Changing eating behaviours to treat childhood obesity in the community using Mandolean: the Community Mandolean randomised controlled trial (ComMando) – a pilot study

Julian Hamilton-Shield,[1,2*] Joanna Goodred,[3] Lesley Powell,[3] Joanna Thorn,[4] Jon Banks,[3] Sandra Hollinghurst,[3] Alan Montgomery,[5] Katrina Turner[3] and Debbie Sharp[3]

[1]School of Clinical Sciences, University of Bristol, Bristol, UK
[2]Bristol NIHR Biomedical Research Unit in Nutrition, Bristol, UK
[3]Centre for Academic Primary Care, School of Social and Community Medicine, University of Bristol, Bristol, UK
[4]School of Social and Community Medicine, University of Bristol, Bristol, UK
[5]Nottingham Clinical Trials Unit, University of Nottingham, Queens Medical Centre, Nottingham, UK

*Corresponding author

Declared competing interests of authors: All authors received advice, support and in-person tutorials during nurse training programme with AB Mando, Huddinge, Sweden.

Published July 2014
DOI: 10.3310/hta18470

Scientific summary

The Community Mandolean randomised controlled trial: a pilot study

Health Technology Assessment 2014; Vol. 18: No. 47
DOI: 10.3310/hta18470

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

The continued high prevalence and long-term implications of childhood obesity is one of the most pressing public health issues facing the UK. There are few robust data demonstrating how to successfully address the lifestyle behaviours resulting in excess childhood weight gain. Furthermore, we are unsure in which setting such interventions should be delivered. Speed of eating is a modifiable behaviour that is linked to obesity risk; those who consume food quickly appear to have a greater risk of obesity. In a previous hospital-based study in obese adolescents, we conducted a randomised trial that involved dietary and exercise advice to improve health as standard care. Half of patients also received daily eating behaviour retraining to teach them to consume their meals slower using a device termed Mandometer® [now Mandolean® (Mikrodidakt AB, Lund, Sweden)]. Twelve months post randomisation, those adolescents receiving standard care plus Mandometer had improved their body mass index standard deviation score (BMI *z*-value) more than twofold over those receiving standard care only (–0.4 vs. –0.14, respectively), a difference maintained 6 months after treatment. On average, those receiving Mandometer therapy self-elected to eat 45 g less food per main meal than their baseline consumption while feeling equally as full, suggesting that eating behaviour retraining reduced overall appetite and, thus, aided weight loss.

Objectives

The aims of the main Community Mandolean randomised controlled trial (ComMando) were to:

1. determine if Mandolean therapy could be delivered in the community by trained nurses in order to obtain a BMI *z*-score improvement at least 0.25 greater than standard care in obese children
2. examine the clinical effectiveness of Mandolean therapy in obese parents
3. explore the effect of parental usage of Mandolean on child weight loss
4. examine the cost-effectiveness of Mandolean therapy compared with standard care
5. assess patient and practitioner experience and acceptability of Mandolean and standard care
6. develop a 'toolkit' for future users of this technology in other settings.

Aims of the built-in pilot study:

1. establish recruitment methodologies and ensure strategies were successful in terms of rate of recruitment
2. engage three hub practices to deliver treatment and a number of spoke general practices to feed into the hubs
3. train nurses at the three hubs to deliver treatment
4. develop a protocol for treatment delivery
5. refine trial paperwork and study design
6. explore the acceptability of Mandolean therapy to families
7. examine treatment adherence.

Design

A two-arm, parallel, randomised controlled trial. Participants were randomised into one of two groups: (1) standard care plus Mandolean training; or (2) standard care alone.

Setting

General practices across Bristol, North Somerset and South Gloucestershire primary care trusts. At trial termination, there were nine hub practices where participants were recruited and treatment delivered, as well as 29 spoke practices from which participants were recruited to receive care in the most convenient hub practice.

Participants

Obese children [body mass index (BMI $\geq$ 95th percentile)] aged 5–11 years. The pilot phase aimed to recruit 36 families within 9 months of trial commencement. The main trial aimed to recruit a further 604 families.

Interventions

The interventions were designed to be delivered over 12 months. Participants were randomised to receive standard care or standard care plus Mandolean therapy. In standard care, emphasis was placed on implementing changes to increase levels of enjoyable physical activity to national recommended levels (60 minutes' exercise a day for children) alongside a balanced diet, based on the 'eatwell plate'. Motivational interviewing techniques were utilised by study nurses to engage the families in positive changes to improve health. Standard care appointments were delivered at 3-monthly intervals over a 12-month period (five appointments in total). These appointments were delivered by the study nurses at the hub practices. In addition, three telephone support calls at 5, 8 and 11 months were provided to reinforce behaviours discussed in the face-to-face sessions. Randomisation to standard care plus Mandolean resulted in both the index child and a parent being trained to use Mandolean in the home setting. In brief, Mandolean is a computer device linked to a weighing scale that provides visual and oral feedback when a participant is eating a meal. When consuming food off a dinner plate, placed on the scale, participants can see if their eating pattern is deviating from a training line, which is visible and preset to guide eating speed. They also receive voice messages, asking them to eat more slowly or quickly. The aim is to facilitate the main meal of the day being eaten over a 10- to 12-minute period. During the meal, participants are asked to rate their sense of fullness (satiety) at intervals of 1.5 minutes. The aim is to slow the speed of eating, while relearning a sense of satiety at meal completion. The participants (and their participating parent) were asked to eat their main meal off the Mandolean daily. As retraining required a gradual change in eating speed requiring clinical contact with the therapist, those randomised to this arm received nine appointments and three supportive telephone calls over 12 months.

