Effectiveness of a once per week delivery of a family-based childhood obesity intervention: a cluster randomised controlled trial

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Summary

Background: The effectiveness of once per week (OPW) delivery of a family-based childhood obesity programme was compared with twice per week (TPW) delivery in achieving health and behavioural outcomes at a population level and in improving programme attendance. Both programmes were delivered over 10–weeks, and the contact hours in the OPW and TPW programmes were 20 and 35–h, respectively.

Methods: A cluster-randomised controlled trial with stratification by local health district was conducted. Height, weight and global self esteem of participants and parent-reported diet and physical activity were measured at programme commencement and completion and at 6-month follow-up. Attendance was defined as the proportion of total sessions attended.

Results: There were no differences between the OPW and TPW arms in changes from pre-programme baseline for body mass index (BMI) z-score and other health and behaviourial measures at programme completion and at follow-up, except for the increase in physical activity outside of the programme at programme completion (OPW, 3.5 h/week; TPW, 1.9 h/week; $p = 0.03$). OPW and TPW participants attended 71.2% and 69.2% of the total sessions, respectively. Attendance was the only contributing factor to a positive BMI z-score outcome ($\beta = -2.45$, $p < 0.01$) with no effects of child age and gender, language spoken at home or highest qualification of mother.

Conclusions: A family–based childhood obesity programme can be delivered OPW with no compromise to health or behavioural outcomes compared with TPW. Higher attendance, as a proportion of available sessions, leads to better outcomes for children.

Keywords: Childhood obesity, Family-based intervention, population level, attendance.

Background

Childhood obesity is a major public health concern worldwide with short-term and long-term risks to the health, psychosocial and social well-being of children. Multi-level and multi-strategic community-based approaches involving families are considered best practice in managing childhood obesity (1).

The Go4Fun programme in New South Wales (NSW), Australia, described elsewhere (1,2), is a family-based community childhood obesity treatment programme for overweight and obese children aged 7–13 years, adapted from the UK Mind Exercise Nutrition Do it (MEND) programme (3). Briefly, Go4Fun includes two weekly sessions over 10 weeks, each of which includes a 1-h physical-activity component encouraging participation and skills development, a theory component covering nutrition and health behaviour and a facilitated discussion with parents or carers ('parents'). With facilitator support, participants set weekly goals for health-related behaviours (data not collected). Children are self-referred to Go4Fun by their parents or can be referred by health practitioners.

Of the 2499 children participating in Go4Fun between 2009 and 2012, 57.4% attended at least 75% of the programme sessions (1). A 2012-programme review using mixed methods found the twice per week (TPW) attendance requirement for families a key deterrent to enrolment and sustained participation (4). In response, a once per week (OPW) version was developed by condensing the educational and physical activity components of the TPW version while retaining programme elements targeting weight-related behaviours (Supplemental Table 1). The total contact hours in the OPW programme were reduced to 20 from 35 h in TPW with physical activity reduced from 15 to 7 hours. The sequence of the programme sessions was also revised to ensure their consistency in intensity and length. During programme development, the OPW model was implemented by experienced programme facilitators who found it feasible to deliver.

Considerable research on the duration of childhood obesity programmes suggests longer interventions are more effective than shorter ones, and it seems that low-intensity long-term programmes have limited effectiveness in achieving health and behavioural outcomes (5). However, no studies have been conducted on the frequency of attendance required within specific programmes to achieve outcomes or sustain participation.

The primary objectives of the study were to compare health (BMI z-score), behavioural (physical and sedentary activities, diet) and psychosocial (self-esteem) outcomes at programme completion and 6 months after completion ('follow up') for children attending OPW and TPW Go4Fun programmes. Attendance, defined as the proportion of total programme sessions attended, and weekly cumulative attendance were also compared. As secondary objectives, the study determined the predictors of BMI z-score improvements at programme completion and assessed the changes from pre-programme in outcome measures at programme completion and follow-up.

Methods and subjects

A cluster-randomised controlled trial stratified by Local Health District (LHD) was conducted. LHDs are geographical areas in NSW within which health services are provided and managed. The study adapted elements of pragmatic trial design to enhance generalisability and applicability of the findings (6).

