Twelve-Month Outcomes of the Loozit Randomized Controlled Trial

A Community-Based Healthy Lifestyle Program for Overweight and Obese Adolescents

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Objectives: To assess the outcomes of the Loozit adolescent weight management intervention and to evaluate the effect of additional therapeutic contact 12 months into the program.

Design: A 24-month, 2-arm randomized controlled trial. Results at 12 months are presented.

Setting: Community health center and children’s hospital in Sydney, Australia.

Participants: A total of 151 overweight or obese 13- to 16-year-olds.

Intervention: In the first 2 months (phase 1), participants received 7 adolescent and parent weekly sessions focused on lifestyle modification. From 2 to 24 months (phase 2), adolescents attended booster sessions once every 3 months. During phase 2, adolescents randomized to the additional therapeutic contact arm also received telephone coaching and electronic communications once every 2 weeks.

Outcome Measures: Baseline to 12-month changes in body mass index z score and waist to height ratio (primary outcomes) and changes in metabolic, psychosocial, and behavioral variables.

Results: Of 151 randomized adolescents, 82.1% completed 12-month follow-up. Intent-to-treat analyses showed significant reductions in mean body mass index z score (−0.09; 95% CI, −0.12 to −0.06), waist to height ratio (−0.02; 95% CI, −0.03 to −0.01), total cholesterol level (−4 mg/dL; 95% CI, −8 to 0 mg/dL; to convert to millimoles per liter, multiply by 0.0259), and triglycerides level (geometric mean, −80 mg/dL; 95% CI, −88 to −71 mg/dL; to convert to millimoles per liter, multiply by 0.0113). Most psychosocial outcomes improved, including global self-worth, but there were few dietary, physical activity, or sedentary behavior changes. No difference was found in primary outcomes between participants who did or did not receive additional therapeutic contact.

Conclusions: The Loozit randomized controlled trial produced a significant but modest reduction in body mass index z score and improved psychosocial outcomes at 12 months. Supplementary telephone and electronic contact provided no additional benefit at 12 months.

Trial Registration: anzctr.org.au Identifier: 12606000175572


Obesity in adolescence is a major public health problem. Although effective primary prevention of obesity in this age group is important, so too is the development of effective interventions for treating obese adolescents across a variety of health care settings.

Behavioral family lifestyle interventions can lead to clinically significant overweight reduction in both children and adolescents. However, most published interventions have involved intensive clinical programs provided in tertiary care settings, with few lifestyle studies conducted in adolescents. Few studies have investigated less resource-intensive treatment programs in community care settings, reported long-term health outcomes, or examined strategies for the long-term maintenance of positive weight management outcomes. Hence, there is currently limited evidence on clinically effective, long-term weight management interventions that are sustainable in community settings, where most overweight and obese adolescents should be treated.

The Loozit weight management program was developed as a low-intensity, behavioral family lifestyle intervention that is potentially sustainable in a community setting. The 24-month intervention involves an initial, more intense 2-month
treatment phase, followed by a 22-month maintenance phase during which adolescents in one study arm receive additional therapeutic contact (ATC) via telephone coaching and electronic communications. Although interactive electronic interventions appear to be a promising approach for the management of pediatric obesity, few high-quality studies have investigated long-term outcomes. To our knowledge, the Loozit study is the first randomized controlled trial (RCT) of a sustainable, community-based adolescent weight management intervention examining long-term outcomes and evaluating the effect of ATC.

The short-term (2-month) outcomes of the Loozit study showed stabilization of overweight and improvements in several metabolic, psychological, and behavioral outcomes. The aims of this article are, first, to evaluate the effectiveness of the Loozit adolescent weight management program and, second, to compare the effect of ATC provided as an adjunct to the Loozit group program 12 months into the program.

