# Engaging adolescents in changing behaviour: a programme of research to improve the diets and physical activity levels of adolescents

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
11/07/2019		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/08/2019	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
10/09/2025	Other			

#### Plain English summary of protocol

Background and study aims

Poor diet and lack of exercise cost the NHS £7 billion a year and cause many to die early. The researchers aim to build and test an intervention to help teenagers eat better and exercise more. Habits formed as teenagers tend to last, and physical and psychological changes during adolescence make it an important time to help them form healthier habits. Making small sustained changes, e.g. eating more fruit and vegetables and being more active, can reduce risks of heart disease or diabetes in later life. Existing interventions for helping teenagers eat better or exercise more, only work for those ready to change, or who see diet and exercise as important. It is known that school-based interventions may be most effective, face-to-face support is helpful, the role of friends/family is important, websites and smartphones are widely used, and teenagers spend time playing games on phones and computers. Using existing knowledge, the researchers have developed an intervention that motivates and supports teenagers to eat better and exercise more, and wan to test this with teenagers from state secondary schools.

#### Who can participate?

School children aged 12-13 (Year 8) at state schools in Hampshire and surrounding areas

#### What does the study involve?

Participating schools are randomly allocated to either the intervention group or the control group. The intervention contains three elements:

- 1. Participation in LifeLab at the University of Southampton: a three-week science module linked to the National Curriculum, which helps teenagers think about science and their health
- 2. Encouragement from teachers trained to support students to improve their diets and exercise
- 3. A specially-designed, interactive smartphone app that involves friends and has game features The control group receive no intervention. Intervention duration is 3 weeks for the teaching of the LifeLab module and up to 3 months for the other components including the digital app. There is one follow-up data collection at 12 months.

What are the possible benefits and risks of participating?

The possible benefits of taking part are: improved awareness about the links between healthy lifestyles and long term health; a better understanding of the role of health research; improvements in dietary quality and physical activity levels. There are no risks involved in participating in this trial and a risk assessment has been done as part of the ethics application.

Where is the study run from?

Medical Research Council Lifecourse Epidemiology Unit (MRC LEU), University of Southampton (UK)

When is the study starting and how long is it expected to run for? January 2016 to December 2023

Who is funding the study?
NIHR Programme Grants for Applied Research (UK)

Who is the main contact?
Professor Mary Barker, meb@mrc.soton.ac.uk

# Contact information

#### Type(s)

Scientific

#### Contact name

Prof Mary Barker

#### **ORCID ID**

https://orcid.org/0000-0003-2976-0217

#### Contact details

NIHR Southampton Biomedical Research Centre University of Southampton MRC Lifecourse Epidemiology Unit Southampton General Hospital Southampton United Kingdom SO16 6YD +44 (0)23 8077 7624 meb@mrc.soton.ac.uk

# Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

# Study information

#### Scientific Title

Engaging adolescents in changing behaviour (EACH-B): a programme of research to improve the diets and physical activity levels of adolescents

#### Acronym

EACH-B

#### **Study objectives**

The hypothesis is that LifeLabPlus, comprising engagement with the LifeLab educational programme followed by support from trained teachers and a digital intervention, will improve diet and physical activity levels in 12- to 13-year-old school students.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Pilot trial approved 21/11/2017, full trial approved 21/06/2019, Ethics and Research Governance Online (Faculty of Medicine, University of Southampton, Building 85, Life Sciences Building, Highfield Campus, Southampton, SO17 1BJ; 023 8059 5000; rgoinfo@soton.ac.uk), ref: 30054.

#### Study design

Multicentre cluster randomised controlled trial

#### Primary study design

Interventional

#### Study type(s)

Prevention

# Health condition(s) or problem(s) studied

Dietary quality and physical activity levels of teenagers aged 12-13 years old.

#### Interventions

Randomisation will be carried out by the University of Southampton's Clinical Trial Unit and will be at the school level. There will be 25 intervention and 25 control schools.

The intervention contains three elements:

- 1. Participation in LifeLab at the University of Southampton: a three-week science module linked to the National Curriculum, which helps teenagers think about science and their health
- 2. Encouragement from teachers trained to support students to improve their diets and exercise
- 3. A specially-designed, interactive smartphone app that involves friends and has game features

The pilot trial finished in May 2019 with six schools involved. These are: Upper Shirley High School, Oasis Lordshill, Oasis Mayfield, Woodlands, Wildern, and Swanmore secondary schools, all are based in Hampshire, UK.

The control group will receive no intervention.

Intervention duration is 3 weeks for the teaching of the LifeLab module and up to 3 months for the other components including the digital app. There is one follow-up data collection at 12 months.

#### **Intervention Type**

Behavioural

#### Primary outcome(s)

- 1. Dietary quality measured by purpose-made, validated Food Frequency Questionnaire (FFQ) at baseline and 12 months post intervention
- 2. Physical activity measured by accelerometry at baseline and 12 months post baseline

#### Key secondary outcome(s))

Current secondary outcome measures as of 01/09/2025:

Measured at baseline and 12 months post-intervention:

- 1. Well-being measured using Child Health Utility (CHU 9D) and Cantril ladder
- 2. Self-regulation and motivation for having a healthy lifestyle in adolescence measured using purpose-made Confidence and Behavioural Autonomy questionnaires (undergoing validation)
- 3. Body composition: height and weight used to calculate BMI Z-scores, taking account of both sitting and standing height as an indicator of pubertal status change
- 4. Compliance/adherence to intervention protocol measured through process evaluation
- 5. Self-efficacy for healthy eating and physical activity measured through CBA questionnaires
- 6. Registration and use of the digital intervention measured through app usage data as part of the process evaluation
- 7. Teachers' competence in HCS use measured as part of process evaluation
- 8. Educational outcomes, including science GCSE choices at three years post-intervention
- 9. Others specified by intervention planning (WP2.2)
- 10. Cost of intervention measured via health economics analysis
- 11. Categories of physical activity measured by accelerometry and validated YPAQ questionnaire
- 12. Qualitative feedback on implementation, mechanisms of impact and context. Measured by inperson and online interviews conducted as part of the process evaluation. Interviews conducted with students, teachers, heads of science and parents from intervention and control arm schools which took part in the EACH-B main RCT.

