EVALUATION OF A PARTICIPANT CO-DESIGNED LIFESTYLE CHANGE PROGRAM FOR YOUTH

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DEDICATION

This is dedicated to my lovely Lara.

ACKNOWLEDGEMENT

Thank you, God, for everything that I have. I am deeply thankful to have my family who supports, loves, and motivates me all the time.

I am deeply thankful for my husband Yousef. He supports, loves, and cares for me and has been a light in my darkest time. Without him, I could not have completed this degree.

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EVALUATION OF A PARTICIPANT CO-DESIGNED LIFESTYLE CHANGE PROGRAM FOR YOUTH

Introduction: Increasing obesity in children leads to an increase in the risk of Type 2 diabetes (T2D). Therefore, it is important to promote healthier lifestyles in youths and encourage their caregivers(s) to provide a healthy lifestyle environment. The PowerHouse program focuses on improving food choices, increasing physical activity, and adopting behavior changes for the reduction of obesity and the prevention of T2D.

Method: The aim of this study was to assess the effects of implementing the PowerHouse program on both clinical and quality of life outcomes in high-risk, low-income youth and their caregivers. Primary outcomes were BMI standard deviation and BMI percentile in youths. Secondary outcomes included physical activity of youths and quality of life for both youths and their caregivers. Attendance rates were also calculated. Linear effect mixed models were used to test for time effects for all outcomes.

Results: Clinical outcomes did not improve over time, except for youth HbA1c (p-value = 0.0447). Some improvements in youth quality-of-life outcomes were noted: specifically, the Sports Index score of the Fels Physical Activity Questionnaire for Children (adjusted p-value = 0.0213) and the Physical Summary (p-value = 0.0407), Psychosocial Summary (p-value = 0.0167), and Total score (p-value = 0.0094) for the youth-reported Pediatric Quality of Life Inventory. Quality of life did not change over time for caregivers. For attendance, there was an improvement after the intervention was modified to improve access to fresh produce (p-value = 0.0002).

Conclusion: HbA1c and quality of life improved over time for youth; however, there was not an improvement in caregiver outcomes over time. The data suggest that more time may be needed to see the full effects of the intervention, and/or that a booster intervention may be needed.

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LIST OF ABBREVIATIONS

Body Index Mass (BMI)

Diabetes Prevention Program (DPP)

Fels Physical Activity Questionnaire (Fels PAQ)

Human-centered design (HCD)

Impaired fasting glucose (IFG)

Pediatric Quality of Life Inventory (PedsQL)

Research Electronic Data Capture system (REDCap)

Standard Deviation (SD)

Type 2 diabetes (T2D)

Institutional Review Board (IRB)

Chapter One: Introduction

The prevalence of type 2 diabetes (T2D) in children has increased by 30.5% in U.S from 2001 to 2009 (1). This increase is associated with the childhood obesity epidemic, as increased adiposity is a major risk factor for T2D. One in 5 children meet the diagnostic criteria for prediabetes, which is associated with increased lifetime risk for diabetes and diabetes-related complications (2). Prediabetes is defined as one or any combination of the following: impaired fasting glucose (IFG 100-125mg/dL); impaired glucose tolerance (2-hour blood glucose 140 – 199 mg/dL for oral glucose tolerance test); elevated glycated hemoglobin A1c (HbA1c 5.7-6.4%) (3). If prediabetes progresses to T2D, children's blood sugar can be difficult to control leading to diabetes-related complications and reduced life expectancy (4). The progression from prediabetes to T2D could possibly be slowed or prevented by improving children's eating habits, increasing physical activity, and/or decreasing childhood obesity (5). It is a disease that disproportionately impacts marginalized, minority race/ethnicity, low-income youth (6).

A few previous studies, such as the healthy lifestyle program at Yale, have shown an association between changes in children's lifestyles and decreased severity or number of risk factors for T2D (7). Although it is evident that healthy lifestyle interventions should be further studied for diabetes prevention in youth (8-9), there are several barriers to implementing these types of interventions, such as lack of physical activity places for children, healthy food availability, family socioeconomic status, and surroundings for marginalized populations(10).

Effective prevention strategies that target at-risk low-income youth are of vital importance and innovative strategies are needed to explore effective T2D prevention modalities in this understudied and vulnerable population. Previously, we translated the National Diabetes Prevention Program for use with families (ENCOURAGE Healthy Families) (11-12) and found this to be beneficial for reducing BMI in youth. As a next step, we co-designed, with youth and families, a community-based lifestyle program called "PowerHouse". The purpose of this study was to assess the effects of implementing the co-designed PowerHouse program, on both clinical and quality of life outcomes in high-risk, low-income youth and their caregivers.

