

SPRING: Southampton pregnancy intervention for the next generation

Submission date 01/08/2013	Recruitment status Suspended	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 12/09/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/05/2020	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Mothers nutritional status influences the growth and development of infants during pregnancy and after birth, and growth and development at these stages in life will improve bone growth and influence risk of long-lasting conditions such as heart disease and obesity in adulthood. Studies have shown that women of childbearing age from disadvantaged backgrounds are more likely to have a poor diet, and that those with the least healthy diets were found to be less likely to follow a good infant feeding pattern. It is also found that one third of women have insufficient vitamin D in late pregnancy, which can affect their childrens fat and bone mineral content. This study aims to find out whether a behaviour change intervention given by nurses and aimed at improving lifestyle during pregnancy will help improve a vitamin D supplementation intervention and have a positive effect on maternal and infant health.

Who can participate?

Pregnant women who are 18 years and over will be eligible if they attend the participating hospital for nuchal translucency or dating scans between 9 and 17 weeks of pregnancy and are aiming to give birth at a local maternity hospital.

What does the study involve?

A research nurse will approach women at their screening or dating scan visits, screen them for eligibility and gain written informed consent. At their first visit at 14 weeks, body measurements and a blood sample will be taken and they will be chosen, at random, to receive either vitamin D tablets or placebo (dummy) tablets to be taken during the study. Neither they nor the nurse will know which they are taking. They may also be chosen, at random, to have additional support from the nurse to explore in a conversation how to have a healthy pregnancy, and to set some goals for health behaviour change. At 19 weeks women will have a routine NHS ultrasound scan and a research ultrasound scan. Those in the behaviour change group will be engaged in a second conversation and review of progress with their goals. At 26 weeks, a nurse will phone the women to check on the progress of the pregnancy and confirm the date of the next appointment. Those in the behaviour change group will be engaged in a third conversation and review of progress. At 34 weeks, women will have an extra 3D ultrasound scan, fill in a questionnaire and measurements taken at 14 weeks will be repeated. Those in the behaviour change group will be engaged in a fourth conversation and review of progress. At birth, when

the women have had their babies, the midwife will collect samples from the placenta and the cord. Women will be invited to bring their babies for a bone scan and body measurements. A month after birth, a nurse will visit participants at home to discuss the health and well-being of the mother and their children. Those in the behaviour change condition will be engaged in a final conversation and review of goals. All mothers will be asked if they are prepared to be contacted again in the future to follow-up their babies as they grow.

What are the possible benefits and risks of participating?

Women will have 3D ultrasound scans of their babies, receive prints from the scan and an assessment of their baby's bone mass. These are not freely available to women under routine NHS care. Participants in the behaviour change group will be offered an opportunity to discuss issues arising with their pregnancy and skilled support in making changes to their lives and habits. This may lead to lasting improvements in their health and well-being, and in that of their child. The infant and childhood bone scan is associated with a low dose of radiation exposure, but this is equivalent to 2 days background radiation in Cornwall or 6 days in the UK generally. There is a possible and very small risk of asthma in children born to mothers in the top levels of vitamin D. The dose of vitamin D supplementation will bring women just into the normal range, to avoid over dosage. If the conversations cause distress, they will be stopped. All research staff are equipped with a list of helpline numbers so that participants can be referred to the appropriate service should it be necessary.

Where is the study run from?

Princess Anne Maternity Hospital, Southampton (UK)

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

October 2013 to October 2022

Who is funding the study?

The Medical Research Council, University Hospital Southampton NHS Foundation Trust, and NIHR Nutrition Biomedical Research Centre, Southampton (UK)

Who is the main contact?