Outcome measures

The primary outcome measure for the main trial was change in BMI *z*-value at 12 months. The trial was not completed and, thus, the outcomes reported here relate to those deemed necessary for the pilot study to move forward to the main trial. Pilot outcomes were:

1. recruitment of at least 36 families in the pilot phase of 9 months who would be eligible for the main study
2. 90% of patients randomised to Mandolean to be successfully eating off the device at least five times a week
3. at least 60% of those using Mandolean to have demonstrated a decrease in speed of meal consumption from baseline measures within 3 months of starting therapy
4. at least 80% of participants in both arms to have attended the 3-month nurse appointment.

Results

Within the 9-month period of the pilot phase, 21 of the target 36 (58%) patients had been randomised. The pilot phase utilised only three hubs, all in areas of significant deprivation. Recruitment did improve when further sites for both hub practices and extra feeder spoke practices were opened up in month 10. However, it never reached the level necessary for target recruitment, which was 26 participants randomised per month. We had believed that the National Child Measurement Programme (NCMP), and its feedback to individual families in Bristol, would be a major source of referrals highlighting to parents the need to address their child's obesity. Unfortunately, the primary care trust decided not to provide feedback to parents on the results of their child's measurements, thus denying the study of a major impetus for families to seek help. There were a number of pathways used in the study by which participants could be recruited: (1) direct general practitioner (GP) referrals; (2) through searches for BMI > 95th percentile on GP databases for children in relevant ages, with a letter sent to parents asking them to consult their GP if interested; (3) through school nurse referrals; (4) from other practice-based health-care professional (HCP) referrals; and (5) self-referral from advertisements in the *Primary Times* (a termly, school-delivered newsletter) or in doctors surgeries. Although GP and self-referrals did garner significant recruits, we tried to accelerate recruitment through mass mailings to all families with children on GP databases, irrespective of their BMI, as so few children had their BMI recorded in GP records. A total of 10,077 families were contacted asking if they were worried about their child's weight and, if so, how to go about seeking referral to ComMando. With the current prevalence of obesity being 15% across the age range, we would have expected over 1500 families to be eligible. We received 114 initial responses (~7.5% of those likely eligible), from which 37 participants were eventually randomised (~2.4%).

The Mandolean arm had a target of 90% of participants to be eating off a Mandolean at least five times a week. Only one-fifth of those receiving therapy achieved this. The qualitative study was useful in elucidating reasons for this lack of treatment compliance. In some cases the families found it difficult to incorporate the Mandolean therapy into mealtimes because of logistic problems, such as lack of dining space or close access to an electric point. In others, the families described practical difficulties using Mandolean because of either malfunctions or small keypads. Although some families found the Mandolean relatively easy to use with practice, others, especially the children, became fed up with the oral feedback and probably developed boredom in using the device long term as it was not particularly engaging or child friendly. Children also found the concept of rating their level of fullness during meals difficult to understand. Another significant problem described by those withdrawing from treatment was time constraints and the additional effort needed to set up the device prior to eating.

We also encountered problems in nurse follow-up sessions for those randomised to the Mandolean. The ability of the devices to reliably interface with the central Mandolean database, which was essential to alter participant training lines, proved difficult through the IT systems in many hub practices. The unreliability of the system caused significant frustration to nursing staff and participants, a point which came out within the qualitative data. This 'technical glitch' was eventually circumvented (96% reliability) by changing a cable attaching Mandolean to the computer used to input data and by using laptops with separate internet connections in place of inbuilt GP systems. Identifying the cause for this technical problem proved time-consuming and complex for the technical support from Sweden. It was likely a significant aspect in some families withdrawing from the intervention.

Although we have insufficient data to do a formal analysis of changes in eating speed and amount consumed, a visual inspection of the eating graphs does not suggest that those using Mandolean altered their speed of eating or total meal consumption in a consistent and replicable fashion. However, the qualitative study did suggest that Mandolean training encouraged children to think about their speed of eating and formalise mealtimes while helping parents understand portion size and what amount of different food types should be eaten.

The final important outcome for the pilot study was that 80% of families in both arms would attend their 3-month general practice appointment. This target was not achieved, with only 44% of patients attending this appointment across both arms.

