



***Effects of the lifestyle intervention program:
Lekker Pûh!!!
in Dutch overweight and obese children
aged 5 to 16 years***

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ABSTRACT

Background

Multicomponent lifestyle intervention programs are proven most effective in secondary childhood obesity treatment. Evidence is mostly based on randomized control trials (RCTS), while evidence from longitudinal studies in day-to-day setting is required. In the present study the effectiveness of *Lekker Pûh!!!*, a multicomponent longitudinal intervention, is studied.

Methods

In the present study 2585 overweight and obese participants aged 5-16 years of the *Lekker Pûh!!!* treatment program are included. The majority are Caucasians. Anthropometric data until three years after intake are included. During consults with weight coaches, height, weight and BMI were registered. Primarily the change in mean BMI z-scores, adjusted for socio-economic status (SES), is assessed by Linear Mixed Models. Additionally, the change in quality of life (QoL) is estimated via in-depth interviews with 13 out of the 37 weight coaches from the *Lekker Pûh!!!* team.

Results

A significant decrease by -0.019(95 CI, -0.021 to -0.017) per month in BMI z-scores is calculated for the first 18 months from intake, with overweight individuals showing lower fall in BMI z-scores than obese individuals. Afterwards an increase by 0.01 per month is calculated till three years follow up. An inverse association between SES and BMI z-scores (-0.071; 95 CI, -0.093 to -0.049) is found. Furthermore, according to the weight coaches self-esteem and physical activity improve during the program.

Conclusion

Lekker Pûh!!! is effective in the first 18th months among Caucasian children aged 5-16 years with different socio-economic status. These effective results are clinical relevant after a year. Besides, a positive change in quality of life (QoL) is suggested.

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TABLE OF CONTENTS

ABSTRACT.....	2
ACKNOWLEDGEMENTS.....	3
TABLE OF CONTENTS.....	4
LIST OF TABLES.....	5
LIST OF FIGURES.....	5
BACKGROUND.....	6
2. METHODS.....	8
2.1 LEKKER PÛH!!!: DESIGN.....	8
2.2 PARTICIPANTS.....	8
2.2. STUDY DESIGN.....	9
2.2.1 QUANTITATIVE STUDY.....	9
2.2.2. QUALITATIVE STUDY.....	10
2.4 Statistical analysis.....	11
3. RESULTS.....	13
3.1 BASELINE.....	13
3.2 CHANGE IN BMI Z-SCORES PER TIME POINT.....	13
3.2.1 SHORT-TERM.....	15
3.2.2 LONG-TERM.....	16
3.3 INFLUENTIAL FACTORS.....	16
3.4 DROPOUTS.....	18
3.5 IMPACT LEKKER PÛH!!! AMONG DUTCH YOUTH.....	18
3.6 Quality of life (QoL).....	19
DISCUSSION.....	21
CONCLUSION.....	25
REFERENCES.....	26
APPENDICES.....	1
APPENDIX I. TOPIC LIST.....	1
APPENDIX II. RESULTS FROM THE INTERVIEW.....	4
APPENDIX III.....	13

LIST OF TABLES

Report

Table 1	Categories SES by restricted cubic spline regression	11
Table 2	Baseline characteristics of the included participants in the outcome evaluation study of the lifestyle intervention program <i>Lekker Pûh!!!</i> ($n = 2652$)	13
Table 3	Change in primary and secondary outcomes in the participants of <i>Lekker Pûh!!!</i> (5-16 years) over time	14
Table 4	Changes in BMI z-scores by baseline BMI z-scores, age, Status Scores and gender	17
Table 5	Characteristics of the remainders and drop outs in the <i>Lekker Pûh!!!</i> intervention program	18

Appendices

Table 1	Reasons for dropping out of the program	4
Table 2	The estimated change in QoL indicators throughout <i>Lekker Pûh!!!</i> including possible differences between gender and age groups $n=13$	5
Table 3	Strengths and Limitations of <i>Lekker Puh!!!</i>	10
Table 4	The documented reasons for dropping out	11
Table 5a	Change in mean BMI z-scores by Status Scores and age	13
Table 5b	Change in mean BMI z-scores by weight status and gender	15
Table 6	Changes in BMI, BMI z-scores, Weight and WC in the first 18 months and onwards	17

LIST OF FIGURES

Report

Figure 1	Flowchart of the selection procedure of the participants for the outcome evaluation of the lifestyle intervention program <i>Lekker Pûh!!!</i>	8
Figure 2	Mean BMI Z-SCORES per SES category, age group, gender and baseline weight status per time point.	15
Figure 3	(Relative) changes in outcome measures over time	16
Figure 4	Change in BMI z-scores in overweight and obese <i>Lekker Pûh!!!</i> participants compared to the participants from the PIAMA study (reference group)	18

BACKGROUND

Childhood obesity is worldwide a proclaimed major public health crisis due to its high prevalence and severe health and psychosocial consequences, even in adulthood (Rolland-Cachera, 2011). According to WHO(2014), the prevalence of childhood obesity increased from 32 million in 1990 to 42 million in 2013 and might double by 2025.

An increasing trend in childhood obesity and overweight is seen in The Netherlands too. Between 1981 and 2011, the prevalence of obese and overweight children and adolescents (4-20 years) increased from 8% to 10.1% (CBS, 2015). Childhood obesity rates in this period, fluctuate between 2.1% and 2.7%. Differences in rates are seen between girls and boys and age groups, and can partially be explained by socio-economic and cultural factors (De Groot & Bruggink, 2012; Kist-Van Holthe *et al.*, 2012). The latest update of these rates in 2015 showed a prevalence of 9.3% and 2.8%, for respectively overweight and obese individuals (CBS, 2015). A reverse trend in the overweight prevalence is seen, which was earlier suggested by Schönbeck *et al.* (2011). The authors conducted the fifth Dutch nation-wide growth study, to assess the prevalence of childhood overweight and obesity. The authors observed a stabilization of prevalence rates in major cities, which could be explained by the large-scale implementation of governmental prevention programs in the major cities.

Childhood overweight and obesity is associated with health consequences as high blood pressure, high cholesterol, type 2 diabetes, depressive symptoms and low self-esteem (Owens, 2013; Schönbeck *et al.*, 2011). These medical and psychological consequences can prolong into adulthood (Karnik & Kanekar, 2015; Kelsey *et al.*, 2016.) as well as obesity, the latter depends on the age of onset (Pandita *et al.*, 2016). Knowing that 49.2% of Dutch adults (≥ 18 yrs) is overweight (De Groot&Bruggink,2012), and adulthood obesity is difficult to manage (Pandita *et al.*, 2016), prevention and treatment programs in early stages of life become more important and even promising, given that long-term complications can be prevented too.

Unfortunately, prevention and treatment of childhood obesity is complex. Childhood overweight and obesity are due to environmental and behavioral changes related to diet and inactivity. Therefore, the treatment and prevention programs focus on diet, physical activity and/ or parenting behavior (Oude Luttikhuis *et al.*, 2009 & Waters *et al.*, 2011). Multicomponent treatment programs are most effective in treating overweight children (Rajmil *et al.*,2017). According to the meta-analysis by Van Hoek *et al.* (2014), a pooled mean change in BMI z-scores of -0.08 (95 CI -0.13 to -0.03) is seen for low intensity programs (<10 hours). For moderate (26-75hours) to high intensity (>75hours) treatment programs a pooled mean change of -0.46(95 CI, - 0.53 to - 0.39) is observed. The included studies in this meta-analysis varied in duration (12 weeks to 1 year) and age of the participants (2-18 years).

Looking at Dutch multicomponent treatment programs, two acknowledged programs by the 'Nederlands Jeugdinstituut'(NJI) are *Real fit* and *Weet en Beweeg*. *Real fit* targets overweight children aged 13-18 years and provides sports classes, nutrition educational classes, consults with dietician and psychologists and parent meetings. In total this program takes up on average 23 hours in 13 weeks (Nederlands Jeugdinstituut, 2014). At one year follow up, a significant decrease in BMI z-scores (-0.41; CI, -0.67 to -0.15) was observed in the study group

Weet en Beweeg targets overweight and obese children aged 6-18 years and provides nutritional education classes, sports classes, parent meetings and family coaching (Nederlands Jeugdinstituut, 2014). This program takes up 24 hours in 6 weeks. At one year follow up, a significant decrease in BMI z-score of 0.7 was seen.

In the present study, the *Lekker Pûh!!!* intervention program targets overweight and obese children aged 5-18 years. This program is going on for 10 years and keeps improving. *Lekker Pûh!!!* is a health centred program. In this program coaching is offered during regular consults to parents and participants to work towards a family based weight management plan. The aim is getting individuals adapt to a healthy lifestyle.

The participants are put in charge of their journey. Together with them goals are set and evaluated. The participants are coached in stress management, in dealing with cravings and in making healthy dietary choices. Besides, increasing the daily physical activity is encouraged as well as the engagement by family and friends. Therefore increasing the social support. At last, participants can sign up for consults till their 18th birthday. Overall, these activities contribute to the implementation of healthy behaviors by the individual and the family (Jalali *et al.*,2016).

Compared to the previous mentioned programs, which guide individuals for 6-13 weeks with fixed plans, *Lekker Pûh!!!* offers more personal coaching till the 18th birthday, making it an unique concept.

Other advantages *Lekker Pûh!!!* has, regarding its design, are the longitudinal data present and that it is a family based intervention in normal day-to-day circumstances. At present, data is lacking on this type of intervention programs (Reinehr *et al.*, 2016). This gap in literature is explained by the great amount of evidence from RCTs (Wake *et al.*, 2015). In these studies, effects around 6months follow up are not evident at 12 months follow up. To get a better understanding of the effectiveness of multicomponent programs and to explain their success, more longitudinal studies are required (Reinehr *et al.*, 2016). Therefore, the aim of the present study is to contribute to the existing knowledge on multicomponent intervention programs and to meet the need for more evidence from longitudinal studies, by performing an effect evaluation study on *Lekker Pûh!!!*.

The effectiveness of *Lekker Pûh!!!* is assessed from a quantitative (change in BMI z-score) and a qualitative point of view (change in quality of life). The primary objective of the present study is, assessing the effectiveness of the lifestyle intervention program *Lekker Pûh!!!* in Dutch overweight and obese children aged 5-16 years, by evaluating on one hand the measured and calculated predictors for childhood overweight and obesity, adjusting for influential factors and missing data, and on the other hand the change in quality of life (QoL). Accordingly, the following secondary objectives are:

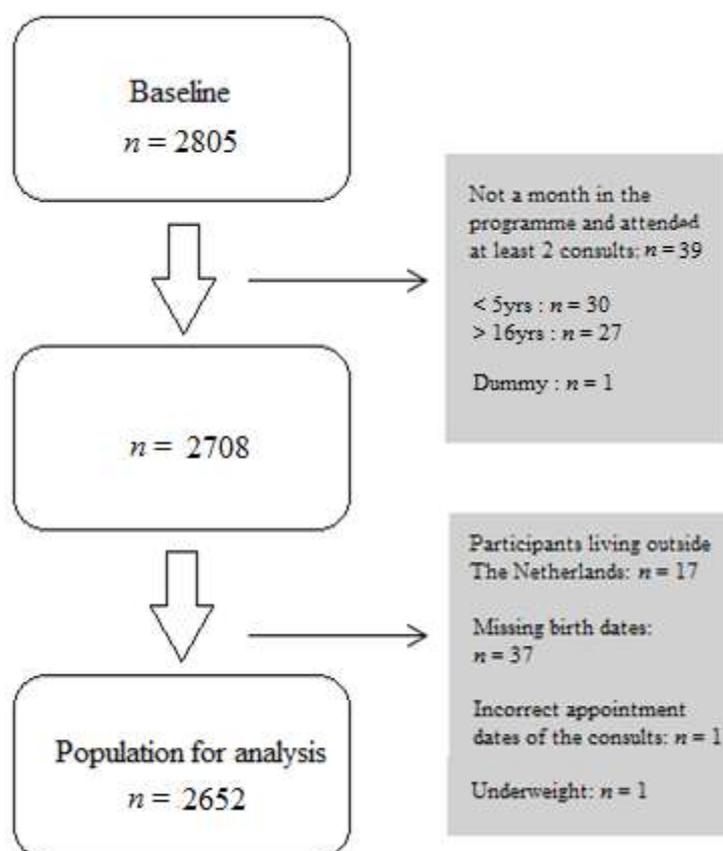
- Study the estimated change in weight, waist circumference (WC), body mass index (BMI) and BMI z-scores by *Lekker Pûh!!!* during the 15 fixed consults and onwards, adjusted for influential factors and missing data.
- Investigate the reasons for dropout.
- Study the estimated change in QoL among the target groups of the *Lekker Pûh!!!* assessed by professionals throughout the consults.