Professor Cyrus Cooper
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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2013-002854-66

Protocol serial number
452623v.1

Study information

Scientific Title

Randomised controlled trial of an intervention to improve the diets, lifestyles and body composition of pregnant women and their offspring

Acronym

SPRING

Study objectives

Lifestyle support in pregnancy improves maternal vitamin D levels and body composition assessed by dual energy x-ray absorptiometry (DXA) at birth, in infants born to women who have been randomised to receive vitamin D supplements or placebo, and further randomised to receive behaviour change support in pregnancy by trained nurses or to receive usual care. It is an investigator-initiated translational study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hampshire B, 12/09/2013, ref: 13/SC/0409

Study design

Phase II randomised controlled trial with process evaluation

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Musculoskeletal

Interventions

Women attending the Princess Anne Hospital for dating scans will be recruited and randomised to receive vitamin D or a placebo, and further randomised to receive support from nurses

trained in supporting women to change their health behaviours or to receive usual care. There will therefore be four groups of participants:

1. Vitamin D supplemented plus usual care
2. Placebo plus usual care
3. Vitamin D supplemented plus behaviour change support
4. Placebo plus behaviour change support.

Randomisation to vitamin D or placebo will be blinded. This is not possible for randomisation to the behaviour change condition. Women are likely, however, to be unaware of their intervention status. All women will have contact with the research team at four time points during pregnancy. Obstetric details will be recorded at birth, and mothers and babies will be visited one month post-natally. Vitamin D levels, body composition, lifestyle and psychosocial outcomes in women and children will be compared across the four groups.

Intervention Type

Mixed

Primary outcome(s)

Current primary outcome measures as of 15/06/2018:

1. Maternal circulating plasma 25(OH) vitamin D concentration at 34 weeks' gestation
2. Maternal diet quality at 34 weeks' gestation assessed with a 20-item food frequency questionnaire

Previous primary outcome measures as of 30/05/2018:

1. Maternal circulating plasma 25(OH) vitamin D concentration at 34 weeks
2. Maternal diet quality at 34 weeks gestation assessed with a 20-item food frequency questionnaire

Previous primary outcome measures:

1. Vitamin D status of mother measured by assay at baseline and again at 34 weeks of pregnancy
2. Body composition of infants at birth measured by DXA scan

Key secondary outcome(s)

Current secondary outcome measures as of 15/06/2018:

1. Women's level of self-efficacy at 34 weeks' gestation, assessed with the General Self-Efficacy scale
2. Pregnancy weight gain assessed by gain in weight between recruitment and 34 weeks' gestation
3. Maternal diet quality 1 month after birth
4. Breastfeeding status 1 month after birth (yes/no)
5. Neonatal whole body bone mineral content (BMC), lean and fat mass within 2 weeks after birth assessed by dual-energy X-ray absorptiometry (DXA)

Previous secondary outcome measures:

1. Maternal weight gain in pregnancy measured in kg at 14 and 34 weeks pregnancy
2. Rates of breastfeeding initiation and duration measured by questionnaire at 1 month after birth
3. Dietary quality of women measured by questionnaire and assay at 14 and 34 weeks of pregnancy
4. Self-efficacy measured by questionnaire at 14 and 34 weeks and 1 month after birth

Completion date

31/10/2022

Eligibility

Key inclusion criteria

Women attending the Princess Anne Hospital for nuchal lucency or dating scans in early pregnancy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Women under the age of 18
2. Living outside a Southampton postcode area
3. Multiple pregnancy
4. Severely unwell
5. Allergic to peanuts or soya
6. Involved in another research study

Date of first enrolment

01/04/2014

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

University of Southampton

Southampton

United Kingdom

SO16 6YD

Sponsor information

Organisation

University Hospital Southampton NHS Foundation Trust (UK)

ROR

<https://ror.org/0485axj58>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Funder Name

Added 03/07/2014:

Funder Name

NIHR Nutrition Biomedical Research Centre, Southampton (UK)

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised data will be made available on request and will be stored at the MRC Lifecourse Epidemiology Unit, University of Southampton.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/10/2016		Yes	No
HRA research summary			28/06/2023	No	No