Go4Fun programmes are implemented by the LHDs over the school year (January to December, with four terms). For the study, programmes commencing in three school terms (Terms 3 and 4 2013 and Term 1 2014) were included. LHDs selected the programme sites to be included after considering pre-existing arrangements. For example, venues already contracted to deliver the TPW model during the study period could not be included. The included sites were randomised to OPW or TPW by the researchers using Microsoft Excel. Families were enrolled into the programme via the usual enrolment pathways such as self-referral (88.4%) or by their health practitioners. Programmes at research sites were delivered by LHD-allocated facilitators who had all undertaken MEND training, a prerequisite for employment as a facilitator (7). Because of the pragmatic nature of the study, the facilitators within both OPW and TPW arms had varying levels of programme delivery experience. The programme was not run in the sites with three or fewer registrations.

Children with BMI equal to or more than the 85th but less than the 95th percentile for their age category on the World Health Organisation chart were considered overweight, and those with BMI equal to or more than 95th percentile for their age were considered obese.

Families were invited to participate in the study only after enrolment and allocation to either an OPW or TPW programme in their geographical area. The risk of contamination, particularly in the metropolitan programmes due to their proximity, was controlled by enforcing the geographical boundaries. Families were required to attend the programme to which they were allocated. Children were usually enrolled a few weeks before programme commencement. A pre-programme pack sent to the programme enrolees included a participant information sheet with detailed description of the study. The parent attending the first session was required to sign a written consent to participate in the study. Families participating in the OPW programme attended one weekly 2-h session

for 10 weeks, and those participating in the TPW programme attended two weekly 2-h sessions for 10 weeks. Ethics approval was obtained from South Western Sydney Local Health District Human Research Ethics Committee.

Measurements

Measurements were conducted at pre-programme and post-programme and follow-up. The data collectors were staff members at seven LHDs and external exercise physiologists at the remaining four LHDs. To facilitate consistent measurements, all data collectors attended a half-day training and practice workshop on study measurement and questionnaire administration.

For behavioural and psychosocial outcomes, parents completed a questionnaire on physical activity, sedentary activities and dietary behaviour (consumption of fruit and vegetables, sugary drinks and energy-dense nutrient-poor foods) of their participating child/ren. Soft drinks, cordials, sports drinks and fruit juice were considered as sugary drinks. Energy-dense nutrient-poor food included chips, wedges, fried potatoes, crisps and fast food including burgers and pizzas. Parent questionnaire items were adapted from previously validated parent-reported dietary questionnaire for children aged 2-5 years (8) and self-reported physical-activity (9) and sedentary-behaviour (10) questionnaires for adolescents. The self-response phrasing of the physical-activity and sedentary-behaviour questions was modified for parent response without changing the questions and the response items. Physical-activity items relate only to physical activity outside the programme. Total weekly duration of physical activity was determined by adding the time spent participating in organized sports and non-organized physical activity outside of the Go4Fun programme. Weekly sedentary-behaviour questions were on small screen time for recreation and homework and sedentary travel modes. Each child completed a modified Rosenberg self-esteem questionnaire (11), which was adapted for use with children by simplifying some of the language without changing the questions and the response items. The pre-programme parent questionnaire also included questions about the highest qualification of mother to represent socioeconomic status and language spoken at home, adapted from the Australian Census (12).

For health outcomes, physical measurements were height using a height measuring rod (HM200P, Charder Medical, Taichung City, Taiwan) and weight using a digital scale (Seca clara 803, Seca, Hamburg, Germany). Waist circumference was also measured,

but these data were not analysed because of concerns raised recently in Australia (17) regarding its reliability in children (18).

All data were entered into a central database, also used by programme staff to record attendance at each session. BMI z-score at post-programme and follow-up were treated as missing values if the difference score for BMI was $\pm5\,kg/m^2$ from pre-programme.

Sample size

The sample size required for this study was calculated from routinely collected Go4Fun programme data. To detect a difference in BMI of $1\,kg/m^2$ between the OPW and TPW arms with 80% power, 131 children were needed in each arm if randomised at the individual level. Adjusting for an intra-cluster coefficient (13) of 0.0056, based on the variance of regular programme data, and assuming an average of 10 children in each programme site, 138 children were needed in each arm.