Conclusions

The fundamental problem with this weight management intervention was the inability to recruit sufficient patients in a reasonable time frame to fulfil pilot study objectives. There are undoubtedly a number of factors that contributed to this disappointing result. There is a well-documented inability within parents and HCPs to recognise both the extent and implications of significant childhood obesity. Furthermore, there is reluctance among parents and HCPs to address the subject of obesity in children for fear of stigmatising either their own child or in the case of HCPs, the families. Feedback from the NCMP to families would have served two purposes: (1) to alert families to their child's weight status and (2) as a prompt to engage with HCPs without the need for that professional to take the first step in bringing up what is, without doubt, an extremely sensitive topic.

The mass mail-out methodology also produced a disappointing level of recruitment. Similar factors as described above in terms of parental recognition of obesity are probably a major factor. However, it is also likely given the paucity of responses that many families are yet to be convinced that childhood obesity has serious enough health implications as to warrant a significant family effort to engage in weight management programmes. It is noteworthy that, ambivalence to the health-care message that obesity in childhood is a serious concern has been well documented from qualitative studies on NCMP feedback while a number of community-based weight-management interventions such as the Mind, Exercise, Nutrition, Do it (MEND) programme in Bristol have struggled to recruit sufficient families to provide a viable, long-term care pathway.

In terms of adherence post randomisation, none of the pilot study targets were attained. Participant usage of Mandolean was suboptimal in 80% of cases and related to issues of family time constraint, practicalities of usage and dissatisfaction with the device itself and to the methodology of feedback, which was deemed unexciting and difficult to comprehend for this age group. Early withdrawal from active treatment was a feature of both the Mandolean and standard-care arms. This contrasts with our previous hospital-based, adolescent Mandometer intervention where study retention was 86%. Undoubtedly this group was different not only in terms of age and level of adiposity (average BMI *z*-value +3.2) but also in that they had elected to be referred to and attend a weight management service. Clinic non-attendance was also an issue that reflects our experience in a previous, primary care weight management trial we conducted [Primary Care – Care of Childhood Obesity (PC-COCO)], which had a non-attendance level of 45%. We had envisaged that the extra feedback provided with Mandolean would improve engagement and push attendance and adherence up to levels somewhat near the hospital-based study, but this did not happen. In retrospect it might have been prudent to conduct additional formative research with families, clinics, and nurses to more fully understand some of the issues that may be involved in translating this approach to the clinic and home environments in terms of both family acceptability and technical issues with the Mandolean.

The failure to recruit sufficient participants to the trial mirrors reports from other UK community-based, research and clinical interventions. Taken together with data on parental perceptions of childhood obesity in terms of recognition and attitudes to feedback such as the NCMP, it suggests we have yet to convince a significant proportion of the target population that childhood obesity is concerning. Two large primary care-based trials in Australia reported no discernible benefit from weight management interventions in children aged between 3 and 10 years, while a further report in younger children from the USA reported a similar lack of efficacy. Taken as a whole, current evidence suggests that primary care weight management interventions for childhood obesity neither engage the target population nor are clinically effective. Before

further interventions are considered, we need to understand better the barriers to engagement in terms of both recruitment and treatment adherence.

In terms of the Mandolean as a specific therapy, what appeared effective in a self-motivated group of adolescents attending a hospital-based clinic seems too complex and time-consuming for a significant majority of those families recruited through and treated by primary care. There are device development strategies that could enhance young children's experience of using the Mandolean in the future, but there are obvious concerns that the intervention is considered too complex by families and requires too much commitment to be used on a regular basis to really imprint a better eating pattern over the longer term.

Trial registration

The trial is registered as ISRCTN90561114.

Funding

This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 18, No. 47. See the NIHR Journals Library website for further project information.

Health Technology Assessment

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Five-year impact factor: 5.804

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index and is assessed for inclusion in the Database of Abstracts of Reviews of Effects.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

The full HTA archive is freely available to view online at www.journalslibrary.nihr.ac.uk/hta. Print-on-demand copies can be purchased from the report pages of the NIHR Journals Library website: www.journalslibrary.nihr.ac.uk

Criteria for inclusion in the *Health Technology Assessment* journal

Reports are published in *Health Technology Assessment* (HTA) if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the reviewers and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

HTA programme

The HTA programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The journal is indexed in NHS Evidence via its abstracts included in MEDLINE and its Technology Assessment Reports inform National Institute for Health and Care Excellence (NICE) guidance. HTA research is also an important source of evidence for National Screening Committee (NSC) policy decisions.

For more information about the HTA programme please visit the website: www.hta.ac.uk/

This report

The research reported in this issue of the journal was funded by the HTA programme as project number 09/127/04. The contractual start date was in January 2012. The draft report began editorial review in September 2013 and was accepted for publication in January 2014. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

Published by the NIHR Journals Library (www.journalslibrary.nihr.ac.uk), produced by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk).