information on providing and encouraging social support amongst participants to align with Self Determination Theory (SDT). Two walk leaders will accompany each walk, one at the front and one at the back of the group. Leaders will set the pace of the walk and ensure the safety of pupils. Walks will take place in a one of the preplanned routes around the school grounds. At the end of each walk, walk leaders will stamp each participants' card and note attendees to monitor compliance with the intervention.

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CONTROL: During the intervention period, schools (and participants) in the control group will be instructed to continue with their normal PA habits.

Intervention Type

Behavioural

Primary outcome measure

Objectively measured total physical activity (counts per minute) of participants is measured using the Actigraph GT3X accelerometer device for 7 consecutive days at baseline, end of intervention and 13 months post-follow-up.

Secondary outcome measures

- 1. Body Mass Index (BMI) (height and weight) is measured at baseline, end of intervention and 13 months post-follow-up.
- 2. Waist:hip ratio (waist and hip circumference) is measured at baseline, end of intervention and 13 months post-follow-up.
- 3. Sedentary behaviour and light, moderate and vigorous intensity physical activity are measured using accelerometer data at baseline, mid- and end of the intervention and 13 months postfollow-up.
- 4. Proportion of pupils meeting current physical activity recommendations is measured using accelerometer data at baseline, mid- and end of the intervention and 13 months post-follow-up.

- 5. Wellbeing, sleep and social media usage are measured using the following validated questionnaires at baseline, end of intervention and 13 months post-follow-up
- 5.1. Emotion regulation questionnaire for children and adolescents
- 5.2. Pittsburgh Sleep Quality Index.
- 5.3. Social media use integration scale.
- 5.4. Body weight and appearance satisfaction.
- 6. Reasons for participating in physical activity is measured using BREQ-2 at baseline, end of intervention and 13 months post-follow-up.
- 7. Self-efficacy for physical activity and walking is measured using the Children's PA self- efficacy scale at baseline, end of intervention and 13 months post-follow-up.
- 8. Health-related quality of life is measured using KIDSCREEN 10 at baseline, end of intervention and 13 months post-follow-up.
- 9. Effect of social networks on physical activity behaviour is measured using friendship nominations at baseline, end of intervention and 13 months post-follow-up.
- 10. The motivation for change and how elements of the environment may have affected the delivery of the intervention are measured using interviews with walk leaders at baseline, midand end of intervention.
- 11. How participants currently spend their break/lunchtimes, levels of physical activity during the school day and social media usage are measured using focus groups in each school.
- 11.1 Factors that affected participation, motivation and enjoyment of the intervention are measured using a focus group at the end of the intervention.
- 12. Key elements that might have affected the implementation of the intervention are measured using an in-depth interview with one school contact per intervention school at the end of the intervention.

Added 19/10/2021:

13. Reported physical activity measured using the International Physical Activity Questionnaire (IPAQ) at baseline, mid-intervention, end of intervention and follow-up intervention

Overall study start date

01/04/2019

Completion date

31/05/2023

Eligibility

Key inclusion criteria

- 1. Female pupils attending schools selected to participate.
- 2. Aged 12-14 years (i.e. Year 9/10 (NI) or First/Second Year (Rol)).
- 3. Healthy and free from any medical condition that limits their participation in a brisk walking intervention.

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

12 Years

Upper age limit

14 Years

Sex

Female

Target number of participants

450 (18 schools will be recruited and within each school at least 24 children will be recruited)

Total final enrolment

590

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/09/2019

Date of final enrolment

30/10/2021

Locations

Countries of recruitment

England

Ireland

Northern Ireland

United Kingdom

Study participating centre

Ulster University

Magee Campus Northland Road Londonderry United Kingdom

BT48 7JL

Study participating centre Letterkenny Institute of Technology

Port Road Letterkenny Ireland F92 FC93

Study participating centre University of Bristol

Senate House Tyndall Ave Bristol United Kingdom BS8 1TH

Study participating centre University of Wolverhampton

Wulfruna St Wolverhampton United Kingdom WV1 1LY

Sponsor information

Organisation

Ulster University

Sponsor details

Research Governance
Jordanstown Campus
Newtownabbey
Belfast
Northern Ireland
United Kingdom
BT37 0QB
028 9036 6518 - Research Governance Officer
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Sponsor type

University/education

Website

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

ROR

https://ror.org/01yp9g959

Funder(s)

Funder type

Government

Funder Name

Department of Health, Northern Ireland

Alternative Name(s)

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

United Kingdom

Funder Name

Health Service Executive (ROI)

Results and Publications

Publication and dissemination plan

To ensure the results are disseminated to the scientific community and policy makers, it is planned that there will be at least four publications in high-impact peer-reviewed journals. In addition to publication of a protocol paper, a paper outlining the main findings (physical activity), a paper detailing the results of the process evaluation and a paper including which includes the findings on the qualitative evaluation of the intervention will be published. All papers will be submitted for publication in open access journals.

Intention to publish date

31/05/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request. The datasets have not yet been finalised, however when available more information will be added to our trial registration with full instructions on how data access requests can be made.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
	protocol		23/04		

<u>Protocol article</u>		21/04/2020	/2020	Yes	No
Statistical Analysis Plan	version 1.0	09/03/2023	09/03 /2023	No	No
Results article		23/11/2023	24/11 /2023	Yes	No
Results article	Effectiveness of the WISH intervention	19/02/2024	21/02 /2024	Yes	No