Statistical analysis

Statistical analysis was conducted in two stages and accounted for *cluster*, i.e. hierarchical clusters of programmes within LHDs. Outcome measures were adjusted for *data collector* to account for the potential differences between external data collectors and local programme staff.

Primary objectives

Mean difference scores for BMI z-score, physical activity, fruit and vegetable intake and child self-esteem at post-programme (programme completion and follow-up) from pre-programme were compared between the OPW and TPW groups after adjusting for data collector and cluster using the analysis of variance test on available cases.

Difference in attendance (proportion of total sessions attended) between the two arms was compared using chi-squared tests. The weekly cumulative attendance at each programme week was calculated as a percentage of the number of sessions attended by a participant to the total number of sessions up to that particular week.

Secondary objectives

Analysis by intention to treat, substituting missing values by imputation, was used to identify the predictors of improvement in BMI z-score at programme completion and the difference scores of anthropometric

and behavioural measurements at post-programme and follow-up.

Twenty imputations were created using the method of multiple imputation by chained equations assuming missingness at random (14,15), similar to the approach used in a community-based lifestyle intervention (16). This approach results in an approximately 1% power fall off for 60% attrition (17) and has been used in a randomised longitudinal trial with similar loss to follow-up to this study (18). Age, gender and pre-programme height and weight of children, study arm and LHD were included as covariates in the multivariate sequential regression analysis for imputation of programme completion variables. In the regression model for imputation of follow-up variables, imputed programme completion variables were included in addition to the previous variables. Sensitivity analysis of the imputed data was conducted by comparing residual plots and assessing the plausibility of the imputed datasets (19).

Predictors of BMI z-score improvement at post-programme were analysed on the imputed datasets using a multilevel linear mixed model. Each imputation was analysed separately, and the coefficients were pooled to determine the predictor of improvements in BMI z-score at the post-programme stage. Covariance effects of data collector and cluster were incorporated as random effects. The fixed effects included in the model were programme arm, age and gender of the children, attendance, highest qualification of mother and language spoken at home.

Statistical analyses were conducted using IBM SPSS statistics v21 (IBM Inc, NY, USA) and Stata v12 (StataCorp LC, TX, USA).

Results

Of the 68 programme sites randomised to the study, 16 were cancelled before the study commenced because of insufficient participant numbers (≤3 participants). Twenty seven OPW and 25 TPW programme sites across 11 of 15 LHDs in NSW were included in the study. Nine programme sites were outside metropolitan areas in each of OPW (33.3%) and TPW (36.0%) arms.

