Cultural adaptation of an existing children's weight management programme: the CHANGE intervention and feasibility RCT

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Scientific summary

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Scientific summary

Background

Childhood obesity is a public health priority in the UK. The prevalence of obesity in children aged 10 or 11 years is 20%, with a further 14% being overweight. Childhood obesity is associated with a range of short- and long-term health consequences and also tracks strongly into adulthood. South Asians are particularly at risk of the cardiometabolic consequences of obesity and a higher prevalence of obesity is seen in children of South Asian ethnicity in later childhood. Community-based children's weight management programmes have been shown to be effective, at least in the short term, in reducing body mass index in children who are overweight or obese. Programmes involving parents, which target both diet and physical activity and include behaviour change techniques, are the most likely to be effective. Effectiveness is also related to programme attendance, and there is evidence that the greatest weight change is achieved by those who complete the programme. There is evidence that families from ethnic minority communities in the UK are less likely to complete children's weight management programmes and, to date, there is little research into the adaptation of programmes for these families. The Child weigHt mANaGement for Ethnically diverse communities (CHANGE) study aimed to adapt culturally an existing children's weight management programme (First Steps, which is available to families of overweight children aged 4–11 years) to make it more suited to families from Pakistani and Bangladeshi communities, but also to ensure that the programme was acceptable to families of all ethnic and cultural backgrounds.

Objectives

The study was undertaken in two phases: a programme adaptation process (phase I) and a feasibility study (phase II). The objectives of phase I were to:

- explore factors that promote or discourage engagement with, and completion of, existing childhood obesity treatment programmes among Pakistani and Bangladeshi families in the UK
- use this information, together with existing research evidence and theoretical frameworks for cultural adaptation and complex intervention development, to design a culturally adapted, theoretically informed childhood obesity treatment programme that is appropriate for all families but is culturally adapted to meet the particular needs of Pakistani and Bangladeshi families.

The objectives of the feasibility study in phase II were to:

- assess the proportion of Pakistani and Bangladeshi families, and proportion of all families, that completed the adapted programme
- assess the acceptability of the programme to Pakistani and Bangladeshi families and to families from other ethnic groups
- assess the feasibility of delivery of the adapted programme
- assess the feasibility of participant recruitment, randomisation and follow-up
- assess the feasibility of the collection of cost data from both a health and a societal perspective to inform a future trial evaluating intervention clinical effectiveness and cost-effectiveness
- collect data on recruitment, attrition and other relevant measures to inform parameters of a future trial.

Phase I: children's weight management programme adaptation

A qualitative study was undertaken with Pakistani and Bangladeshi parents/carers of overweight children who had previously had contact with the First Steps children's weight management programme ($n = 43$) to explore their experiences of the programme, the barriers to and enablers of engaging with the programme and the elements that needed to change within the programme to ensure cultural suitability. We recruited those who had completed the First Steps programme ($n = 13$) to participate in focus groups (FGs) and those who had partially attended or not attended the programme ($n = 30$) to participate in interviews. Researchers from Pakistani and Bangladeshi communities (community researchers) undertook interviews and FGs in the participants' preferred languages. The key messages that emerged from the resulting data concerning the programme were the logistical considerations of attending (location, timing, etc.), the language barriers to participation, the need for less focus on weight reduction and more focus on healthy behaviours, the need for children to attend all sessions with their parents, a desire for more physical activities and general interactivity within the programme, the value of sharing experiences and supporting each other within the group environment and a need for help with making behavioural changes in their children at home.

The qualitative data, together with information from the First Steps weight management programme providers and the recommendations from the National Institute for Health and Care Excellence (NICE)'s public health guideline number 47 [NICE. *Weight Management: Lifestyle Services for Overweight or Obese Children and Young People*. London: NICE; 2013. URL: www.nice.org.uk/guidance/ph47 (accessed June 2017)] on lifestyle services for overweight and obese children and young people and other relevant literature, were used to inform the adaptation of the First Steps programme. The qualitative data were mapped to two frameworks: (1) the behaviour change wheel framework for complex intervention development and (2) the typology of cultural adaptation and health promotion programme theory. The former framework enabled a theoretical understanding of the factors influencing behaviour that needed to be addressed within the intervention programme. The latter framework enabled consideration of the types of cultural adaptation that could be undertaken to address the issues raised through the qualitative data across the different programme cycle stages.

The resulting adapted intervention programme comprised weekly 90-minute sessions that were delivered to both children and parents over 6 weeks. The key adaptations of the programme were greater provision of programmes at weekends; more interactivity; flexibility of delivery to enable responsiveness to each individual family context; encouragement of social interactions, sharing of experiences and peer support; greater physical activity content; and attractive materials and resources for use in sessions and for families to be able to take away for home use.

Phase II: feasibility study

Design and setting

A small-scale two-armed cluster randomised controlled trial was undertaken in Birmingham, UK. All of the First Steps children's weight management programmes delivered across the city within two school terms (September 2015–April 2016) were randomised to intervention (adapted programme) or comparator (standard programme) arms in a 2 : 1 ratio.

Participants

The primary outcome of the feasibility study was the proportion of Pakistani and Bangladeshi families completing the programme (defined as attendance at $\geq 60\%$ of the programme), and a secondary outcome was the proportion of families of all ethnicities completing the programme. Anonymised data on programme attendance were used to estimate these outcomes. These data were collected for all families attending a children's weight management programme in Birmingham within the study period.

