ISRCTN13385965 https://doi.org/10.1186/ISRCTN13385965

Dundee Family Health Study

Submission date
04/12/2017

Recruitment status
No longer recruiting

Registration date
10/12/2017

Overall study status
Completed

Last Edited
05/10/2020

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Play, sleep routine and family meals are known to be important for the overall health and wellbeing of young children, some studies have shown positive changes in these habits at nursery and school and that this makes a difference to the future health of the children. The Dundee Family Health Study aims to offer families with a child aged 2-5 years (pre-school), living in Dundee, an opportunity to build healthy family lifestyles linked to 4 behaviours or habits; PLAY and ACTIVITY, SLEEP ROUTINE, SCREEN TIME and FAMILY MEALS. The study takes place in families own homes and aims to understand if involvement in the study makes a difference to everyday routines and to the health of families.

Who can participate?
Children aged 2-5 year and their families, living in Dundee, Scotland.

What does the study involve?
For families who sign-up to be involved in this study, the researcher will visit the family home and use measures such as questionnaires and small pedometer type devices to record play, sleep routine, screen time and family meals. Families are randomly allocated to one of two groups. Those in the first group get 'a lot' of the programme. Those in the second group get 'a little' of the programme. Families receive supermarket gift vouchers at the beginning and again at the end of the study. The maximum number of visits is 7 over 6month and the least number of visits is 2 during a 6 month period.

What are the possible benefits and risks of participating?
The results will show if participation in the Dundee Family Health Study is beneficial to children and families in terms of physical activity, active play, family mealtimes, sleep routine and sedentary behaviour. There is no serious risk involved in participation in the study.

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

When is the study starting and how long is it expected to run for?
October 2016 to February 2019

Who is funding the study?
The Hannah Research Foundation (UK)

Who is the main contact?
Jenny Gillespie (Public)
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Translation of Healthy Habits, Happy Homes early childhood obesity prevention intervention to families in Scotland: Feasibility Trial

Study objectives
It is hypothesized that participation in the intervention will see improvements to time spent being physically active (active play), families eating together at mealtimes, sleep routine and a reduction in sedentary behaviour when compared to controls.

Study aims:
The primary aim is to determine if a full-scale efficacy trial of the adapted Healthy Habits Happy Homes study will be feasible and acceptable with families who live in more deprived communities in Scotland. This will involve an investigation of the following: testing a co-production approach to adaptation of study materials and development of promotional materials, the percentage of participant families who complete baseline and follow-up measures, appropriateness and practicality of the methods for obtaining outcome measures, acceptability of the intervention duration, content and delivery.

Ethics approval required

Old ethics approval format

Ethics approval(s)
The University of Strathclyde School of Psychological Sciences and Health Ethics Committee,12 /10/2017

Primary study design
Interventional

Study design
Feasibility randomised trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obesity, sedentary behaviour (at home), physical activity (at home), sleep (at home), family meals.

Interventions
This study, Dundee Family Health study (www.dfhstudy.com), adapts the original Healthy Habits Happy Homes (HHHH) home-based obesity prevention intervention for Scotland. The original HHHH study was used mainly in Latino families in Boston, USA and the feasibility of the intervention in Scotland needs to be determined.

Recruitment of around 40 participant families is expected. Families who live in a defined area within the North East area of Dundee City, with postcodes that are defined by the Scottish Index of Multiple Deprivation (SIMD) from the three most deprived quintiles are eligible to sign up to the study. A co-production approach is used for development and design of posters and fliers to promote recruitment of families to the study which will include a description of study design and incentives that is acceptable to the target group. These posters and fliers are placed in family friendly venues (community centres, libraries, toddler groups) and posted on local social media sites recommended by workers, parents and families.

The researcher contacts interested families and applies an eligibility questionnaire to assess suitability of families. For families that have given written consent for the study, baseline data collection is completed. Physical activity is measured over 4 consecutive days (using the ActivPAL accelerometer) as is night-time sleep. Anthropometric measures of height, weight, and body composition (as measured by bioelectrical impedance) are taken at home.

Following baseline measures, families are then randomised to receive either the control or intervention arm. Families receive an incentive (a grocery voucher) for completion of baseline data and again when the measures are repeated at the six month follow up.

Families randomised to the intervention group (n=20) receive 4 visits to the family home over the space of 6 months. The visits use a motivational interviewing approach to support the families to make positive lifestyle changes linked to the 4 key health behaviours of sleep, physical activity, screen time and family meal routine.

Families randomised to the control group (n=20) receive/ emailed general healthy lifestyle information linked to sleep routine, family meals, physical activity and screen time.

Intervention Type
Behavioural

Primary outcome(s)
1. BMI z-score is measured using height and weight measured at baseline and 6months
2. Physical activity is measured using the activPal accelerometer to be worn at baseline for five consecutive days and at 6 month - again for five consecutive days
3. Sedentary behaviour is measured using the activPal accelerometer to be worn at baseline for five consecutive days and at 6 month - again for five consecutive days
4. Acceptability issues is measured qualitatively using Semi-structured interviews or focus groups with parents (answering the questions: What is the acceptability of the intervention, and family views on enhancing acceptability? What is the acceptability of the trial procedures and outcome measures?) at 6month follow up

Key secondary outcome(s)
1. Sleep is measured using the activPal accelerometer at baseline and follow-up
2. Body composition (bio-electrical impedance) is measured using the Bodystat 1500 at baseline and follow-up
3. Family eating meals together is measured by parental questionnaire at baseline and follow-up
4. Screen time is measured by self report through parental questionnaire at baseline and follow up
5. Health related Quality of Life (HRQOl) is measured through PedsQL at baseline and follow up

Completion date
30/09/2019

Eligibility

Key inclusion criteria
1. Male or female
2. Pre-school children, aged 2-5 years old
3. Live in Dundee
4. Parental consent provided

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
26

Key exclusion criteria

Participants’ families where English language is not spoken.

Date of first enrolment
11/12/2017

Date of final enrolment
31/10/2018

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
University of Strathclyde (Scotland)
Physical Activity for Health Group
School of Psychological Science
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Sponsor information

Organisation
Univeristy of Strathclyde

ROR
https://ror.org/00n3w3b69

Funder(s)

Funder type
Charity

Funder Name
Hannah Research Foundation

Results and Publications

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?
Results article	results	01/11/2020	05/10/2020	Yes	No
Protocol article	protocol	07/06/2019	09/06/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes