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A cluster randomized controlled trial of the effectiveness of a Parents Plus group-based parenting program to promote healthy lifestyles among children and their families

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Abstract

Background Childhood obesity is a global public health concern. In Ireland, the age standardized prevalence rates for obesity in children and adolescents are about 1% higher than the average for countries in the WHO European Region. The Parents Plus Healthy Families program (PP-HF), an 8-week, group-based, multicomponent parent training intervention, was designed to prevent childhood obesity by helping parents promote healthy habits within their families.

Methods A multisite cluster randomized controlled trial was conducted to investigate the effectiveness of the PP-HF program across 16 community-based and clinical settings. Sixty-eight parents were assigned to the PP-HF group and 70 were assigned to the treatment as usual (TAU) control group. Parents completed measures assessing healthy habits, child lifestyles behaviors, parental lifestyle-specific self-efficacy, parental satisfaction, family dysfunction, and child behavior problems at baseline and post-intervention. Parents in the PP-HF group completed measures at 6-weeks follow-up.

Results Multi-level modelling analyses demonstrated that post-intervention, compared to the control group, parents in the PP-HF condition reported significant improvements on measures of healthy habits, parental satisfaction, family-functioning, and child behavior problems. Gains were maintained at 6-weeks follow-up. No change was observed on measures of child lifestyle behaviors, or parental lifestyle specific self-efficacy compared to the control group.

Conclusion The PP-HF program may be effective in improving healthy habits, parental satisfaction, family functioning, and child behavior problems among families with children aged 2–12 across both clinical and community settings.

Trial registration This trial was retrospectively registered on Open Science Framework on 11.th April 2023. Registration DOI: <https://doi.org/https://doi.org/10.17605/OSF.IO/4PY63>

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Text box 1. Contributions to the literature

- Although multi-factorial lifestyle interventions are recommended for children with overweight and obesity, most interventions target only diet and/or physical activity. Furthermore, most interventions target children who already have obesity, when early intervention may be more efficacious.
- Our study showed that a multi-faceted parent training preventative intervention that can be delivered in both clinical and community settings was associated with positive lifestyle changes, and positive family and child level outcomes.
- More research is needed to understand if this intervention is most effective in clinical or non-clinical populations.

Background

Childhood obesity and overweight are a growing public health concern. Globally, the prevalence of childhood obesity increased tenfold between 1975 and 2016 [1]. In Ireland, overweight and obesity among children aged 5–12 years increased from 12% in 1990 to 25% in 2005 and decreased again to 16% in 2019 [2]. Similar plateaus have been seen across other European countries [3], however, these tend to be temporary, and globally childhood obesity levels are increasing exponentially [4]. Compared with the average for countries in the WHO European Region, in Ireland there are higher age standardized prevalence rates for obesity in children (12.5% vs. 11.6%) and adolescents (8.2% vs. 7.1%) [4].

These trends are based on the World Health Organization's method for defining obesity as a chronic, complex disease characterized by excessive adiposity for which Body mass index (BMI) is a marker [4]. BMI is calculated as weight in kilograms divided by height in meters squared. For young people under 18 years, BMI categories for defining obesity vary by age and gender, based on WHO growth charts. Children aged 0 to 5 years have obesity if their BMI is more than 3 standard deviations above the median. For children and adolescents aged 5 to 19 years, a BMI more than 2 standard deviations above the median (or the 95th centile) is the diagnostic criterion for obesity.

Childhood overweight and obesity contribute significantly to the global burden disease [5], increasing the risk of numerous health conditions, including type 2 diabetes, cardiovascular disease, and certain types of cancer [6]. Obesity and overweight in childhood have also been linked to increased prevalence of mental health difficulties and lower levels of self-esteem [7]. The development of over-weight, obesity and obesity-related behaviors and risk of related health conditions have been shown to strongly persist into adulthood [8]. BMI reduction outcomes of obesity interventions in adulthood tend to be poor [9]. Hence, the recent increased emphasis on managing obesity as a chronic disease and focusing on

improving quality of life, function, and health in obese adults [4]. Health-related habits are developed and laid down in early childhood [10], indicating that childhood is a pivotal time for early intervention for the treatment and prevention of overweight and obesity [2].

The development of childhood obesity is complex arising from an interplay of genetic, environmental, social, and family-level factors [11]. Family wellbeing, characterized by a low level of family stress, authoritative parenting, and parental reinforcement of healthy habits is a protective factor in preventing obesity [11, 12]. This provides a rationale for preventative childhood obesity interventions that aim to improve family wellbeing as an aspect of healthy family lifestyles. Several high-quality systematic reviews [13–16] indicate that the most effective interventions for the treatment and prevention of childhood obesity are parent or family-focused and multi-faceted, targeting meals, physical activity, and behavioral change. An umbrella review of Cochrane reviews of interventions for the treatment of pediatric obesity concluded that intensity of parental involvement and parents' role as role-models may be important determinants of effective weight management interventions [14]. However, despite evidence for the effectiveness of multi-component interventions, a review of the content of parent-based interventions [17] found that most studies targeted diet (90%) and physical activity (82%), while media use (55%) and sleep (20%) were less frequently targeted. Only 16% of 119 interventions included in the review targeted all four behavioral domains [17].

In Ireland, the new public Health Service Executive (HSE) model of care for the management of childhood overweight and obesity [18] recommends enhanced parenting programs as part of a tiered approach to treatment and prevention. Indeed, parent only interventions may be more cost-effective than interventions that involve the whole family [19, 20] while being equally effective [19, 21]. Multi-component parent-only interventions may thus represent a beneficial and cost-effective way of managing childhood overweight and obesity [19, 20]. Although the HSE guidelines specifically recommend enhanced parenting programs for the management of pediatric obesity, there is a dearth of evidence on the existence and efficacy of such programs in Ireland. High quality evidence on the efficacy of such interventions in an Irish context is crucial to the implementation and evidence base of this new care model.

The Parents Plus (PP) programs are a suite of evidence-based, group-based parent training interventions designed to enhance family wellbeing and parent–child relationships of families in community and clinical and settings [22]. The PP Healthy Families program (PP-HF) is a preventative group-based parenting program which

targets factors that contribute to obesity and overweight in Irish children. The PP-HF program combines dietary, behavioral, and physical activity elements as well as strategies aimed at aiding sleep, emotional well-being, and technology use. To facilitate parental self-regulation and mindful parenting, in the PP-HF program parents also learn mindfulness skills. The program involves eight weekly, two-hour group sessions and is delivered by pairs of trained co-facilitators across a range of settings. A pilot study of the PP-HF program [23], summarized in supporting information, which included 42 families, showed that it was highly acceptable to parents and resulted in positive changes in healthy habits, children's lifestyle problems, parents confidence in changing children's lifestyle behaviors, parental satisfaction, child behavior problems, and child prosocial behavior when delivered in-person or online.

The current study was a cluster randomized control trial (RCT) that aimed to evaluate the effectiveness of the PP-HF program in promoting healthy habits and other positive outcomes. Specifically, the RCT aimed to investigate if the 8-week PP-HF program led to significant improvements on outcome measures of healthy habits, parental satisfaction, family dysfunction and child behavior problems compared to a treatment as usual (TAU) control group. The PP-HF group also completed outcome measures six weeks after the PP-HF program to assess if gains were maintained at follow-up.

Based on the aims outlined above, the study addressed the following three research questions:

- (1) Is participating in the PP-HF program associated with increased healthy lifestyle behaviors among families compared to a TAU control group?
- (2) Is participating in the PP-HF program associated with positive increases in parental satisfaction, family functioning and child behavior problems compared to a TAU control group?
- (3) Are positive outcomes among families maintained six weeks after the PP-HF program has been completed?

Method

Study sites and context

Sixteen agencies were recruited through Parents Plus. Fifteen were based in Ireland and one agency was based in the UK. The agencies recruited in Ireland included three public health service primary care centers, two public health service children's disability network teams, two schools for disadvantaged children, six family resource centers, one child protection agency, and a free national online service for parents. The UK service was a community-based child and family agency. Participating

agencies received program materials, training, and supervision free of charge from Parents Plus.

Ethical approval

Ethical approval for this study was granted by the UCD Human Research Ethics Committee (ref HS-21-79) and the Public Health Service Executive South-East Research Ethics Committee.

Study design

This study was a parallel cluster-randomized non-blinded control trial. There were two groups: an intervention group who attended the 8-week PP-HF program and a control group who received TAU. Fourteen of the 16 agencies contributed one cluster to the design, and two agencies each contributed two clusters. From this set of 18 clusters, nine were randomized to the PP-HF intervention condition and nine to the TAU control condition. Within this design, a case referred to a parent who wanted to improve healthy habits in their family. If two parents from the same family took part in the study, only data from one randomly selected parent was included as a case. In fact, this only occurred in a single case.

Participants in both groups completed self-report assessment instruments at baseline and post-intervention when the 8-week PP-HF program had concluded. The intervention group was also assessed at six to eight weeks follow-up. Families assigned to the TAU control group were offered a place in the PP-HF program once they had completed their post-intervention questionnaire. This was offered for ethical reasons, and was not part of the study design. For this reason, parents in the control group were not assessed at follow-up.

This trial was non-blinded. The researchers, facilitators in the participating agencies, and the participants themselves were aware of whether participants were in the intervention or control arm. The researchers were not involved in administering the outcome measures to participants nor were they involved in facilitating any of the intervention groups.

Randomization

A total of 18 clusters from 16 participating agencies were assigned to matched pairs and then randomized to the intervention or control groups using a coin flip method. Randomization for the first phase of the data collection took place in December 2021 and for the second phase of data collection in July 2022. The coin flip was carried out by two members of the project team (COD and BD) using a coinflip website [24]. Pairs of agencies were matched on a pragmatic basis within the context of limited resources of time and funding of the trial. Effort was made to group agencies that serve similar populations together, such as

matching public health primary care centers with one another and matching family resource centers to one another. A description of each of the agencies in the nine matched pairs is outlined in Table S1.

Participants

To determine sample size, a power analysis was conducted using G*Power 3.1 [25]. The power analysis showed that a minimum total sample size of 128 would be required to detect a medium effect size ($d=0.5$), significant at $p < 0.05$, with a power of 0.8, in a 2 X 2, Groups X Time design with multiple dependent variables. With an allowance for attrition a total of 138 cases were

recruited and randomized, 68 to the PP-HF group and 70 to the TAU group.

Eligibility criteria were parents/guardians with at least one child aged between 2–12 years who wished to increase the extent to which their families engage in healthy lifestyles. Exclusion criteria were parents/guardians with no children aged between 2–12. The flow of participants through the study is shown in the CONSORT flow diagram, Fig. 1 [26]. Participants included both self-referred parents who wanted to engage in a healthy lifestyle intervention, and parents who were offered the PP-HF program while their children were on waiting lists

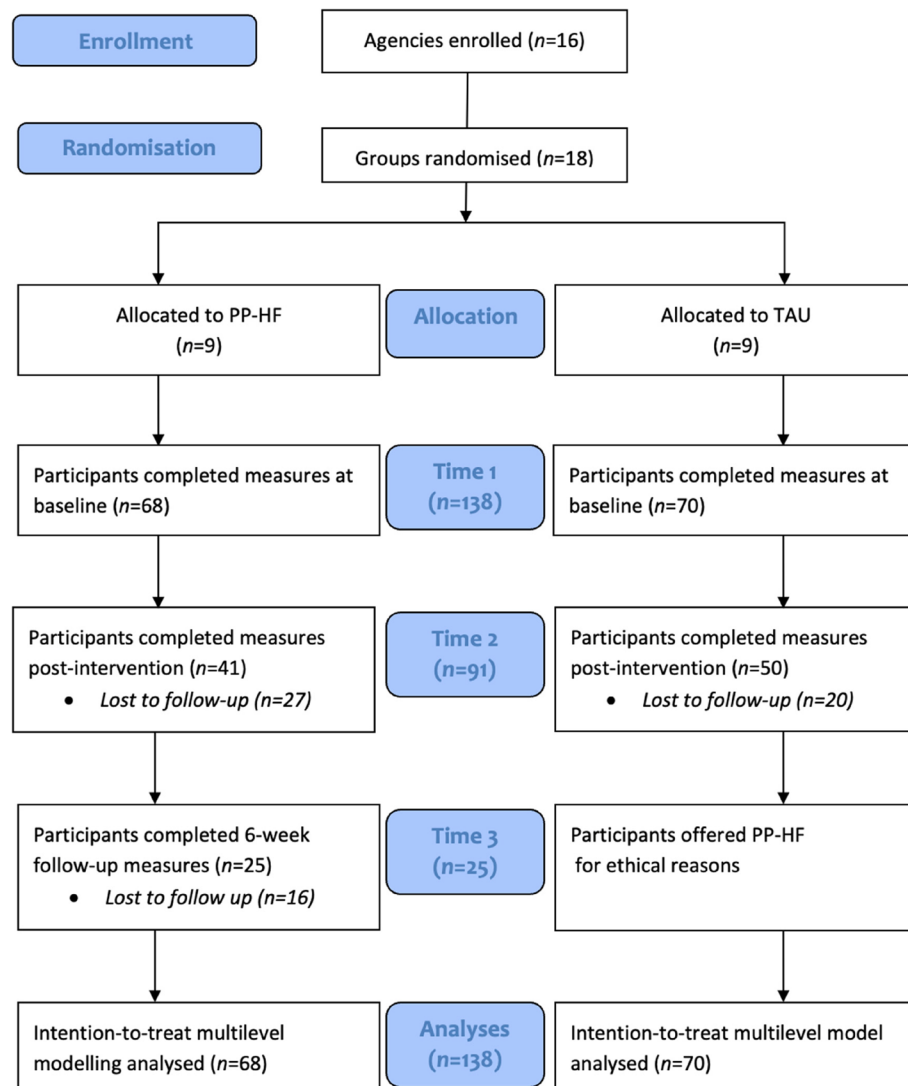


Fig. 1 Participant flow through the study. Agencies are organizations from which participants were recruited. Groups are groups of 6–12 parents who received PP-HF or TAU. PP-HF is the Parents Plus Healthy Families program. TAU is treatment as usual. Only one parent per child was included in the analysis

for other services that addressed children's emotional and behavioral difficulties.

Assessment protocol

Psychometric measures used in the assessment protocol are outlined below. Cronbach's alpha reliability coefficient on all total scale scores exceeded 0.70, which is the cut-off for acceptable reliability [27].

Demographic questionnaire

This 11-item instrument was designed to gather information on family demographics including age and gender of family members, parental relationship status, employment status, occupation, and ethnicity.