METHODS

STUDY DESIGN

The Loozit RCT is a 2-arm, community-based lifestyle intervention for overweight to moderately obese 13- to 16-year-olds. The study was conducted at a local community health center and an affiliated children’s hospital in Sydney, Australia. The full RCT protocol has been published elsewhere. This study is registered with the Australian New Zealand Clinical Trials Registry (No. 1260600175572) and has been approved by the Human Research Ethics Committees of The Children’s Hospital at Westmead, Sydney West Area Health Service, and the University of Sydney.

STUDY PARTICIPANTS

From April 2006 to June 2009, adolescents were recruited mainly through the media, schools, health professionals, and community organizations. Details of the recruitment process have been published elsewhere.

In brief, eligibility criteria for adolescents were overweight to moderately obese (ie, body mass index [BMI]; calculated as weight in kilograms divided by height in meters squared) z score range, 1.0-2.5) but otherwise healthy, age of 13 to 16 years, available to attend the initial group sessions with one of their parents or caregivers on specified days, and ability to access a landline telephone and e-mail and/or a mobile telephone. Eligibility was assessed over the telephone and confirmed at a face-to-face appointment. Written informed consent was obtained from eligible adolescents and one of their parents or caregivers.

Computer-generated randomization sequences stratified by sex, age group (13-14 years or 15-16 years), and intervention site were provided by the study hospital’s Clinical Epidemiology Unit staff. Allocation to either the Loozit group program or Loozit group program plus ATC was concealed in sequentially numbered opaque envelopes prepared by the trial manager and revealed once informed written consent was obtained.

INTERVENTION

The Loozit group program adheres to Australian clinical practice guidelines for the management of childhood and adolescent overweight and obesity in its healthy lifestyle recommendations and is based on a cognitive behavioral approach. The 24-month intervention consists of an intensive treatment phase followed by a longer maintenance phase. In phase 1 (baseline to 2 months), participants receive the Loozit group program, which involves seven 75-minute weekly group sessions held separately for adolescents and their parents or caregivers. In phase 2 (2-24 months), adolescents continue to attend booster group sessions approximately once every 3 months during each school term (in total, seven 60-minute sessions, including 2 outcome assessment sessions held at 12 and 24 months). All sessions are facilitated by trained dietitians. In addition, adolescents in one study arm (Loozit and ATC) receive ATC during the treatment phase, followed by a longer maintenance phase. In phase 2 (2-24 months), adolescents continue to attend booster group sessions approximately once every 2 weeks in the form of telephone coaching, e-mails, and/or short message service text messages (total of 32 electronic messages and 14 telephone coaching sessions). A detailed description of the group sessions and ATC received is provided elsewhere.

OUTCOME MEASURES

Outcome measures were assessed at baseline, 2 months (completion of phase 1), and 12 months (almost midway through phase 2) after baseline. This article focuses on the 12-month outcomes. The results of the phase 1 study (baseline to 2 months) have been previously published, and the collection of 24-month follow-up data (completion of phase 2) is still under way.

Primary outcomes are baseline to 12-month changes in BMI z score and waist to height ratio. Secondary outcomes include parallel changes in metabolic and self-reported psychosocial and behavioral variables. Any adverse events observed or reported during the study were documented.

Anthropometry

Trained, masked assessors measured height, weight, waist circumference, and blood pressure using standard procedures and calibrated equipment. The BMI z scores were calculated based on age- and sex-specific reference values.

Metabolic Profile

Fasting blood samples were collected at a nationally accredited external pathology laboratory and analyzed for cholesterol (total, high-density lipoprotein, and low-density lipoprotein), triglycerides, glucose, insulin, and alanine aminotransferase levels.

Psychosocial Factors

Participants completed several questionnaires measuring psychosocial well-being. The Mental Health Inventory 5 (5 indicating most favorable health and 0 indicating least favorable health), a 5-question mental health assessment component of the Medical Outcomes Study 36-Item Short-Form Health Survey, was used to assess quality of life. Participants selected current perceived body shape and ideal body shape from sex-specific, 9-figure scales ranging from thin to fat body shapes (scoring, 1-9), with body dissatisfaction being the difference between the 2 selected shapes. The MacArthur Scale of Subjective Social Status, adapted from a 10-point vertical ladder scale (1 indicating extremely low and 10 indicating extremely high), was used to evaluate social acceptance with adolescent peers. The 45-item Harter Self Perception Profile for Adolescents provided a measure of global self-worth (1 indicating low and 4 indicating high) and perceived mean competence in 8 domains (scholastic, social acceptance, athletic, physical appearance, job, romantic appeal, close friendship, and
behavioral conduct). The importance attributed to each domain was also measured using a 16-item scale.

### Lifestyle Behaviors

Dietary intake was assessed from a 15-item food frequency questionnaire, which featured additional questions on eating behaviors that were used for an Australian study of adolescent dietary intake. Responses were categorized into dichotomous variables to indicate whether adolescents met Australian dietary recommendations.

Physical activity and sedentary behaviors were measured with the Children's Leisure Activities Study Survey. Time spent in total physical activity (the sum of 42 activities) and at various intensity levels (light, moderate, and vigorous) was calculated. Sedentary leisure activities (total of 13 activities) were classified as screen and non–screen based. Participants whose sedentary leisure activity time exceeded 72 hours per week were excluded according to established protocols.

### SAMPLE SIZE

It was estimated that a sample of 128 adolescents (ie, 64 in each study arm) would ensure 80% power to detect a 0.4-unit difference in mean change of BMI z score from baseline to 2, 12, and 24 months after baseline in the 2 intervention groups (2-group t test = 0.05, 2-tailed significance). We aimed to enroll a total of 168 adolescents to account for a potential 30% study dropout rate. However, recruitment of adolescents to the trial was challenging, and prolonged recruitment efforts led to funding constraints.

### STATISTICAL ANALYSIS

Data were analyzed using SPSS statistical software for Windows, version 19 (SPSS, Inc). Consistent with an intent-to-treat approach, all available data for participants as originally randomly assigned were retained. For most outcome variables, linear mixed models with an unstructured covariance structure were used to test for the effects of time and group. Group unstructured covariance structure were used to test for the effects of time (as repeated factor; treated as categorical with levels: baseline, 2 months, and 12 months) and group. A similar analysis was performed for variables that were not normally distributed after log transformation. For dichotomized dietary variables, generalized estimating equation models are presented as odds ratios (ORs) with 95% CIs. Statistical significance was accepted at a level of P < .05.

### RESULTS

#### PARTICIPANT BASELINE CHARACTERISTICS

The Figure shows participant flow in the study up to 12-month follow-up. Of 474 inquiries, 78 and 73 eligible adolescents were randomized to the Loozit only and Loozit and ATC intervention arms, respectively. Of these randomized participants, 60 (76.9%) and 64 (87.7%) completed the first 12 months of the study (ie, completers, not formal withdrawals), whereas 50 participants (64.1%) in the Loozit only arm and 57 participants (78.1%) in the Loozit and ATC arms had 12-month anthropometric assessments. No significant differences were found between 12-month completers (n = 124) and withdrawals (n = 27) in baseline demographic or anthropometric characteristics. Of participants without anthropometric follow-up at 12 months (n = 44), half had mothers with a university degree compared with a third of participants with follow-up data (n = 107); no significant differences were found in other baseline demographic characteristics or anthropometric variables. No adverse events were observed.

The demographic characteristics and pubertal stage of adolescents enrolled in the study have been reported previously. Table 1 reports the baseline anthropometric and metabolic characteristics of study participants (151 [48.3%] male). No differences were found between study arms in baseline demographic, anthropometric, or metabolic characteristics.

### ANTHROPOMETRIC AND METABOLIC OUTCOMES

Table 2 lists the mean values for anthropometric and metabolic outcomes at baseline and 12 months in individual treatment groups and differences in outcomes by treatment group and time. Significant time effects were found for several variables, including mean reductions from baseline to 12 months in BMI z score (−0.09; 95% CI, −0.12 to −0.06; P < .001), waist to height ratio (−0.02; 95% CI, −0.03 to −0.01; P = .001), total cholesterol level (−4 mg/dL; 95% CI, −8 to 0 mg/dL; to convert to millimoles per liter, multiply by 0.0259; P = .02), and triglycerides level (geometric mean, −80 mg/dL; 95% CI, −88
to −71 mg/dL; to convert to millimoles per liter, multiply by 0.0113; \( P = .01 \).

Of the 107 participants with 12-month anthropometric follow-up, 40.2% reduced their BMI by 5% or more and 25.2% by at least 10%. Mostly no group effects were found for anthropometric and metabolic variables, except for systolic blood pressure, which was higher in the Loozit and ATC group compared with the Loozit only group at each time point (group difference, 3 mm Hg; 95% CI, 0 to 6 mm Hg; \( P = .048 \)). No significant group \( \times \) time interactions were observed at 12 months. Adjusting for sex and age at baseline did not change anthropometric and metabolic outcomes at 12 months.

### PSYCHOSOCIAL OUTCOMES

Significant time effects were found at 12 months from baseline with improvements in Mental Health Inventory 5 score (−0.97; 95% CI, −1.72 to −0.22; \( P < .001 \)), body shape dissatisfaction (−0.56; 95% CI, −0.74 to −0.38; \( P < .001 \)), subjective social status (0.89; 95% CI, 0.48 to 1.31; \( P < .001 \)), global self-worth (0.21; 95% CI, 0.10 to 0.32; \( P < .001 \)), and most other self-perception domains (Table 3). Except for lower scholastic competence in the Loozit and ATC group compared with the Loozit only group at each time point (group difference, −0.21; 95% CI, −0.42 to 0.00; \( P = .049 \)), no group differences were found in any of the psychosocial outcomes. The only significant group \( \times \) time interaction was an increase in social acceptance in the Loozit and ATC group at 12 months.

### BEHAVIORAL OUTCOMES

At 12 months, participants reported less frequent consumption of high-fat meat products (OR, 0.34; 95% CI, 0.21 to 0.54), potato crisps (OR, 0.35; 95% CI, 0.22 to 0.59), and lunch (OR, 0.64; 95% CI, 0.41 to 1.00). Significant time effects were also found at 12 months in reported time spent in front of screens (geometric mean, −0.8 hours; 95% CI, −1.0 to −0.7 hours; \( P = .043 \)), including watching television (geometric mean, −0.8 hours; 95% CI, −1.0 to −0.7 hours; \( P = .01 \)).
However, no time effects for other behavioral outcomes at 12 months and no differences between groups or significant group × time interactions were found. Behavioral outcomes at 12 months did not change after adjusting for sex and age at baseline.

### ADDITIONAL ANALYSES

#### BMI z Score Change

Participants with 12-month anthropometric data (n = 107) were grouped into 3 categories based on BMI z score...
change from baseline to 12 months: 5% or greater reduction (n=43), between 0% or greater and less than 5% reduction (n=28), and any increase (n=36). Compared with the 2 other subgroups, participants with 5% or greater BMI z score reduction reported higher body image satisfaction at baseline. Compared with the subgroup with an increase in BMI z score, participants with a 5% or greater BMI z score reduction also had lower weight, waist size, and waist to height ratios at 2 months. No differences were found between subgroups in baseline age, sex, or other outcome variables at baseline or 2 months.

Phase 1 Attendance

Of enrolled adolescents, 124 (82.1%) attended 70% or more of phase 1 group sessions (high phase 1 attendees). Approximately half of these had fathers born in Australia compared with a third of participants with lower

| Table 3. Psychosocial Measurements and Differences in Outcomes by Treatment Group and Time |
|------------------------------------------|-----------------|-----------------|-----------------|
| Variable                                | Mean (SD)       | Mean (95% CI)   | Time Differencea (12 mo Minus Baseline) |
| Mental Health Inventory 5 scoreb        | Loozit Only Group | Loozit and ATC Group | Group Difference (Loozit and ATC Minus Loozit Only) |
| Baseline                                | 13.09 (4.35)    | 13.44 (4.81)    | 0.14 (−1.10 to 1.39) |
| 12 mo                                   | 11.75 (3.86)    | 12.23 (3.94)    | −0.97 (−1.72 to −0.22)c |
| Body shape dissatisfactiond               | Loozit Only Group | Loozit and ATC Group | Group Difference (Loozit and ATC Minus Loozit Only) |
| Baseline                                | 2.41 (1.10)     | 2.46 (0.93)     | 0.10 (−0.17 to 0.38) |
| 12 mo                                   | 1.82 (1.07)     | 1.91 (0.96)     | −0.56 (−0.74 to −0.38)c |
| Perceived body shapee                   | Loozit Only Group | Loozit and ATC Group | Group Difference (Loozit and ATC Minus Loozit Only) |
| Baseline                                | 6.26 (0.93)     | 6.38 (0.85)     | 0.13 (−0.16 to 0.41) |
| 12 mo                                   | 5.86 (1.12)     | 5.98 (1.04)     | −0.43 (−0.61 to −0.25)c |
| Ideal body shapee                       | Loozit Only Group | Loozit and ATC Group | Group Difference (Loozit and ATC Minus Loozit Only) |
| Baseline                                | 3.86 (0.94)     | 3.91 (0.90)     | 0.01 (−0.26 to 0.27) |
| 12 mo                                   | 4.04 (0.89)     | 4.07 (0.85)     | 0.19 (0.04 to 0.34)c |
| Self-perception profilef                | Global self-worth | Scholastic competence | Social acceptance |
| Baseline                                | 2.59 (0.58)     | 2.58 (0.76)     | −0.16 (−0.35 to 0.03) |
| 12 mo                                   | 2.93 (0.61)     | 2.77 (0.63)     | 0.21 (0.10 to 0.32)c |
| Perceived body shapef                   | Baseline        | 2.79 (0.74)     | −0.21 (−0.42 to 0.00)b |
| 12 mo                                   | 3.08 (0.54)     | 2.87 (0.72)     | 0.21 (0.12 to 0.31)c |
| Ideal body shapef                       | Baseline        | 3.06 (0.74)     | −0.05 (−0.26 to 0.15) |
| 12 mo                                   | 3.18 (0.61)     | 3.14 (0.59)     | 0.21 (0.11 to 0.30)c |
| Athletic competence                     | Baseline        | 2.34 (0.76)     | −0.22 (−0.45 to 0.00) |
| 12 mo                                   | 2.46 (0.64)     | 2.27 (0.76)     | 0.12 (0.03 to 0.22)c |
| Physical appearance                     | Baseline        | 1.92 (0.61)     | −0.15 (−0.34 to 0.05) |
| 12 mo                                   | 2.38 (0.61)     | 2.02 (0.70)     | 0.30 (0.19 to 0.41)c |
| Job competence                          | Baseline        | 3.06 (0.56)     | −0.12 (−0.29 to 0.05) |
| 12 mo                                   | 3.23 (0.57)     | 3.20 (0.61)     | 0.23 (0.12 to 0.33)c |
| Romantic appeal                         | Baseline        | 2.34 (0.57)     | −0.04 (−0.22 to 0.14) |
| 12 mo                                   | 2.63 (0.63)     | 2.52 (0.63)     | 0.21 (0.10 to 0.33)c |
| Behavioral conduct                      | Baseline        | 2.84 (0.73)     | −0.05 (−0.26 to 0.16) |
| 12 mo                                   | 2.98 (0.64)     | 2.98 (0.66)     | 0.08 (−0.02 to 0.18) |
| Close friendship                        | Baseline        | 3.27 (0.77)     | 0.01 (−0.19 to 0.22) |
| 12 mo                                   | 3.27 (0.70)     | 3.35 (0.64)     | 0.06 (−0.07 to 0.19) |
| Subjective social statusg               | Baseline        | 6.04 (2.75)     | −0.06 (−0.67 to 0.54) |
| 12 mo                                   | 7.27 (1.51)     | 6.75 (1.87)     | 0.89 (0.48 to 1.31)c |