Of 593 children enrolled in the programme, 575 (97.0%) agreed to participate in the study of which 81 (13.6%) did not commence the programme, and 36 (6.3%) were excluded from the study because their pre-programme BMI was lower than the 85th percentile for age (Fig. 1). The average number of children enrolled in OPW programme sites (12.5 ± 3.2) was higher than TPW (10.2 ± 3.2). There were no discernible patterns of withdrawals from the study based on study arm or geographical location. Of the 458 children (average age 9.5 ± 1.8 years;
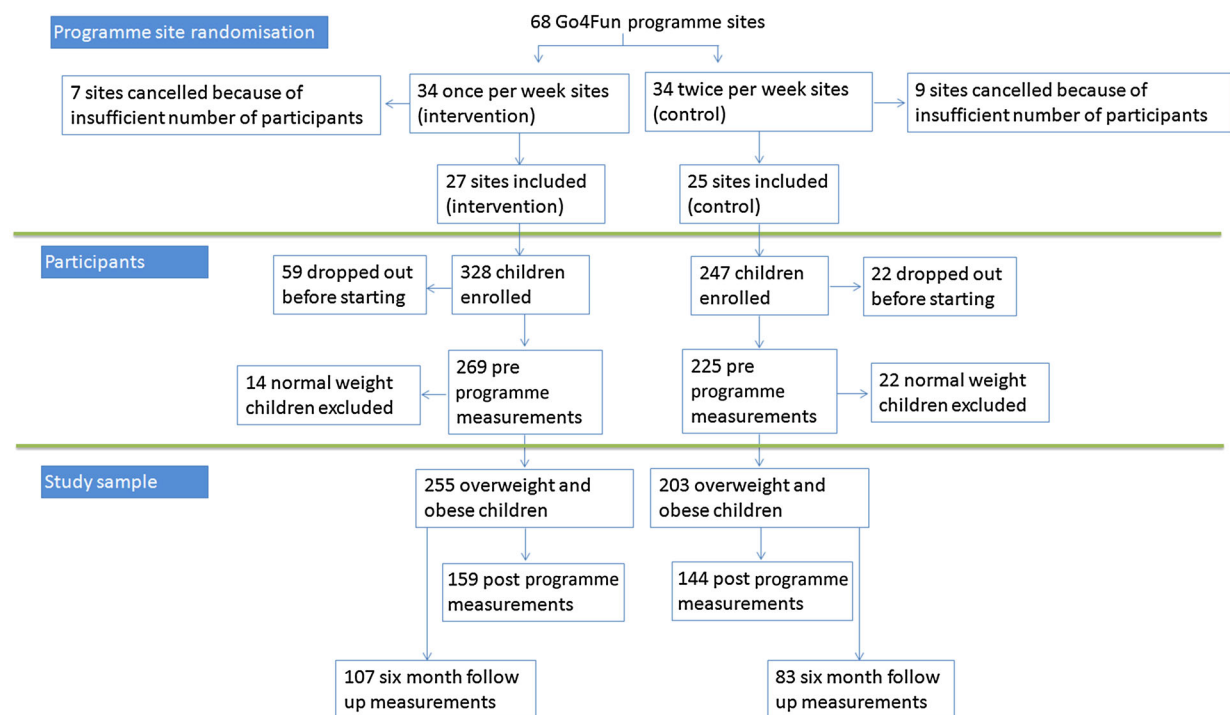

Figure 1 Study sites and particicpants.

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Table 1 Pre-programme characteristics of all participants and those lost to follow-up at post-programme and follow-up

	OPW				TPW		
	All	Lost at post-programme	Lost at follow-up	All	Lost at post programme	Lost at follow-up
No of participants	255	96	148	203	59	120
Obese	193 (75.7)	73 (76.0)	123 (83.1)	151 (74.4)	45 (76.3)	98 (81.7)
Average age (years)	9.4 (1.6)	9.6 (1.6)	9.8 (1.4)	9.6 (1.8)	9.7 (1.7)	9.9 (1.8)
Female	136 (53.1)	48 (50.0)	75 (50.9)	104 (51.2)	31 (52.5)	63 (52.5)
Mother not university qualified	172 (67.4)	68 (68.7)	97 (65.5)	141 (69.4)	38 (64.4)	95 (79.2)
English spoken primarily at home	196 (75.3)	77 (80.2)	121 (81.8)	139 (68.5)	44 (74.6)	103 (85.8)
Aboriginal background	20 (7.8)	7 (7.3)	11 (7.5)	16 (8.0)	5 (8.5)	8 (6.6)
BMI (kg/m^2)	25.3 (4.5)	25.5 (3.5)	25.3 (4.2)	25.4 (4.7)	25.8 (4.1)	25.5 (4.9)
BMI z-scores	1.91 (0.52)	1.97 (0.49)	1.94 (0.41)	1.91 (0.56)	1.98 (0.44)	1.90 (0.58)
Child self-esteem (Mean ± SD)	2.8 (0.4)	2.8 (0.4)	2.8 (0.3)	2.8 (0.4)	2.8 (0.5)	2.8 (0.4)
Fruit and veg intake (serves/day)	3.3 (0.9)	3.7 (0.6)	3.6 (1.0)	3.6 (1.2)	3.4 (0.9)	3.8 (0.9)
Sugary drinks intake (cups/day)	1.3 (1.4)	1.3 (1.3)	1.3 (1.3)	1.4 (1.6)	1.3 (1.4)	1.3 (1.3)
Energy dense nutrient poor food (times/day)	0.5 (0.6)	0.5 (0.5)	0.5 (0.5)	0.6 (0.7)	0.6 (0.7)	0.5 (0.6)
Physical activity (hr/week)	5.1 (3.7)	5.2 (3.9)	5.2 (3.7)	5.7 (4.2)	5.6 (4.8)	5.8 (4.3)

Data presented as mean (SD) or N (%)

52.4% female; 7.9% Aboriginal) in the study, 344 (75.1%) were obese, and 114 (24.9%) were overweight. English was the primary language spoken at home by 335 children (73.1%), and the mothers of 313 children (68.3%) did not have a university degree.

