The effectiveness and health impact of a wholesystems physical activity intervention at increasing the physical activity levels of children aged 5-11 years

Submission date	Recruitment status No longer recruiting	Prospectively registered		
09/09/2021		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
17/02/2022	Ongoing	Results		
Last Edited	Condition category	Individual participant data		
02/10/2024	Other	[X] Record updated in last year		

Plain English summary of protocol

Background and study aims

Research consistently finds that children in the UK do not do enough physical activity. This is particularly worrying because being active is beneficial for physical and mental health throughout the lifespan. There have been a wide range of interventions designed to improve physical activity in young children, however many have not been effective in the long-term because they tend to be one-dimensional and do not account for wider societal influences. This research aims to evaluate the effectiveness of JU:MP, an intervention which accounts for individual children, school and community factors to enable a whole-system approach to increasing physical activity.

Who can participate?

Children can participate in this study if they will be in Year 1, Year 2 or Year 3 in Primary school when data collection starts in September 2021. They also need to attend school in either North Bradford (the area selected to receive the JU:MP intervention) or in an area in West Yorkshire that has been matched as having similar people living their (e.g. similar ethnicities, levels of deprivation etc.). They must have their parent's consent to take part, and they need to want to be a part of this study themselves!

What does the study involve?

In this study we will go into schools and measure children's height, weight and waist circumference. We will also fit them with a waist-worn device which they will wear for a week measures how active they are and how long they spend sitting down and resting. We will ask their teachers to fill in a questionnaire which contains questions about how social the child is and how well they can control their emotions. We will also ask their parents to fill in questionnaires asking about their child's physical activity, sleep patterns, health and local community.

What are the potential benefits and risks of participating? Children living in the areas where the intervention is happening will have access to a whole host of new and exciting opportunities to be physically active. This will hopefully mean they can live happier and healthier lives! Children that take part in the experiment also get the opportunity to help out with one of the largest science experiments of its kind in the UK! As a thank you to all children taking part, they will also receive a 'goodie bag' filled with stickers, water bottles pens etc. There are no expected risks to participating in this research.

Where is the study run from?

This study is happening in West Yorkshire, in the United Kingdom, led by the Bradford Institute for Health Research. The intervention will be happening in Bradford, one of the youngest cities in the UK with large variations in ethnicity and high levels of child poverty. We also need control areas (which are matched based on similar demographics) to see whether changes in physical activity are due to the intervention, or whole population changes!

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

Data collection for this study will begin in September 2021 and will run for three years. We want to follow the children receiving this intervention long-term to see whether they can increase their levels and sustain these improvements.

When is the study starting and how long is it expected to run for? June 2021 to September 2025

Who is funding the study?

This research is being funded by Sport England (https://www.sportengland.org/), to increase the physical activity levels of children living in disadvantaged areas (who are highly susceptible to being inactive during their lifetime).

Who is the main contact?
Dr Daniel Bingham, Daniel.Bingham@bthft.nhs.uk

Contact information

Type(s)

Scientific

Contact name

Dr Daniel Bingham

ORCID ID

https://orcid.org/0000-0002-5809-7357

Contact details

Bradford Institute for Health Research Bradford Royal Infirmary Duckworth lane BD9 6RJ Bradford United Kingdom BD9 6RJ +44 (0)1274 364 474 daniel.bingham@bthft.nhs.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

JUMP-CT

Study information

Scientific Title

The effectiveness of a whole-systems physical activity intervention (Join Us: Move. Play; JU:MP) implemented at the neighbourhood level in increasing children's (age 5-11 years) accelerometer measured physical activity: a quasi-experimental non-equivalent groups design

Acronym

JUMP

Study objectives

- 1. To what extent is JU:MP, a whole-system physical activity intervention for children aged 5-11 years old, effective at increasing MVPA after 24 months and 36 months of intervention?
- 2. What outcomes moderate and mediate JU:MP intervention effects?
- 3. What are the wider implications of JU:MP on child health outcomes?
- 4. Is the JU:MP programme acceptable to children and parents/carers?
- 5. To what extent was there intervention fidelity within JU:MP?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 07/06/2021, University of Bradford Research Ethics Committee (Humanities, Social and Health Sciences Research Ethics Panel, University of Bradford, Richmond Road, Bradford, BD7 1DP, UK; no telephone number provided; ethics@bradford.ac.uk), ref: E891

Study design

Quasi-experimental non-blinded interventional study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

The physical activity levels of children aged 5-11 years is being studied.