Healthy Habits Questionnaire (HHQ) [28] assesses healthy family behaviors in multiple domains. It includes items such as "My children get active" and "We sit down together as a family to eat meals." Parents rated items on a 3-point scales from 0 (rarely) to 2 (mostly). There are 48 and 23 item versions of the HHQ. The 23-item version was developed from the 48-item version using factor analysis. The HHQ-48 contains items in the following eight a priori domains: parent empowerment, family connection, healthy food routines, healthy meals, active play, managing technology, restful sleep, and healthy and happy mind. The HHQ-23 includes items in the following four factor scales: screens and routines, activity, parent-child connection, and healthy food / good example. Ranges for total scores on the 48 and 23 item versions of the HHQ are 0–96 and 0–46 respectively, with high scores indicating healthier behavior. Both versions of the HHQ have good overall reliability and construct validity. However, the short version also has factorial validity [28].

Lifestyle Behavior Checklist (LBC) [29] is a 25-item measure that yields a total problem score that reflects parental perceptions of their children's over-weight and obesity-related behaviors including eating, screen-time, and physical activity and a total confidence score, reflecting parents' self-efficacy in dealing with these behaviors. On the problem scale, parents rated the extent to which a behavior is a problem for them on a scale from 1 (not at all) to 7 (very much). Items include "watches too much television" and "refuses to do physical activity." On the confidence scale, parents rated how confident they are dealing with the problem behavior from 1 (Certain I can't do it) to 10 (Certain I can do it). The clinical cut-off values for the LBC problem scale are scores greater than 50 (range=25–175), and high scores indicate greater problems [28]. For the LBC confidence scale, the clinical cut-off are scores under 204 (range=25–250) and low scores indicate less parental confidence [28]. The LBC has been shown to have high internal reliability [29–31] and good

consistency with other child behavior and parent measures [29, 31].

Kansas Parental Satisfaction Scale (KPS) [32] is a 3-item parent self-report scale that measure parents' satisfaction with themselves as a parent, the behavior of their children, and their relationship with their children. Parents responded to each item on a seven-point scale ranging from 1 (extremely dissatisfied) to 7 (extremely satisfied). Items are summed to generate a total parental satisfaction score ranging from 3–21 with higher scores indicating greater satisfaction. A clinical cut-off score of 15 or less (range=3–21) has been suggested to indicate low parental satisfaction [33]. An example of a KPS item is "How satisfied are you with yourself as a parent?" The KPS has been found to have adequate internal consistency and criterion validity in a series of studies [33].

Systemic Clinical Outcome and Routine Evaluation-15 (SCORE-15) [34] is a 15-item self-report scale that yields an overall family dysfunction score and scores on subscales that assess family strengths, difficulties, and communication. Parents rated items on six-point scales ranging from 1 (describes my family extremely well) to 6 (that does not describe my family at all). Items include "Each of us gets listened to in our family" and "It feels miserable in our family." Negatively worded items are reversed, and the items are summed and divided by the total number of items to obtain a total mean score ranging from 1–5, with high scores indicating greater family dysfunction. A systematic review [34] indicated that the SCORE-15 has high test-retest reliability and satisfactory internal reliability. The clinical cut-off for the SCORE-15 total was reported as 2.92 in a norming study of 403 Irish parents [35].

Strengths and Difficulties Questionnaire parent version (SDQ) [36, 37] is a 25-item instrument that assesses child behavior problems and prosocial behavior and among children aged 2 to 16 years. Parents rated their agreement with each of the 25 items on a three-point scale from 0 (not true) to 2 (certainly true). The total difficulties score of the SDQ was used in this study; it is calculated by summing the scores across the emotional difficulties, conduct difficulties, hyperactivity/inattention, and peer relationship difficulties subscales. Items include "my child has at least one good friend" and "my child thinks things out before acting." The score range for the SDQ total difficulties scale is 0–40 with higher scores indicating more problems. Total difficulties scores above the 90th percentile predict a significantly higher probability of psychiatric diagnoses [37]. Internal consistency, test-retest reliability and inter-rater agreement of the SDQ parent version have been reported as satisfactory in numerous studies [38].

Evaluation of the program

Participants in the PP-HF group were asked four questions about their experience of attending the program at Time 2. These questions were regarding what they liked best about the program, what were the benefits of the program, whether they felt there was anything missing and if there was anything they felt would improve the program.

PP-HF intervention

The PP-HF program is a group parent training intervention. It is designed to help parents promote healthy habits within their families and to prevent childhood obesity. The program is suitable for families with children aged 0–12 years. It consists of eight 2-h sessions. The program curriculum and session content are outlined in Table 1. In the PPHF program participants develop parenting skills that promote supportive family relationships and healthy habits, especially healthy eating, regular physical activity and exercise, limiting screen-time, and healthy sleeping routines. Parents also learn mindfulness skills which facilitate self-regulation and mindful parenting. The following training techniques are used in the PP-HF program: mindfulness meditation, goal setting and review, didactic instruction, video modelling, rehearsal role-plays, feedback, group discussion, handouts, homework, and homework review. It is delivered by pairs of trained co-facilitators to groups of 6 to 12 parents. Parents and their partners, but not children, are invited to attend. The PP-HF program incorporates video footage of parent–child interactions and advocates a mindful, cooperative, assertive parenting style. The video scripts are written in an Irish idiom, and the actors speak in Irish accents.

A typical session involves a welcome from the facilitators, a review from the participants of how they have put into practice the new ideas from the previous week's session, introduction of the current week's topic, video input and discussion of the topic, role play and skills rehearsal, planning for the next week and summing up. Each parent in the study received a workbook summarizing the session content and suggested between-session tasks.

TAU control group

Parents randomized to the TAU control group received routine services provided by the agencies from which they were recruited. These included public health primary care centers, public health disability services, schools for disadvantaged children, family resource centers, a child protection agency, and a free national online service for parents. Thus, there was considerable

variability in the interventions received by control group participants.

Procedure

The trial was carried out over two phases. Eight clusters participated in the first phase of data collection (January 2022 to May 2022). Ten clusters took part in the second phase (September 2022 to March 2023). Parents were recruited by host agencies through their usual methods of recruiting for parenting groups.

Interested parents attended a screening interview with one of the trained facilitators in their host agency prior to consenting to participate in the study. Parents who wished to take part in the PP-HF program but not in the research study were permitted to do so. In the PP-HF condition, parents either completed the pre-study questionnaire at this interview or were emailed a link to complete the questionnaire online prior to the beginning of the group. Screening interviews in all agencies took place 1–2 weeks prior to the beginning of the group. In the control group, screening interviews took place at the same time as the PP-HF screening interviews, approximately 8 weeks prior to the end of the PP-HF program. Parents in the control condition completed the questionnaire at the pre-screening interview or were emailed the link to the online questionnaire to return within a week.

Six weeks after the program finished, parents in the training group condition completed follow-up measures. The questionnaire link was emailed to them by the facilitators in their host agency and a reminder email was also sent. A final reminder email was sent one to two weeks later by the researchers for any outstanding questionnaires.

At all participating agencies (with one exception) data were collected through the online platform Qualtrics [39], an electronic data capture platform, fully compliant with Good Clinical Practice, 21 CFR Part 11, GDPR, 20 ISO 27001 and ISO 9001:14. In one agency, the data were collected using paper-based questionnaires and consent forms.

Treatment fidelity

All program facilitators attended a two-day training course on facilitating the PP-HF program delivered by the program developers. Facilitators received regular supervision throughout the trial. A comprehensive facilitator booklet and parent booklet were developed to accompany the PP-HF program and included all the course materials. All the groups were run using the facilitator manual and the parent booklet, which was distributed to parents during the first session. Facilitators were instructed to follow the Parents Plus Quality Protocol which includes parental goals and session feedback

Table 1 Description of the Parents Plus Healthy Families (PP-HF) program

Session	Topic	Material covered	Parent exercise	Worksheets	Videos
1	Empowering parents	Starting new positive habits, protecting children from negative media and marketing influences, teaching children about importance of health and wellbeing, creating a healthy home environment, involving the whole family, leading by example	Mindfulness of the breath	What influences my child's health and wellbeing?: Setting positive goals	Making healthy changes in the family; Irish Heart Foundation- Stop targeting kids campaign
2	Family connection	Spending fun time with each child, one to one daily check-in with children, doing something enjoyable for yourself daily, making time for relationships, actively listening to children	Loving kindness meditation	Dealing with challenges to family relationships; Positive wellbeing and family relationships	The importance of play and special time; Siblings fighting; Helping children learn how to share
3	Healthy food routines	Balanced diet, portion sizes, food labels, drinks, healthy meals and snacks, habits around treats, meal planning	Mindful eating	Dealing with challenges to healthy eating; My weekly meal planner	Learning about the food pyramid; Preparing meals with a younger child; Involving children in meals; Dealing with a toddler demands for juice; Pester power: Agree on the treat routine in the home; Meal planning for the week
4	Healthy mealtimes	Eating as a family, keeping mealtimes screen free, teaching children good eating habits, making mealtimes social, encouraging children to eat healthy food, teaching children to notice hunger and fullness signs	Mindfulness of hunger scale	Dealing with challenges at mealtimes; establishing mealtime routines	Making mealtimes social; Encouraging babies and toddlers to feed themselves; Changing a family habit; Getting child back to the table; Encouraging a child to try new vegetables; Ignoring mealtime sulking; Refusing to eat dinner
5	Active play	Creating an active environment, teaching children to be active, being active as a family, building exercise into daily routine, organizing activities that children enjoy	Mindfulness of nature	Setting up the right environment; overcoming obstacles to active play	Active play outdoors; getting active as a family; active in play with baby; getting active-nagging child to do sports; motivating child to get active
6	Managing technology	Setting limits on screen time, having screen free places, keeping children safe online, making screen time social, encouraging alternatives to screen time, leading by example	Mindfulness body scan	Dealing with challenges to screen time and technology; picking alternatives to screen time; creating our family media plan	Irish Heart Foundation- Stop targeting kids; screen time battles; agree screen routine in advance; implementing screentime rules and consequences; establishing new screen time family habits
7	Restful sleep	Ensuring you child gets enough sleep, creating the right environment for sleep, screen free bedtimes, bedtime routines, encouraging children to fall asleep by themselves	Relaxation techniques	Dealing with challenges to sleep; Establishing a good bedtime routine	Bedtime reward charts with young child; bedtime chart with an older child

Table 1 (continued)

Session	Topic	Material covered	Parent exercise	Worksheets	Videos
8	Happy healthy mind	Encouraging children rather than criticizing, talking to children about their feelings, helping children manage their feelings, taking care of your own emotional wellbeing, giving children responsibilities, encouraging children's passions	The Three Minute Breathing Space	Dealing with challenges to my child's happiness and well-being; Encouraging children's passions; Encouraging children	Encouragement rather than criticism; Naming feelings through play; Setting the table; The best way to encourage children

forms, session planning and review forms and facilitator quality checklists. Adherence to the quality protocol was not assessed as part of the research.

In some agencies the intervention was delivered online. Efforts were made to ensure consistency of the delivery of the program between online and face to face formats. For example, where role-plays were required, these were done on breakout rooms on Zoom. Multi-media material such as videos and PowerPoints were the same across online and face to face groups. The pilot study, summarized in supporting information, indicated that there were no significant differences in effectiveness across online and face to face groups [23].

Data analysis

All statistical analysis was carried out using IBM SPSS Statistics 27. Data were explored for assumptions of normality. All total scale scores had skewness and kurtosis levels within the normal range of -2 to $+2$ [40], except for the LBC Total Problem scale at follow-up. The linear mixed-effects models (MIXED) procedure on IBM SPSS Statistics 27 was carried out for repeated measures analyses of primary (HHQ-48) and secondary (all other) outcome measures. Two separate multilevel models were fitted; the first for baseline and post-intervention data from PP-HF intervention and TAU control groups, and the second for baseline, post-intervention, and six-week follow-up data from the PP-HF intervention group only. The MIXED procedure facilitates modified intention-to-treat analyses (mITT) by including all available data from participants, as well as multi-level analysis. For the two-group analysis, time-points (Level 1) were nested within participants (Level 2) who were located in randomized trial conditions (Level 3) [41]. The models were specified to include fixed effects for time (baseline, post-intervention), treatment condition (PP-HF, TAU) and their interaction (time*treatment), in addition to random effects for time. For the PP-HF single group analysis, time-points (Level 1) were nested within participants (Level 2) and models were specified to include fixed effects for time (baseline, post-intervention, follow-up). To ensure model convergence, participants who completed outcome measures at baseline and post-intervention or follow-up were included in the analysis regardless of how much of the intervention they had received. Optimal model fit was confirmed by testing covariance structures and retaining those with the smallest Akaike Information Criterion [41]. In addition, to elucidate the covariance and correlation between baseline scores on variables and their linear growth estimates across time, *unstructured* and *unstructured: correlation metric* covariance matrices were also specified.

For participants who were missing less than 10% of data on a scale, the average of the sum of the scale was used to replace the missing values. To reduce the impact of missing data on analyses, multilevel models were fitted that incorporated all available participant data.

Statistical tests for significant baseline difference between the intervention and control groups were not performed, in line with the CONSORT guidelines [26]. The process of randomization in an RCT means that any testing would be carried on two samples from the same population, and significant baseline differences are considered as occurring randomly [42].

A total of 38 parents who took part in the PP-HF intervention group provided free text responses to the four questions pertaining to the evaluation of the program. Free-text responses were coded and categorized using a content analysis framework [43]. Questions 1 and 2 pertained to the benefits of the program and so responses to these two questions were combined and analyzed together. Similarly, Questions 3 and 4 pertained to changes that participants would make to the program so responses to these two questions were also combined for analysis. Initial codes were developed and categorized into themes.

Results

Sociodemographic characteristics of participants at baseline are outlined in Table 2. Data were provided by 138 participants at baseline. Of those 138 participants, 91 participants provided data post-intervention (attrition rate 34.06%). The attrition rates at post-intervention for the PP-HF and TAU control groups were 39.7% and 28.5%, respectively. A total of 25 participants from the PP-HF group completed follow-up measures (attrition rate 39.0%). A chi-square analysis revealed that there were no significant differences in the attrition rate between the PP-HF group and TAU control group at post-intervention, ($\chi^2(1, 138) = 1.44, p = 0.230$).

Participants' mean scores on the primary and secondary outcome measures at baseline, post-intervention and follow-up are presented in Table 3. A series of independent t-tests revealed that there were no statistically significant baseline differences between completers and those lost to attrition on any of the primary or secondary outcomes. (See Table S2 in supporting information). This indicates that dropouts did not affect the power of statistical tests to evaluate the significance of group differences in outcome measures.

