

Move Well, Feel Good feasibility trial

Submission date 10/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 18/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2024	Condition category Mental and Behavioural Disorders	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Children's motor skill ability is linked to mental health problems such as anxiety and depression. The COVID-19 lockdown restrictions negatively affected children's mental health and reduced their participation in physical activity, which is vital for motor skill development. As school-based programmes are promising ways to tackle declines in motor skills and mental health, this study evaluated the feasibility of an intervention to improve children's mental health and motor skills.

Who can participate?

Year 5 (age 9-10 years) children from mainstream primary schools who are physically able to participate in Physical Education lessons.

What does the study involve? (for participants)

The children took part in the 'Move Well, Feel Good' intervention programme during school time over one school term. The programme components included Physical Education lessons, break-time activities, home-based tasks, and cross-curricular activities.

What are the possible benefits and risks of participating?

Benefits: improvements in mental health, motor competence, and psychosocial skills

Risks: this was a low-risk project which presented risks of the same magnitude as those which occur during a regular school day.

Where is the study run from?

Edge Hill University (UK)

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

November 2021 to December 2022

Who is funding the study?

Waterloo Foundation (UK)

Who is the main contact?

Prof. Stuart Fairclough, stuart.fairclough@edgehill.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Stuart Fairclough

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

MWFG1023

Study information

Scientific Title

A primary school-based motor competence and psychosocial skills feasibility intervention to improve children's mental health and wellbeing

Acronym

MWFG

Study objectives

1. The Move Well, Feel Good intervention programme improves children's mental health and wellbeing more than usual practice
2. The Move Well, Feel Good intervention programme improves children's motor competence more than usual practice
3. The Move Well, Feel Good intervention programme improves children's psychosocial skills more than usual practice

Ethics approval required

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Ethics approval(s)

approved 01/12/2021, Edge Hill University Science Research Ethics Committee (Edge Hill University, St Helens Road, Ormskirk, L39 4QP, United Kingdom; +44 (0)1695584636; ResearchSystems@edgehill.ac.uk), ref: ETH2122-0062

Study design

Pre-post design without control group

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Mental health

Interventions

A co-produced intervention programme over one school term consisting of one weekly Physical Education lesson, classroom-based activities, home-based tasks, and activities at break times.

Intervention Type

Behavioural

Primary outcome(s)

Mental health measured using the Strengths and Difficulties Questionnaire at baseline and at end of intervention (12 weeks post-baseline)

Key secondary outcome(s)

1. Motor competence measured using the Canadian Agility and Movement Skill Assessment at baseline and at the end of intervention (12 weeks post-baseline)
2. Social skills measured using the prosocial behaviour subscale of the Strengths and Difficulties Questionnaire at baseline and at the end of intervention (12 weeks post-baseline)

Completion date

16/12/2022

Eligibility**Key inclusion criteria**

1. Year 5 (aged 9-10 years) children from one or two-form entry mainstream primary schools
2. Physically able to participate in Physical Education lessons

Participant type(s)

Learner/student

Healthy volunteers allowed

No

Age group

Child

Lower age limit

9 years

Upper age limit

10 years

Sex

All

Total final enrolment

108

Key exclusion criteria

1. Children younger than age 9 years and older than age 10 years
2. Not physically able to take part in Physical Education lessons

Date of first enrolment

03/04/2022

Date of final enrolment

09/09/2022

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Edge Hill University

St. Helens Road

Ormskirk

United Kingdom

L39 4QP

Sponsor information

Organisation

Edge Hill University

ROR

<https://ror.org/028ndzd53>

Funder(s)

Funder type

Charity

Funder Name

Waterloo Foundation

Alternative Name(s)

The Waterloo Foundation, TWF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the study will be stored in anonymised format via the publicly available Open Science Framework at <https://osf.io/qfmc7/>

The type of data stored: child-level demographic, anthropometric, and outcome data

Dates of availability: available now with no end date

Whether consent from participants was required and obtained: required and obtained

Any ethical or legal restrictions: none, the data are totally de-identified

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/06/2024	14/06/2024	Yes	No
Dataset			10/10/2023	No	No
Participant information sheet			10/10/2023	No	Yes
Protocol file			10/10/2023	No	No