To assess the feasibility of trial processes and collection of outcome data, we aimed to recruit 80 children aged 4–11 years and their families. Families who were referred to the children's weight management service in the study period were invited to participate. Families of all ethnicities were included in the study sample. Informed consent from parents and assent from children was obtained from all participating families.

Intervention and comparator

The adapted First Steps programme, as described in *Phase I: children's weight management programme adaptation*, was delivered in the intervention arm. The standard First Steps programme was delivered in the comparator arm. The standard programme consisted of weekly hour-long sessions, delivered to parents over a school half-term (5–7 weeks) and children attended with their parents at the first and last sessions only. The standard programme was delivered predominantly within school time, but there was some provision on Saturdays. To avoid contamination, different facilitators delivered the intervention and comparator programmes.

Evaluation of programme acceptability and feasibility of implementation

In addition to the estimation of the proportion of families completing the adapted programme, the acceptability and feasibility of programme delivery were assessed through direct observation of the delivery of programme sessions, contemporaneous feedback from the programme facilitators, interviews with parents and children and interviews with the facilitators after completion of the study intervention period.

Collection of outcome data

Outcome data were collected from children and their families through home visits at three time points: time 0, baseline; time 1, directly after the end of the programme; and time 2, 6 months after the end of the programme. Outcome data collection from children included anthropometric measurements, psychosocial questionnaire measures (including a utility-based quality-of-life measure), parent-reported dietary intake patterns and accelerometer-measured physical activity. Outcome data from parents included anthropometric measurements and questionnaire measures on family nutrition and physical activity habits, parenting style, child feeding practices and parental self-efficacy. Other family members present at the data collection home visit were also invited to have anthropometric measures taken.

Collection of cost data

Methods for measuring costs from a societal perspective were tested in the feasibility study. Data on programme delivery costs were collected from the children's weight management service providers. Costs to families (e.g. time off work, child-care costs and changes to the weekly food bill) were captured through a questionnaire administered to all families at the last programme session. Cost data were collected for both intervention and comparator programmes.

Results

In the intervention arm, of the Pakistani and Bangladeshi families attending at least one programme session ($n = 80$), 78.8% completed the programme [95% confidence interval (CI) 64.8% to 88.2%]. Of all families attending at least one session ($n = 169$), 76.3% completed the programme (95% CI 67.0% to 83.6%). In the comparator arm, of all families attending at least one session ($n = 74$), 58.1% completed the programme (95% CI 46.5% to 68.8%).

The programme was observed to be feasible to deliver and this was confirmed by facilitator feedback. However, some refinements to the programme were required, particularly in relation to the nutrition content and some of the interactive components. These refinements were made in the first 8 weeks of the study intervention period. Interviews with parents ($n = 16$), children ($n = 9$) and facilitators ($n = 2$) showed that there was a high level of enjoyment in both delivering and attending the programme. Aspects that were particularly valued were the flexibility of programme delivery, the presence of children at all sessions, the interactivity of the programme and the peer support gained through attending the programme.

The wide age range of children attending the programme proved challenging for facilitators and families, and the families expressed the wish for even more physical and other interactive activities.

A total of 92 families participated in the CHANGE study. Many families who were referred to the children's weight management service were willing to participate in the study; however, logistically, it was challenging to undertake baseline assessments with families after recruitment and before commencement of a programme. Attrition proved to be a significant issue, despite the use of home visits for follow-up data collection. Only 60 families were followed up at 6 months (65%). There was also differential attrition across the two study arms (29.0% and 52.2% in the intervention and comparator arms, respectively).

Outcome data collection proved to be feasible on the whole; however, home visits were resource intensive. The number of questionnaire outcome measures presented too much of a burden for many parents and this was compounded when participants did not speak English (in these cases community researchers verbally translated the questionnaires for participants and recorded their responses). Concealment of a participant's study arm from the researchers undertaking data collection was highlighted as an issue that would need to be addressed in the design of a future trial. The completeness of outcome data was variable. Anthropometric measures with children were well completed. Waist circumference had the most missing data. Questionnaires with children were well completed but questionnaires with parents were less well completed. Two types of accelerometers were tested in the study; the wrist-worn GENEActiv© (Activinsights Limited, Kimbolton, UK) and the hip-worn ActiGraph (ActiGraph, Pensacola, FL, USA). The GENEActiv was more likely to be returned with valid wear-time than the ActiGraph. Anthropometric measures with parents and other family members proved to be problematic, as consent was often not given and different family members were present at the different data collection time points.

The incremental cost of the adapted programme per family attending was estimated to be £33. Data capture of costs to families was incomplete and in a future trial these data would be best collected alongside outcome measures at a home data collection visit, rather than at the final programme session.

Exploratory analysis of outcomes showed that there was a small mean reduction in anthropometric measures in both study arms at programme end and at the 6-month follow-up. Meaningful interpretation of the exploratory analysis is precluded by a number of factors, including the differential attrition in the study arms.

Conclusions

We successfully culturally adapted an existing children's weight management programme, using formative research with Pakistani and Bangladeshi parents, existing evidence-based recommendations and two frameworks that guided the adaptation process. The resulting programme is a theoretically underpinned, flexible and responsive programme that is highly acceptable to children and families from all ethnic and sociocultural backgrounds and feasible to deliver. Therefore, consideration should be given to a future trial to evaluate the clinical effectiveness and cost-effectiveness of the adapted programme. However, the feasibility study highlighted several issues that would need to be addressed in the design and methodology of a future trial, including the logistics of participant recruitment and baseline data collection, participant burden and study attrition.

Trial registration

The trial is registered as ISRCTN81798055.

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