Healthy Habits: HHQ-48 and HHQ-23

Comparison between PP-HF and TAU groups

A multilevel model investigating differences in the HHQ-48 between the PP-HF group and TAU control group

Table 2 Sociodemographic characteristics of all participants and those in the Parents Plus Healthy Families (PP-HF) group and the treatment as usual (TAU) control group at baseline

		PP-HF N = 68	TAU N = 70	Total N = 138
Gender Parent				
Mother	<i>f</i>	63	62	125
	%	92.6%	88.6%	90.6%
Father	<i>f</i>	5	8	13
	%	7.4%	11.4%	9.4%
Parent's age				
20–29	<i>f</i>	3	5	8
	%	4.4%	7.1%	5.8%
30–39	<i>f</i>	29	29	58
	%	42.6%	41.4%	42.0%
40–49	<i>f</i>	33	28	61
	%	48.5%	40.0%	44.2%
50–59	<i>f</i>	3	7	10
	%	4.4%	10.0%	7.2%
60 or over	<i>f</i>	0	1	1
	%	0%	1.4%	0.7%
No. children				
1–3 children	<i>f</i>	59	56	115
	%	86.8%	80.0%	83.3%
4–6 children	<i>f</i>	9	12	21
	%	13.2%	17.1%	15.2%
7–9 children	<i>f</i>	0	2	2
	%	0%	2.9%	1.4%
Gender children				
Boys	<i>f</i>	17	17	34
	%	25.0%	24.3%	23.8%
Girls	<i>f</i>	20	17	37
	%	29.4%	24.3%	25.9%
Boys and girls	<i>f</i>	31	36	67
	%	45.6%	51.4%	46.9%
Child's age				
Mostly under 5 years	<i>f</i>	18	14	32
	%	26.5%	20.0%	23.2%
Mostly between 6–12 years	<i>f</i>	30	35	65
	%	44.1%	50.0%	47.1%
Ages spread from under 5 years to 12 years	<i>f</i>	20	21	41
	%	29.4%	30.0%	29.7%
Parental marital status				
Married	<i>f</i>	42	36	78
	%	61.8%	51.4%	56.5%
Single	<i>f</i>	13	14	27
	%	19.1%	20.0%	19.6%
Separated	<i>f</i>	5	5	10
	%	7.4%	7.1%	7.2%
Divorced	<i>f</i>	1	5	6
	%	1.5%	7.1%	4.3%

Table 2 (continued)

		PP-HF N = 68	TAU N = 70	Total N = 138
Living with partner	<i>f</i>	7	10	17
	%	10.3%	14.3%	12.3%
Widowed	<i>f</i>	0	0	0
	%	0%	0%	0%
Ethnicity				
Irish	<i>f</i>	47	41	88
	%	69.1%	58.6%	63.8%
Other white background	<i>f</i>	16	24	40
	%	23.5%	34.3%	29.0%
Asian	<i>f</i>	4	0	4
	%	5.9%	0%	2.9%
Irish traveler	<i>f</i>	0	3	3
	%	0%	4.3%	2.2%
African	<i>f</i>	1	2	3
	%	1.5%	2.9%	2.2%
Employment status				
Employed	<i>f</i>	40	35	75
	%	58.8%	50.0%	54.3%
Unemployed	<i>f</i>	28	35	63
	%	41.2%	50.0%	45.7%
Employment type				
Unskilled work	<i>f</i>	2	5	7
	%	2.9%	7.1%	5.1%
Semi-skilled work	<i>f</i>	9	6	15
	%	13.2%	8.6%	10.9%
Non-manual work	<i>f</i>	1	1	2
	%	1.5%	1.4%	1.5%
Managerial/technical work	<i>f</i>	11	11	22
	%	16.2%	15.7%	16.1%
Professional/employer	<i>f</i>	22	13	35
	%	32.4%	18.6%	25.5%
Farmer	<i>f</i>	2	1	3
	%	2.9%	1.4%	2.2%
Own-account workers	<i>f</i>	0	1	1
	%	0%	1.4%	0.7%
Other	<i>f</i>	21	31	52
	%	30.9%	44.3%	38.0%

revealed a statistically significant *time* × *condition* interaction, $\beta = 6.07$, $p = 0.023$, 95% CI [0.83, 11.32]. This finding indicates that participants in the PP-HF group reported increased healthy habits assessed with the HHQ-48 from baseline to post-intervention at a greater rate than participants in the TAU control group. In contrast, a multilevel model investigating differences in the HHQ-23 between the PP-HF group and TAU control group did not reveal a statistically significant *time* × *condition* interaction, $\beta = 2.28$, $p = 0.139$, 95% CI [−0.75,

Table 3 Means (M) and standard deviations (SD) for Parents Plus Healthy Families group (PP-HF) and the treatment as usual (TAU) control group on the Healthy Habits Questionnaire (HHQ), Lifestyle Behavior Checklist (LBC), Kansas Parental Satisfaction Scale (KPS), Systemic Clinical Outcome Routine Evaluation-15 (SCORE-15), and Strengths and Difficulties Questionnaire (SDQ) at baseline, post-intervention, and follow-up for all available data

		PP-HF			TAU	
		Baseline	Post intervention	Follow-up	Baseline	Post-intervention
		N = 68	N = 41	N = 25	N = 70	N = 50
Healthy habits						
HHQ-48 total	M	69.29	78.54	80.56	64.83	66.66
	SD	12.61	9.89	9.17	12.82	14.65
HHQ-23 total	M	34.47	38.20	39.80	31.94	32.80
	SD	7.13	5.54	4.76	7.29	7.69
Lifestyle problems and parental confidence changing these						
LBC problems	M	66.18	55.00	54.54	67.21	69.83
	SD	26.20	20.96	28.67	23.57	27.37
LBC confidence	M	178.61	205.12	211.92	176.49	180.04
	SD	54.15	39.80	43.21	41.70	44.72
Parental satisfaction						
KPS total	M	14.19	16.44	16.56	13.61	13.68
	SD	3.31	2.55	2.96	3.05	3.77
Family dysfunction						
SCORE-15 total	M	2.17	2.01	1.93	2.32	2.58
	SD	0.65	0.62	0.65	0.78	0.78
Child behavior problems						
SDQ total difficulties	M	14.39	11.97	12.38	16.53	17.06
	SD	6.29	5.67	7.16	7.40	7.01

5.30]. These two sets of contrasting results indicate that the 48-item version of the HHQ is more sensitive to differential change in PP-HF and TAU groups than the HHQ-23. This is due to the broader range of lifestyle issues covered in the HHQ-48.

Changes across time in the PP-HF group

A multilevel model revealed statistically significant changes in HHQ-48 total scores across time in the PP-HF group, $\beta = 6.32$, $p < 0.001$, 95% CI [4.21, 8.43]. HHQ-48 scores at baseline were significantly lower than those at follow-up, $\beta = -11.62$, $p < 0.001$, 95% CI [-15.98, -7.27], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = -2.76$, $p = 0.236$, 95% CI [-0.737, 1.84]. Similarly, a multilevel model revealed statistically significant changes in HHQ-23 total scores across time in the PP-HF group, $\beta = 2.88$, $p < 0.001$, 95% CI [1.79, 3.97]. HHQ-23 scores at baseline were significantly lower than those at follow-up, $\beta = -5.51$, $p < 0.001$, 95% CI [-7.78, -3.24], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = -2.03$, $p = 0.095$, 95% CI [-0.441, 3.58].

Children's lifestyle problems and parental confidence changing these: LBC problems and LBC confidence

Comparison between PP-HF and TAU groups

On the LBC, multilevel models revealed no statistically significant *time* \times *condition* interactions in problems, $\beta = -9.90$, $p = 0.052$, 95% CI [-19.90, 0.09] or confidence, $\beta = 17.15$, $p = 0.127$, 95% CI [-4.92, 39.22].

Changes across time in the PP-HF group

A multilevel model revealed statistically significant changes in LBC problems across time in the PP-HF group, $\beta = -6.12$, $p = 0.022$, 95% CI [-9.99, -2.24]. LBC problem scores were significantly higher at baseline, indicating more severe child lifestyle problems, than at follow-up, $\beta = 11.40$, $p = 0.006$, 95% CI [3.37, 19.43], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = 2.87$, $p = 0.498$, 95% CI [-5.55, 11.29].

