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 6 to 11 years

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Scientific summary

The Families for Health RCT

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Scientific summary

Background

Childhood obesity, both in the UK and internationally, is a major public health burden. One-third of children in year 6 (aged 10–11 years) in England were classified as either overweight or obese in 2013/14. Obesity in childhood increases the risk of poor physical and mental health in childhood, and there is evidence that childhood obesity also affects adult health.

The prevention and management of childhood obesity is now a public health priority. Effective interventions are needed to treat children who are obese, in order to reduce ill health in children and to reduce the proportion whose obesity continues into adulthood. A Cochrane systematic review of interventions to treat obesity identified 64 randomised controlled trials (RCTs) and, of these, only two were from the UK. They concluded that it is difficult to recommend any particular intervention, but indicated that family-based lifestyle interventions combining dietary, physical activity and behavioural components can produce 'a significant and clinically meaningful reduction in overweight' (Oude Luttikhuis H, Baur L, Jansen H, Shrewsbury VA, O'Malley C, Stolk RP, Summerbell CD. Interventions for treating obesity in children. *Cochrane Database Syst Rev* 2009;**1**:CD001872). Parental involvement was identified as useful with children aged < 12 years. Although family-based interventions for the treatment of childhood obesity have become more common, the focus on parenting skills within a programme is less so. A review of the limited research on interventions focusing on parenting to treat childhood obesity shows a small to moderate effect on weight-related outcomes, meriting further investigation.

'Families for Health' is a family-based group intervention for the treatment of children aged 6–11 years who are overweight or obese. The programme puts greater emphasis on parenting skills, relationship skills and emotional and social development than other similar interventions, and combines this with information about lifestyle. A pre–post pilot of Families for Health in 27 children showed that mean reductions in children's body mass index (BMI) z-scores from baseline were sustained at 9 months [–0.21, 95% confidence interval (CI) –0.35 to –0.07; $p = 0.007$] and 2 years (–0.23, 95% CI –0.42 to –0.03; $p = 0.027$). There were also other health-related improvements. As Families for Health was a promising new childhood obesity intervention, definitive evaluation of its clinical effectiveness by RCT was now required.

Aim and objectives

Our aim was to assess the effectiveness and cost-effectiveness at 12 months of the Families for Health programme using a RCT methodology.

Our objectives were to:

- assess the effectiveness of the Families for Health programme in reducing BMI z-scores in children aged 6–11 years who are overweight or obese
- evaluate the cost-effectiveness of the Families for Health programme [expressed in terms of incremental cost per quality-adjusted life-year (QALY) gained]
- investigate parents' and children's views of the programme and their observations on approaches to maximising impact
- investigate facilitators' views of the programme and their observations on approaches to maximising impact.

Methods

A multicentre, investigator-blind RCT, randomised at family level, in which Families for Health version 2 was compared with usual care, was carried out. Families for Health version 2 is a 10-week, family-based programme run in a community venue, with parallel groups for parents and children, addressing parenting, lifestyle change and social and emotional development. 'Usual care' was the usual support for the treatment of childhood obesity that was currently provided within each NHS locality. Alongside the evaluation of effectiveness, a parallel economic evaluation and process evaluation were carried out.

Recruitment of families

Participants were recruited from three sites (NHS primary care trusts) within the West Midlands, England, UK, using both active and passive recruitment methods. Active recruitment methods are those where eligible participants were identified and targeted, such as with a letter following measurement in the National Child Measurement Programme or by referral from a health-care professional. Passive methods are those where the community was informed using flyers, posters, public events and media, and then participants identified themselves as potential participants.

The inclusion criteria were families with at least one child aged 6–11 years who was overweight ($\geq$ 91st centile BMI) or obese ($\geq$ 98th centile BMI), with at least one parent or guardian and the overweight child willing to take part. Exclusion criteria were if the parent or child had insufficient command of English and would find it difficult to participate in the group; the child had a metabolic or other recognised medical cause of obesity; or the child had severe learning difficulties and/or behavioural problems, and would find it difficult to participate in a group-based programme.