2. METHODS

2.1 LEKKER PÛH!!!: DESIGN

Lekker Pûh!! is a family-based multi-component, behavioral treatment program targeting overweight and obese youth aged 5-18 years. It aims at the reduction of overweight and obesity by promoting healthy food choices and more daily physical activity during 15 topic based consults and follow up consults. During the consults, theoretical and practical activities are undertaken by the children. On one hand different topics are discussed to create awareness and give the child tools to adapt to a new lifestyle. On the other hand, exercises are performed to create new habits. A journal called "Het boek over jezelf", is kept to organize the discussed theory, and to keep track of progress, tips and tricks, which aid the weight loss process. The parents, who are advised to join the consults, get advice on behavior change strategies and receive coaching when required.

The consults are provided by weight coaches. Each consult last at least 45 minutes. In the first month of *Lekker Pûh!!!*, the participants attend consults weekly. In the second and third month, the participants attend consults every two weeks. From the fourth to the sixth month, the participants attend consults monthly. Afterwards, every quarter or half a year the participants attend a follow up consult. This way the intervention lasts 1.5 to 2.5 years. Follow up consults can be scheduled till the 18th birthday. *Lekker Pûh!!!* adapts its program to the needs of the family and child. Therefore, the order of topics, the amount of consults, and the timing of consults are not fixed, but personalised



2.2 PARTICIPANTS

Lekker Pûh!!! is an ongoing treatment program. At start of the present study, data collected until 17th November 2016 is included in the study (n=2805). Inclusion criteria in the present study specifies that participants were aged 5-16 years at intake, and that they participated at least 1 month in the program and had at least 2 consults in which anthropometric data was collected. The exclusion criteria included: dummy cases; underweight participants; non-Dutch residents; incorrect and missing date of birth and incorrect appointment dates for the consults (see Figure 1). At baseline, 2652 participants were included in the study group.

For the longitudinal analysis, data only on overweight and obese participants at baseline were included (n = 2585).

Figure 1. Flowchart of the selection procedure of the participants for the outcome evaluation of the lifestyle intervention program *Lekker Pûh!!!*

2.2. STUDY DESIGN

A longitudinal design is used to study the effectiveness of the lifestyle intervention program *Lekker Pûh!!!* the present evaluation study consists of a quantitative and a qualitative part.

In the quantitative part, the change in outcome measures is calculated and adjusted for influential factors and missing data in time (or by time points). To examine the change in outcome measures per time point, the collected data is summarized at 8 time points from intake (t_0). Short-term (≤ 1 year) includes t_0-4 , which are each 3 months apart. Long-term includes t_5-8 , which are each 6 months apart. To include as much as data possible, the time points denote time intervals. At each time point, averages of the outcome measures are presented. At t_1-t_4 , the average of measurements 6 weeks before and after a time point was taken. At t_5-t_8 , the average of measurements 12 weeks before and after a time point was calculated. Intervals between time points as well as the amount of consults averaged per time point, differed. The amount of consults per time interval varied from 5 to 12 consults. For the changes by time, all data is included.

To study the impact of *Lekker Pûh!!!* in the Dutch population, the data of the study group was compared to the data of a reference group. The reference group consists of data on children from the PIAMA study. These participants were included from their birth. In the present study, data from the age of 5 to 16 is included.

In the PIAMA study, parent-reported anthropometric data which was annually collected till the age of 8. From 8 years onwards, both the parents and participants reported the measurements. At the age of 8, the WC was measured by parents. Afterwards, at the age of 11, 12, 14 and 16 relevant data was collected. Data of the children on weight and height were collected for the last time at age 14-15.

For the qualitative part the positive side effects of *Lekker Pûh!!!* on the psycho-social health of participants is assessed by in-depth interviews with weight coaches. The gathered information will be used as input for further research in QoL, since conflicting information is available on the psychosocial changes accompanying weight reduction (Morano *et al.*, 2015).

2.2.1 QUANTITATIVE STUDY

Measurements

Anthropometric measurements included weight, height and waist circumference. These were collected during the consults by well-trained weight coaches, situated across the Netherlands. The measurements were performed according the guidelines by TNO (Talma, 2010). BMI was calculated as kg/m^2 and BMI z-scores were calculated using the WHO Anthroplus software (WHO, 2009). This syntax provided by the WHO calculates the BMI z-scores based on the WHO Reference 2007 for 5-19 years.

Three categories for weight status (normal weight, overweight and obese) are identified. The categories are based on BMI z-scores and selected according the cut off points by the WHO (n.d.b.):

- Normal weight: $1 \leq \text{SD} \leq 1$
- Overweight: $1 < \text{SD} \leq 2$
- Obese: $\text{SD} > 2$

Sociodemographic factors

SES

Parental SES is represented by Status Scores, developed by the Dutch Government (Sociaal en Cultureel Planbureau, 2015). Cities with at least 100 inhabitants get a score assigned based on education, income and occupation. These scores correspond to a numerical combination of the postal code. The larger the score the higher the SES. By calculating the SD by the corresponding score (last calculated for 2014: 0.28 ± 1.09) the SES can be categorized in high ($\text{SD} > 1.09$), low ($\text{SD} < -1.09$) and average ($-1.09 \leq \text{SD} \leq 1.09$).

Missing values for status scores are on one hand due to the fact that towns with less than 100 inhabitants do not get a score. On the other hand, the Status Scores were updated in 2014. Towns registered afterwards are yet not assigned a score.

Age

The study population was grouped into participants aged 5-8 years, 9-12 years or 13-16 years. These categories correspond to the often used age categories in scientific literature.

Height

Diurnal stature variation, that was believed to be acceptable in the target population (5-16 years), was +1.8cm to -3.0cm. This is an adaptation of the advice by Siklar *et al.* (2005) stating that a variation from +1.8 cm to -2.7 cm was allowed.

Health characteristics

Information on the general health (see Table2) of children is gathered by the weight coaches. The classification in health status of the participants, was decided upon in agreement with the youth health doctor, Wendelyn Disse. She is a collaborating physician with *Lekker Pûh!!!*

2.2.2. QUALITATIVE STUDY

For the qualitative study 37 weight coaches, were approached by e-mail. The in-depth interviews are performed by telephone, and recorded with the permission of the weight coaches.

During the interviews, weight coaches were asked to give an indication of the mean change in wellbeing during the period the participants attended the *Lekker Pûh!!!* sessions. Besides, the success factors and points for improvements within *Lekker Pûh!!!* are checked with the weight coaches.

A self-compiled topic list with 14 questions was used (See Appendix 1) during the interviews. This questionnaire is based on generic and obesity specific QoL questionnaires, as advised by Modi & Zeller (2008). The questionnaires reviewed for the interview questions are: Parent PedsQL™4.0(generic), the Child Health Questionnaire Parent Form 50 (CHQ-PF50) (generic), and Sizing them up (specific).

The interview questions address indicators of QoL which are emotional health, school functioning, physical health, social functioning and self-esteem (Wille *et al.*, 2009; Tsiros *et al.*, 2009 & Buttita *et al.*, 2014). The first three show significant improvement in Dutch trials with multicomponent intervention programs (Vos *et al.*, 2014; Hofsteenghe *et al.*, 2013). Besides, differences between boys and girls, and the different age groups is also addressed, since age and gender can affect the associations between QoL and its indicators (Wille *et al.*, 2009).

2.4 STATISTICAL ANALYSIS

At first, all variables were assessed for normality using the One-Sample Kolmogorov-Smirnov non-parametric test. Influential factors taken into account in the present study are: age, gender, SES and baseline BMI. These factors are chosen, because, age, gender and weight status affect changes in BMI over time (Sacher, 2013), while parental SES has a significant influence on body weight in children (Cameron *et al.*, 2015).

To assess the mean difference in BMI z-scores, BMI, weight and waist circumference per time point, compared to intake or preceding time point, a paired comparison test between the concerning time points is performed (Table 3 & Figure 2). The dependent t-test is applied, since it can be used safely for non-normal or unknown distribution of the outcome measures (Maggio & Sawilowsky, 2014). Therefore, for this test outcome measures are not log transformed.

The dependent t-test was performed in strata for age, gender, SES and baseline BMI. The sample size of 36 participants per time point per strata is considered to be valid in the present study. This is based on the range of participants (30 to 100) seen per study or control group in several comparable RCTS (Van Hoek *et al.* 2014; Peirson *et al.*, 2015). Therefore, taking into account a dropout rate of 20%, 36 participants are at least required per stratum.

Long-term growth in BMI z-scores, BMI, weight and WC over time were analysed using a Linear Mixed Models, with an unstructured correlation matrix (Table 3 and 4). With this matrix it is assumed that the correlations between variances is unknown. By using Mixed Models, presence of missing data, fixed effects (SES, age, and gender) and random effects (subjects and time) is allowed for. It was assumed that each participant is defined by random intercepts and slopes, concerning the outcome measures. Hence, the random slope model was applied. Besides, it was assumed that data was missing at random.

To continue, in order to use this model, assumptions for normality and linearity (same for linear regression) should be met. Weight, BMI and WC, were not normally distributed. Therefore, they were log transformed. In order to present the direction of the change in outcome measurements, the calculated estimates (converted in %) are used to denote the changes in outcome measures.

The outcome measures were adjusted for age, gender, SES and baseline weight status. SES (Status Scores) and Time in months) were non-linear associated with the outcome measures. To avoid residual confounding by Status Scores and time, these independent variables were categorized as suggested by Groenwold *et al.* (2013). The restricted cubic spline regression method is assumed to be one of the appropriate techniques, which is applied for Status Scores. Status Scores were categorized in 5 groups (5%, 22.5%, 50%, 72.5% and 95%) and included in the models. Hereby, an estimate is calculated for Status Scores overall, as well as the several levels, making stratification by Status Scores irrelevant. The change in the levels for Status Scores were compared to level 5 (=reference). Percentages denoting the Status Scores distribution correspond to the following Status Scores and SES categories (Low, Average & High):

Table 1. Categories SES by restricted cubic spline regression

1	2	3	4	5
Status Scores <-0.06	-0.06<= Status Scores <0.38	0.38<= Status Scores <0.85	0.85<= Status Scores <1.38	1.38<=Status Scores
Low SES (SD<-1.09) and Lower Average SES (-1.09<SD<0)	Lower Average SES (-1.09<SD<0) & Higher Average SES (0<SD<1.09)	Higher Average SES (0<SD<1.09)	Higher Average SES (0<SD<1.09) & High SES (SD > 1.09)	High SES (SD > 1.09)

For time, dichotomization was used, to keep models simple and avoid non convergence of data. By testing for the time categories (t_1-t_8), 18 months was chosen as cut off point for time. Besides, a significant turn in the trend of results was mostly found on 18 months with the dependent t-test. Hence the estimates for the change in outcome measures, were calculated for the first 18 months, and 18 months onwards.

The impact of *Lekker Pûh!!!* in the Dutch population is shown, by plotting the BMI z-scores by age (years) of both the study group and the reference group (Figure 4). In order to, detect a possible treatment effect, observations from 6 consults (2months in theory) onwards of the study group, are included.