A multilevel model revealed statistically significant changes in LBC confidence scores across time in the PP-HF group, $\beta = 13.06$, $p = 0.003$, 95% CI [4.46, 21.67]. LBC confidence scores were significantly lower at baseline, indicating lower levels of parental confidence, than at follow-up, $\beta = -22.83$, $p = 0.012$, 95% CI [-40.49,

–5.18], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = -1.00$, $p = 0.915$, 95% CI [–19.68, 17.67].

Parental Satisfaction: KPS

Comparison between PP-HF and TAU groups

A multilevel model investigating differences in parental satisfaction between the PP-HF group and TAU control group revealed a statistically significant *time* × *condition* interaction, $\beta = 1.88$, $p = 0.015$, 95% CI [0.36, 3.40]. This finding suggests that participants in the PP-HF group reported increased parental satisfaction on the KPS from baseline to post-intervention at a greater rate than participants in the TAU control group.

Changes across time in the PP-HF group

A multilevel model revealed statistically significant changes in parental satisfaction across time in the PP-HF group, $\beta = 1.24$, $p < 0.001$, 95% CI [0.65, 1.82]. Indeed, parental satisfaction scores at baseline were significantly lower than those at follow-up, $\beta = -2.12$, $p < 0.001$, 95% CI [–3.31, –0.93], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = -0.03$, $p = 0.966$, 95% CI [–1.29, 1.24].

Family Dysfunction: SCORE-15

Comparison between PP-HF and TAU groups

A multilevel model investigating differences in the SCORE-15 total between the PP-HF group and the TAU control group revealed a statistically significant *time* × *condition* interaction, $\beta = -0.38$, $p = 0.012$, 95% CI [–0.68, –0.08]. This finding suggests that participants in the PP-HF group reported a decreased level of family dysfunction on the SCORE-15 from baseline to post-intervention at a greater rate than participants in the TAU control group.

Changes across time in the PP-HF group

A multilevel model revealed no statistically significant changes in SCORE-15 total scores across time in the PP-HF group, $\beta = -0.09$, $p = 0.084$, 95% CI [–0.20, 0.01]. There were no significant differences in SCORE-15 total scores at baseline compared to those at follow-up, $\beta = 0.17$, $p = 0.141$, 95% CI [–0.06, 0.39], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = 0.02$, $p = 0.863$, 95% CI [–0.21, 0.25].

Child behavior Problems: SDQ total difficulties

Comparison between PP-HF and TAU groups

A multilevel model investigating differences in the SDQ total difficulties score between the PP-HF group and TAU control group revealed a statistically significant

time × *condition* interaction, $\beta = -2.72$, $p = 0.044$, 95% CI [–5.37, –0.07]. This finding suggests that participants in the PP-HF group reported decreases in SDQ total difficulties from baseline to post-intervention, indicating a reduction in child behavior problems, relative to participants in the TAU control group.

Changes across time in the PP-HF group

A multilevel model revealed a statistically significant change in SDQ total difficulties across time in the PP-HF group, $\beta = -1.00$, $p = 0.010$, 95% CI [–1.76, –0.24]. SDQ total difficulties scores were significantly higher at baseline compared to those at follow-up, $\beta = 1.59$, $p = 0.039$, 95% CI [0.81, 3.10], while no statistically significant difference was detected between post-intervention and follow-up, $\beta = -0.64$, $p = 0.418$, 95% CI [–2.20, 0.93].

Figure 2 contains graphs showing dependent variables on which the PP-HF group showed significantly greater improvement from baseline to post-intervention compared with the TAU control group.

Completer sensitivity analyses

A set of ancillary completer sensitivity analyses were conducted for all dependent variables. For the *time* × *condition* interaction from baseline to post-intervention in the PP-HF and TAU conditions, similar results were obtained in completer and intention-to-treat analyses for six out of seven dependent variables. Different results were obtained for analyses of the KPS which assessed parental satisfaction. The KPS result was significant in the intention-to-treat analysis where missing values were imputed ($N = 138$), but not in the completer analysis ($N = 91$). In the intention-to-treat analysis the KPS p value was 0.015 whereas in the completer analysis it was 0.082 and not significant at $p < 0.05$.

In the completer analysis, for the change over time from baseline through post-Intervention to follow-up in the PP-HF condition, similar results were obtained in completer and intention-to-treat analyses for five out of seven dependent variables. Different results were obtained in the intention-to-treat and completer analyses of the SDQ total difficulties scale which assesses child behavior problems, and the LBC problems scale which assesses children's lifestyle problems. The SDQ result was significant in the intention-to-treat analysis where missing values were imputed ($N = 67$), but not in the completer analysis ($N = 22$). In the intention-to-treat analysis the SDQ total difficulties scale p value was 0.010 whereas in the completer analysis it was 0.212 and not significant at $p < 0.05$. In contrast, the LBC problems scale result was not significant in the intention-to-treat analysis where missing values were imputed ($N = 67$), but was significant in the completer analysis ($N = 22$). In the intention-to-treat

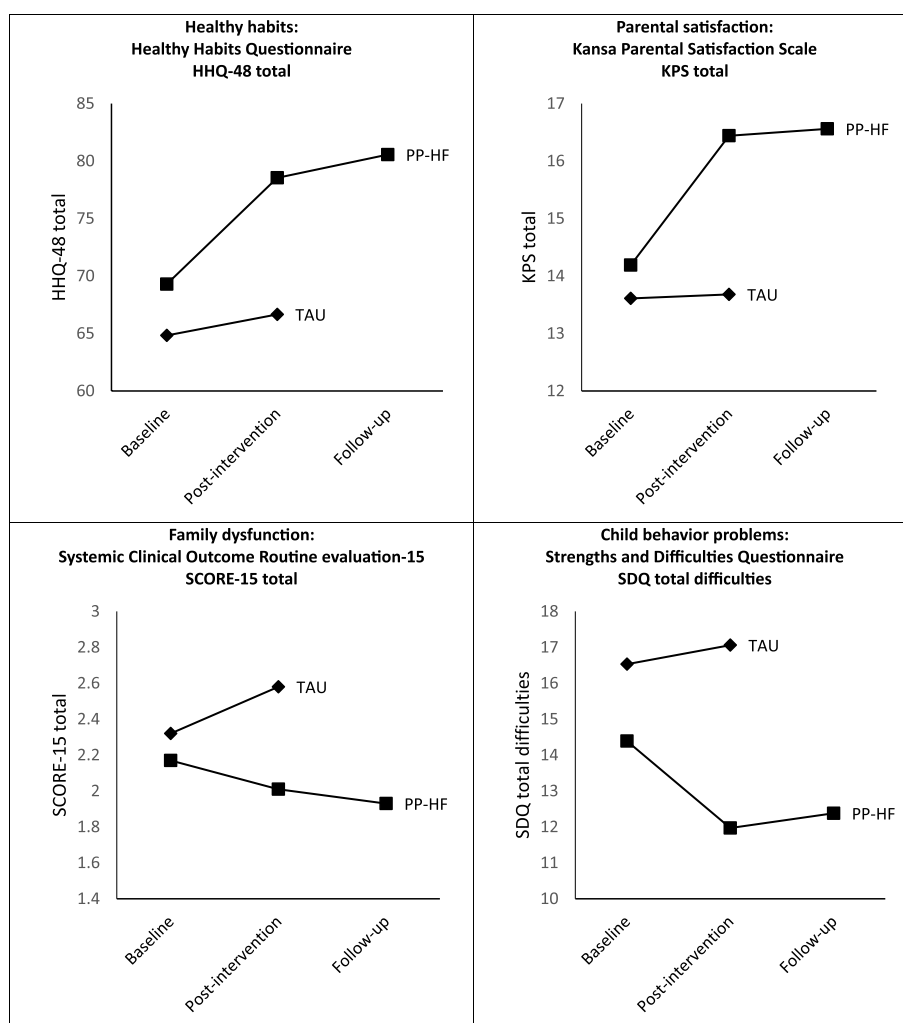


Fig. 2 Dependent variables on which the Parents Plus Healthy Families (PP-HF) group showed significantly greater improvement from baseline to post intervention compared with the treatment as usual (TAU) control group

analysis the LBC problems scale p value was 0.22 whereas in the completer analysis it was significant at 0.001. Results of completer and intention-to-treat analyses are in Table S3 in supporting information.

Relationship between baseline scores and improvement

A set of ancillary analyses (in Table S4 in supporting information) were conducted to determine the relationships between baseline scores and levels of improvement from baseline through post-intervention to follow-up for all dependent variables. Models were specified to estimate the correlations between intercepts (baseline scores) and slopes (trajectories of scores across time). Lower scores at baseline were associated with greater improvements across time in healthy habits (HHQ-48, $r = -0.74$, $p < 0.001$; HHQ-23, $r = -0.91$, $p < 0.012$), parent confidence in addressing their children's lifestyle problems

(LBC confidence, $r = -0.67$, $p < 0.001$), and parental satisfaction (KPS, $r = -0.66$, $p < 0.001$), but not family dysfunction (SCORE-15) or child behavior problems (SDQ). For children's lifestyle problems, however, improvements in problems across time were greater for those with lower baseline scores ($r = -0.51$, $p < 0.001$).

Evaluation of the program

A total of three themes emerged from the analysis of the free-text responses regarding the benefits of the program: (1) the support of the group (2) time and space for reflection (3) new knowledge and skills. Four themes emerged from the analysis of responses regarding changes to the program: (1) no changes needed (2) change in program length (3) additional content (4) changes to the format/structure of the program. Illustrative data along with a description of each theme are presented in Table 4.

Table 4 Findings from the evaluation of the program

Theme	Description of theme	Illustrative quotes
Benefits of the program		
The support of the group	Parents commented on the benefits of sharing experiences and advice with other parents. Several parents reported that hearing from other parents showed them that they were not alone. Parents also commented on the support they received from the facilitators and other parents	<p>"Meeting others and hearing their stories made everything seem normal!"</p> <p>"Reassurance that we are not alone and are doing as best as we can"</p> <p>"It really gave me the extra support that I needed. [The facilitators] were wonderful support and very understanding. I also learned a lot from the other parents, it was nice to feel their support."</p>
Time and space for reflection	Parents reported that the group gave them the space and time to reflect on their parenting and helped them to refocus on their priorities for their families	<p>"Loved the program it gave me time to sit and think about my parenting during these busy times."</p> <p>"Time to reflect on how we are doing and get tips on what can help move things in the right direction."</p> <p>"I learned some really good coping strategies and I took a hard look at the ways I could change my way of thinking and doing things to achieve a better outcome."</p>
New knowledge and skills	Parents commented on the range of knowledge and skills they learned from attending the program, including around mealtimes, sleep, and healthy eating. Several reported that it either increased their confidence or provided reassurance around their parenting	<p>"I feel the course has empowered me as a parent and has given me the tools I need to get to where I want to be. I feel we have more structure and feel more connected with my family. Since I started the course, my bin is now full of fruit peeling rather than sweet wrappers."</p> <p>"Awareness of taking time to stop and tune in and observe what is going on before reacting. Also, awareness of the importance of family time, self-care, and family mealtimes"</p> <p>"I got an excellent book as a guide to look back on with many parenting tips in it"</p>
Changes to the program		
No changes needed	For the most part, parents reported that they wouldn't change anything about the program	<p>"I think it covered everything for me."</p> <p>"I really enjoyed the course, and the three leaders made the whole thing so enjoyable. I would not have changed a thing."</p>
Change in program length	Several parents suggested a change to the group length. Of those who made this suggestion, most reported that they would have liked more sessions. One parent reported that they would have liked more sessions but for them to be longer in duration. One parent reported that they felt the program was too long	<p>"Been ran longer as it was great to meet up with the other parents"</p> <p>"Nothing, just longer maybe 12 weeks"</p> <p>"Maybe short sessions but more of them"</p> <p>"Was too long"</p>
Additional content	Several parents suggested that the group would have benefitted from additional content. The additional content suggestions were for more information around special needs and autism, more information on healthy eating, and information around organizing daily activities such as chores around the home	<p>"More discussion around talking about feelings. Last session could have been a double session"</p> <p>"Sharing of recipes or meal ideas. I would have liked a list of easy lunch/dinner recipes to look back on"</p> <p>"Not sure if it is part of this but better organization and better ways to organize home dealing with daily chores but otherwise overall brilliant course"</p> <p>"Not sure, maybe more autism centric material"</p>
Changes to the format/structure of the program	Several parents suggested changes to the format or structure of the group. Two parents commented that it would have been nice to have seen more fathers participate in the course. Another parent suggested using more breakout rooms while another commented on the flexibility of having your camera off	<p>"It was sad to see there were no Dad's available to partake in the course and I feel this needs to be addressed!"</p> <p>"It would have been nice to meet another Daddy parent on the course."</p> <p>"I enjoyed the breakout rooms and discussions in small groups. More of this."</p> <p>"Nothing really, flexibility regarding camera on/off was appreciated."</p> <p>"To have it in person!"</p> <p>"Possibly a more suitable time for working parents"</p>

Discussion

The cluster randomized controlled trial described above, addressed three research questions listed at the end of the introduction. With respect to the first research question, concerning the impact of the PP-HF program on healthy lifestyle behaviors, a comparison of outcomes for the PP-HF and TAU groups indicated that the program led to a significantly greater increase at post-intervention in healthy lifestyle behaviors assessed with the HHQ-48. With respect to the second research question concerning the impact of the PP-HF program on parental satisfaction, family functioning, and child behavior problems, a comparison of outcomes for the PP-HF and TAU groups showed that the program led to significantly greater improvements at post-intervention in parental satisfaction assessed with the KPS, family dysfunction assessed with the SCORE-15, and child behavior problems assessed with the SDQ. Regarding the third research question, concerning the maintenance of positive outcomes at follow-up, analyses of baseline, post-intervention, and follow-up data from the PP-HF group showed that significant positive outcomes shown immediately following completion of the PP-HF program were maintained at six-week follow-up for healthy lifestyle behaviors assessed with the HHQ-48, parental satisfaction assessed with the KPS, family dysfunction assessed with the SCORE-15, and child behavior problems assessed with the SDQ. There were three negative results. No significant differences between the PP-HF and TAU groups' post-intervention scores were found on the HHQ-23, the LBC child problems scale, or the LBC parental confidence scales, although gains made by the PP-HF group on these three variables group were maintained at six-weeks follow-up.

These results from the planned analyses were largely supported by the ancillary completer sensitivity analysis. A further ancillary analysis showed that greater improvement, per variable, occurred for parents in the PP-HF group with lower baseline levels of healthy habits (HHQ-48 and HHQ-23), parental satisfaction (KPS), parental confidence in addressing children's lifestyle problems (LBC confidence), and who viewed their children as having a lower baseline level of lifestyle problems (LBC problems).

There was a discrepancy between the HHQ-48 and HHQ-23 results. From baseline to post-intervention, the mean HHQ score of the PP-HF group increased significantly more than that of the TAU control group for the 48-item version, but not the 23-item version of the HHQ. The greater sensitivity of the HHQ-48 to change arising from parents engaging in the PP-HF program was due to the broader range of issues covered by the additional 25 items, and the sensitivity of these additional items to

change. Parent empowerment and family connection were two content domains containing items sensitive to change and poorly represented in the HHQ-23.

