Improving the assessment and management of obesity in UK children and adolescents: the PROMISE research programme including a RCT

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Scientific summary

The PROMISE research programme including a RCT

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Scientific summary

Study A: impact of the National Child Measurement Programme

Summary

After children are measured as part of the National Child Measurement Programme, parents are provided with feedback letters about their child's weight status (i.e. underweight, healthy weight, overweight, very overweight).

The research team worked with the National Child Measurement Programme to assess the impact of the feedback on parental perceptions of their child's weight and health, and health-related behaviours. A longitudinal study was conducted of 1844 parents of children in Reception (aged 4–5 years) and Year 6 (aged 10–11 years), who were measured as part of the 2010–11 National Child Measurement Programme in five primary care trusts. Parents were surveyed before they received National Child Measurement Programme feedback (response rate 18.9%) and 1 and 6 months after the feedback (response rate, 54.3%). Qualitative interviews were conducted with 52 parents with overweight children.

Key findings

Baseline

- Three-quarters of parents of overweight and obese children do not recognise their child to be overweight. Before they received the National Child Measurement Programme feedback, only 14% of parents with overweight children and 35% of parents with obese children perceived their child to be overweight. Parents were likely to classify their children as overweight only if the child's body mass index was above the 99.7th centile (much higher than the standard 95th centile used by the National Child Measurement Programme).
- Many parents do not consider their child's overweight status to be a health risk: 41% of parents who acknowledged their child to be overweight did not perceive this to be a health risk. Interviews with parents suggested that parental definitions of health frequently did not include weight; some parents did not consider the National Child Measurement Programme result to be credible because it did not take into account their child's background or lifestyle.
- Cultural factors as well as deprivation may explain high levels of obesity among black and South Asian children in England. After accounting for deprivation and other sociodemographic characteristics, black and South Asian children were three times more likely to have an obesogenic lifestyle than white children. Qualitative work indicated that being overweight was not viewed negatively by some non-white parents.

After National Child Measurement Programme feedback

- Most parents (87%) found National Child Measurement Programme feedback to be helpful. More than one-fifth of parents of overweight children reported feeling upset, but only 1.8% of parents stated that they would withdraw their child from the National Child Measurement Programme in the future.
- One-quarter of parents of overweight children and half of parents of obese children sought further information regarding their child's weight. The most frequently reported sources of information were friends and family (reported by 14.4% of parents), the internet (9.9%), a general practitioner (8.9%) and a school nurse (8.4%).
- National Child Measurement Programme feedback has positive effects on parental knowledge, perceptions and intentions. After receiving National Child Measurement Programme feedback, parents' general knowledge about the health risks associated with child overweight improved, particularly among non-white parents. The proportion of parents who recognised their child to be overweight nearly doubled after feedback, but remained low, at 38%. Nearly three-quarters of parents reported an intention to change lifestyle behaviours following NCMP feedback.

- National Child Measurement Programme feedback has little impact on actual lifestyle behaviours. After feedback, there were no changes in reported dietary behaviours or screen time. There was a slight increase in the proportion of obese children meeting recommended levels of physical activity, but physical activity levels did not change in other BMI groups.
- 'Proactive' feedback may be more effective than letters alone. In areas where 'proactive' NCMP feedback (telephone call or face-to-face meeting) was given to parents of obese children in addition to the letter, there was a greater improvement in parental recognition of child overweight and health risks. However, telephonic feedback required additional resources (£9.50 vs. £1.24 per child) and most parents reported a preference for feedback by letter.