At study commencement, average numbers of children in each arm were 9.4 in OPW and 8.1 in TPW. Loss to follow-up at post programme and follow-up was 37.6% and 58.0% for the OPW arm, and 29.1%% and 59.1% for TPW. Demographic characteristics and dietary behaviour of children at pre-programme were similar between the OPW and TPW arms. There were no differences in these baseline characteristics between all participants and those lost at post-programme and follow-up. Although not statistically significant, the proportion of obese children in both arms who left the study at follow-up was slightly higher than at post-programme (Table 1).

Primary objectives

The difference scores of OPW and TPW arms for the primary outcomes at programme completion were similar except physical activity outside the Go4Fun programme, with OPW participants participating in more physical activity. At follow-up, no difference score was statistically significant (Table 2).

There was no statistically significant difference between the OPW and TPW arms in attendance, with OPW and TPW participants attending 71.2% and 69.2% of the total sessions, respectively. Weekly cumulative attendance showed that the proportion of children attending the programme dropped consistently from week 2 onwards and recovered slightly for the final measurement week (Supplemental Fig. 1).

Secondary objectives

In the mixed-model analysis allowing for data collector and cluster, the only predictor of a positive BMI z-score outcome was attendance (Supplemental Table 2). Other factors including child age and gender and the socio economic characteristics of the families were not significant predictors.

Body mass index z-score was significantly lower at follow-up than at pre-programme, although a reversal effect from the positive changes found at programme completion was seen for other outcome measures (Supplemental Table 3).

Discussion

Our findings show that similar levels of health and behavioural outcomes for overweight and obese children can be achieved up to 6 months after programme completion by delivering the OPW version of Go4Fun in comparison with the previously recommended TPW. The OPW participants received fewer opportunities for physical activity as part of the programme. However, they seem to have used some of the available time outside the programme to participate in physical activity. This may explain their similar levels of improvement in BMI z-score (20) to TPW participants. Cost effectiveness of delivering the OPW compared with TPW programme could not be measured in this study as resource requirements to run the OPW programme were yet to be determined. Nonetheless, the reduced attendance requirement could be expected to increase the programme's cost effectiveness.

The only contributing factor to an improvement in BMI z-score outcome in this study was attendance as a proportion of total sessions attended, irrespective of programme model. Other factors such as age and gender of children and socio economic status did not predict a positive outcome, as reported in previous studies (21,22). It is possible that the parents of families who attended more sessions were more motivated (23), and the children would have achieved similar outcomes even by attending fewer sessions. Parental influence and involvement play a significant role in the healthy behaviours of children as demonstrated by recent studies (24,25). Nevertheless, the finding of this study highlights the importance of retaining children in childhood obesity treatment programmes.

Contrary to our expectation, reduced programme frequency did not improve attendance. Some of the reasons for non-completion of childhood obesity programmes reported by previous studies such as psychological issues and depressive symptoms of children, programme components, scheduling and proximity of programme site are modifiable (26,27) and need to be considered as part of programme design and delivery. Importantly, retention strategies need to be implemented from programme outset as participation rates drop from the second session onwards

Body mass index z-score improved for both OPW and TPW arms at programme completion and the improvements were maintained at follow-up. The effect size for BMI z-score in this study for both arms was smaller than the MEND study (3), but this would

Table 2 Comparison* between the OPW and TPW arms of the changes from pre-programme in outcome measures at programme completion and follow up with 95% confidence intervals after adjusting for data collector and cluster