Chapter Two: Methodology

Study population

The study was approved by the Indiana University the Institutional Review Board (IRB). Participants were eligible if the child's age was between 7-18 years, they met criteria for overweight (BMI was ≥85th percentile for age and sex), and they had two or more additional risk factors for T2D: 1) family history of T2D in a first- or second-degree relative, 2) history of maternal gestational diabetes, 3) belonging to a minority race/ethnicity, 4) physical signs of insulin resistance as assessed by a physician. At least one caregiver (parent or guardian) was required to participate in the program with the youth participant. All the adult participants (≥18 years old) signed informed consent and youth participants signed informed assent prior to study participation.

PowerHouse Program Description

The PowerHouse program is a 16-week program, with 2 hours of in-person meeting time per week. This program is based on the tenants of the National Diabetes Prevention Program (DPP) (13) and guided by the findings of human-centered design (HCD) sessions (14). Community partners offered indoor and outdoor physical activity space, space and appliances for cooking, a shared meal, and meeting space. The PowerHouse intervention was based on social cognitive theory (15),and designed to provide access to facilities and personnel to facilitate learning and participating in self-

care and life skills including cooking, recipe modification, gardening, physical activity, and mindfulness activities for both children and their caregivers. There was a slight modification to the intervention during the study designed to help improve participants' satisfaction (and thus attendance) with the program. Participants were provided greater access to fresh produce in partnership with a local community program.

There were two primary outcomes for the youth in this study: 1) BMI standard deviation score (also called BMI *Z*-score); and 2) BMI percentile at each follow-up assessment. The primary outcome for the caregivers was percent change in body weight at each follow-up assessment. Secondary outcomes included: 1) changes in glycemia measured with hemoglobin A1c (both youth and caregivers); 2) changes in self-report physical activity (youth only); and 3) global health status and quality of life: Pediatric Quality of Life Inventory for youth (via self-report and caregiver proxy) and SF-36 for the caregiver; 4) Program attendance rates.

Outcome Measures

Data were collected at baseline, 6 months, and 12 months by trained research coordinators who entered the data into a Research Electronic Data Capture (REDCap) system, a secure internet application for building and managing online surveys and databases (16).

Height was measured to the nearest 0.1 cm using a stadiometer (SECA Model 213 1821009). Weight was measured to the nearest 0.1 kg with a digital scale (Healthometer

Professional Model 349KLXN, Dectecto Scale Model 758C). Study staff calculated BMI using National Institutes of Health online BMI calculator (https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi-m.htm) or the Centers for Disease Control online BMI percentile calculator for children and teens https://www.cdc.gov/healthyweight/bmi/calculator.html) and calculated BMI standard deviation using Children's Hospital of Philadelphia website (https://zscore.research.chop.edu/resultbmi.php). HbA1c was assessed through point-of-care testing (Alere Afinion AS100 machine, Alere, Orlando, FL).

Physical activity and quality of life outcomes were collected by paper surveys completed by the youths using the Fels Physical Activity Questionnaire for Children (Fels PAQ) and Pediatric Quality of Life Inventory (PedsQL). The Fels PAQ measures sports, leisure, and work physical activity for youth 7-18 years and includes a total score. Higher scores indicate greater physical activity. The PedsQL has age-appropriate measures (PedsQL 8-12 and PedsQL 13-18 years old) and parallel proxy measures obtained from their caregivers. The range of scores is 0 to 100 with higher scores indicating better quality of life. Lastly, the 36-Item Short-Form Health Survey (SF-36) is composed of 36 items and has two component scores (Physical and Mental) and 9 subscales (physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional, mental health, and health transition). The range of scores is 0-100 with higher scores indicating better health status.

Attendance data was collected at 6 months as a percent of possible sessions attended calculated.

Statistical analysis

All data analysis was conducted using SAS version 9.4 (SAS Institute, Inc., Cary, NC). To assess for bias due to dropout, two-sample *t*-tests were used to compare participants who completed baseline and both follow-up time points with those who completed baseline and only one follow-up timepoint.