Interventions

The JU:MP intervention seeks to commission projects and invest in capital opportunities, bespoke to each neighbourhood, to account for different barriers and facilitators to physical activity in each neighbourhood, as well as differences in pre-existing assets. It is research-led and is therefore being iteratively: however, it is flexible and adaptive, and is co-designed with key local stakeholders to ensure relevance in each of the neighbourhoods. How the intervention looks, and is administered will therefore look very different across neighbourhoods.

Children will be assigned to intervention [JU:MP] or control [no active intervention] based on the neighbourhood where they attend school. Sport England selected North Bradford as a local delivery pilot (LDP) area (which aims to increase physical activity) to target children and young people aged 5-14 years living in areas of high deprivation. Children attending living in Sport England selected neighbourhoods in North Bradford will receive the intervention. Control neighbourhoods in other areas of West Yorkshire will be matched based on school census data, and will be required to have: (i) no more than 1 index of multiple deprivation (IMD, a measure of socioeconomic status) decile median difference than a JU:MP neighbourhood, (ii) no more than 10% difference of the proportion of children eligible for free school meals, and (iii) the same predominate ethnic group (majority or large minority) as a JU:MP neighbourhood with ideally no more than a 15% difference.

Summary of intervention for parents of children who are in the intervention arm: The Join US: Move Play (JU:MP) programme is happening over the next few years in the neighbourhood where your child attends school. JU:MP is a four-year programme funded by The National Lottery through Sport England and is led by Active Bradford. The JU:MP programme aims to support children and families in parts of North Bradford to be more active.

Summary of intervention for parents of children who are in the control arm: The Join US: Move Play (JU:MP) programme is a four-year programme funded by The National Lottery through Sport England. The JU:MP programme aims to support children and families in parts of North Bradford to be more active. North Bradford has the JU:MP programme because Active Bradford and Born in Bradford were successful in applying for Bradford to be 1 out 12 areas to receive funding from Sport England to try out new ways to increase physical activity (https://www.sportengland.org/campaigns-and-our-work/local-delivery)

The total duration of intervention and follow-up for all study arms – The total duration of the intervention is three years (Autumn/winter 2021 to End of 2024). The follow-up for the study arms are 2 years (Autumn/winter 2023 and autumn/winter 2024).

Intervention Type

Behavioural

Primary outcome measure

Average daily moderate to vigorous physical activity (MVPA) will be measured using Actigraph accelerometers, worn for 7 consecutive days (excluding bathing and swimming), across three time points: (i) basline data collection, commencing September 2021, (ii) 24 months later – during the intervention, and (iii) 36 months post-baseline – after the intervention has finished.

Secondary outcome measures

- 1. Average daily light physical activity, measured using Actigraph accelerometers at three time points (baseline, 24 months and 36 months)
- 2. Average daily sedentary time, measured using Actigraph accelerometers at three time points (baseline, 24 months and 36 months)
- 3. Socioemotional development, measured using teacher-reported Strengths and Difficulties Questionnaire (SDQ) at three time points (baseline, 24 months and 36 months)
- 4. Anthropometrics including height, weight and waist circumferences measured using a Seca213 stadiometer (d=1mm), a digital scale such as the Tanita Body composition Analyser SC-240MA III and a measuring tape (Seca 201, d=1mm) respectively, will be measured at three time points (baseline, 24 months and 36 months)
- 5. Parent reported child physical activity, measured using the Youth Physical Activity Profile, will be measured at three time points (baseline, 24 months and 36 months)
- 6. Children's average sleep time, measured by parent report for both weekdays and weekend days will be measured at three time points (baseline, 24 months and 36 months)
- 7. Places where children are active, measured by a purpose-made parental questionnaire, will be measured at three time points (baseline, 24 months and 36 months)
- 8. Attendance to, and activity at religious settings, measured by a purpose-made parental questionnaire, will be measured at three time points (baseline, 24 months and 36 months)
- 9. Characteristics of the child's local neighbourhood, measured by parental-report using questions from the neighbourhood characteristics questionnaire and the physical activity parenting practices questionnaire, will be measured at three time points (baseline, 24 months and 36 months)
- 10. Children's quality of life, measured using a parental report version of the EQ-5D-Y and Pediatric Quality of Life Survey (PedsQL), will be measured at three time points (baseline, 24 months and 36 months)

Overall study start date

07/06/2021

Completion date

01/09/2025

Eligibility

Key inclusion criteria

- 1. Children attend a primary school in either a JU:MP neighbourhood or a matched control neighbourhood
- 2. Children in Primary school years 1-3 (aged 5-8 years old) when baseline testing begins in September 2021
- 3. Children who have parental consent to take part in the study
- 4. Children who verbally assent to take part or proxy assent (for SEND children who may not have the capacity to assent)

