LifeLab Southampton: improving health behaviours in teenagers

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/02/2015		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
25/03/2015	Completed	[X] Results		
Last Edited 06/05/2021	Condition category Circulatory System	Individual participant data		

Plain English summary of protocol

Background and study aims

There is increasing scientific evidence that a healthy lifestyle at an early age can have profound consequences on our long-term health, and on the health of our future children - a message that we need to get across to teenagers before they have children of their own. As many young people have never been inside a hospital or visited a research laboratory, such an experience can make a great impression. Over the past 5 years, the LifeLab project at the University of Southampton (UK) has established an educational programme for 11–15 year olds, focusing on developing their understanding of the science underpinning non-communicable disease risk in themselves and their future children. Our initial studies have shown changes in their attitudes and health-related behaviours 6–12 months later. The aim in this study is to assess the effectiveness of this intervention, in this age group, in producing attitude and behaviour change over 12 months.

Who can participate?

Secondary schools in and around Hampshire (UK) will be approached via contact with the Head of Science to offer the opportunity to be involved.

What does the study involve?

Our LifeLab intervention with school students has been tried and tested by the same project team over 5 years. It consists of curriculum-linked modules designed for 11–15 year olds, integrated with school science programmes and focusing on non-communicable disease risk and relevant science and health concepts. Key to this approach is hands-on visits to dedicated laboratories in a university/hospital research setting. Schools will be randomly allocated to the intervention or control group. We will compare control and intervention groups by matched preintervention and post-intervention validated questionnaires, to measure change in knowledge, attitude and behaviour in adolescents and their families. The control schools will only take part in the completion of questionnaires. Within each intervention school, three Year 9 classes of about 30 students each will be chosen for the intervention. The intervention will consist of the following components: a 4–6 week module of work for use in Year 9; teacher professional development workshops relating to science and science education relevant to implementation of the modules and including access to online support materials that describe the underpinning science; a single day (5 hour) LifeLab hands-on programme, conducted within the setting of a

customised hospital research laboratory, held part way through the module of work. Students interact with real stories of science and current data, meet in small groups with scientists, and experience first-hand activities utilising resources not available in a school laboratory. Examples of these activities include taking various physiology measurements (grip strength, jump height, flexibility, peak flow), measurement of arterial blood-flow and carotid artery wall thickness, and extraction of their own DNA to explore the effect of lifestyle on gene expression. These are all non-invasive activities.

What are the possible benefits and risks of participating?

This project will give school students a greater awareness of their own health and the health of teenagers in and around Southampton. Students and teachers will have the opportunity to take part in activities using equipment generally not available at school, to interact with scientists at the University and hospital and to find out more about the research taking place in the city. The activities are not associated with more risk than are those done in the normal science classroom at school; the activities are all completely safe and non-invasive. None of the activities will be testing for any specific health disorders. They are designed only as an educational tool. LifeLab teachers are not medically trained and will not be making any medical assessments based on the results the students find. Students will not be made to do any tests they do not wish to and may withdraw from any activities at any time; no results will be recorded.

Where is the study run from? University of Southampton (UK).

When is the study starting and how long is it expected to run for? November 2014 to November 2018

Who is funding the study? British Heart Foundation (UK)

Who is the main contact?
Dr Kathryn Woods-Townsend
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Contact information

Type(s)

Public

Contact name

Dr Kathryn Woods-Townsend

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Assessment of LifeLab Southampton: a cluster randomised trial of an intervention to engage secondary school students in improving their health behaviours and increasing their interest in science

Study objectives

Does an educational intervention in the form of LifeLab improve school students':

- 1. Science and health literacy and ability to use CPR techniques?
- 2. Health behaviours with respect to diet and lifestyle?
- 3. Understanding of the long-term influences of their health behaviours on their subsequent cardiovascular health and that of their future children?
- 4. Self-efficacy in relation to diet and lifestyle?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Governance Office, Faculty of Social and Human Sciences Ethics Committee, 07/11/2014, Ethics Committee identification RGO12328

Study design

Single-centre interventional cluster randomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Risk reduction of non-communicable diseases, with a focus on cardiovascular disease

Interventions

The intervention arm comprises:

- 1. Professional development for the teachers
- 2. Baseline questionnaires for all participating students
- 3. A 2–3 week module of work for use with year 9 school students (age 13–14 years old), linked to the UK National Curriculum encompassing both pre-lessons and post-lessons to be delivered in school
- 4. A hands-on practical day visit to LifeLab in the NIHR Southampton Biomedical Research Centre (UK) in nutrition, held part way through the module
- 5. Post questionnaires delivered around 12 months after the baseline questionnaires

The control arm comprises:

- 1. Baseline questionnaires for year 9 students
- 2. Follow-up questionnaires for year 9 students, delivered around 12 months after the baseline questionnaires

Intervention Type

Behavioural

Primary outcome measure

Nutrition and lifestyle literacy based on the critical nutrition literacy scale developed by Guttersrud et al, adapted for use by teenagers and supplemented with broader lifestyle questions

Outcomes will be measured using a questionnaire delivered at 12 months following the LifeLab intervention.

Improving measurement in nutrition literacy research using Rasch modelling: examining construct validity of stage-specific 'critical nutrition literacy' scales.
Guttersrud O, Dalane JØ, Pettersen S. Public Health Nutr. 2013 Apr;17(4):877-83

Secondary outcome measures

Students' understanding of influences on their

- 1. Cardiovascular health
- 2. Children
- 3. Health behaviours such as dietary patterns, physical activity, smoking and alcohol consumption, their self-efficacy scores in relation to diet and lifestyle
- 4. Choice of options for GCSEs
- 2. For your secondary outcomes, please provide any details on the method used to measure the outcome (e.g., pain, measured using the visual analogue scale [VAS]).

Secondary outcomes will be measured using a questionnaire. The questionnaire will be put together using methods previously used to assess dietary patterns (Development of a 20-item food frequency questionnaire to assess a 'prudent' dietary pattern among young women in Southampton Crozier SR, Inskip HM, Barker ME, Lawrence WT, Cooper C, Robinson SM; SWS Study Group. Eur J Clin Nutr. 2010 Jan;64(1):99-104.) and self efficacy (SPRING study: intervening to optimise the nutritional status of young women in pregnancy - being led by colleagues in MRC LEU), along with other questions designed to assess self reported physical activity levels. The questionnaire will also include questions assessing their knowledge and understanding of influences on their cardiovascular health and that of their subsequent children.

Overall study start date

10/11/2014

Completion date

10/11/2018

Eligibility

Key inclusion criteria

- 1. Registered on roll at participating school (all state secondary schools in the region are eligible for inclusion)
- 2. Year 9 student (aged 13–14 years)
- 3. Middle ability science student (teacher's classification)

Participant type(s)

Healthy volunteer

Age group

Child

Lower age limit

13 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

32 schools (clusters) 16 Intervention and 16 Control, with \sim 90 students in each school

Total final enrolment

3119

Key exclusion criteria

- 1. School has participated in the LifeLab programme in the previous year
- 2. Student has attended LifeLab as part of a previous class trip

Date of first enrolment 10/11/2014

Date of final enrolment 23/07/2015

Locations

Countries of recruitment

England

United Kingdom

Study participating centre University of Southampton

LifeLab, LD150, Level D Southampton General Hospital Southampton United Kingdom SO16 6YD

Sponsor information

Organisation

University of Southampton

Sponsor details

Research Governance Office George Thomas Building 37 Room 4079 University of Southampton Highfield Southampton England United Kingdom SO17 1BJ

Sponsor type

University/education

ROR

https://ror.org/01ryk1543

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

When all participating schools have completed the 12 month questionnaire, the data will be collated and subject to analysis. Dissemination will be through publication in science and education academic journals. All participating schools will be sent a summary of results and we would aim to interest both national and local media in reporting the findings. We will use social media to publicise the results as well.

2019 results in poster https://www.efolio.soton.ac.uk/blog/lifelab/files/2019/10/DOHaD-2019-BHF version5-1.pdf (added 08/04/2020)

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	21/08/2015		Yes	No
Results article		05/05/2021	06/05/2021	Yes	No