Sample size

Power calculations assumed a residual standard deviation in the BMI z-score of 0.22, a standard deviation of the random family effects of 0.14 (corresponding to a within-family intracluster correlation of 0.27), an intracluster correlation of 0.1 in the intervention groups, a two-sided significance of 5% and that 60% of participating families have one overweight/obese child and 40% have two. Allowing for clustering effects by family and for group effects in the intervention arm, a sample size of six groups of 10 families (60 families) in the intervention arm and 60 families in the control arm gives a power of 94% to detect an intervention effect of 0.2 in BMI z-scores. If 30% of families drop out, the study retains a power of 88%.

Randomisation

Randomisation was carried out after all baseline measurements had been obtained. Randomisation was by family unit using a 1 : 1 allocation, with a target of 120 families, and carried out by a central telephone registration and randomisation service at the Warwick Clinical Trials Unit. Randomisation was stratified by the three sites using a biased-coin ($p = 2/3$) minimisation method within each site to ensure approximately equal numbers of families were randomised to the Families for Health programme and control.

Interventions

Families for Health version 2 was run in a community venue, with parallel groups for parents and children, addressing parenting, lifestyle change, and social and emotional development. Usual care was the usual support for the treatment of childhood obesity that was currently provided within each NHS locality. Usual care varied by site, being group based in site A, one-to-one support in site B, and either group-based or one-to-one support in site C. Usual care had evolved from virtually nothing to reasonably high-level provision in the time between the pilot and the implementation of the trial.

Outcome measures

Measurements with children and parents were taken at home at baseline, and at 3 and 12 months' follow-up. The primary outcome measure of effectiveness was change in children's BMI z-score at the 12 months' follow-up compared with the change in the control group. Secondary outcome measures included changes in children's waist circumference; percentage body fat; physical activity using an

accelerometer; fruit and vegetable consumption; and health-related quality of life as measured using the European Quality of Life-5 Dimensions Youth version (EQ-5D-Y). Parents' BMI and mental well-being, family eating and activity, parent–child relationships and parenting style were also assessed. The primary statistical analysis was carried out on an intention-to-treat basis.

Economic evaluation

A trial-based economic evaluation was conducted from a NHS and Personal Social Services perspective (and separately, for the purposes of a sensitivity analysis, from a societal perspective). Economic components encompassed measurement and valuation of service utilisation, including the costs of running Families for Health and usual care, and broader resource utilisation provided via researcher-administered interviews at each follow-up point, as well as EQ-5D-Y health outcomes that measured QALYs. Cost-effectiveness was expressed in terms of incremental cost per QALY gained (baseline outcome for the cost-effectiveness analysis) and incremental cost per change in BMI z-score at 12 months' follow-up. A range of sensitivity and subgroup analyses were performed. The primary analysis was carried out on an intention-to-treat basis.

Process evaluation

Process evaluation documented recruitment, reach, dose delivered, dose received and fidelity, using mixed methods. Interviews were carried out with parents and children from both trial arms and focus groups were carried out with the facilitators of each of the Families for Health groups. Interviews and focus groups were digitally recorded, transcribed verbatim and coded using NVivo 10 (QSR International, Melbourne, VIC, Australia). Coding was thematic based on the interview schedules with the addition of emergent themes.

Results

Recruitment

The study recruited 115 families, including 128 children (63 boys and 65 girls), between March 2012 and February 2014. A total of 56 families were randomised to Families for Health version 2 intervention arm and 59 families to the usual-care control arm. Passive recruitment methods resulted in a higher proportion of the total number of families recruited [passive (72/115) vs. active (43/115); $p < 0.007$].

Baseline characteristics were similar across the two arms, with the exception of socioeconomic status, with the Families for Health arm having a higher proportion of families from managerial and professional occupations than the control arm.

Follow-up

There was 80% retention of families in the study at 3 months and 72% retention at 12 months. Follow-up was lower for usual care at 12 months [Families for Health (78.6%) vs. usual care (66.1%)].