In text, summary statistics for continuous variables are reported as mean \pm SD and mean difference (95% CI). For categorical variables, mean (%) was chosen. Statistical significance was set at $p < 0.05$. Analyses were carried out using IBM SPSS Statistics 22.

3. RESULTS

3.1 BASELINE

Baseline characteristics of the study group ($n=2652$) are presented in Table 2. The target population has a mean±SD BMI z-score of 2.3 ± 0.7 . The strata with the highest BMI z-scores are participants aged 5-8 years (2.3 ± 0.8), boys (2.3 ± 0.7) and 'Low' SES (2.2 ± 0.7). Next, the study group has a mean BMI of 25.1 ± 4.1 kg/m², a mean weight of 58.2 ± 18.3 kg and a mean WC of 84.1 ± 22.7 cm. Among the participants, 30% is overweight and 66% is obese.

In the present study, girls (70%) are overrepresented as well as participants aged 9-12 years (56%) and participants with an 'Average' SES (44%). Boys count for 30% of the target population. The age groups 5-8 years and 13-16 years count for 23% and 20%, respectively, of the target population. 'Low' and 'High' SES groups count, respectively, for 4% and 20% of the population, while upper part of the 'Average' SES group and the 'High' SES group are 53% of the target population.

Looking at the health characteristics at intake, 8% of the participants are regularly victims of bullying. Bellyache is experienced frequently ($\Rightarrow 1x$ per week) by 11% of the participants. Problems with the digestive health account for 40%. In the study group 6% deals with food allergies or intolerances. At last, 11% of the participants take medication.

Table 2. **Baseline characteristics of the included participants in the outcome evaluation study of the lifestyle intervention program *Lekker Pûh!!!* ($n = 2652$)**

Anthropometric characteristics				Health characteristics			
Total ($n=2652$)	$n(\%)^1$	Mean±SD	BMI z-score (Mean±SD)		$n(\%)^1$		$n(\%)^1$
Height (cm)		150.3±14.2		Food allergies/ intolerances		Digestive health	
Weight(kg)		58.2±18.3		No	1267(47)	Daily	1357(51)
WC(cm)		84.1±22.7		Yes	165(6)	Not daily	44(2)
BMI(kg/m ²)		25.1±4.1				Every other day	66(2)
BMI z-scores		2.3±0.7		Bellyache		>1 day	32(1)
Normal weight ($-1\leq SD\leq 1$)	67(3)			No	742(28)	No	742(28)
Overweight ($1\leq SD\leq 2$)	791(30)			$\Rightarrow 1x$ per week	286(11)	Diarrhoea	11(0.4)
Obese ($SD>2$)	1745(66)			<1x per week	584(22)	Constipation	26(1)
Socio-demographic characteristics				<1xper month	81(3)	Other problems	152(6)
Age(years)		10.4±2.5		Medication		Being bullied	
5-8	598 (23)		2.3±0.8	No	730(28)	No	1197(45)
9-12	1496(56)		2.0±0.7	Yes	304(11)	Yes	199(8)
13-16	558 (21)		2.0± 0.7	Asthma		Sometimes	241(9)
Gender				Bronchitis ¹²	53(1)	Rarely	40(2)
Boys	798 (30)		2.3±0.7	Melatonin	31(1)		
Girls	1854(70)		2.0± 0.7	Obstipation	57(2)		
SES		0.6±1.0		ADD/ADHD	46(2)		
Low($SD<-1.09$)	99(4)		2.2±0.7	Hay fever	21(1)		
Average ($-1.09\leq SD\leq 1.09$)	1176(44)		2.1±0.7	Other	95(4)		
Average($SD<0$)	269(10)		2.2±0.8				
Average($0<SD$)	875(33)		2.1±0.7				
High ($SD>1.09$)	537 (20)		1.9±0.6				

3.2 CHANGE IN BMI Z-SCORES PER TIME POINT

Table 3. Change in primary and secondary outcomes in the participants of *Lekker Puh!!!* (5-16 years) over time

	n	BMI SDS			Weight			Abdominal girth			BMI			Height		
		Mean (SD)	Mean difference (95%CI)	p-value	Mean (SD)	Mean difference (95%CI)	p-value	Mean (SD)	Mean difference (95%CI)	p-value	Mean (SD)	Mean difference (95%CI)	p-value	Mean (SD)	Mean difference (95%CI)	p-value
t0	2585	2.37 (0.66)			58.47 (18.19)			84.32 (22.70)			25.21 (4.13)			150.22 (14.14)		
t1	2508	2.14 (0.71)	-0.22 [-0.23;-0.21]	0.000	56.02 (17.73)	-1.92 [-2.03;-1.81]	0.000	79.80 (11.84)	-4.53 [-5.65;-3.41]	0.000	23.89 (4.07)	-1.31 [-1.54;-1.08]	0.000	151.15 (13.86)	1.13 [1.07;1.18]	0.000
t2	2334	2.03 (0.71)	-0.32 [-0.33;-0.30]	0.000	55.61 (17.00)	-1.89 [-2.12;-1.66]	0.000	78.86 (11.47)	-4.83 [-5.10;-4.56]	0.000	23.39 (3.91)	-1.73 [-2.00;-1.47]	0.000	152.34 (13.20)	2.37 [2.30;2.44]	0.000
t3	1731	1.92 (0.69)	-0.42 [-0.44;-0.40]	0.000	56.03 (16.35)	-1.15 [-1.44;-0.86]	0.000	79.50 (11.11)	-4.74 [-5.10;-4.38]	0.000	23.38 (3.89)	-1.66 [-1.99;-1.34]	0.000	153.19 (12.80)	3.53 [3.42;3.64]	0.000
t4	1581	1.92 (0.70)	-0.44 [-0.46;-0.41]	0.000	57.82 (16.06)	0.02 [-0.35;0.38]	0.935	79.61 (11.64)	-4.05 [-4.50;-3.60]	0.000	23.44 (3.83)	-1.64 [-2.02;-1.25]	0.000	154.17 (12.49)	4.81 [4.63;4.98]	0.000
t5	457	1.75 (0.65)	-0.60 [-0.64;-0.55]	0.000	57.35 (14.82)	2.23 [1.74;2.72]	0.000	79.76 (10.91)	-3.20 [-3.81;-2.59]	0.000	23.32 (3.35)	-1.69 [-2.14;-1.24]	0.000	155.47 (11.94)	7.05 [6.79;7.31]	0.000
t6	259	1.68 (0.66)	-0.64 [-0.71;-0.58]	0.000	57.25 (13.35)	4.72 [3.94;5.51]	0.000	79.24 (10.14)	-2.25 [-3.18;-1.31]	0.000	23.14 (3.04)	-1.67 [-2.27;-1.06]	0.000	156.30 (11.24)	9.87 [9.49;10.25]	0.000
t7	139	1.66 (0.63)	-0.67 [-0.76;-0.58]	0.000	59.17 (13.55)	7.07 [5.94;8.20]	0.000	80.28 (10.02)	-1.58 [-2.85;-0.31]	0.015	23.49 (3.15)	-1.62 [-2.44;0.80]	0.000	157.77 (10.75)	11.84 [11.20;12.47]	0.000
t8	85	1.59 (0.73)	-0.73 [-0.88;-0.59]	0.000	60.47 (15.32)	9.57 [7.87;11.26]	0.000	79.89 (8.66)	-0.16 [-2.00;1.69]	0.865	23.61 (3.62)	-0.86 [-2.02;0.30]	0.143	158.99 (11.49)	14.12 [13.10;15.15]	0.000

In Table 3 the estimated mean changes on the several time points compared to intake (*t0*), calculated with the dependent t-test, are presented. For height a significant increase is seen per time point. The mean changes between the time points grow gradually. For weight a decrease per time point is seen from *t1* to *t3*. At one year follow up, weight does not show a significant increase (0.28; 95% CI, -0.11 to 0.67). After a year, the mean changes between time points grow gradually and rapidly. For WC a significant decrease is seen per time point. The mean change between the time points gets gradually smaller per time point. At 3 years follow up, the mean change in WC (-0.16; 95% CI, -2.00 to 1.69) is not significant. For BMI a significant decrease is seen per time point. At three years follow up, the mean change is not significant (-0.86; 95% CI, -2.02 to 0.30). At *t3* and *t8* set backs are seen in the BMI mean changes, although afterwards the decrease per time point continues. For BMI z-scores a significant decrease is seen per time point. The mean changes between the time points grow gradually.

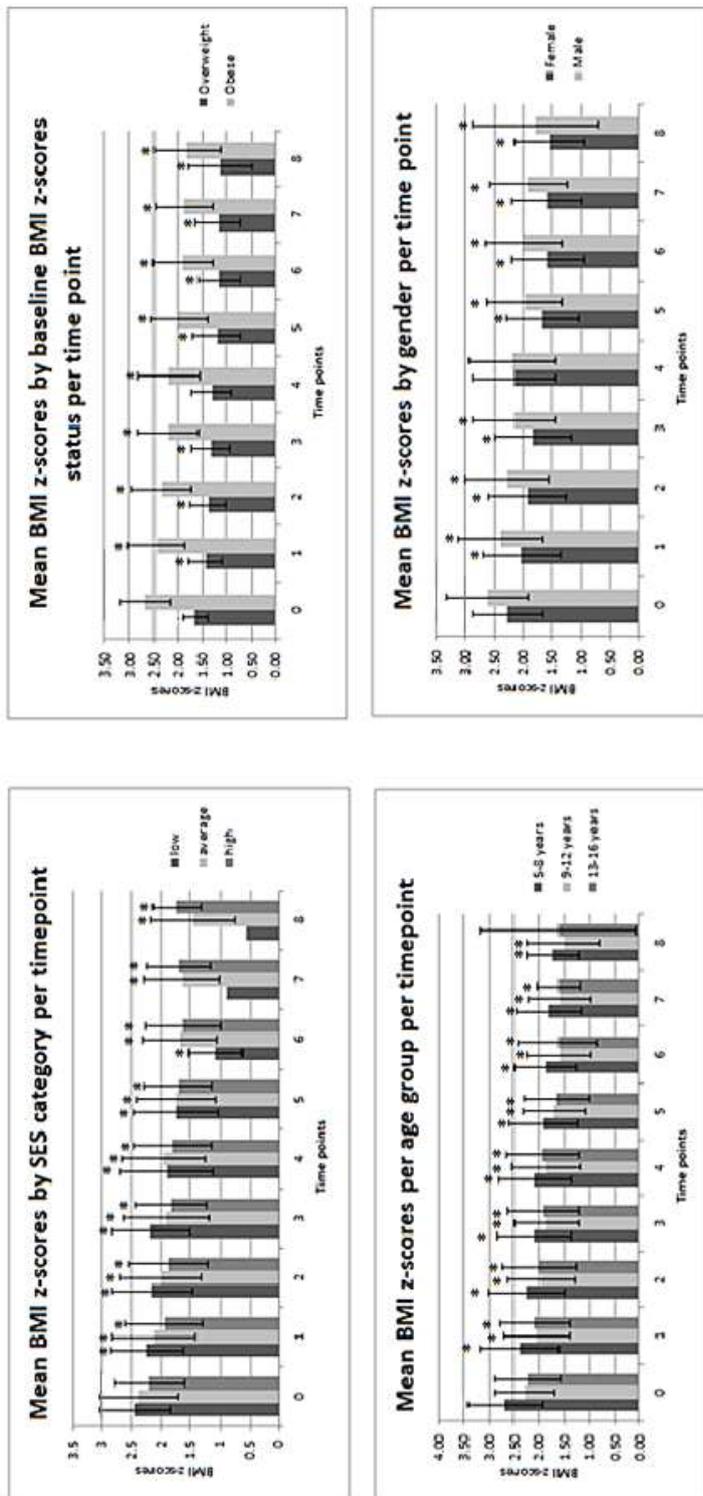


Figure2 . Mean BMI Z-SCORES per SES category, age group, gender and baseline weight status per time point. *indicates a significant mean change in BMI Z-SCORES at a time point, compared to intake($p < 0.05$). t_1 -4, are 3 months apart. t_4 -8 are a half year apart. The error bars depict de standard deviation by mean. All measurements, irrespective of meeting the required sample size, are mentioned.

3.2.1 SHORT-TERM

Figure 2. depicts the mean changes in BMI z-scores per time point and per influential factor (baseline BMI z-score, gender, age and status score) from intake till 3 years follow up. These values are derived by the dependent t-test. In Table 5a and 5b (Appendix III) the absolute changes in BMI z-scores are presented.

On short-term (≤ 1 year), the BMI z-scores decrease significantly per time point (see Figure 2), compared to intake. The mean change at t_1 and t_2 , occur rapidly, while afterwards the mean changes continue at a slower pace.

Among overweight and obese participants, the largest significant decrease in BMI z-scores is seen at 9 months follow up (-0.35; 95% CI, -0.38 to -0.32) and at 1 year follow up (-0.47; 95 CI, -0.50 to -0.44), respectively. Among boys and girls, the largest significant decrease in BMI z-scores is seen at 9 months follow up (-0.49; 95 CI, -0.54 to -0.44) and at 1 year follow up (-0.42; 95 CI, -0.45 to -0.39), respectively. Among participants aged 5-8 years and 9-12 years, the largest significant decrease in BMI z-scores is seen both at 1 year follow up: -0.57(95 CI, -0.64 to -0.51) and -0.44(95CI, -0.47 to -0.41), respectively. Among participants aged 13-16 years, the largest significant decrease is seen at 9 months follow up (-0.29; 95CI, -0.34 to -0.25). In the 'Low' SES and 'High' SES categories, the largest significant decrease is seen both at 1 year follow up (-0.59; 95 CI, -0.79 to -0.38) and (-0.40, 95CI, -0.45 to -0.35), respectively. In the 'Average' SES category, the largest significant decrease in BMI z-scores is seen at 9 months follow up (-0.48; 95CI, -0.51 to -0.44).

3.2.2 LONG-TERM

On long term (>1year), the BMI z-scores decrease significantly per time point, compared to intake (see Figure 2). The mean changes between the time points occur slowly. Longitudinal calculations are less often not significant compared to short term calculations. Besides, an adequate sample size ($n > 36$) is more often missing on long term.

Among overweight and obese participants, the largest decrease in BMI z-scores is seen at 2.5 years follow up (-0.49; 95 CI, -0.64 to -0.34) and at 3 years follow up (-0.84; 95 CI, -1.02 to -0.66), respectively (see Table 4, Appendix III). Among overweight participants, at 3 years follow up the required sample size was not met. Among boys and girls, the largest decrease in BMI z-scores is seen at 1.5 years follow up (-0.66; 95 CI, -0.74 to -0.57) and at 2 years follow up (-0.66; 95 CI, -0.73 to -0.59), respectively. Among the participants aged 5-8 years and 9-12 years, the largest decrease in BMI z-scores is observed, at 1 year follow up (-0.73; 95 CI, -0.83 to -0.64) and at 3 years follow up (-0.72, 95 CI, -0.91 to -0.52), respectively. Among the participants aged 13-16 years, only at 1.5 years follow the sample size requirement was met (-0.44; 95 CI, -0.55 to -0.32).

In the 'Low' SES category, at each time point the required sample size is not met. This holds partly for the 'High' SES category. In this category, data at 1.5 years follow up and 2 years follow up is present. The largest decrease in mean BMI z-scores is seen, at 2 years follow up (-0.68; 95 CI, -0.82 to -0.54). In the 'Average' SES category, the largest decrease in BMI z-scores is seen at 3 years follow up (-0.84; 95 CI, -1.05 to -0.64).

3.3 INFLUENTIAL FACTORS

Figure 3 depicts the magnitude of the changes in BMI, BMI z-scores, weight and WC during the study period, adjusted for covariates by Linear Mixed Models. The absolute values are depicted in Table (Appendix III). In the first 18 months, a significant decrease per month is seen for all the outcome measures. BMI decreased with -0.87% per month, BMI z-scores by -0.019[95 CI, -0.021;-0.017] per month, weight by -0.85% per month and WC by -0.74% per month. From 18 months onwards, a significant increase per month is seen for all the outcome measures. BMI increases with 1.03% per month, BMI z-scores with 0.01 per month, weight with 0.89% per month and WC with 0.54% per month.

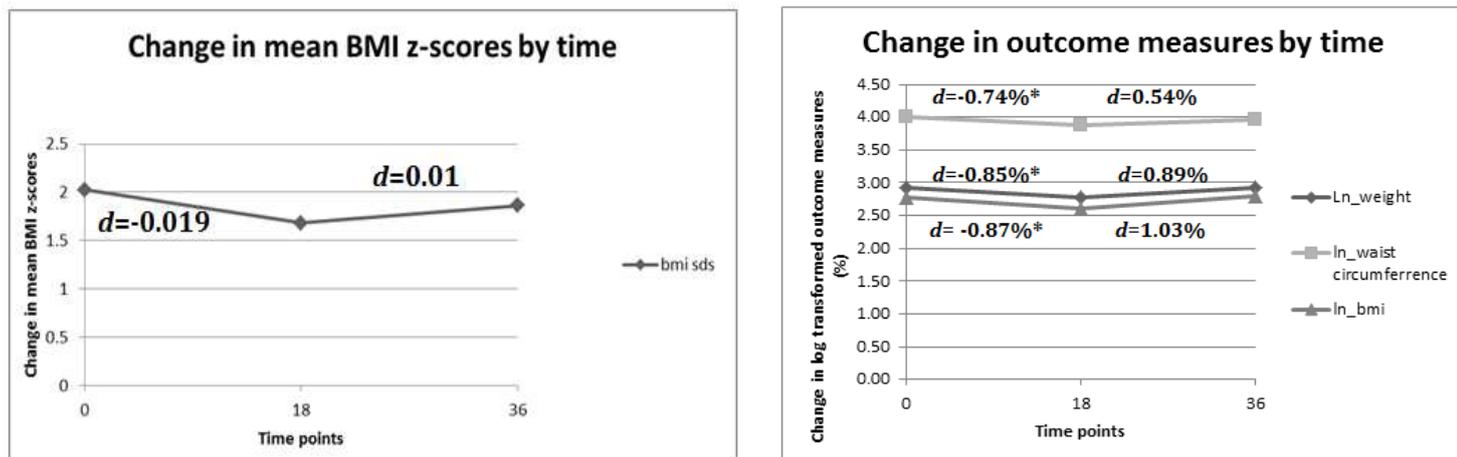


Figure 3. (Relative) changes in outcome measures over time

Note. All models are adjusted for Status Scores. The model for BMI is additionally adjusted for age, while the models for weight and WC, are additionally adjusted for age and gender.

Table 4. Changes in BMI z-scores by baseline BMI z-scores, age, Status Scores and gender

Categories		Weight status		Gender		
		Overweight	Obese	Girls	Boys	
Intercept		1.46	2.34	1.92	2.28	
ΔBMI z-scores	<18 months	-0.010 [-0.014;-0.007]	-0.022 [-0.024;-0.019]	-0.016 [-0.019;-0.014]	-0.025 [-0.030;-0.021]	
	18 months	0.018 [0.007;0.028]	0.029 [0.020;0.038]	0.023 [0.016;0.030]	0.042 [0.024;0.060]	
	>18 months	0.008	0.007	0.005	0.017	
Categories		Age			Status Score	
		5-8 years	9-12 years	13-16 years		
Intercept		2.30	1.96	1.94		
ΔBMI z-scores	<18 months	-0.026 [-0.030;-0.021]	-0.019 [-0.021;-0.016]	-0.012 [-0.017;-0.007]	-0.071 [-0.093;-0.049]	
	18 months	0.033 [0.022;0.042]	0.028 [0.018;0.038]	0.026 [-0.015;0.067]		
	>18 months	0.005	0.009	0.014		
Categories		Status Scores				
		1(5%)	2(27.5%)	3(50%)	4(72.5%)	5(95%)
ΔBMI z-scores		0.279	0.233	0.089	0.081	.
		[0.181;0.378]	[0.133;0.334]	[-0.011;0.189]	[-0.016;0.178]	

In Table 4 the magnitude of changes in BMI z-scores per strata by weight status, age, gender and Status Scores, calculated with Linear Mixed Models, is presented. On average, the changes in the first 18 months for the different strata (Status Scores not included), are within the 95% confidence interval of the overall change in BMI z-scores (-0.019; 95 CI, -0.020 to -0.018) (see Table 4). The only exception is seen for overweight participants with -0.010 (95 CI, -0.014 to -0.007) change in BMI z-scores per month.

Per unit increase in Status Scores, a significant decrease by 0.071(95 CI, -0.093 to -0.049) per month in BMI z-scores is observed. Regarding the categories for Status Scores, the change in BMI z-scores in category 1, is 0.279(0.181 to 0.378) times larger than category 5. The change in BMI z-scores in category 2 is 0.233(0.133 to 0.334) times larger than category 5. Category 3 and 4 do not differ significantly from category 5.

After 18 months, a significant increase in BMI z-scores is seen in the different strata. Rounded up to two decimals, the changes from 18 months onwards for the different strata (Status Scores not included), is on average the same as the estimate for the overall change in BMI z-scores (0.01) per month (see Table 4). Exceptions are boys, among who the change in BMI z-scores per month is on average 0.02. In addition, for the age group 13-16 years, the positive change in BMI z-scores is not significant.

3.4 DROPOUTS

In the present dataset, a total of 91 participants are known to be drop outs. The average duration of their participation was 11±7 months and they took part in 13±4 consults. The participants dropped out due to: financial issues (18.89%), and lack of motivation to continue the program among parents (26.67) or children (27.78%) (See Table 4, Appendix II).

Table 5. Characteristics of the remainders and drop outs in the *Lekker Pûh!!!* intervention program

	Remainders (n=2499)		Drop outs (n=91)		
	Total (n=2585)	Over- weight ¹ (n=791)	Obese ¹ (n=1745)	Over- weight (n=27)	Obese (n=63)
Age(years)					
5-8 n,%	595(23)	94(16)	476(80)	3(0.5)	12(2.0)
9-12 n,%	1463(57)	472 (32)	914 (62)	17(1.2)	33(2.3)
13-16 n,%	527(20)	198 (38)	292 (55)	7(1.3)	18(3.4)
Gender					
Boys n,%	791(31)	151(20)	599(76)	4(1.3)	24(3.0)
Girls n,%	1794(69)	613(34)	1083(60)	23(0.5)	39(2.2)
SES					
Low (SD<-1.09) n,%	96(4)	19(20)	68(71)	1(1.3)	3(3.1)
Average (-1.09<=SD <=1.09) n,%	1156(45)	322(28)	767(66)	15(1.3)	30(2.6)
High (SD>1.09) n,%	517(20)	204(39)	283(55)	4(0.8)	17(3.3)

from the 'High' SES groups are underrepresented. Among the **obese** drop outs, compared to the obese remainders, participants aged 13-16 years and participants with a 'High' SES background, are overrepresented. Participants aged 5-8 years and participants from 'Low' SES group are underrepresented.

Among the drop outs, BMI z-scores is significantly reduced by 0.031 (95% CI, -0.042 to -0.019) per month for the first 6 months in *Lekker Pûh!!!* Afterwards a significant increase by 0.01 per month was seen till 1.5 years follow up. These changes in BMI z-scores are different from the study group. In the study group a significant change of -0.019(95 CI, -0.020 to -0.018) per month was seen till 1.5 years follow up. Overall, the drop out group differs from the rest of the study group. No patterns are seen in the influential factors, when comparing the drop outs with the remainders.

In Table 5. the distribution of age groups, gender, SES groups per weight status is depicted for remainders and drop outs. Drop outs in the present study are individuals who quit the programme with a notice. When comparing the remainders and drop outs by weight status, differences are observed in age groups, gender and SES groups. Among the **overweight** drop outs, compared to the overweight remainders, boys and participants from 'Low' & 'Average' SES groups are overrepresented. Participants

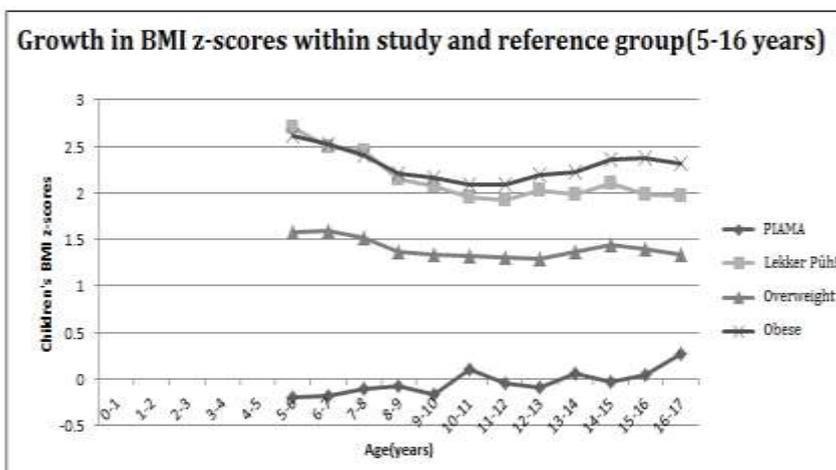


Figure 4. Change in BMI z-scores in overweight and obese *Lekker Pûh!!!* participants compared to the participants from the PIAMA study (reference group)

3.5 IMPACT LEKKER PÛH!!! AMONG DUTCH YOUTH

Figure 3. depicts the trend in BMI z-scores change per age in the study group and the reference group. For the study group separate trend lines are depicted by weight status. Looking at the gap between the trend lines for

the study group and the reference group, this grows closer from the age of 5 till the age of 10, whereafter the changes in BMI z-scores fluctuate around 2.0 for the study group and 0.0 for the reference group. Regarding the trend lines by weight status, the gap with the reference group grows closer till the age of 8, whereafter the trend lines stabilize in contrary to the trend line for the reference group. A slight increase in the trend lines by weight status groups is seen between the age of 12 and 14 years. From the age of 14 the gap compared to the reference group grows closer, since a slight decrease in the trend lines by weight status is seen while the trend line for the reference group elevates.

3.6 QUALITY OF LIFE (QoL)

The change in QoL, was estimated via in-depth interviews with weight coaches on four indicators of the QoL: emotional health, social health, physical health and school functioning. The results are summarized in Appendix II.

In the qualitative study 13 out of the 37 weight coaches are interviewed. These coaches differ in their experiences with *Lekker Pûh!!!* Most of them work with *Lekker Pûh!!!* for approximately 3 years. In the qualitative study an indication of the estimated change in QoL among the participants is indicated via interviews with the weight coaches. The interviewed weight coaches have had either 10-20 participants, 50 participants or more than 100 participants. Most of the children were between 9 to 13 years and had approximately 12 consults. Besides, the coaches were situated mostly in cities, and mainly treated overweight and female clients.

Looking at the indicators of QoL, emotional health and social health are given more importance than physical health and school functioning by the weight coaches. Looking at the perception of the overall health by children, the majority of the weight coaches think that the children are not fully aware of their health status. The latter holds especially for the younger children in primary school. Moreover, when weight loss is observed and the participants improve their physical health, their awareness increases as well as their self-esteem and self-confidence.

Overall, according the weight coaches, *Lekker Pûh!!!* seems to create awareness about the lifestyle of the participants, increase the knowledge on maintaining a healthy lifestyle and increase the ability of the participants to make healthy dietary choices.

Emotional health

Regarding emotional health of the participants, different factors seem to affect the emotional health. The actual weight loss and support by their family, promote positive emotions as happiness, confidence and feelings of support. Setbacks and a lack of support are associated with negative emotions as loneliness and disappointment. Arguments were registered at the beginning of *Lekker Pûh!!!* or in certain settings. For example, when expectations of parents were not met, when children were not offered tasty food at home, and when interference by family members, coaches and teachers occur.

Looking at differences between boys and girls, and the different age groups, it is seen that girls do express their emotions easier than boys. They also are more open to their friends about their weight loss than boys. By opening up, more support is received from friends, benefitting the success of *Lekker Pûh!!!* and self-esteem of the participants.

Next to the emotions, the sleep patterns were also evaluated. Mostly the weight coaches mentioned that the participants did not sleep enough. Associations with age or gender are not clear.

Social health

The role of parents in *Lekker Pûh!!!* is unanimously chosen as the key factor for success. Participants express their need for parental support that seems to be associated with a successful outcome of the intervention program. A noticeable amount of children is content with the support they get. Furthermore, an improvement in the relationship with the parents is seen too.

Support from friends experienced by the participants, seems to depend on how willing the participants are to involve friends. This can differ for boys and girls, as mentioned earlier.

The need for support from families seems to differ for gender and age groups. At younger ages, children depend on their parents. However, at older ages, more support from parents is longed for.

At older ages, boys and girls seem to have different needs. Where boys prefer more support, girls prefer to be in charge themselves.

School functioning

School functioning was the category with the least collected information on. In this section problems with concentration and absence at school, due to weight status, were evaluated. The majority of the weight coaches had no idea whether the concerned topics were important for the children and youngsters. These topics had not been evaluated in consults of *Lekker Pûh!!!* The few coaches, who did give an answer, did not experience problems with concentration at school or skipping classes due to the weight status.

Physical health

Concerning physical activity the participants of *Lekker Pûh!!!* were bothered by their poor fitness. An increase in daily physical activity during *Lekker Pûh!!!* is observed. Boys seem to improve their fitness levels, while girls more often seem to focus on their looks.

Strengths and weaknesses within *Lekker Pûh!!!*

Elements within *Lekker Pûh!!!* that are often mentioned to contribute to the success of this program are:

- the activating learning method that is used;
- the multicomponent approach;
- its flexibility: The weight coach focusses on the process and thinks of solutions to maintain a healthy lifestyle rather than providing a strict plan, and
- the intensive and personal bond the weight coach has with the participants and family.

Often mentioned points for improvement are tailoring the program to different age groups, and update the topics, the content and the lay out of the consults. (See Table 3 in Appendix II for a complete overview of the strengths and weaknesses).

Drop outs

The most frequent mentioned reasons to quit the program are financial issues, parents and participants who were not motivated at a certain point in time, and parents who were confident to carry on without the help of the weight coach. (See Table 1 in Appendix II for a complete overview of reasons for dropping out).

DISCUSSION

In the present study the effectiveness of the *Lekker Pûh!!!* intervention program is assessed based on the predictors of childhood overweight and obesity, and the change in QoL. Participants improved in the degree of adiposity as well as the estimated change in QoL assessed by the weight coaches.

CHANGES IN OUTCOME MEASURES

Four outcome measures were evaluated: BMI, BMI z-scores, weight and WC. BMI z-scores are designated as the primary outcome of this study, since it is additionally adjusted for age and gender. Additionally, BMI z-scores are appropriate for statistical and longitudinal analyses, where a continuous indicator for relative weight is preferred. BMI is reliably associated with adiposity and other indices of obesity related health impairment like WC (Sacher, 2010). However, it is not sensitive for change in lean mass, whereas WC is. WC is even associated with the degree of change in BMI z-scores (Kolotourou *et al.*, 2013). Therefore, the change in fat mass, indicated by the changes in BMI z-scores, can be evaluated with WC.

WAIST CIRCUMFERENCE

In Figure 3 the mean changes in BMI z-scores and WC, decrease significantly in the first 18 months whereafter an increase is observed. This indicates that the change in BMI z-scores represents changes in adiposity. Therefore, fat loss in the first 18 months. Differently would be concluded, if the direction of the trend line for WC would not be in line with changes in BMI z-scores.

BMI z-scores

In the first 18 months, BMI z-scores decrease significantly by -0.019(-0.021 to -0.017) per month. Afterwards, BMI z-scores increase significantly by 0.02 per month. The change in the first 18 months is in line with the estimates by Wake *et al.* (2015). They state that behavioural interventions in trials with true controls revealed a small significant effect in BMI-z scores of -0.06 (95% CI, -0.12 to -0.01). Besides, a change of -0.019 is close to the 95% CI for the change in BMI z-scores for low intensity programs (<10 hours) (-0.08; 95 CI, -0.13 to -0.03) (Van Hoek *et al.*, 2014).

Regarding comparable Dutch multicomponent intervention programs, *MEND*, *Door Dik & Dun*, and *Cool2Bfit* qualify. *MEND* target overweight and obese children aged 7-13 years and provides sessions on nutritional education, behavior change and physical activity (Sacher *et al.*, 2010). In total, this program takes up 32 hours on average in 9 weeks. At one year follow up, participants reduced significantly BMI z-scores by 0.23 ($p < 0.0001$). *Door Dik & Dun* targets overweight and obese children aged 8-12 years and provides sessions with the dietician, psychologist, sport instructor, physiotherapist and other health care providers (Gezondheidsraad, 2010). In total, this program takes up roughly 40 hours in 14 weeks. At one year follow up, a reduction by 0.32 was seen in the participants. *Cool2Bfit* (Aarnink *et al.*, 2015) targets overweight and obese children aged 8-12 years and provides sports classes, nutrition educational classes, consults with dietician and psychologists and parent meetings. This program is a high intensity intervention program that lasts 1.5 year. At one year follow up, a significant increase in BMI z-scores by 0.68 ($p < 0.001$) is seen. At 18 months follow up, a significant decrease by 0.08 ($p < 0.001$) is seen. So, in children aged 7-13 years the effects at one year follow up are variable. At one year follow up, only the effects of *MEND* resonate with the significant decrease in BMI z-scores observed with *Lekker Pûh!!!* (0.24). On long term, BMI z-scores increase significantly by 0.01 per month within *Lekker Pûh!!!*. This is not in accordance with *Cool2Bfit*.

A significant decrease by 0.24 at one year follow up for *Lekker Pûh!!!*, is nearly clinical significant. So, from one year onwards till 18 months follow up, *Lekker Pûh!!!* likely benefits the health of participants. According to Kolotourou *et al.* (2013), a decrease by at least 0.25 in BMI z-scores (similar to a reduction of one BMI or to a stable weight over one year in growing children), is clinically relevant. Though, such cut-

off points can be misleading, since other outcome measures might improve in the absence of change in BMI z-scores. So, on long term *Lekker Pûh!!!* still might prove to be beneficial to the health of participants.

To continue, differences in BMI z-scores changes between *Lekker Pûh!!!* and other multicomponent treatment programs, could be explained by the differences in study design, treatment, intensity of the programs (Van Hoek *et al.*, 2014; Wake *et al.*, 2016) and possibly by the age of participants. For example, *Cool2BFit* has a strong focus on adherence to the program from 6 months on. First evaluation sessions are planned from 6-12 months, whereafter from 12 months on, an e-coachings program is introduced to monitor the weight status of the participants every two weeks. The activities could explain the success rate from 18 months onwards seen for *Cool2BFit*. It appears, that low treatment adherence is observed at 2 years follow up in clinical practice (Dieris & Reinehr, 2015). King *et al.* (2017) contribute the failure of weight loss interventions to individuals getting almost exclusively the responsibility for their weight management after the intervention, while guidance back into the omnipresent obesogenic environment (schools, community, and media) is required. Interventions as dieting, drugs therapy and/or surgery including advise on behavioral-cognitive instructions (e.g. counting calories and more exercise) to achieve long term weight management, are not associated with long term weight loss. Overeating is a result of the brain attracting energy-dense rewards, that overwhelms the homeostatic satiety signals, when good-tasting/high-calorie foods are available. No upper-level body weight set point can even inhibit this process. Obese individuals are easily tempted by good-tasting food compared to normal-weight individuals, even after the intervention. Therefore, a relapse prevention program is advised by the authors.