The overall results of our RCT are consistent with conclusions from systematic reviews and meta-analysis of parent and family-based interventions for promoting positive lifestyle changes and health behavior for preventing and treating obesity and [13–16, 19, 21]. These reviews show that multicomponent interventions that involve parents and address diet, exercise, and broader lifestyle issues such as screentime, and sleep promote the development of healthy lifestyles.

The positive findings of our study are consistent with two results from the PP-HF pilot study [23], summarized in supporting information, which examined the impact of the PP-HF program using a single group uncontrolled design involving 42 parents. The pilot study, like the current study, found that the PP-HF program led to significant improvements in healthy lifestyle behaviors assessed with the HHQ-48, and child behavior problems assessed with the SDQ. However, the current study extended these findings by showing that these positive changes were significantly greater than those of a TAU control group, and were maintained at six-weeks follow-up.

An important difference between the results of the pilot study and the current trial, is that unlike the current study, the pilot study did not find that the PP-HF program led to improvements in parental satisfaction assessed with the KPS. In the current study, mean KPS scores the PP-HF group improved from a baseline level of 14.19 to a post-intervention level of 16.44, whereas in the pilot study the improvement was from 14.07 to 14.98. It's unclear what accounts for this difference.

The PP-HF pilot study found that the program led to significant improvements in children's lifestyle behavior problems, assessed with the LBC problems scale, and parents' confidence in managing these problems, assessed with the LBC confidence scale. Similar results were found for the PP-HF group in the current study. However, an important negative finding in the current study was that these improvements were not significantly greater than those that occurred in the TAU control group. One potential reason for this outcome could be that parents may have required a longer or more intense intervention to achieve significant changes. A meta-analysis of family-based lifestyle interventions among children with overweight and obesity [15] found that the outcomes of the interventions were positively related to the minutes spent in treatment, indicating that longer interventions may be associated with better treatment outcomes. In our study data were not collected on how many of the eight sessions parents attended, or how many between-session home practice tasks were completed. It is possible that a

longer time spent in treatment, and greater home practice task completion may have further augmented the positive impact on healthy habits for parents. Indeed, one of the themes that emerged from the qualitative evaluation of the program was that parents requested a longer intervention with additional content.

There were several limitations to this study. This trial was non-blinded. Participants knew if they were in the PP-HF or TAU arm of the trial. Also, outcome was assessed with self-report scales, rather than observations made by blind raters. These factors may have biased results in favor of the intervention group. On the other hand, previous research on parenting programs has indicated that parent-report measures may not be as sensitive as researcher-ratings in detecting change, particularly in shorter interventions [44].

A second limitation was the high attrition rates both the PP-HF intervention (39.7%) and TAU control (28.5%) trial arms, which exceeded the expected attrition rate of about 10%. The attrition rate in this study is consistent with that found in other parent-only interventions for pediatric obesity [17, 19]. The high attrition rate could potentially have reduced the study's power to detect significant post-intervention differences between PP-HF and TAU groups. However, the MIXED multi-level modelling data analytic approach used all available data (rather than listwise deletion of cases with missing data) in model fitting, and this minimized risk of bias due to attrition.

A third limitation was that data on the number of sessions attended and the number of between-session home practice tasks completed by each parent were not collected. This precluded conducting per protocol analyses. Future PP-HF trials should collect data on session attendance and between-session home practice task completion as both of these variables have been found to moderate the effectiveness of lifestyle interventions [15] as well as parenting interventions in general [44].

A fourth limitation was that data on recruitment pathways, which may have influenced responsiveness to the program, were not collected. They were, therefore, not taken into account in data analysis. There were two different recruitment pathways. RCT participants included both self-selecting parents who signed up to the PP-HF program due to an interest in improving healthy lifestyles, and parents who were offered the program while their children were on waiting lists for clinical services for a variety of emotional and behavioral difficulties.

A fifth limitation was that data were not collected on in-person and online program delivery format. This, therefore, was not taken into account in data analysis. However, the PP-HF pilot study summarized in supporting information found that both in-person and online

program delivery formats yielded similar outcomes, although the small number of cases in this comparison meant the statistical analysis was underpowered.

A sixth limitation was that father participation in the trial was low, and this may have reduced the impact of the PP-HF program. Two lines of research support this view. Fathers' health related behavior influences their children's health behavior [45], and father involvement increases the effectiveness of parent training programs which target disruptive behavior [46]. It is therefore probable that father involvement may increase the impact of lifestyle change parent training programs.

A final limitation relates to the cluster randomized controlled design of the study. Compared to RCTs in which individual participants are randomized to intervention and control groups, in cluster RCTs, randomizing clusters of participants to intervention and control groups may affect the balance of participants with particular characteristics in intervention and control arms of the trial. This may increase the risk of bias due to baseline differences, and potentially decrease the precision of the trial outcomes [47, 48]. In our study this issue was addressed by randomizing clusters to PP-HF and TAU groups from matched pairs, with matching based on agency setting and type of population served.

The trial had a number of important strengths. First, the PP-HF program was modelled on a suite of evidence-based parent training programs and had been tested in an uncontrolled pilot study, which yielded positive results. Second, within the constraints of available resources, a robust multi-site cluster-RCT research design was used. Third, the trial was conducted in 'real world' Irish and UK community settings, not specialist centers, and so results were generalizable to these contexts. Fourth, PP-HF facilitators were experienced professionals, trained in PP-HF delivery by program developers. Fifth, program integrity was maintained through the use of a facilitator manual, parent booklet, slides, and videos. Sixth, validated psychometric scales were used for data collection and multilevel modelling was used for data analysis.

Conclusions

Despite public health guidelines recommending parent-based preventative programs for the management and prevention of pediatric obesity in Ireland [18] there is currently no such program that has an evidence base in an Irish population. Results from this RCT indicate that the PP-HF program is an effective way of promoting healthy lifestyles as well as parental satisfaction, positive family functioning and positive child behavior among families with preadolescent children in a way that is consistent with Irish healthcare policy for the management

of obesity across the lifespan [18]. This methodologically rigorous trial involved a range of clinical and non-clinical settings across both urban and rural areas of Ireland, suggesting that these findings are especially generalizable to the Irish population.

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13690-025-01555-x>.

Supplementary Material 1.

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Authors' contributions

Study conception—AC, JS, AK, and KL. Design of the study—AC, AK, JS, AD, EM. Acquisition, analysis, and interpretation of data—COD, BD, MOC, AK, KL, FM. Drafting of the manuscript—COD. Critical revision of the manuscript—all authors. Final approval of the submitted version—all authors.

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Data availability

The datasets generated and/or analysed during the current study are not publicly available to ensure the anonymity of participants but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethical approval for this study was granted by the UCD Human Research Ethics Committee (ref HS-21–79) as most of the participating agencies did not have standing research ethics committees. Ethical approval was also granted by the Public Health Service Executive South-East Research Ethics Committee regarding the participation of a public health primary care center in the Southeast of Ireland. All participants provided written informed consent to partake in the study and were informed of their right to withdraw without consequence.

Consent for publication

Not applicable.

Competing interests

JS is the founder and clinical director of the Parents Plus Charity and was one of the developers of the Healthy Families Programme. AK is employed by the Parents Plus Charity and was one of the developers of the Healthy Families programme. AC works as an expert consultant to the Parents Plus Charity. The authors declare no other known conflicts of interest.

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