Implications

- National Child Measurement Programme feedback has a positive effect on parental perceptions and intentions to make lifestyle changes, and is acceptable to most parents. However, intentions do not necessarily translate into behaviour change. There is a need to ensure that local services and networks are in place to support parents in making and maintaining lifestyle changes following National Child Measurement Programme feedback.
- Parents seek advice about their child's weight from the general practitioner and school nurse, as well as informal sources such as friends and the internet. Parents must be directed towards accurate, reliable information, and primary care professionals must be trained and equipped with the resources to treat childhood overweight.
- Parental perceptions of child overweight and health risk are not aligned with those of health professionals, even after National Child Measurement Programme feedback. There is a need to understand how these parental perceptions are formed, and to identify more effective ways of communicating messages about healthy weight and health risk to parents.
- The impact of the National Child Measurement Programme feedback may be greater among the parents of non-white children than among those of white children and, therefore, may help in reducing health inequalities. Culturally appropriate feedback could be considered to enhance this.
- Proactive forms of feedback may be more effective in changing parental perceptions than feedback letters, but are more resource intensive and most parents report a preference for written feedback. The cost-effectiveness and acceptability of alternative forms of feedback need to be further evaluated.

Study B: improving childhood obesity management

Part of the information in the *Scientific summary* has been adapted from Park MH, Skow Á, Puradiredja DI, Lucas A, Syrad H, Sovio U, *et al.* Development and evaluation of an online tool for management of overweight children in primary care: a pilot study. *BMJ Open* 2015;**5**:e007326. Published by the BMJ Publishing Group Limited. This is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license, which permits others to distribute, remix, adapt and build upon this work, for commercial use, provided the original work is properly cited. See: http://creativecommons.org/licenses/by/4.0/.

An online tool [Computer-Assisted Treatment of CHildren (CATCH)] was developed to aid primary care practitioners in assessing and treating childhood obesity. The tool incorporates risk estimation models to identify children at risk of obesity-related comorbidities who may need referral to secondary care, and provides families with tailored, printable lifestyle advice.

An uncontrolled pilot study with integral process evaluation was conducted at three GP clinics in north-west London, to evaluate the acceptability to families and practitioners of using Computer-Assisted Treatment of CHildren in primary care. Families with concerns about excess weight in a child aged 5–18 years (n = 14 children) had a consultation with a general practitioner or practice nurse using Computer-Assisted Treatment of CHildren. Families and practitioners completed questionnaires to assess the acceptability and usefulness of the consultation, and participated in semistructured interviews that explored user experiences.

Key findings

- A consultation using an online tool is acceptable to families presenting at a general practice clinic with concerns about excess weight in a child: the majority of families ($n = 12$, 86%) were satisfied with the Computer-Assisted Treatment of CHildren-assisted consultations, and all respondents found the personalised lifestyle advice useful or somewhat useful.
- In interviews, parents described the consultation as informative, and several referred to the consultation as a 'wake-up call' that alerted them to the severity of their child's weight problem.
- Parents felt that the use of visual aids such as the body mass index chart to show the child's weight status and printed lifestyle advice reinforced the practitioner's message. Similarly, practitioners felt that the tool could enhance the impact of their advice. It was suggested that the tool could be used as positive reinforcement for patients with a BMI in the healthy range and who had a healthy lifestyle.
- Practitioners ($n = 4$) were satisfied with the tool-assisted consultation and reported that the tool was easy to use.
- All practitioners were in agreement that the tool (or a version of it) would be something they would continue to use in the future and would like to see integrated into their clinical software system. Work is needed to further develop and evaluate the tool's impact on health.
- Families and practitioners identified a need for practical, structured support for weight management following the consultation: several parents suggested that follow-up appointments for monitoring and guidance on weight management would be beneficial.

Study C: Healthy Eating and Lifestyle Programme randomised controlled trial

Summary

The Healthy Eating and Lifestyle Programme was developed as a specific adolescent-focused intervention, designed for obese 12- to 18-year-olds seeking help to manage their weight. A randomised controlled trial of HELP was undertaken, consistent with a Phase III trial in the Medical Research Council guidance on complex interventions. The primary outcome was the difference in mean body mass index (kg/m^2) between groups at the end of the intervention (week 26), adjusted for baseline body mass index, age and sex. A total of 174 subjects were randomised (87 in each arm), of whom 145 (83%) provided primary outcome data at week 26. At week 26, there were no significant effects of the intervention on body mass index. At weeks 26 and 52, there were no significant differences between groups in any secondary outcomes. The Healthy Eating and Lifestyle Programme intervention was no more effective than a single educational session for reducing body mass index in a community sample of obese adolescents. This most probably reflects a mismatch between the intervention, based on evidence developed largely from affluent white populations, and the ethnically diverse and highly deprived community sample we recruited.