Linear mixed effect models with random effects were used to estimate the change of the outcomes over time in participants enrolled in the intervention program using a participant-nested-within-family random effect to allow for both the repeated measures over time and the correlation between multiple participants within a family. Separate models were fit for youth and caregivers. Time was treated as a categorical variable in the model with baseline as a reference.

$$Y = X\beta + Zb + \varepsilon$$

$$b \sim N(0, G)$$

$$\varepsilon \sim N(0, R)$$

The model included a fixed effect for time and random intercept for participant-nested within-family with unstructured correlation for the random intercept. ε was a vector of Normally-distributed random error. Y was independent outcomes, XB the regression parameter and design matrix association with time and Zb is the random effect and design matrix for the random effect for participant-nested-within-family. G and R were the variance matrices for b and ε, respectively. For each model fit, the residuals were checked for normality using a quantile - quantile plot. If the overall test for time was significant

in the linear mixed models, pairwise t-tests were conducted within the linear mixed model to see which time points differed. For subscales, we also adjusted the overall p-value for multiple testing using the Bonferroni approach. For percent change in weight for the caregiver, 6- and 12-month percent changes were tested for equality to zero using one-sample *t*-tests. For attendance, descriptive statistics were generated and attendance before vs after the intervention modification was compared using a two-sample *t*-test.

Chapter Three: Results

Sample

In this study, all families included at least one caregiver and one youth who had a baseline assessment and at least one follow-up assessment. The sample included 56 families with 65 caregivers and 78 youth. Forty-eight families had 1 caregiver enrolled, 7 families had two caregivers enrolled, and one family had three caregivers enrolled. Forty families had 1 child enrolled, 11 had two, 4 had three, and one had four. Of the 78 youth, 43 were between 8 and 12 years old and 34 were between 13 and 18 years old, and one child was less than 8 years old.

The average age of the youth was 12.9 years, 67.1% were female, and 32.9% were male; 37.8% were white, 35.6% were black, 4.9% were Latino and 21.7% were other races. When we compared those with 12-month follow-up to those who completed only 6-month follow-up, we found there were no differences between two groups (see Table A1 in the Appendix).

Intervention Effects for Clinical Outcomes

In the linear mixed models, the residuals for all the clinical outcomes were normally distributed except the BMI percentile scores for youth. Ninety-six percent of the BMI percentile values were greater than 90%, with 57.5% of the BMI percentile values being exactly 99% and 3.9% being >99%. Over the course of the study, BMI

percentile score decreased for 13 youth and did not change or increased for 51 youth. Given the lack of variation in this outcome, no statistical analyses were conducted.

For the normally distributed outcomes, there were no changes over time observed for BMI *Z*-score of youth, but for HbA1c in youth there was an overall time effect (p-value = 0.0447). Post hoc *t*-tests indicated the 6-month mean did not differ from baseline (p-value = 0.7168), but the 12-month mean was lower than baseline (p-value = 0.0357). The 12-month mean was also lower than the 6-month mean (p-value = 0.0199). The percent change in body weight at each follow-up assessment for the caregivers was not different from zero at either 6-months (p-value = 0.1294) or 12-months (p-value = 0.5889), nor were they different from each other (p-value = 0.5211). Descriptive statistics for the four outcomes are shown in Table 1.

Table 1: Clinical Outcomes

Variables	**Time Point**						**P-value[1]**	
	Baseline		6 months		12 months		Unadjusted	Adjusted
	N	Mean ± SD	N	Mean ± SD	N	Mean ± SD		
BMI *Z*-score, youth	78	2.26±0.47	57	2.25±0.52	44	2.16±0.58	0.4581	1.000
HbA1c(mmol/mol), youth	**76**	**5.3±0.3**	**57**	**5.3±0.3**	**45**	**5.2±0.3**	**0.0447**	**--**

							B,12: t=-2.13, p=0.0357 **6,12:t=2.37, p=0.0199**	
HbA1c(mmol/mol), caregiver	62	5.6±1.1	46	5.7±1.2	35	5.8±1.6	0.8011	1.000
Percent Change in Bodyweight, caregiver	-	-	47	0.66±7.07[2]	34	0.72±3.19[2]	0.5211	1.000

SD = standard deviation
[1]From the linear mixed model. [2]Not different from zero based on one-sample t-test.

Intervention Effects for Quality-of-Life Outcomes

In the linear mixed models, the residuals for all quality-of-life outcomes were normally distributed. Table 2 displays the means and standard deviations over time. The FELS PAQ Work Index, Leisure Index, and Total score did not change over time for youth, but the Sport Index score indicated an overall time effect (adjusted p-value = 0.0213). Post hoc *t*-tests indicated the 6-month mean was greater than baseline (p-value = 0.0044), and the 12-month mean was lower than the 6-month mean (p-value = 0.0100). The 12-month mean was not different than baseline (p-value = 0.9289). PedsQL measures from youth showed improvements over time for Physical Summary (p-value = 0.0407).

Post hoc *t*-tests indicated the 6-month mean was not different than baseline (p-value = 0.7448), but the 12-month mean was greater than baseline (p-value = 0.0156) and the 6-month mean (p-value = 0.0397). Similarly, the Psychosocial Summary also improved over time (p-value = 0.0167) with improvements from baseline to 6 month (p-value = 0.0330) and baseline to 12-month (p-value = 0.0084) but no difference between 6- and 12-month (p-value = 0.4778). Lastly, the Total Scale also indicated improvement over time (p-value = 0.0094). Post hoc *t*-tests indicated the 6-month mean was not different than baseline (p-value = 0.1252), but the 12-month mean was greater than baseline (p-value = 0.0024) and 6-month (p-value = 0.0024). There were no changes observed for the Emotional, Social, or School subscales after adjusting the p-values for multiple testing. For the PedsQL parent proxy, measures did not indicate any change over time though there was a pattern of improved scores over time similar to that seen in the youth. Likewise, the Short-Form Health Survey (SF-36) for the caregivers also did not indicate change over time.

Table 2: Quality of Life Outcomes

	Variables	Baseline		6 months		12 months		P-values[1]	
		N	Mean ± SD	N	Mean ± SD	N	Mean ± SD	Unadjusted	Adjusted
FELS PAQ	Total Score	78	2.78 ± 0.65	57	2.79 ± 0.87	45	2.79 ± 0.53	0.0791	--
	Sports Index Score	**78**	**2.73 ± 0.87**	**57**	**3.04 ± 0.89**	**45**	**2.74 ± 0.91**	**0.0071** **B,6: t=2.92, p=0.0044** **6,12: t=2.63, p=0.0100**	**0.0213**
	Leisure Index Score	76	2.03 ± 0.83	57	2.06 ± 0.82	44	2.19 ± 0.84	0.4581	1.0000
	Work Index Score	78	3.62 ± 1.07	57	3.79 ± 0.87	45	3.43 ± 1.01	0.1872	0.5616
PedsQL (child)	**Physical Summary, youth**	**74**	**75.60 ± 16.83**	**57**	**77.19 ± 16.03**	**44**	**80.35 ± 12.87**	**0.0407** **B,12: t=2.46, p=0.0156**	**--**

							6,12: t=-2.08, p=0.0397	
Psychosocial Summary, youth	**74**	**62.42 ± 18.90**	**57**	**68.92 ± 16.35**	**44**	**69.71 ± 16.91**	**0.0167** **B,6: t=2.16, p=0.0330** **B,12: t=2.69, p=0.0084**	**--**
Emotional subscale, youth	74	61.05 ± 23.12	57	65.02 ± 21.32	43	64.48 ± 23.65	0.1992	0.5976
Social subscale, youth	73	67.18 ± 26.25	57	72.93 ± 21.98	42	75.05 ± 17.02	0.0449	0.1347
School subscale, youth	73	65.41 ± 20.85	57	68.77 ± 18.38	43	68.66 ± 19.96	0.3459	1.0000
Total Score, youth	**74**	**68.45 ± 17.08**	**57**	**71.80 ± 13.70**	**44**	**73.44 ± 14.26**	**0.0094** **B,12: t=3.12, p=0.0024**	**--**

PedsQL (parent)	Physical Summary, parent	76	68.54 ± 20.72	56	69.53 ± 20.81	45	73.74 ± 20.01	0.4073	--
	Psychosocial Summary, parent	76	64.45 ± 16.95	56	65.30 ± 13.51	45	68.06 ± 15.36	0.1275	--
	Emotional subscale, parent	76	61.44 ± 21.94	56	63.13 ± 21.05	45	64.89 ± 19.20	0.1380	0.4140
	Social subscale, parent	75	67.87 ± 24.47	56	67.23 ± 19.35	44	72.33 ± 20.53	0.1834	0.5502
	School subscale, parent	74	63.40 ± 20.86	56	65.54 ± 18.16	43	67.47 ± 21.18	0.2204	0.6612
	Total Score, parent	76	65.73 ± 16.50	56	66.79 ± 13.86	45	70.12 ± 15.09	0.1715	--
SF-36	Physical Component Scale	51	43.01± 9.77	33	45.55 ± 9.39	26	43.76 ± 10.86	0.2578	--
	Mental Component Scale	51	35.77 ± 9.46	33	36.66 ± 7.43	26	36.79 ± 8.03	0.6229	--
	Physical Functioning Scale	65	72.60 ± 31.40	48	73.07 ±2 7.74	36	71.58 ± 30.88	0.9242	1.0000

Role Physical Scale	65	16.92 ± 9.91	48	17.66 ± 10.10	36	17.71 ± 9.03	0.5274	1.0000
Bodily Pain Scale	64	57.86 ± 26.88	48	64.44 ± 25.09	36	60.44 ± 28.83	0.0572	0.1716
General Health Scale	65	59.43 ± 21.78	48	62.43 ± 22.16	36	60.39 ± 22.81	0.2487	0.7461
Vitality Scale	63	48.97 ± 26.46	48	49.48 ± 27.60	35	50.18 ± 25.15	0.8089	1.0000
Social Functioning Scale	65	77.12 ± 24.86	48	82.55 ± 20.26	36	83.68 ± 18.86	0.1545	0.4635
Role Emotional Scale	65	18.33 ± 9.34	48	20.49 ± 7.48	36	18.29 ± 8.41	0.2787	0.8361
Mental Health Scale	51	65.10 ± 20.15	33	69.24 ± 14.20	26	65.75 ±18.09	0.2308	0.6924
Health Transition Item	64	2.61 ± 1.06	48	2.60 ± 1.03	36	2.72 ± 0.81	0.6760	1.0000

SD = standard deviation

[1]From the linear mixed model.

Program attendance

There were 16 possible sessions for the Intervention. Eight families did not attend the sessions program at all. Table 3 provides the descriptive statistics of the attendance overall and before and after the modification. Overall, participants attended about one-half of the sessions, and there was an improvement in session attendance after the modification was made from less to 6 sessions on average to almost 9 sessions on average ($p = 0.0002$).

Table 3: Intervention Session Attendance

variable	N	Mean ± SD	Median	Minimum	Maximum
Sessions attendance overall	142	7.18 ± 5.19	7.5	0	16
Sessions attendance prior to intervention modification	80	5.79 ± 5.10	4	0	14
Sessions attendance after intervention modification	62	8.98 ± 4.78	9	0	16

SD = standard deviation

Chapter Four: Conclusion

Youth at risk for T2D often have limited access to healthier meals and snacks, space for physical activity, and support for making beneficial lifestyle changes associated with diabetes prevention. Previously, we translated the National Diabetes Prevention Program for use with families using a community-engaged, participant co-design strategy to allow greater community stakeholder participation in the process of developing an intervention called "PowerHouse". The aim of the present study was to assess clinical and quality of life effects of implementing the co-designed PowerHouse program for youth and their caregivers. We found that participating youth with overweight/obesity and multiple risk factors for T2D at baseline had no change in BMI z-score and a slight decrease in HbA1c during the course of the 12-month study. They had improved quality of life indices for Sports index, Physical summary, Psychosocial summary, and the total score.

The finding of stable BMI z-score over the course of 12 months among participants can be considered clinically relevant. It may be argued that this is a positive finding, given the upward trajectory of BMI in adolescents with obesity. Often the initial goal of weight management is to reverse the trajectory of weight gain to weight maintenance. Moreover, there is ample evidence that adolescents in the age group of this study do not have great success with weight loss; however, risk factors for diabetes may still improve with lifestyle change.

There was some improvement seen based on child HbA1c and child reported outcomes. Child HbA1c was lower at 12 months compared to baseline. HbA1c was not clinically elevated at baseline in most participants. It may be beneficial to intervene in

patients with a strong family history and multiple risk factors for type 2 diabetes before they have elevated blood glucose, as interventions to date have had mixed results for preventing the progression of prediabetes to diabetes (17-18).

The findings of increased quality of life indices, including increased physical, psychosocial, and total score is encouraging. The Sports Index from the Fels PAQ showed more physical activity at 6 months compared with baseline, but the increase was temporary because the 12-month time point was not different from baseline. Continuous engagement is needed to keep youth involved in physical activities over time. It is important that youth are able to release their energy in safe places. For PedsQL, the youth-reported Physical Summary, Psychosocial Summary, and Total score all indicated improvements over time. This was not seen in the parent proxy reports; however, it could be argued that the youth perspective of their own quality of life is more relevant that parent perspective. Access to social engagement and physical activity may help to improve or at least stabilize mental health and quality of life. This is especially in youth given the decline in mental health being observed (19-20).

