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Trial of Families for Health: helping families with children who are overweight to manage their weight

Submission date
17/08/2011

Recruitment status
No longer recruiting

Registration date
18/08/2011

Overall study status
Completed

Last Edited
09/01/2017

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
The prevalence of childhood obesity in the UK is high, and the NHS needs programmes which are effective in helping children who are already obese or overweight. A new programme called Families for Health has been developed at the University of Warwick to help families reduce obesity in children aged 7 to 11. This is a group-based programme, 10 weeks long, involving children and their parents. In addition to a focus on healthy eating and activity, it is designed to help parents develop their parenting skills to support these lifestyle changes within the family. Families for Health has been piloted in Coventry; children were less overweight after the programme, and the change was sustained up to 2 years. Improvements in childrens quality of life and lifestyle were also shown. This parenting approach was received very well by parents who found the programme helpful and supportive to bring about change in the family and with the management of their child with obesity.
The next stage of this research is to test how well this programme works in a larger study called a randomised controlled trial. The aims of the research are to find out if the Families for Health programme manages to reduce overweight in children aged 7 to 11 and to estimate whether the programme is value for money. We are also interested in the childrens and parents views of the programme, its value to them and its impact on their lives.

Who can participate?
Families with at least one child aged 7-11 years who is overweight or very overweight.

What does the study involve?
The study will take place at three Primary Care Trusts in the West Midlands NHS Coventry, NHS Warwickshire and Wolverhampton City PCT. Families will be randomly allocated to either the Families for Health intervention (60 families) or to a control group who receive usual care (60 families). The results from the groups will be compared to examine how well Families for Health works. The main measurement that we will use is the change in the childrens body mass index (BMI) (kg/m2). We will also carry out other measurements including childrens quality of life and physical activity, measures of the home eating and activity environment, parent-child relationships and parenting style. To assess if the programme is worth the money spent, the

costs to the NHS to run the programme will be documented and costs then related to the changes in the childrens BMI z-score and quality of life.

What are the possible benefits and risks of participating?
A possible risk is the amount of time this study would take for parents and children. In particular, for families in the Families for Health group, attendance at the group sessions is a weekly commitment for 10 weeks.

Where is the study run from?
The research measurements will be made at the homes of participating families. The Families for Health intervention will be run in venues in the community (e.g. leisure centre, school).

When is the study starting and how long is it expected to run for?
October 2011 to September 2014

Who is funding the project?
National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme, and NHS Coventry, NHS Warwick and Wolverhampton City PCT

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
HTA 09/127/41

Study information

Scientific Title

A randomised controlled trial evaluating the effectiveness and cost-effectiveness of Families for Health, a family-based childhood obesity treatment intervention delivered in a community setting for ages 7 to 11

Study objectives
What is the effectiveness and cost-effectiveness of the 'Families for Health' (FFH) programme in the treatment of overweight and obesity in 7-11 year olds compared to usual care, as measured by reduction in BMI z-scores at one year post recruitment?

The objectives are to:
1. Assess the effectiveness of the Families for Health programme in reducing BMI z-score in children aged 7 to 11 who are overweight and obese
2. Evaluate the cost-effectiveness and cost-utility of the Families for Health programme
3. Investigate parents and childrens views of the programme and their observations on approaches to maximising impact
4. To investigate facilitators views of the programme and their observations on approaches to maximising impact

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. NRES Committee West Midlands - Coventry & Warwickshire, 03/10/2011, ref: 11/WM/0290
2. Substantial amendment approved 23/01/2012

Primary study design
Interventional

Study design
Multi-centre randomised controlled trial with economic analysis

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Childhood overweight and obesity

Interventions
Families will be randomised to:
1. Families for Health (60 families)
2. Control group receiving usual care (60 families)

Intervention arm:
Families for Health is a 10 week family-based intervention delivered in a community setting which is aimed at the treatment of children (7-11yrs) who are overweight or obese. The programme focuses on parenting combined with social and emotional development, as well as lifestyle change. Delivery is group-based with up to 10-12 families, with children and parents attending parallel groups and meeting mid-way for a healthy snack and activity. The programme is manualised, with detailed handbooks available to facilitators, parents and children.

Usual Care Control Group:
Families assigned to the control arm will not be offered a specific intervention, but can receive the usual care available in their area.

Intervention Type
Behavioural

Primary outcome(s)
1. Change in children's BMI z-score at 12 months follow-up (change from baseline) (BMI (kg/m2) will be measured at baseline, 3 months and 12 months follow-up, and converted into standard deviation scores (z) from 1990 UK growth reference curves [Cole 1995])

Key secondary outcome(s)
Children's measurements at baseline, 3 and 12 months:
1. Waist circumference (z-score)
2. Percentage body fat
3. Habitual activity (7-day accelerometer recording) (not at 3 months)
4. Quality of life (PedsQL) (Varni 1998)
5. Fruit and vegetable consumption (Edmunds 2002)

Parents' measurements at baseline, 3 and 12 months:
1. BMI
2. Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) (Tennant 2007)
3. Family eating and activity (Golan 1998)
4. Quality of parent-child relationships (Pianta 1992)
5. Parenting style (Robinson 2001)
6. Health state valuation (EQ-5D) (Dolan 1997)

Economic evaluation:
1. Incremental cost per quality-adjusted life year (QALY) gained, estimated using responses to the EuroQol EQ-5D-Y health state valuation (youth version) (Ravens-Sieberer et al, 2010), costs to deliver the programme and questionnaire of costs to attend completed by parents
2. A de novo decision-analytic model will also be developed in order to estimate the lifetime clinical and economic consequences of the Families for Health intervention, using established economic modelling techniques

Process evaluation:
1. To investigate the parents and childrens perceptions of the Families for Health programme in Coventry, Warwickshire and Wolverhampton. Interviews will be carried out with up to 24 intervention group parents and their children at the end of the intervention and at 12 months
2. To investigate the fidelity of the implementation and delivery of the Families for Health programme in Coventry, Warwickshire and Wolverhampton. Programme fidelity will be assessed using flip-charts used during the sessions, parents weekly evaluation, facilitators weekly log of delivery, and audio recorded discussions with facilitators for four sessions in each programme
3. Success of recruitment methods, attendance rates (number of sessions attended) and drop out rates will be recorded

Completion date
30/09/2014

Eligibility

Key inclusion criteria
1. Families with at least one overweight (>91st centile for BMI) or obese (very overweight) (>98th centile for BMI) child aged 7-11 years
2. At least one parent/guardian and child willing to take part

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
11 Years

Sex
All

Key exclusion criteria
1. Parent or child with insufficient command of English, who would find it difficult to participate in the group
2. Metabolic or other recognised medical cause of obesity
3. Children with severe learning difficulties and/or behavioural problems

Date of first enrolment
01/10/2011

Date of final enrolment
30/09/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick (UK)

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NHS Coventry

Funder Name
NHS Warwickshire

Funder Name
Wolverhampton City Primary Care Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	25/11/2015		Yes	No
Results article	results	01/01/2017		Yes	No
Protocol article	protocol	20/03/2013		Yes	No