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Move Well, Feel Good feasibility trial

Submission date
10/10/2023

Recruitment status
No longer recruiting

Registration date
18/10/2023

Overall study status
Completed

Last Edited
14/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[X] 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

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Additional identifiers

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
Ethics approval required

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

Primary study design

Interventional

Study design
Pre-post design without control group

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