Previous secondary outcome measures as of 06/05/2020:

Measured at baseline and 12 months post-intervention:

- 1. Well-being measured using Child Health Utility (CHU 9D) and Cantril ladder
- 2. Self-regulation and motivation for having a healthy lifestyle in adolescence measured using purpose-made Confidence and Behavioural Autonomy questionnaires (undergoing validation)
- 3. Body composition: height and weight used to calculate BMI Z-scores, taking account of both sitting and standing height as an indicator of pubertal status change
- 4. Compliance/adherence to intervention protocol measured through process evaluation
- 5. Self-efficacy for healthy eating and physical activity measured through CBA questionnaires
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- 8. Educational outcomes, including science GCSE choices at three years post-intervention

- 9. Others specified by intervention planning (WP2.2)
- 10. Cost of intervention measured via health economics analysis
- 11. Categories of physical activity measured by accelerometry and validated YPAQ questionnaire

Previous secondary outcome measures:

Measured at baseline and 12 months post-intervention:

- 1. Well-being measured using EQ-5D-Y and Cantril ladder
- 2. Self-regulation and motivation for having a healthy lifestyle in adolescence measured using purpose-made Confidence and Behavioural Autonomy questionnaires (undergoing validation)
- 3. Body composition: height and weight used to calculate BMI Z-scores, taking account of foot size and height changes as an indicator of pubertal status change
- 4. Compliance/adherence to intervention protocol measured through process evaluation
- 5. Self-efficacy for healthy eating and physical activity measured through CBA questionnaires
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#### Completion date

31/12/2023

# Eligibility

#### Key inclusion criteria

School children aged 12-13 years (Year 8) at state schools in Hampshire and surrounding areas

#### Participant type(s)

Other

#### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

12 years

#### Upper age limit

13 years

#### Sex

All

#### Key exclusion criteria

Single-sex schools

# **Date of first enrolment** 11/09/2019

# Date of final enrolment 31/12/2022

# Locations

# Countries of recruitment

United Kingdom

England

## Study participating centre Swanmore College

New Road Swanmore United Kingdom SO32 2RB

# Study participating centre Wildern School

Wildern Lane
Hedge End
Southampton
United Kingdom
SO30 4EJ

# Study participating centre Woodlands Community College

Minstead Avenue Harefield Southampton United Kingdom SO18 5FW.

## Study participating centre Upper Shirley High School

Bellemoor Road Shirley Southampton United Kingdom SO15 7QU

### Study participating centre Oasis Academy Mayfield

Ashley Crescent Southampton United Kingdom SO19 9NA

# Study participating centre Oasis Academy Lordshill

Nursling Southampton United Kingdom SO16 0XN

# Sponsor information

#### Organisation

University Hospital of Southampton Foundation Trust (UHSFT)

#### **ROR**

https://ror.org/0485axj58

# Funder(s)

## Funder type

Government

#### **Funder Name**

Programme Grants for Applied Research

#### Alternative Name(s)

NIHR Programme Grants for Applied Research, PGfAR

## **Funding Body Type**

Government organisation

# Funding Body Subtype

National government

# **Results and Publications**

#### Individual participant data (IPD) sharing plan

Quantitative data (from primary and secondary outcome measures) collected from schools which took part in the National Institute for Health Research (NIHR)-funded EACH-B trial will be anonymised and uploaded to Pure, the University of Southampton's institutional research repository (https://eprints.soton.ac.uk/). Data will be uploaded in sections, as and when they are used in published journal articles. This is in line with the university's policy that all research outputs and activities are recorded in the institutional repository. Data uploaded to Pure will be retained permanently; however, the research team can request that any data within Pure be deleted at any time. Data uploaded to Pure will be designated under the 'public' category to comply with the university's Research Data Management Policy, meaning it will be accessible to anyone. This data sharing plan aligns with the NIHR data sharing policies, which promote openness and transparency in research. Demographic data will only be made available upon reasonable request to Professor Mary Barker, by bona fide researchers and will be fully anonymised and redacted as necessary.

Qualitative data (written transcripts from interviews conducted with students, teachers and parents) collected as part of the process evaluation will be shared with bona fide researchers upon request to Professor Mary Barker, in line with institutional data sharing regulations. All qualitative data collected will be anonymised in accordance with the UK Data Service's guidance on anonymisation of qualitative data (https://ukdataservice.ac.uk/learning-hub/research-data-management/anonymisation/anonymising-qualitative-data), which includes de-identifying names of people and places, including geographical locations and companies. Geographical locations will be anonymised and aggregated at a regional level (for example, 'Portsmouth' would be replaced by 'city in Southern England'). Names of people will be replaced with identifiers (for example, 'person A'). Names of schools will be replaced with identifiers (for example, 'school A').

All data anonymisation will be conducted by members of the EACH-B research team, and no other researchers will have access to data prior to anonymisation.

#### IPD sharing plan summary

Stored in publicly available repository, Available on request

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Cost-effectiveness	17/07/2022	10/09/2025	Yes	No
Protocol article	protocol	15/10/2020	22/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes