

# Lifeways cross-generation cohort study

<b>Submission date</b> 15/09/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/10/2017	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/12/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many factors, including genetic, environmental and lifestyle, affect the way children grow and continue to develop into adulthood and later life. Over the last 20 years or so, many birth cohort studies have been established in various countries, tracking the health status of children from birth, and attempting to determine the combination of physical and environmental factors that influence their long-term health status. The Lifeways cross-generation cohort study was established in 2001 to perform this function in an Irish context, and furthermore to look at grand-parental as well as parental influences on childhood development.

### Who can participate?

Mothers during pregnancy, their subsequent child/children, the father and grandparents of the child.

### What does the study involve?

Mothers who consent to participate are asked to complete a comprehensive health and lifestyle questionnaire, and to grant access to their hospital records and those of their child. The consenting fathers and grandparents complete a similar comprehensive health and lifestyle questionnaire, with the grandparents also being invited to undertake a simple physical exam, measuring height, weight and blood pressure, and to provide a blood sample to determine cholesterol levels. At child aged 3 years, family doctors are requested to complete a health questionnaire on all consenting participants (children, parents, grandparents) attending their health service. At child aged 5 years, the child and parents are invited to undertake a physical exam, measuring height, weight and waist circumference, and the mothers are asked to complete another comprehensive health and lifestyle questionnaire on behalf of herself, her child and her family. At child aged 9 years, the mothers and children are again invited to undertake a physical exam, measuring height, weight and waist circumference. Grandparents are also invited to a similar physical exam, but are furthermore asked to provide a blood sample to determine cholesterol levels. Parents and grandparents are also asked to complete a shortened health questionnaire at this time. At this follow-up time, children, parents and grandparents were also asked to provide a sample of hair and saliva. Finally, at this follow-up time, family doctors are requested to complete a health questionnaire on all consenting participants (children, parents, grandparents) attending their health service. As the children continue to age, further follow-up of the study participants is planned, involving similar physical exams and health and lifestyle questionnaires.

What are the possible benefits and risks of participating?

There are no direct benefits or risks (other than the general risks relating to blood tests) in taking part in this study, but the results of the study may help improve the health of families and children in Ireland.

Where is the study run from?

1. Coombe Women and Infant's Hospital (Italy)
2. University Hospital, Galway (Italy)

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

January 2000 to January 2038

Who is funding the study?

Health Research Board (Ireland)

Who is the main contact?

Professor Cecily Kelleher

[lifeways@ucd.ie](mailto:lifeways@ucd.ie)

### **Study website**

<https://www.ucd.ie/lifeways/>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Prof Cecily Kelleher

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## **Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

0

# Study information

## Scientific Title

Lifeways: to study the influence of socio-economic and familial characteristics on the health status and early-life development of children in Ireland

## Acronym

Lifeways

## Study objectives

To establish a longitudinal birth cohort in Ireland, including cross-generation information on children, their parents and grandparents:

1. To record the physical and psychological health status and socio-economic circumstances of individuals at birth, during early childhood, early adulthood and early middle age in Ireland
2. To follow them prospectively in order to measure their changing health status, and to assess the extent to which health status relates to social circumstances

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Baseline:

Coombe Women and Infant's Hospital, Dublin, 10/12/2001

University College Hospital, Galway (UCHG); National University of Ireland, Galway (NUIG), 23/09/2000 and 22/02/2001

Irish College of General Practitioners (ICGP), 16/10/2001 and 13/05/2002

Year-3 follow-up:

ICGP, UCHG and Coombe Women and Infant's Hospital, 16/11/2004 and 13/11/2004

Year-5 follow-up:

University College, Dublin (UCD)- 06/02/2007

Year-10 follow-up:

UCD, 10/02/2011 and 01/02/2012

UCHG, 27/06/2011

Coombe Women and Infant's Hospital, Dublin, 04/10/2012

St. Vincent's University Hospital, Dublin (SVUH), 06/12/2012

## Study design

Observational longitudinal cross-generation cohort study

## Primary study design

Observational

## Secondary study design

Longitudinal study

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Patient information sheets from each sweep of data collection can be accessed on the project website.

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

General health

**Interventions**

Participating adults are asked to complete comprehensive health and lifestyle questionnaires, including information on diet (food frequency questionnaire), health and morbidities, exercise, and household and economic circumstances. Questionnaire completion to date has been requested at baseline, year 5 follow-up and year-9 follow up.

Mothers are asked to consent to their hospital records and those of their children be made available to the study team. From these, pregnancy related data is extracted, such as pregnancy complications, child birth-weight and other neo-natal measurements.

All participants are asked to undergo a simple physical exam at least once, either in the home, attending at a specified clinic, or at their family doctor. For children, the primary physical exam is at age 5, with a subsequent exam at age 9.

A blood sample is also requested from participating grandparents at baseline and at year 9 follow-up, and from participating children at age 9 who were happy to do so.

Hair and saliva samples are requested from all participants at year 9 follow-up.

Family doctors of all participants who consented are asked to provide information on the health status of participants attending their practice, including any blood lipid and glucose measurements, and blood pressure measurements. This was undertaken at both year 3 and year 9 follow-up.

**Intervention Type**

Other

**Primary outcome measure**

Child Body Mass Index at 5 years old

**Secondary outcome measures**

1. Child's birth weight
2. Child's Body Mass Index at 9 years old
3. Child's asthma status at 3, 5 and 9 years old
4. Child's medical services use at 3,5 and 9 years old

**Overall study start date**

01/01/2000

**Completion date**

01/01/2038

## Eligibility

**Key inclusion criteria**

1. Pregnant women attending ante-natal clinics in two hospitals in Ireland, each representing distinct regions (East and West) of the country
2. Their live-born child/children of the women from that pregnancy
3. The child/children's father
4. At least one living grandparent of the child/children

**Participant type(s)**

Mixed

**Age group**

Mixed

**Sex**

Both

**Target number of participants**

1000 mothers during pregnancy, their child/children from that pregnancy, their husband /partner, and at least one living grandparent of the child/children

**Total final enrolment**

1882

**Key exclusion criteria**

Mothers born outside Ireland

**Date of first enrolment**

02/10/2001

**Date of final enrolment**

04/04/2003

## Locations

**Countries of recruitment**

Ireland

**Study participating centre**

Coombe Women and Infant's Hospital  
Cork Street

Dublin  
Ireland  
D08 XW7X

**Study participating centre**  
**University Hospital, Galway**  
Newcastle Road  
Galway  
Ireland  
H91 YR71

## **Sponsor information**

**Organisation**  
Health Research Board, Ireland

**Sponsor details**  
Grattan House  
67-72 Lower Mount Street  
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Ireland  
D02 H638  
+353 (0)1 2345000  
hrb@hrb.ie

**Sponsor type**  
Government

**Website**  
[www.hrb.ie](http://www.hrb.ie)

**ROR**  
<https://ror.org/003hb2249>

## **Funder(s)**

**Funder type**  
Research council

**Funder Name**  
Health Research Board

**Alternative Name(s)**

Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Ireland

## Results and Publications

**Publication and dissemination plan**

Over 20 peer-reviewed journal papers have been published from this cohort. Publication of results is ongoing: as of October 2017, there are currently 4 submitted journal papers undergoing peer review, with a further 3 publications planned in the next 12 months. A full list of publications and presentations is available on the project website. Study instruments and allied data can be accessed on the project website. Please see <https://www.ucd.ie/lifeways/research/>

**Intention to publish date**

23/10/2018

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

The datasets generated during and/or analysed during the current study are not expected to be made available. This is an observational study linking participant physical examination data, participant questionnaire data and data from the participants' general medical practitioners. As the study is ongoing, and to comply with the terms of engagement with the general practitioners, there is no plan in the short to medium term to archive the data for public use. The study data is held and managed by the Lifeways Study team at the School of Public Health, Physiotherapy and Sport Science at University College, Dublin, Ireland. Access to the study data is only available through direct collaboration with the Lifeways study team, contactable at [lifeways@ucd.ie](mailto:lifeways@ucd.ie).

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2018		Yes	No
<a href="#">Results article</a>	results	01/06/2019		Yes	No
<a href="#">Results article</a>	10 year follow up results	01/02/2020	12/12/2019	Yes	No