

# The TrimTots programme for prevention and treatment of obesity in preschool children: evidence from two randomised controlled trials

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## Abstract

**Background** There are few lifestyle interventions that target obesity in preschool children. We report the results of two randomised controlled trials assessing an intervention to reduce obesity risk in children aged 1–5 years (TrimTots Healthy Lifestyle Programme). We hypothesised that participating children would reduce their risk of obesity compared with those not yet having taken part.

**Methods** TrimTots is a multicomponent programme including diet, physical activity, and behaviour change with an emphasis on family involvement and learning through art and play. Education was delivered through interactive teaching sessions and practical workshops. Behaviour change was encouraged by setting SMART (specific, measurable, achievable, realistic, and timely) goals to achieve small sustainable changes in diet and activity. Children and parents participated in music and movement and active games and learned about nutrition and physical activity through art workshops. The programme was delivered twice weekly in 2-h sessions over 6 months at Sure-Start Children's Centres in Hertfordshire between June, 2008, and December, 2012. Parents were given exercise equipment, games, and music CDs to encourage home-based activities. TrimTots was assessed in two randomised, single-blind (investigator masked), controlled trials. Trial 1 recruited children with body-mass index (BMI) at or above the 91st centile or whose weight had crossed centiles upwards on the UK–WHO growth reference (mean age 2.5 years [SD 1.0]; n=88). Trial 2 included ten further children's centres and recruited children irrespective of weight status (mean age 2.1 years [SD 0.8]; n=85). Children were randomly assigned by an independent statistician by a computer-generated permuted block design to either start the intervention immediately or to a waiting list control. Analysis was by intention to treat. The sample size in each trial was calculated to detect a 0.6 SD difference in BMI Z score between randomised groups at 5% significance and 80% power. The 2-year analysis used a paired *t* test to analyse within-participant changes in BMI Z score. The trial is registered with ClinicalTrials.gov, NCT0067562.

**Findings** 64 of 88 (73%) and 64 of 85 (75%) children completed trials 1 and 2, respectively. In trial 1, BMI and waist circumference were significantly lower at the end of the programme in the intervention group than in the control group (mean difference for BMI Z score  $-0.9$ , 95% CI  $-1.4$  to  $-0.4$ ;  $p=0.001$ ; mean difference for waist circumference adjusted for age and sex  $-3.6$  cm,  $-6.0$  to  $-1.3$ ;  $p=0.003$ ). In 42 of 88 (48%) children measured at 2-year follow-up, BMI Z score was lower than at baseline (mean difference  $-0.3$ , 95% CI  $-0.6$  to  $-0.1$ ;  $p=0.007$ ). In trial 2, BMI Z score and waist circumference did not differ significantly between groups (mean difference for BMI Z score  $-0.3$ , 95% CI  $-0.8$  to  $0.3$ ;  $p=0.3$ ; mean difference in waist circumference  $-2.5$  cm,  $-4.5$  to  $0.02$ ;  $p=0.05$ ). For both trials combined, BMI and BMI Z scores were lower in the intervention group than in the control group (mean difference for BMI Z score  $-0.4$ , 95% CI  $-0.8$  to  $-0.02$ ;  $p=0.04$ ). Blood pressure was lower after the intervention in both trials, although not significantly in trial 2 (mean difference  $-6$  mm Hg, 95% CI  $-11$  to  $-1$ ;  $p=0.01$  in trial 1; and  $-2$  mm Hg,  $-2$  to  $6$ ;  $p=0.3$  in trial 2). No adverse events were reported during the trials.

**Interpretation** TrimTots was acceptable to families and centre staff and resulted in a significant reduction in obesity risk in overweight or high-risk children. Longer term follow-up found the effect on BMI to be sustained. These findings suggest that the programme is a feasible intervention for management of obesity in preschool children.

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## Contributors

JL and AS conceived and designed the study. SC coordinated the study and supervised data collection. MK and TB collected data. JL did the statistical analysis and wrote the abstract with input from AS. All authors have seen and approved the final version of the abstract for publication.

## Conflicts of interest

We declare that we have no conflicts of interest.

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