Key findings

- Across all young people in the study, approximately one-third reduced their body mass index, one-third increased their body mass index and one-third had the same body mass index at 6 and 12 months after starting the study.
- Recruitment to the trial was difficult, with a large degree of work required to recruit obese young people into the trial.
- No difference was found in the body mass index of young people between the Healthy Eating and Lifestyle Programme group and the control group at 6 or 12 months post randomisation. This means that Healthy Eating and Lifestyle Programme and the single nurse-delivered session had very similar effects on the body mass index of young people and their cardiovascular risk over the 6 and 12 months of the study.

- Regarding secondary outcomes, there was no difference in young people's waist circumferences, blood pressure and other cardiovascular risk markers (e.g. cholesterol, glucose and insulin levels), measures of quality of life, self-esteem or problem eating behaviours at 6 or 12 months between those young people who received the Healthy Eating and Lifestyle Programme and those who received the nurse session.
- Regardless of trial group, young people and their families reported that joining the trial had helped them make positive changes to their diet, activity levels and motivation.
- Mean intervention costs per subject were £918 for the Healthy Eating and Lifestyle Programme and £68 for enhanced standard care. Adjusted costs were significantly higher in the intervention group (mean incremental cost for HELP vs. enhanced standard care £1003, 95% confidence interval £837 to £1168). There were no differences in quality-adjusted life-years between the HELP and the nurse-session groups.

Study D: evaluation of anti-obesity drug use in children

Summary

Three drugs were approved for obesity treatment in the UK between 1998 and 2006: (1) orlistat (Alli®; GlaxoSmithKline plc, Brentford, UK), (2) sibutramine (Meridia®; Abbott Laboratories, Abbott Park, IL, USA) and (3) rimonabant (Acomplia®; Sanofi, Paris, France). However, sibutramine and rimonabant were subsequently withdrawn from the market. In 2014, the revised National Institute for Health and Care Excellence (NICE) guidelines (NICE. *Obesity: Identification, Assessment and Management. NICE Clinical Guideline Clinical Guideline 189*. London: NICE; 2014) recommended treatment with orlistat in children aged ≥ 12 years only if physical comorbidities (such as orthopaedic problems or sleep apnoea) or severe psychological comorbidities are present. Treatment should be started in a specialist paediatric setting, by multidisciplinary teams with experience of prescribing in this age group. Metformin (Glucophage®; Merck Serono, Darmstadt, Germany) is the most commonly used drug in paediatric obesity.

A series of studies was undertaken to improve the understanding of how anti-obesity drugs are used in clinical practice:

- A systematic review and meta-analysis was conducted to evaluate the efficacy and safety of anti-obesity drugs from published randomised controlled trials in children and adolescents.
- Cohort studies were conducted to investigate prescribing patterns (orlistat, sibutramine, metformin) to young people in primary care settings.
- A survey study was conducted to determine current practice in prescribing these drugs to young people for obesity treatment by examining general practitioner-completed questionnaires across UK general practices (England, Scotland, Wales and Northern Ireland).
- Semistructured interviews with young people aged 13–18 years and their parents from three specialist obesity clinics were conducted to understand children's and families' perspectives of treatments.

Key findings

- Evidence from published randomised controlled trials has shown that orlistat and sibutramine significantly reduced body mass index compared with placebo in young people: orlistat together with behavioural therapy reduced body mass index by 0.83 kg/m^2, with a high number of gastrointestinal adverse drug reactions. Sibutramine with behavioural therapy reduced body mass index by 2.20 kg/m^2. The pooled analysis based on 12 randomised controlled trials has shown a body mass index reduction with metformin treatment compared with placebo of 0.64 kg/m^2 after 6 months of treatment.
- The majority of anti-obesity drug prescriptions were rapidly discontinued before patients could see any weight benefits: prescribing anti-obesity drugs (orlistat, sibutramine) to children and adolescents increased dramatically (15-fold) between 1999 and 2006. However, approximately 45% of orlistat and 25% of sibutramine prescriptions were discontinued after 1 month of treatment. This indicates that these drugs are poorly used in the general population.

- There was a steady increase in metformin prescribing to obese and overweight young people: the use of metformin increased fivefold between 2000 and 2010 in primary care, particularly in girls aged 16–18 years.
- Over half of general practitioners who initiated pharmacological treatment to obese and overweight young people did not consult a specialist for advice: 151 questionnaires were sent out to those general practitioners who prescribed orlistat and/or metformin to their young patients for obesity treatment. A total of 121 general practitioner-completed questionnaires were returned (80% response rate). Approximately 61% of general practitioners responded that they issued the drugs to their patients without secondary or tertiary care team advice. Despite comprehensive guidance provided in the NICE guideline, general practitioners expressed a need to develop a new guide for prescribing AODs to young people.
- Young people and parents described side effects as a significant experience and few adhered to prescribed regimens, independently changing lifestyle and dosage to tolerate medications.

Implications

- Pharmacological treatment is unlikely to be effective without further assistance such as lifestyle modification or psychological support.
- General practitioners require more support from a specialist in managing the treatment of obesity in children in the community.
- There should be further research to develop a collaborative, prospective, obesity management surveillance network for children and adolescents across other specialist centres in the UK. This could examine the clinical effectiveness, safety and prescribing patterns of medications along with other interventions (e.g. psychological intervention, bariatric surgery) for paediatric weight management in clinical practice.

Study E: evaluation of acceptability and early outcomes of adolescent bariatric surgery in the UK

Summary

Bariatric surgery in adults is accepted to be a clinically effective and cost-effective solution for severely obese individuals. NICE guidelines endorse bariatric surgery as an appropriate treatment for obese adolescents in exceptional circumstances; however, the outcomes of adolescent bariatric surgery in the NHS have not been evaluated.

A series of linked studies was undertaken to (1) examine the outcomes of adolescent bariatric surgery in one centre in the UK, (2) understand clinicians' and young people's decision-making about bariatric surgery, (3) investigate factors influencing outcomes in bariatric surgery and (4) examine the cost-effectiveness of bariatric surgery for adolescents.

Key findings

- Outcomes of adolescent bariatric surgery in a NHS service compare favourably with international outcomes, and such surgery shows promise as a safe, effective treatment for severe obesity. Further work is needed to improve patient selection, to better match patient needs to operative type and to reduce pre- and post-surgical attrition.
- Decisions about bariatric surgery differ between clinicians and young people. For clinicians, there is a predominant theme of 'uncertainty' about whether surgery is appropriate for young people. Young people also share this uncertainty, but use a number of strategies to 'bracket away' these dilemmas in the hope of a better future. Both clinicians and young people see bariatric surgery as a 'last resort'.
- Systematic review evidence shows that quality of life and depressive symptomatology improve after bariatric surgery, although not in all patients. Improvement appears to peak at 6–12 months. Improvements in psychological function appear to be associated with reduction in body mass index rather than with baseline psychological function.

- There is weak evidence that psychological function predicts body mass index outcomes after surgery; those with higher baseline levels of loss of control eating and family conflict appear to have poorer BMI outcomes.
- Bariatric surgery of severely obese adolescents is a cost-effective alternative to no surgery over a lifetime in obese adolescents, from a NHS perspective.
- The full third National Bariatric Surgery Register report will be released in 2020. This will involve an updated data set – adding patient identifiers (i.e. NHS numbers), glycosylated haemoglobin (HbA_{1c}) levels and EuroQol-5 Dimensions quality-of-life measurements – which will help with making outcomes more patient centred (which also fits with the Healthcare Quality Improvement Partnership mandate).

Trial registration

This trial is registered as ISRCTN99840111.

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