Measure	Programme completion			Follow-up		
	OPW	TPW	p value	OPW	TPW	p value
% of children	62.3 (159/255)	41.9 (107/255)		70.9 (144/203)	40.1 (83/203)	
BMI z-score	−0.19 (−0.22 to −0.16)	−0.20 (−0.23 to −0.17)	ns	−0.15 (−0.34 to −0.05)	−0.12 (−0.19 to −0.05)	ns
Physical activity (h/week)	3.5 (2.7 to 4.2)	1.9 (0.8 to 3.0)	0.03	1.5 (0.4 to 3.6)	1.0 (−0.5 to 2.5)	ns
Sedentary activities (h/week)	−4.5 (−6.4 to −2.7)	−5.5 (−8.4 to −2.5)	ns	−3.1 (−5.3 to −0.9)	−1.1 (−6.4 to 4.1)	ns
Fruit and veg intake (serves/day)	0.9 (0.5 to 1.1)	0.7 (0.3 to 1.1)	ns	0.7 (0.3 to 1.1)	0.5 (0.0 to 1.0)	ns
Sugary drinks** (cups/day)	−0.7 (−1.3 to −0.5)	−0.8 (−1.2 to −0.3)	ns	−0.6 (−1.0 to −0.2)	−0.7 (−1.1 to −0.2)	ns
Energy dense nutrient poor food*** (times/day)	−0.4 (−0.7 to −0.3)	−0.6 (−0.9 to −0.3)	ns	−0.3 (−0.6 to 0.0)	−0.2 (−0.7 to 1.2)	ns
Child self-esteem score	2.3 (1.5 to 3.1)	1.5 (0.5 to 2.5)	ns	0.4 (−1.0 to 1.7)	0.9 (−1.5 to 2.5)	ns

*Comparison was conducted using available cases. At follow-up, the sample size was inadequate to detect differences between the groups.
**Composite score for fruit juice, soft drinks, cordials and sports drinks; 1cup = 250 ml
***Composite score for chips, wedges, fried potatoes, crisps and fast food.

be expected as the MEND study was conducted on obese children only, whereas Go4Fun also includes overweight children. The population level rollout of the MEND programme (28) included overweight children in addition to obese children and achieved similar BMI z-score outcomes to this study.

Consistent with other longitudinal childhood obesity studies (29,30), reversal effects in the health behaviour improvements at post-programme were seen at follow-up with the time spent in physical activity dropping to pre-programme levels. The reversals in dietary and sedentary behaviours were less pronounced. It is crucial to implement maintenance strategies to sustain improvements in health and behavioural outcomes attained through childhood obesity programmes.

The limitations of this study are mostly due to the pragmatic aspects of the study design and higher than expected attrition. The data collectors were not blinded and had access to pre-programme and other data when conducting the follow-up measurements. Measurements were conducted only once on each occasion and not necessarily by the same data collector at the three measurement points increasing the chances of inaccuracies (31). Also, the data collectors had varying levels of experience, and a half-day training could have been inadequate to change their measurement techniques. It was not possible to assess the inter-rater reliability of the data collectors as it was not practicable to have adequate numbers of children at the training sessions. Further, as the dietary and physical activity behaviours were parent reported, there is potential for social desirability bias. Although missing data were multiply imputed using techniques used by lifestyle studies with similar attrition rates (18) with negligible loss to power (17), when large proportions of the data are missing, small deviations on the regression model can skew outcomes (15). The findings of this study however relate directly to real-world settings and are therefore useful for enhancing community-based childhood obesity interventions.

In conclusion, our study shows that family-based childhood obesity programme can be delivered OPW with no compromise to health or behavioural outcomes compared with TPW. Irrespective of the frequency of interaction during the programme, the effect of the programme on health behaviour decreases over time warranting the need for maintenance strategies. Higher attendance leads to better health outcomes for the children, and retention strategies need to be considered during programme development.

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Conflict of interest statement

Acknowledgements

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Supporting Information

Additional supporting information may be found in the online version of this article at the publisher's website:

Table S1. Outline of the weekly sessions for the once per week and twice per week Go4Fun programmes. Sessions in bold italics are attended by the parents/carers and the children together. In the physical activity component, children participate in games and skills-based activities to develop confidence and skills to improve participation in regular physical activity.

Table S2. Factors affecting body mass index z-score outcome at the post programme stage after adjusting for data collector and cluster using imputed data.

Table S3. Means and 95% confidence interval of the primary outcome measures at the three measurement points after adjusting data collector and cluster.