Clinical outcomes

The primary analysis was prespecified to be a comparison of the change in children's BMI z-score from baseline to 12 months' follow-up conducted on an intention-to-treat basis. The analysis allowed for clustering within the family and adjusted for the child baseline BMI z-score, sex and locality. The primary analysis did not find any difference in the BMI z-score at the 12-month follow-up between the usual-care arm and the Families for Health arm (0.114, 95% CI –0.001 to 0.229; $p = 0.053$, model 1). The within-group analysis showed that the BMI z-score was significantly reduced in the usual-care arm (–0.118, 95% CI –0.203 to –0.034; $p = 0.007$), whereas there was no significant change in the Families for Health arm (–0.005, 95% CI –0.085 to 0.078; $p = 0.907$). Apart from a significant improvement in activity level in parents in the usual care arm compared with the Families for Health arm, there were no other significant differences between groups for the other secondary outcomes. Although imputation analysis suggests that these results are robust, the possibility that the findings are attributable to differential loss to follow-up cannot be ruled out.

Economic evaluation

The economic evaluation showed that mean costs for the 12-month post-randomisation period were significantly higher in the Families for Health arm than in the usual-care arm (£998 vs. £548), with a cost difference of £450 (95% CI £249 to £650; $p < 0.001$). This was mainly driven by the higher cost of the Families for Health programme, which was more expensive than all the various usual-care provision. There was no significant difference in mean QALYs over the 12-month post-randomisation period between the Families for Health arm and the usual-care arm (0.83 vs. 0.83; mean difference 0.0009). The mean incremental cost-effectiveness of Families for Health was estimated at £552,175 per QALY gained, and the probability that Families for Health is cost-effective is approximately 28% at a £20,000 cost-effectiveness threshold. When health outcomes were measured in terms of longitudinal change in BMI z-score, the mean incremental cost-effectiveness of Families for Health was dominated by usual care in health economic terms, and the probability that Families for Health is cost-effective did not exceed 2% across a range of cost-effectiveness thresholds.

Process evaluation

Seven Families for Health groups were run across the three trial sites. The proportion of families that attended at least one session was higher in the Families for Health arm (42/56, 75%) than in the usual care arm (24/59, 40.7%) ($p = 0.001$). There were 62.5% of families who completed at least five sessions of Families for Health, and were defined as completers. Families for Health was delivered broadly, as planned, but challenges included families waiting more than 3 months to receive the intervention, delivering the programme with an insufficient number of families and tailoring a manualised programme to meet individual family needs. Key aspects received well by families were better understanding of food labelling, informing food choices, positive influence on parenting skills, support from others and raising their child's awareness of health. Based on the quantity and quality of what was delivered, the process evaluation indicates that the intervention was implemented reasonably well, probably as well as could be expected when scaled up over three sites.

Conclusions

Families for Health was neither clinically effective nor cost-effective for the management of obesity in children aged 6–11 years, in comparison with usual care.

Implications for public health

Usual care for obesity management evolved from nothing to a reasonably high level of provision in the time between the pilot evaluation of Families for Health and the implementation of the trial. Usual care differed in different sites and may have evolved to suit local needs, making the best of local practitioner skills and local resources, which may explain why it is more effective than Families for Health. However, at least 47.5% of families did not receive the usual-care intervention, and so informing parents of their child's weight may actually be the effective component.

Childhood obesity is hard to treat. Even treatment interventions that are shown to be effective may only have a modest impact.

Further research implications

Broader reporting of adverse events, including the negative effect of treatment on primary outcomes, is required. In the current study, the wide range of responses in BMI z-scores in children at the 12-month follow-up ranged from a difference from baseline of –0.746 to 0.895 across the two groups, indicating that some children had a clinically significant benefit, whereas others showed a worse outcome with treatment. Exploration of these extreme cases by treatment group and engagement in the intervention is warranted from this trial.

Rather than a focus on the treatment of obesity, shifting attention to the role of parents in the prevention of obesity, alongside school-based prevention initiatives, may be worthy of future research. The 'whole-systems approach' to tackle obesity advocated by Public Health England is also a very important new research programme.

Trial registration

This study is registered as ISRCTN45032201.

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