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

Submission date	**Recruitment status**	[X] Prospectively registered
11/07/2019	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/08/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/03/2022	Other	[ ] Record updated in last year

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?
Dr Sofia Strommer
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

RP-PG-0216-20004

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

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a PIS

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 measure
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

Secondary outcome measures
Current 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
6. Registration and use of the digital intervention measured through app usage data as part of process evaulation
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

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

6. Registration and use of the digital intervention measured through app usage data as part of process evaulation
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

Overall study start date
01/01/2016

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

Age group
Child

Lower age limit
12 Years

Upper age limit
13 Years

Sex
Both

Target number of participants
Pilot trial: 3 intervention and 3 control schools; Main trial: 2,300 participants from 50 schools, each school represents one cluster

Key exclusion criteria
Single-sex schools

Date of first enrolment
11/09/2019

Date of final enrolment
31/12/2022

Locations

Countries of recruitment

England

United Kingdom

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)

Sponsor details
Tremona Road
Southampton
England
United Kingdom
SO16 6YD
+44 (0)23 8077 7222
Mikayala.King@uhs.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhs.nhs.uk

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Main output from this research will be a fully-developed, replicable intervention to improve adolescents' diet quality and physical activity. The researchers will determine the success of co-creation processes with adolescents, short, medium and long-term health benefits from intervening in adolescence, intervention cost-effectiveness, including reach/affordability and feasibility of rapid/inexpensive roll-out into routine practice in schools via the national curriculum.

Dissemination pathways include: close collaboration with stakeholders, reporting findings to teachers and students, interactive workshops with stakeholders; conference presentations and a series of papers in open access peer-reviewed journals; links with professional societies and policy-makers; regular press releases.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	15/10/2020	22/10/2020	Yes	No