Participant type(s)

Other

Age group

Child

Lower age limit

5 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

A sample size calculation was conducted using STATA V.15, function 'power two means cluster'. This calculation found that a minimum sample of n=1200 children (n=600 per condition, n=200 per neighbourhood, n=32 per school) would be required to have adequate power (80%) to detect a \geq 10 minute change in mean MVPA minutes (the primary outcome) at both 24 months follow-up and 36 months follow-up. The Sample size calculation factored in six clusters (three intervention neighbourhoods, three control neighbourhoods) with a 5% two-sided alpha; assumed control average daily value of MVPA of 53.7 minutes, a standard deviation (SD) of 19.7, and an intra-cluster correlation (ICC) value of 0.007, which was conservatively rounded up to 0.01. As the JU:MP project is a neighbourhood level intervention and no previous studies of this type could be identified that used accelerometers as an outcome with children or young people, the values of an average daily MVPA, SD and ICC were derived from an unpublished pilot study from the pilot phase of the JU:MP project (n=564, n=3 neighbourhoods and n=12 primary schools). Missing data were conservatively factored into sample size calculation by assuming a 30% loss on accelerometer non-compliance at baseline, followed by further 50% (30% accelerometer non-compliance, 20% loss to attrition) of data at both 24 months follow-up and 36 months follow-up.

Key exclusion criteria

- 1. Children attending school outside of JU:MP and matched control neighbourhoods
- 2. Children under the age of 5 and over the age of 8 when baseline testing begins (September 2021)
- 3. Children without parental consent
- 4. Children who do not assent, or proxy assent (for SEND children who may not have the capacity to assent)

Date of first enrolment 05/07/2021

Date of final enrolment 01/03/2022

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Wolfson Centre for Applied Health Research

Bradford Royal Infirmary Duckworth lane BD9 6RJ Bradfford United Kingdom BD9 6RJ

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details

Bradford Institute for Health Research Bradford Royal Infirmary Duckworth lane Bradfford England United Kingdom BD9 6RJ +44 (0)1274 383 418 Bradfordresearch@bthft.nhs.uk

Sponsor type

Research organisation

Website

https://www.bradfordresearch.nhs.uk/

ROR

https://ror.org/05gekvn04

Funder(s)

Funder type

Charity

Funder Name

Results and Publications

Publication and dissemination plan

This work will be submitted for publication in a high impact factor physical activity journal, with a view to making the article open access. There is no plan to share the data from this study publicly due to constraints with ethical approval.

Intention to publish date

01/07/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

The datasets generated during and/or analysed during the current study are/will be available upon request from the lead researchers Dr Daniel Bingham Daniel.bingham@bthft.nhs.uk, Dr Sally Barber sally.barber@bthft.nhs.uk and the Born in Bradford (BiB) executive who are ultimately responsible for the use of data. All data shared will be anonymised and all particnipants will have had consented to sharing their anonymised data for the use of future scientific publications and analysis. Scientists are encouraged and able to use the trail data and any other BiB data, which are available through a system of managed open access. Details are stated below:

Please read the guidance on how to access BiB data - https://borninbradford.nhs.uk/research /how-to-access-data/. Before you contact BiB, please make sure you have read our Guidance for Collaborators (https://borninbradford.nhs.uk/research/guidance-for-collaborators) Our BiB executive review proposals on a monthly basis and we will endeavor to respond to your request as soon as possible. You can find out about the different datasets which are available (https://borninbradford.nhs.uk/research/documents-data/). A data dictionary of the JUMP trial data will published online with other BiB data dictionary's when available. If you are unsure if we have the data that you need please contact a member of the BiB team (borninbradford@bthft. nhs.uk). Once you have formulated your request please complete the 'Expression of Interest' form available (https://borninbradford.nhs.uk/wp-content/uploads/Expression-of-interest-proforma-v2_DM-12.01.18.doc) and send to borninbradford@bthft.nhs.uk. If your request is approved we will ask you to sign a collaboration agreement https://borninbradford.nhs.uk/wp-content/uploads/BiB_CollaborationAgreement-12.01.18.docx and if your request involves biological samples we will ask you to complete a material transfer agreement https://borninbradford.nhs.uk/wp-content/uploads/BiB_CollaborationAgreement-12.01.18.docx.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Control group version 2.0	20/07/2021	10/09/2021	No	Yes
Participant information sheet	Intervention group version 2.0	20/07/2021	10/09/2021	No	Yes

<u>Protocol file</u>	version 1.0	01/05/2021	10/09/2021	No	No
Protocol article		31/03/2023	03/04/2023	Yes	No