Abbreviation: ATC, additional therapeutic contact.

a Both Loozit only and Loozit and ATC groups combined.

b Scale: 5 indicates most favorable health; 30, least favorable health.

c Linear mixed models (group and time); main effects of group or time significant at P<.05. No significant group × time interactions were found at 12 months except for an improvement in self-perceived social acceptance in the Loozit and ATC group.

d Scale: scores closer to zero indicate lower levels of body shape dissatisfaction.

e Scale: higher scores indicate bigger body shapes (based on a 9-figure scale ranging from thin to fat body shapes).

f Scale: 1 indicates extremely low; 10, extremely high.

g Scale: 1 indicates extremely low; 10, extremely high.

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The Loozit community-based group lifestyle intervention provides significant, albeit modest, improvements in primary weight outcomes (BMI \( z \) score and waist-to-height ratio) and several psychosocial outcomes at 12-month follow-up. Additional telephone and electronic contact did not provide further benefits as an adjunct to the Loozit group program at 12 months.

To our knowledge, the Loozit RCT is the first adolescent weight management intervention to investigate long-term outcomes of a sustainable, community-based lifestyle intervention with extended therapeutic support. The reductions in weight outcomes at 12 months are of somewhat smaller magnitude than higher-intensity, family-based behavioral lifestyle interventions in adolescents.22,23

In a 2009 Cochrane review of lifestyle RCTs for the treatment of obesity, 2 behavioral interventions for adolescents showed significant reductions in BMI \( z \) scores after 6 months of treatment that were sustained at 12-month follow-up (pooled effect size, \( -0.14; 95\% \) CI, \(-0.18 \) to \(-0.10)\).2 Comparable BMI \( z \) score reductions were reported at 12 months after an intensive, 16-week behavioral weight intervention in 13- to 16-year-olds combined with supervised aerobic exercise or peer-enhanced adventure therapy.21

Apart from relatively high perceived social acceptance, close friendship, and job competence (Harter score \( \geq 3\)) at baseline, perceived competencies and body image scores of Loozit participants are comparable to those observed in community samples of obese children and adolescents.22,23 Most important, the small but positive psychosocial outcomes in the Loozit RCT highlight the safety and lack of evidence for psychological harm of the intervention 12 months into the program.

There is limited evidence regarding the most effective modalities for sustaining long-term weight outcomes.2 Interactive electronic interventions have the potential to engage youth, provide immediate and tailored feedback, and be cost-effective.24 Although ATC did not provide further benefits at 12 months, it is possible that the intervention was too mild or that full benefits will only be captured at 24 months. Further research is needed to investigate the effectiveness and best application of different modes of electronic communication, with consideration of optimal intervention dose, user preferences, and engagement.4

The strengths of this study include its randomized controlled design, the recruitment of an adequate sample size, the relatively high attendance and retention rates, the use of comprehensive statistical analyses with an intent-to-treat approach, adjustment for potential confounders, and the reporting of long-term weight management outcomes. The interpretation of the study’s findings may be limited by the absence of a “no treatment” control group. However, withholding treatment of overweight adolescents seeking to participate in this intervention was considered unethical given that pediatric lifestyle interventions for treating obesity are superior to control conditions.2 Another limitation of the study is reliance on self-reported behavioral data. Even if participants did not fully assimilate reported positive behaviors, improvements in these behaviors demonstrate increased knowledge about healthy lifestyle behaviors. Potential bias introduced by dropouts and missing data appears minimal.

The Loozit program was developed by experienced health care professionals as an evidence-based, behavioral family lifestyle intervention that includes long-term weight management support. Participation in the Loozit RCT appears promising in improving primary weight outcomes and several measures of psychosocial well-being at 12-month follow-up. The effect of the intervention will be fully evaluated at 24 months. These findings highlight the potential benefits of a low-intensity weight management program targeted at adolescents that is sustainable in community settings.

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