While these results are encouraging, implementing a healthy lifestyle for youth is not easy and it make take a longer time to adapt new habits to their life, especially for some of the clinical outcomes. Thus, this study may have significant impact on youth and their caregivers but 12 months may not have been long enough to see the full change. In addition, it was not assessed what happens when the intervention ends. More ongoing engagement may be needed to ultimately decrease risk factors for type 2 diabetes in youth. For physical activity, perhaps it would be helpful to have a booster intervention

after 6-months based on the fact that the Sport Index improved at 6-months but returned to baseline by 12-months.

A limitation of this study is that there was no control group so that the natural changes in youth count be accounted for. There was also dropout over time. While we did not see any baseline differences between those with complete data versus those that did not complete the 12-month time point, it is still possible that there could be some bias due to dropout. It may be that the improvement seen (both statistically significant and not) reflect that those who were benefiting from the program were more likely to complete it.

Appendix A:

Table A1. Comparison of demographical characteristics of participants by follow-up status:

Characteristics		Overall		Lost to follow up at 12-month	Completed 12-month time point	P-value
		Miss-ing	Non-miss-ing	Mean ± SD	Mean ± SD	
BMI *Z*-score, youth		33	45	2.35 ± 0.44	2.19 ± 0.48	0.1411
HbA1c, youth		31	45	5.21 ± 0.27	5.30 ± 0.33	0.2142
HbA1c, caregiver		28	34	5.57 ± 1.05	5.59 ± 1.13	0.9503
Weight, caregiver		30	34	103.0 ± 24.52	101.7 ± 22.69	0.6634
FELS PAQ	Sports Index Score	33	45	2.69 ± 0.87	2.77 ± 0.88	0.6916
	Leisure Index Score	33	43	2.02 ± 0.91	2.03 ± 0.77	0.9188
	Work Index Score	33	45	3.68 ± 1.07	3.57 ± 1.09	0.5993
	Total Score	33	45	2.79 ± 0.73	2.78 ± 0.59	0.9109
	Physical	32	42	76.19 ± 15.38	75.15 ± 17.35	0.7949

PedsQL (youth)	Emotional	33	41	60.95 ± 21.32	61.13 ± 24.74	0.9736
	Social	33	40	66.09 ± 27.76	68.08 ± 25.26	0.7504
	School	32	41	62.85 ± 21.86	67.41 ± 20.06	0.3577
	Psycho-social Summary	32	42	63.68 ± 18.04	64.99 ± 19.72	0.7706
	Physical Summary	32	42	76.19 ± 16.38	74.15 ± 17.35	0.7949
	Total child	32	42	68.34 ± 16.41	68.53 ± 17.78	0.9620
PedsQL (youth)	Physical parent	32	44	65.23 ± 24.49	70.9 5± 19.24	0.2374
	Emotional parent	32	44	62.24 ± 24.90	60.85 ± 19.80	0.7876
	Social parent	32	43	68.13 ± 25.33	67.67 ± 24.11	0.9378
	School parent	32	42	62.97 ± 22.14	63.72 ± 20.10	0.8792
	Psycho-social Summary parent	32	44	64.76 ± 19.05	64.22 ± 15.47	0.8927
	Physical Summary parent	32	44	65.23 ± 22.49	70.95 ± 19.24	0.2374

	Total	32	44	64.58 ± 18.15	66.57 ± 15.35	0.6067
SF-36 (care-giver)	Physical Function-ing Scale	29	36	70.04 ± 33.79	74.65 ± 29.65	0.5604
	Role Physical Scale	29	36	18.32 ± 8.93	15.80 ± 10.62	0.3116
	Bodily Pain Scale	29	35	57.07 ± 27.70	58.51 ± 26.57	0.8324
	General Health Scale	29	36	59.72 ± 23.49	59.19 ± 20.64	0.9233
	Vitality Scale	30	33	47.92±26.17	49.94±27.08	0.7648
	Social Function-ing Scale	29	36	73.71 ± 25.52	79.86 ± 24.33	0.3250
	Role Emotional Scale	29	36	18.10 ± 9.73	18.52 ± 9.15	0.8603
	Mental Health Scale	30	21	66.11 ± 20.44	63.65 ± 20.13	0.6722
	Health Transition Item	29	35	2.69 ± 0.97	2.54 ± 1.15	0.5865

Physical Component Scale	30	21	42.72 ± 9.31	43.42 ± 10.61	0.8038
Mental Component Scale	30	21	36.37 ± 8.99	34.92 ± 10.27	0.5961

SD = standard deviation

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