Overall, many interventions are effective in the first year. However, these effects do not prolong on long run. Studies that include a structured relapse prevention program might be more effective, although an optimal condition of influential factors seems a necessary condition, such as parental support, motivating teachers, and support of friends.

BMI z-scores by influential factors

Among the overweight participants, it was observed that the estimate for the change in BMI z-scores was not in line with the overall change in BMI z-scores. This is also observed by Wake *et al.* (2015), who state that larger natural improvements in BMI z-scores are expected in obese individuals rather than in overweight individuals.

SES

In scientific literature, the association between SES and obesity is ambiguous (Bammann *et al.*, 2013) and moderated by factors as living area, sex and race (Bammann *et al.*, 2013 & Banks *et al.*, 2016). In the Western world an inverse relationship is suggested (Wang&Lim, 2012), including The Netherlands (Elsenburg *et al.*, 2016). This is in accordance with the present study (-0.071; 95CI, -0.093 to -0.049).

Looking at the 5 categories of Status Scores, a significant association between the Status Scores categories and changes in BMI z-scores, is only seen for the first two categories ('Low' and 'Average' SES groups), confirming the inverse relationship. These results are also observed by Banks *et al.* (2016) & Watts *et al.* (2016), but not explained. Further research is needed to explain this phenomenon.

DROP OUTS

The drop outs are not a reflection of the study group. No patterns are seen in influential factors when the remainders and the drop outs are compared. The latter is only confirmed by literature for SES (Ligthart *et al.*, 2016). Further research into the association between drop outs, and age and gender is needed.

Most often mentioned reasons by drop outs were related to a lack of finance and decreasing motivation among parents and participants. This is in accordance with the research by Schalkwijk *et al.* (2016) on perceived barriers by health care providers when implementing national integrated health care standard on childhood obesity in The Netherlands. They concluded that for example financial constraints when taking part in an weight management program, lack of motivation among the children, and parents not

motivated to seek help, are barriers for the successful implementation of childhood obesity and overweight management programmes.

PIAMA STUDIE

Data of the reference group in the present study reflects the changes in BMI z-scores in Dutch children aged 5-16 years (see Figure 4). The trend line of the reference group depicts the natural growth in mean BMI z-scores per age category. By comparing this trend line to the trend line for *Lekker Pûh!!!*, a conclusion can be drawn for the latter following the natural growth. However this is not observed in the present study, since the growth in the trend lines for the study group is different from the reference group.

Possible treatment effects could explain the decrease and stabilization in BMI z-scores changes by weight status in the study group. However, no conclusions can be drawn from Figure 4. More research is needed to explain the differences between the trend lines for the study group and the reference group.

CHANGES IN QUALITY OF LIFE

The interviews suggest a positive association between weight loss and QoL, and between *Lekker Pûh!!!* and QoL. Weight loss was believed to contribute to the positive emotional health, like support from the family and friends. The latter is encouraged throughout *Lekker Pûh!!!* Self-confidence and self-esteem were clearly indicated as improved among participants during *Lekker Pûh!!!*. School functioning on contrary, could not properly be measured, since this is not part of the *Lekker Pûh!!!* program. At last, the daily physical activity was increased.

These results are in accordance with an international systematic review and other Dutch trials with multicomponent treatment programmes. In the meta-analysis by Tsiros *et al.* (2009) an inverse linear relationship between health related quality of life (HRQOL) and BMI was found. Regarding Dutch trials, Vos *et al.* (2011) measured a significant increase in overall HRQOL after one year follow up in treatment seeking obese children aged 8-17 years. However, at this time point a significant improvement compared to baseline was only seen for the indicators physical health (90.1, 95CI, 87.1 to 93.1) and emotional functioning (87.0; 95 CI, 81.2 to 82.9). Hofsteenghe *et al.* (2013), observed in a Dutch study a significant improvement in physical health (86.7 ± 11.8) and school functioning (76.6 ± 16.2). These results were measured in obese adolescents (11-18 years), after a 18 months follow up. As mentioned earlier, quantitative, and possibly also qualitative, positive effects after an intervention year are often described, but long term effects are less known.

Other factors affecting QoL besides weight loss, are age and gender (Wille *et al.*, 2009). The latter is also suggested by weight coaches regarding emotional health and social support. Concerning emotional health, weight coaches also mentioned an observed difference between boys and girls. Girls open up quicker than boys. Regarding the need social support, this seems to differ for gender and age groups. At younger ages, children of course depend on their parents. Nevertheless, at older ages youngster also long for parental support. At older ages, boys and girls seem to have different needs. Where boys prefer more support, girls prefer to be in charge themselves. According to Buttita *et al.* (2014) a lower QoL-score is associated with pre-pubertal participants, older adults and girls. In the present study this was not indicated by the weight coaches.

STRENGTHS AND LIMITATIONS

The present study has several strengths. First, the present study includes an unique combination of a quantitative and qualitative study. In the present study, not only the effect by *Lekker Pûh!!!* on the predictors of adiposity, but also the change in QoL and the effect by SES has been studied. These type of studies are not often seen in scientific literature on multicomponent treatment programmes.

Besides, *Lekker Pûh!!!* shows clinical relevant results between one year and 1.5 year follow up. The present study shows promising results, being an addition to scientific literature, already present on effect evaluations of multicomponent treatment programmes.

By using BMI z-scores as outcome measure, comparisons between subpopulations (for example age groups) is easier, since BMI z-scores are adjusted for age, sex, height and weight.

Furthermore, longitudinal data sets are prone to missing data and irregular spacing between measurements. Both aspects are dealt with by applying the Linear Mixed Models (Seltman,2015), which are robust against these errors (Plonsky, 2015).

At last, by using Status Scores as indicator for SES, the effect of *Lekker Pûh!!!* on the outcome measures is adjusted for parental income, occupation and educational level. These variables are indicators of family socioeconomic status and negatively associated with risk behaviors for childhood obesity (Pérez et al, 2013). By using an indicator that combines these variable, comparing different SES groups and monitoring the changes in these groups gets more simpler than compared to studying the variables on their own.

The first limitation of the present study concerns missing data that could have influenced the study results. It is not clear if the missing data is missing at random and/or more drop outs are present. For now only 91 drop outs were registered. It is possible that more participants quit the program due to a lack of motivation, though did not choose to update the weight coaches. In case of data missing at random, the Linear Mixed Models performs poorly (Batterham, 2013). The presence of this error is unknown, since reasons for missing data are not registered.

Next, in the present study a control group is missing. This would be helpful when drawing a conclusion on how effective *Lekker Pûh!!!* is compared to other treatment programs, corrected for a control group. However, clinical relevance on long run is of more importance, since this adds up to the existing evidence present for multicomponent treatment programs.

Furthermore, WHO references are used to calculate the BMI z-scores. These reference values are not entirely representative for the Netherlands (Cole & Lobstein, 2012). By using these reference values, more participants are indicated as obese, while being overweight, introducing information bias. However, this is mostly of concern, when conclusion need to be drawn for absolute outcome measures (for example the change in BMI).

At last, the qualitative part was included to explore the psychosocial health effects by *Lekker Pûh!!!* and the appropriate questions to ask when studying the change in QoL. Although, information on the change in QoL, is based on professional expertise and judgement on the success elements of *Lekker Pûh!!!*, the used questionnaire does not give sufficient information on the change in QoL throughout the program. There was a difference in interpretation of questions, recalling information was hard (introducing recall bias) and talking about average changes in QoL was experienced as difficult by the weight coaches. However, the results presented in this report can be used as input for further research into the psychosocial health effects by *Lekker Pûh!!!*

RECOMMENDATIONS

For future studies on *Lekker Pûh!!!*, active monitoring of reasons for missing consults or dropping out is advised, to calculate valid estimates. Additionally insights in reasons to quit the program is enhanced, and information is collected on participants who are in for the first 18 months only and/or for the long run. Hence, program activities can be adjusted based on this knowledge, in order to increase the success rate of *Lekker Pûh!!!* For now a way to track down the reasons for missing consults, the amount of consults followed and the adherence to the program, is to invite all the participants to the 10th anniversary of *Lekker Pûh!!!* and for example let them fill out a questionnaire on paper or online.

If possible the TNO reference values should be used to calculate BMI z-scores, leading to estimates which entirely apply to the Dutch population.

Next, it is advised to include a control group to assess the effectiveness of *Lekker Pûh!!!* on the included outcome measures. In this way insight is gained, in the benefits of *Lekker Pûh!!!* not only for the study group but also for the Dutch population. The control group can consist of obese and overweight children who did not receive a treatment yet (e.g. participants who are on a waiting list for participating in an intervention program).

In order to assess the QoL per child, weight coaches prefer a questionnaire of 5—10 questions per child. Besides, when performing interviews, the weight coaches can be trained on how to answer the questions, in order to prevent misinterpretation of questions.

Regarding the intervention program, this can be improved on tailoring the content to age groups, and by providing parental coaching. Different age groups need a different approach (Pandita *et al.*, 2016). For example, with pre-pubertal children creating awareness is of importance, while with adolescents it is about reinforcing the knowledge, and adherence to the knowledge and skills gained in the program.

Parental modelling of healthy behaviours and changes to the home environment is associated with successful weight loss among children (Wilfley *et al.*, 2010). Therefore not only children or parents, but both should be targeted. It is advised to set up consults for parents too. In these consults, parenting styles and skills benefitting the weight management of the child can be addressed. Accordingly, the family confidence can be improved, leading to lower dropout rates (Kelishadi & Azizi-Soleiman, 2014).

At last, a relapse prevention program can be integrated from 18 months onwards, like *Cool2BFit*, in order to prolong the success rate in the first 18 months. *Cool2BFit* provides an e-coaching's program to monitor the new lifestyle of the participants, what could be part of the relapse prevention strategy by *Lekker Pûh!!!*

CONCLUSION

In conclusion, participation in the *Lekker Pûh!!!* intervention programme, has shown to be beneficial for the physical and psychosocial health of children. In the first 18 months clinical relevant results are achieved with *Lekker Pûh!!!* The monthly change in BMI z-scores in the first 18 months, are in accordance with evaluation studies on low intensity intervention programmes and observational studies. SES seems to be inversely related to the changes in BMI z-scores. *Lekker Pûh!!!* is one of the few Dutch intervention programmes that is health and family centred. It is practice based and parents and children can, at any given time, come back for renewed advice. The results from the present study, mainly apply to participants from a High SES environment, who can affiliate with the programme. In the future, more children and parents from lower SES and/or non-Western backgrounds should be able to participate. This might need adaptations of the program. A structured relapse program should be integrated in *Lekker Pûh!!!* Based on the effectiveness of this programme, efforts should be made to get this programme acknowledged by insurance companies and governmental parties as National Databank of the NJI.

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APPENDICES

APPENDIX I. TOPIC LIST

Introductie

Het hoofddoel van dit interview is het vastleggen wat Lekker Puh!!! de kinderen oplevert.

Hoe verbetert hun welzijn en hoe tevreden zijn ze met de veranderingen. Hoe komen de kinderen binnen, waarin veranderen ze op korte termijn en waarin op langere termijn. Er volgen eerst enkele introductievragen over uw doelgroep en daarna wat gerichtere vragen over de welzijn van de kinderen.

Hoe lang bent u al een eetcoach bij Lekker Puh?

Hoeveel kinderen heeft u op het moment in begeleiding?

In welke leeftijdsgroep zit het grootste deel van de kinderen?

Hoe is de verhouding tussen het aantal jongens en meisjes?

Hebben de kinderen voornamelijk overgewicht of zijn ze obees?

Hoeveel consulten hebben de kinderen gemiddeld gehad?

