

A preschool intervention to improve child and family health behaviours

Submission date 13/02/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 16/02/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/10/2017	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

One in five children starting school in England is now overweight or obese. Currently, there is a lack of programs with the aim of preventing obesity in preschool-age children in the UK. Previous research has revealed some positive results in changing some health behaviours related to obesity, such as diet and physical activity. However, overall numbers of obesity continue to rise in some age groups and social backgrounds. It has been suggested that preschool settings such as nursery schools may provide opportunities for promoting healthy lifestyles and also to develop and test behaviour-change programs. 'The Study of Kids in Preschool' (SKIP) is a behaviour-change preschool program aimed at improving families eating and encourage families to be more active. The aim of this study is to test whether the nursery staff and parents of preschool children are willing to complete the data collection measures and an intervention to improve health behaviours such as diet and physical activity.

Who can participate?

Families with a preschool child (3-5 years) who attend participating school.

What does the study involve?

Schools are randomly allocated to either receiving the programme or being placed on the waiting list. At the beginning of the programme, parents provide information about their child's activity level, eating habits, height and weight. Children are given cameras to take pictures of what they eat and drink every day for four days. The programme involves five monthly sessions as well as an introduction for parents. These sessions try to increase physical activity by teaching about healthy eating, healthy behaviours and healthy activity. Parents are given monthly newsletters that include information about healthy eating and ideas on how to get their kids to be more active. Parents also set monthly goals with the school staff in order to continue to make healthy choices with their children at home. At the end of the programme, children are given cameras again to take pictures of what they eat and drink for four days. Schools on the waiting list continue as normal during the study and are given the opportunity to participate in the program six months after the programme has ended.

What are the possible benefits and risks of participating?

Participants may benefit from possibly making changes to the family diet and activity and

promoting healthy living. There is a risk that participants may feel pressured to complete the monthly tasks or feeling judged if they were not able to.

Where is the study run from?

Four primary schools located in the North-East of England (UK)

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

February 2010 to July 2012

Who is funding the study?

Fuse, the Centre for Translational Research in Public Health (UK)

Who is the main contact?

Lorraine McSweeney

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PhD02

Study information

Scientific Title

A feasibility study with process evaluation of a preschool intervention to improve child and family lifestyle behaviours

Study objectives

Preschool settings may provide valuable opportunities to access children and their families not only for promoting healthy lifestyles, but also to develop and evaluate behaviour-change interventions.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle University Faculty of Medical Science Ethics Committee, 09/06/2011, ref: 00303_1

Study design

Cluster randomised feasibility trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Lifestyle behaviour change

Interventions

Four local government preschool centres associated with primary schools in the North East of England consent to participate and are randomised to either the intervention or wait list control groups. In order to reduce selection bias the preschools were allocated to intervention or wait list control by a computerised programme by the Newcastle University Clinical Trials Unit.

Intervention group: Families who agree to take part are asked to provide information about their child's diet (how often their child watched TV/DVDs, how active their child was and whether the family took part in activities such as walking, swimming etc). This information is recorded in a diary completed by the parents over 4 days before the start of the project and at the end to see if there were any changes. The child's height and weight are also recorded. To include children in the gathering of information about their diet, they are given disposable cameras and asked to take photographs of everything they ate and drank for four days at the beginning and end of the project. This also provided more information about the child's diet.

The participating schools receive the intervention titled the Study of Kids in Preschool' (SKIP) which consists of five monthly modules plus an introductory session for parents. The five monthly preschool-based sessions target the child and aim at increasing physical activity, knowledge of and prompting of healthy eating. Active Behaviour Change Techniques delivered by the preschool staff provide information on modelling and demonstrating behaviour, prompting practice and providing instruction on how to perform the behaviour.

Parents are given monthly newsletters by preschool staff. These newsletters provide dietary and physical activity information and tips for home-based tasks to increase physical activity and healthy eating and decrease screen time. Active Behaviour Change Techniques distributed via the newsletters are self-monitoring of behaviour, goal setting, action planning and coping planning.

Parents are asked to meet with preschool staff members once a month to set goals, monitor and review family health behaviour using written materials provided within the newsletters. The families are encouraged to share ideas, achievements, photographs and drawings of activities on a communal preschool information board. Home-based tasks include family cooking and tasting, 'No TV day' and increasing family 'active time' challenges.

Control group: Schools are placed on a wait-list and continue as usual for the duration of the study and are given the opportunity to participate six months after the study.

Intervention Type

Behavioural

Primary outcome measure

Feasibility of trial procedures and acceptability of the proposed intervention are measured through:

1. Recruitment rates (the number of eligible participants who consent to participate in the study) at baseline
2. Completion rates of data collection tasks by parents such as completion of food diaries including recording of child accelerometer/pedometer use, recording time of child TV viewing and recording of family active time at baseline and 6 months
3. Lost to follow-up (parents) measured by the number of parents who consent to participate that remain in the study until the end of follow-up at 6 months
4. Adherence to the proposed activities by preschools and parents (i.e. number of worksheets, feedback forms and questionnaires received from nursery staff and parents during the duration of the study) at 6 months
5. Number of pictures taken by children/families of meals consumed at baseline and 6 months

Secondary outcome measures

Children:

1. Height and weight are measured using a Leicester portable height measure with the head in the Frankfort plane, and Tanita scales TBF-300MA at baseline and 6 months
2. Physical activity is measured by either Actigraph GT1M accelerometer or ST-101 pedometer at baseline and 6 months
3. Portion size and eating environment (home, school, restaurant, with family alone etc.) are assessed by photographs taken with a digital camera provided to children and food diaries at baseline and 6 months

Parents:

1. Child eating behaviours are assessed using four day food diaries collected at baseline and 6 months
2. Sedentary behaviours are assessed by recording the time in hours/minutes children spend watching TV/DVDs and engaging in active behaviours in daily diaries at baseline and 6 months

Observational measures:

Child food intake when at preschool (2 week days) is recorded using a food checklist at baseline and 6 months

Overall study start date

08/02/2010

Completion date

16/07/2012

Eligibility

Key inclusion criteria

Families with a preschool child (3-5 years) who attend a local government preschool centre

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

Four clusters - a convenience sample of parents was recruited

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

11/10/2011

Date of final enrolment

25/11/2011

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Falla Park Primary School

Falla Park Road

Felling

Gateshead

United Kingdom

NE10 9HP

Study participating centre

Corpus Christi Primary School

Dunsmuir Grove

Gateshead

United Kingdom

NE8 4QL

Study participating centre

Brighton Avenue Primary School

Brighton Road

Gateshead

United Kingdom

NE8 1XS

Study participating centre

Bridgewater Community Primary School

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Sponsor type

University/education

ROR

<https://ror.org/01kj2bm70>

Funder(s)

Funder type

Research organisation

Funder Name

Fuse, the Centre for Translational Research in Public Health

Results and Publications

Publication and dissemination plan

Planned publication in a high impact peer reviewed journal.

Intention to publish date

31/03/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from lorraine.mcsweeney@ncl.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/03/2017		Yes	No