De volgende vragen gaan over de veranderingen in het welzijn van het kind. We vergelijken de eindsituatie met de startsituatie.

QoL in het algemeen

7(1) Wat levert Lekker Puh!!! de kinderen in het algemeen op?

(2) Hoe ervaren de kinderen hun gezondheid bij de start, gaandeweg en na afloop (van) het programma?

(3) Hoe tevreden zijn kinderen met zichzelf bij de start, gaandeweg en na afloop (van) het programma?

(4) Hoe tevreden zijn ze over hun thuissituatie bij de start, gaandeweg en na afloop (van) het programma?

(5) Hoe tevreden zijn ze over hun vrienden bij de start, gaandeweg en na afloop (van) het programma?

Sociale gezondheid

(5) Gezien hun gewicht:

- A. In welke mate voelen de kinderen zich doorgaans gesteund door familie?
- B. In welke mate voelen de kinderen zich doorgaans gesteund door vrienden?
- C. Hoe tevreden zijn ze hierover?
- D. Hoe verandert dit in de loop van de tijd?
- E. Wat voor impact heeft dit op de gemoedstoestand?
- F. Wat verwachten de kinderen van hun vrienden en familie?
- G. Zijn er verschillen tussen jongens en meisjes? Of verschillen tussen de kinderen en jongeren?

(6) Hoe belangrijk is de betrokkenheid van de ouders voor het welslagen van het programma?

Emotionele gezondheid

(7) Slapen de kinderen/jongeren voldoende?

- A. Hoe verandert dit in de loop van de tijd?
- B. Zijn er verschillen tussen jongens en meisjes? Of verschillen tussen de kinderen en jongeren?

(8) In welke mate ervaren kinderen negatieve gevoelens of positieve gevoelens? Kunt u voorbeelden geven van deze emoties? (frustratie, schaamte, boos, angst, energiek etc.)

- A. Hoe verandert dit in de loop van de tijd?
- B. Zijn er verschillen tussen jongens en meisjes? Of verschillen tussen de kinderen en jongeren?

Functioneren op school

(9) In welke mate kunnen de kinderen zich concentreren op school?

- A. Hoe verandert dit in de loop van de tijd?
- B. Zijn er verschillen tussen jongens en meisjes? Of verschillen tussen de kinderen en jongeren?

(10) Verzuimen de kinderen op school vanwege hun gewicht?

- A. Hoe verandert dit in de loop van de tijd?
- B. Zijn er verschillen tussen jongens en meisjes? Of verschillen tussen de kinderen en jongeren?

Fysieke activiteit

(11) Gezien hun gewicht:

- A. Worden de kinderen belemmerd in het uitvoeren van:
 - i. Dagelijkse activiteiten*
 - ii. Hobbies*
 - iii. Sportactiviteiten (op school en bij de vereniging)**
- B. Hoe tevreden zijn de kinderen over het uitvoeren van dagelijkse activiteiten?*
- C. Hoe tevreden zijn ze over het uitvoeren van hobbies en sportactiviteiten?*
- D. Hoe verandert dit in de loop van de tijd en wat voor impact heeft dit op de gemoedstoestand?*
- E. Zijn er verschillen tussen jongens en meisjes, en kinderen en jongeren?*

Wat zijn de meest voorkomende redenen om te stoppen met Lekker Pûh?

Wat zijn volgens u de succesfactoren van dit programma?

Op welke punten kan dit programma verbeterd worden?

In welke mate geven de volgende onderwerpen informatie over de welzijn van de kinderen? Breng een rangorde aan in de volgende topics: sociale gezondheid, emotionele gezondheid, functioneren op school en fysieke activiteit?

Hoeveel vragen zou u maximaal willen invullen over het welzijn van de kinderen/jongeren als we u zouden verzoeken een vragenlijst in te vullen?

APPENDIX II. RESULTS FROM THE INTERVIEW

Table 1. Reasons for dropping out of the program

Drop outs

- Financial issues(8x)
- Confident to continue on their own because they are familiar with the programme.(6x)
- The participants are not intrinsically motivated.(5x)
- The participant is already familiar with the content of the programme. (The participant already followed the programme once.)(1x)
- Parents are not motivated to continue the programme. This has different reasons, like work; no results; shared custody; travelling distance; illness of the mom. (6x)
- The desired weight loss is reached.(3x)
- Contact with families is not maintained.(2x)
- No weight loss more achieved. (1x)

Table 2. The estimated change in QoL indicators throughout *Lekker Pûh!!!* including possible differences between gender and age groups $n=13$

Ranking	1	2	3	4	Frequency x ranking
Emotional health	8	4	1	1	23
Social health	6	7	1		23
School functioning	1		8	2	32
Physical health		5	4	3	34
Categories QoL	<i>Observation</i>				<i>Estimated change in behaviour and / or number of observations</i>
<i>In general</i>	<i>Knowledge on healthy lifestyle:</i>				<i>Increased 4x</i>
	<i>Ability to make health beneficial dietary choices:</i>				<i>Improved 4x</i>
	<i>Awareness of health status and impact weight status:</i>				<i>Increased 4x</i>
	<i>Awareness of lifestyle :</i>				<i>Increased 5x</i>
	<i>Awareness of tools to overcome a fall back:</i>				<i>Increased 2x</i>
	<i>Overcome setbacks:</i>				<i>Increased 1x</i>
	<i>Perception of their health in general:</i>				<i>Content with their health status 3x</i>
					<i>Not content with their health status 3x</i>
					<i>Several health</i>

complaints 2x
Not aware 8x

Emotional health

Self-esteem Increased 6x
Self-confidence Increased 5x
Image Positively changed 3x

If setbacks occur the children feel/experience: Disappointed 2x
Negative emotions 4x

Due to the weight status the participants feel: Sad 2x
Shy 1x

If the participants lose weight they feel / experience: Happy 2x
More confident 4x
More positive emotions 5x

Support from the environment makes the child feel: More confident 1x
Happy 3x
More supported 2x

If parents do not support the child it feels / experiences Lonely 1x
More negative emotions 3x

Amount of sleep Not enough 4x
Enough 3x
Improved 1x
Not measured 2x

Inducing sleep: Difficult 2x

Arguments with the environment family, coaches, teacher or friends when their secrets come out or there is too much control by supervisors. 1x

Feel positive when they know how a healthy diet impacts their self-esteem and when they are aware that their weight loss is due to their own efforts. 1x

When the participants exercise more their self-esteem increases. 3x

Gender

Girls

No difference in sleeping patterns between boys and girls. 4x
Compared to boys:
- Girls are emotional and show their emotions easier. 3x

Boys	<i>Compared to girls</i>	
	- <i>Boys are more down to earth.</i>	1x
	- <i>Boys do not open up.</i>	4x
	- <i>Boys quit the programme earlier if results stay out.</i>	1x

Age groups

	<i>No difference in sleeping patterns between the several age groups.</i>	1x
Younger participants	<i>Compared to the older participants:</i>	
	- <i>Till the age of ten the participants often get enough sleep.</i>	1x
	<i>Self-esteem is low among participants aged 7-10 years old</i>	1x
	<i>Children from the primary school do not sleep enough.</i>	3x
	<i>Children from the primary school do sleep enough.</i>	1x
Older participants	<i>Compared to the younger participants:</i>	
	- <i>Older children are more aware of their body and are not content with it.</i>	2x
	- <i>Older participants do not sleep enough.</i>	3x
	- <i>Older participants have a lower quality of sleep due to use of social media.</i>	1x
	- <i>Feel more shame to open up about their journey.</i>	2x
	- <i>Are harder on themselves.</i>	1x
	<i>Children aged 11-12 need more support than do the younger children. Children aged 16 need less support than the ones aged 11-12 years.</i>	1x

Social health

Parents

Relationship with parents:	<i>Improved 5x</i>
	<i>Not ideal 2x</i>
Support by parents:	<i>Enough 6x</i>
	<i>Variable 7x</i>

	<i>Crucial 10x</i>
<i>Arguments with parents (in the beginning, when not being allowed sweets, or not being served tasty food).</i>	<i>Present 2x</i>
<i>Mothers are more involved than fathers.</i>	<i>2x</i>
<i>Children require support by parent.</i>	<i>5x</i>
<i>If there is not sufficient amount of parental support, the success of this programme is negatively affected.</i>	<i>3x</i>
<i>When parents are divorced less support to the child is seen.</i>	<i>2x</i>

Friends

<i>Amount of friends:</i>	<i>Increased 4x</i>
	<i>Same 1x</i>
<i>If the children open up about their weight loss journey they get more support of their friends, resulting in better result.</i>	<i>7x</i>

Gender

- Girls

<i>Compared to boys:</i>	
- <i>Girls at older ages want to be more in charge of their journey.</i>	<i>1x</i>
- <i>Girls can feel uncomfortable with the support they get from their parents.</i>	<i>1x</i>
- <i>Girls are more open to their friends about their weight loss journey and ask for help.</i>	<i>2x</i>
- <i>Girls want to know want to understand why something benefits them or not.</i>	<i>1x</i>

- Boys

<i>Compared to girls:</i>	
- <i>Boys appreciate the support being received more.</i>	<i>1x</i>
- <i>Boys at older ages get more support.</i>	<i>1x</i>
- <i>Boys feel more shame to tell their friends about their weight loss journey and ask for help.</i>	<i>2x</i>

- Boys are not curious about why they have to behave in a certain way. 1x

Age groups

- Younger participants
 - Compared to the older participants:
 - The younger participants depend more on their parents. 1x
 - The younger participants are pushed by the parents to finish Lekker Pûh!!! 1x
- Older participants
 - Compared to the younger participants:
 - The older participants do need more support than they get from parents or other needs need to be fulfilled. 2x
 - Support from the environment becomes more important. 1x
 - The older participants find it hard to talk about their weight loss journey with their friends. 2x
 - The older participants want be more in charge of their weight loss journey. 1x
 - Teenagers quit quicker than the younger participants. 1x

School functioning

- Concentration problems:
 - Present 2x
 - Not seen 5x
 - Not measured 3x
- Skipping classes:
 - Seen
 - Not seen 5x
 - Not measured 5x
- Due to an increased self-esteem, attending classes becomes less of an issue. 1x

Physical health

- Physical activity in daily life: Increased 9x

	<i>When the participants stick to the plan, they lose weight, and the self-esteem of the participants increases, they become more physical active.</i>	3x
	<i>Obese children are difficult to motivate to get more active.</i>	2x
	<i>The higher educated junior high participants are different to get in action.</i>	1x
Gender	<i>The participants experience poor physical health.</i>	9x
- Girls	<i>Compared to boys:</i>	
	- <i>Girls give looks more priority.</i>	3x
	- <i>Girls are easily motivated to start working out</i>	1x
- Boys	<i>Compared to girls:</i>	
	- <i>Boys take up sports more serious and quicker.</i>	4x
	- <i>Boys are getting active to improve their fitness.</i>	1x
Age		
- Older participants	<i>Compared to the younger participants:</i>	
	- <i>The older participants suffer from more knee problems.</i>	1x
	- <i>The older participants are more on social media and difficult to mobilize.</i>	1x
	- <i>Participants who tried other ways of losing weight are hard to get in action.</i>	1x

Table 3. Strengths and Limitations of *Lekker Pûh!!!*

Strength	Points for improvement
The required knowledge is provided via 15 consults and not all at once. (1x)	There should be a consult especially for parents: 1 in the beginning and 1 in the end of the programme. These consults should be about different parenting styles and how to raise the participants accordingly. (1x)
The participants are coached regularly for a long period of time.(3x)	
Intensive contact with the participants (1x) This programme focusses more on the process than the weight loss.(2x)	The content of (some) consults should be tailored to the age groups.(5x)
Contact with the families on long term.(1x)	Motivate the participants and parents to follow the programme on long term. (1x)
Informal and personal connection with the families.(1x)	The weight coaches should have a wide network in order to get clients but also advise them properly on potential health care professionals in the neighbourhood that could be approached. (1x)
Personal an informal connection with the child. (1x)	
Weight coach is a confidential advisor who takes the participant seriously and does not get mad.(4x)	This programme is not covered by the insurance.(2x)
A multidisciplinary advisory team is available. (1x)	Have a contract with a regional gym to stimulate physical activity.(1x)
The journal 'Het boek over jezelf', the participants keep during the programme, can be used as a book of reference.(1x)	Let the regional Lekker pûh!!! participants connect with each other and share their experience with each other.(1x)
The programme is tailored to the family(no plans). (3x)	Update the programme (lay out, grammar, examples and topics). (4x)
The consults have no fixed order. (1x)	Provide more information on emotional eating. (1x)
Increased self-esteem of the participants. (1x)	Advice weight coaches in how to rearrange consults in order to tailor the needs of the participants.(1x)
Participants and parents get tools to tackle the weight loss. (4x)	
Keep in touch with families. (1x)	The programme is not suitable for participants who do not speak Dutch really well. (1x)

Lekker Pûh!!! is a multicomponent approach. (3x)

More focus on eating healthy than focussing on weight. (1x)

Activating learning method is being use use (it appeals to the children, it is fun and relatable).(5x)

Develop new consults for participants who stay longer in the programme. (1x)

Table 4. The documented reasons for dropping out

<i>n</i>	Category	Reasons									
		Desired weight achieved	Reached desired lifestyle	Healthy weight	Financial	Motivation parents	Motivation child	Other therapy needed	Parents think they can continue on their own	Child thinks it can continue on its own	Other
92	Drop outs				17	24	25	4	3	3	17

APPENDIX III

Table 5a. Change in mean BMI z-scores by Status Scores and age

		BMI z-scores	Mean difference	<i>p-value</i>			BMI z-scores	Mean difference	<i>p-value</i>
		Mean (SD)	compared to intake (95%CI)				Mean (SD)	compared to intake (95%CI)	
	Low					5-8 years			
t0	96	2,46 (0,60)			t0	595	2,68 (0,74)		
t1	95	2,25 (0,62)	-0,19 [-0,25;-0,13]	0.000	t1	574	2,39 (0,79)	-0,27 [-0,30;-0,25]	0.000
t2	91	2,15 (0,69)	-0,34 [-0,41;-0,26]	0.000	t2	521	2,25 (0,76)	-0,40 [-0,44;-0,36]	0.000
t3	55	2,18 (0,67)	-0,37 [-0,51;-0,23]	0.000	t3	391	2,10 (0,74)	-0,53 [-0,59;-0,48]	0.000
t4	54	1,91 (0,79)	-0,59 [-0,79;-0,38]	0.000	t4	365	2,09 (0,72)	-0,57 [-0,64;-0,51]	0.000
t5	12	1,75 (0,71)	-0,80 [-1,14;-0,47]	0.000	t5	112	1,91 (0,67)	-0,73 [-0,83;-0,64]	0.000
t6	5	1,08 0,45	-1,04 [-1,36;-0,72]	0.001	t6	73	1,87 (0,62)	-0,72 [-0,84;-0,59]	0.000
t7	1	0,88 (-)	-	-	t7	43	1,80 (0,65)	-0,71 [-0,88;-0,53]	0.000
t8	1	0,58 (-)	-	-	t8	31	1,73 (0,52)	-0,78 [-1,01;-0,56]	0.000
	Average					9-12 years			
t0	1156	2,39 (0,67)			t0	1463	2,29 (0,59)		
t1	1124	2,14 (0,71)	-0,24 [-0,26;-0,23]	0.000	t1	1419	2,05 (0,65)	-0,23 [-0,24;-0,22]	0.000

t2	1062	2,03 (0,69)	-0,34 [-0,36;-0,32]	0.000	t2	1332	1,96 (0,66)	-0,32 [-0,33;-0,30]	0.000
t3	755	1,92 (0,72)	-0,48 [-0,51;-0,44]	0.000	t3	988	1,85 (0,64)	-0,42 [-0,45;-0,39]	0.000
t4	680	1,97 (0,70)	-0,47 [-0,51;-0,43]	0.000	t4	894	1,86 (0,67)	-0,44 [-0,47;-0,41]	0.000
t5	225	1,75 (0,66)	-0,61 [-0,68;-0,55]	0.000	t5	285	1,71 (0,63)	-0,57 [-0,63;-0,52]	0.000
t6	136	1,68 (0,62)	-0,63 [-0,71;-0,55]	0.000	t6	164	1,60 (0,64)	-0,63 [-0,70;-0,55]	0.000
t7	77	1,64 (0,63)	-0,65 [-0,77;-0,54]	0.000	t7	88	1,59 (0,63)	-0,66 [-0,76;-0,55]	0.000
t8	45	1,45 (0,72)	-0,84 [-1,05;-0,64]	0.000	t8	49	1,51 (0,73)	-0,72 [-0,91;-0,52]	0.000
	High					13-16 years			
t0	517	2,21 (0,60)			t0	527	2,24 (0,65)		
t1	500	1,96 (0,66)	-0,25 [-0,28;-0,23]	0.000	t1	515	2,09 (0,70)	-0,14 [-0,16;-0,12]	0.000
t2	474	1,88 (0,67)	-0,31 [-0,34;-0,28]	0.000	t2	481	2,00 (0,73)	-0,22 [-0,25;-0,19]	0.000
t3	360	1,83 (0,60)	-0,37 [-0,42;-0,33]	0.000	t3	352	1,92 (0,71)	-0,29 [-0,34;-0,25]	0.000
t4	346	1,81 (0,66)	-0,40 [-0,45;-0,35]	0.000	t4	322	1,93 (0,71)	-0,28 [-0,34;-0,23]	0.000
t5	93	1,71 (0,57)	-0,58 [-0,68;-0,48]	0.000	t5	60	1,64 (0,65)	-0,44 [-0,55;-0,32]	0.000
t6	48	1,63 (0,63)	-0,68 [-0,82;-0,54]	0.000	t6	22	1,63 (0,79)	-0,55 [-0,80;-0,30]	0.000
t7	18	1,71 (0,53)	-0,78 [-1,01;-0,54]	0.000	t7	8	1,61 (0,43)	-0,59 [-1,16;-0,02]	0.045
t8	13	1,74 (0,41)	-0,65 [-1,01;-0,29]	0.002	t8	5	1,62 (1,57)	-0,57 [-1,88;0,75]	0.300

Table 5b. Change in mean BMI z-scores by weight status and gender

		BMI z-scores	Mean difference	<i>p-value</i>			BMI z-scores	Mean difference	<i>p-value</i>
		Mean (SD)	compared to intake (95%CI)				Mean (SD)	compared to intake (95%CI)	
Overweight					Female				
<i>t0</i>	791	1.65 (0.25)			<i>t0</i>	1794	2,26 (0,61)		
<i>t1</i>	769	1,43 (0,34)	-0,22 [-0,24;-0,20]	0.000	<i>t1</i>	1741	2,03 (0,67)	-0,22 [-0,23;-0,21]	0.000
<i>t2</i>	704	1.37 (0.37)	-0.29 [-0.31;-0.26]	0.000	<i>t2</i>	1626	1.93 (0.67)	-0.30 [-0.32;-0.28]	0.000
<i>t3</i>	506	1.32 (0.40)	-0.35 [-0.38;-0.32]	0.000	<i>t3</i>	1187	1.83 (0.65)	-0.40 [-0.42;-0.37]	0.000
<i>t4</i>	468	1.31 (0.42)	-0.35 [-0.40;-0.31]	0.000	<i>t4</i>	1098	2.15 (0.73)	-0.42 [-0.45;-0.39]	0.000
<i>t5</i>	134	1.20 (0.49)	-0.46 [-0.53;-0.39]	0.000	<i>t5</i>	331	1.66 (0.63)	-0.57 [-0.62;-0.52]	0.000
<i>t6</i>	77	1.15 (0.44)	-0.47 [-0.57;-0.38]	0.000	<i>t6</i>	188	1.57 (0.62)	-0.66 [-0.73;-0.59]	0.000
<i>t7</i>	38	1.17 (0.47)	-0.49 [-0.64;-0.34]	0.000	<i>t7</i>	106	1.58 (0.60)	-0.62 [-0.72;-0.53]	0.000
<i>t8</i>	25	1.14 (0.65)	-0.49 [-0.75;-0.23]	0.001	<i>t8</i>	67	1.54 (0.60)	-0.66 [-0.79;-0.52]	0.000
Obese					Male				
<i>t0</i>	1745	2,68 (0,53)			<i>t0</i>	791	2,62 (0,71)		
<i>t1</i>	1693	2,46 (0,59)	-0,22 [-0,23;-0,21]	0.000	<i>t1</i>	767	2,39 (0,73)	-0,23 [-0,25;-0,21]	0.000
<i>t2</i>	1586	2.34 (0.61)	-0.33 [-0.35;-0.31]	0.000	<i>t2</i>	708	2.27 (0.73)	-0.35 [-0.38;-0.32]	0.000
<i>t3</i>	1194	2.20	-0.45	0.000	<i>t3</i>	544	2.15	-0.49	0.000

t4	1083	(0.61)	[-0.48;-0.43]	0.000	t4	483	(0.72)	[-0.54;-0.44]	0.000
		2.19	-0.47				2.18	-0.49	
t5	316	(0.62)	[-0.50;-0.44]	0.000	t5	126	(0.74)	[-0.55;-0.44]	0.000
		1.97	-0.65				1.98	-0.66	
t6	177	(0.57)	[-0.70;-0.60]	0.000	t6	71	(0.64)	[-0.74;-0.57]	0.000
		1.90	-0.72				1.99	-0.60	
t7	97	(0.61)	[-0.79;-0.64]	0.000	t7	33	(0.66)	[-0.73;-0.47]	0.000
		1.87	-0.74				1.92	-0.82	
t8	56	(0.58)	[-0.85;-0.64]	0.000	t8	18	(0.67)	[-1.05;-0.60]	0.000
		1.81	-0.84				1.78	-1.00	
		(0.69)	[-1.02;-0.66]				(1.09)	[-1.47;-0.52]	

Table 6. Changes in BMI, BMI z-scores, Weight and WC in the first 18 months and onwards

		<i>Study group</i>			
		BMI¹	BMI z-scores¹	Weight¹	WC¹
Crude	<18	-0.50%	0.0006	0.06%	-0.40%
	months	0.995[0.9946;0.9954]	[-0.001; -0.000]	1.0006[1.000;1.001]	0.996[0.9957;0.9964]
	18	1.44%	0.014	1.41%	1.07%
	months	1.015[1.013;1.016]	[0.013;0.016]	1.014[1.013;1.016]	1.011[1.010;1.012]
Confounder-adjusted model ¹	<18	-0.87%	-0.019	-0.85%	-0.74%
	months	0.9913[0.9908;0.9918]	[-0.021;-0.017]	0.9914[0.991;0.992]	0.993[0.992;0.9931]
	18	1.65%	0.028	1.74%	1.28%
	months	1.017[1.015;1.018]	[0.021;0.034]	1.018[1.016;1.019]	1.013[1.012;1.014]
Crude model= best fit	>18	1.03%	0.01	0.89%	0.54%
	months	1.010		1.009	1.005
	<i>Drop outs</i>				
	<6	-0.83%	-0.031	-0.32%	-0.63%
months	0.992[0.990; 0.994]	[-0.042;-0.019]	0.997[0.995;0.999]	0.994[0.992;0.996]	
6	1.52%	0.040	1.45%	0.86	
months	1.015[1.012;1.018]	[0.023;0.057]	1.015[1.011;1.018]	1.009[1.004;1.013]	
>6	0.68%	0.010	1.14%	0.24%	
months	1.007		1.011	1.002	

Note. All models are adjusted for Status Scores. The model for BMI is additionally adjusted for age, while the models for weight and WC, are additionally adjusted for gender, age and Status Score.