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Research Article

Primary Care Practice-Based Framework for Childhood Obesity Treatment Utilizing Health Coaching and a Behavioral Screening Tool: the *My Health, My Way*! Randomized Controlled Pilot Trial

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Abstract

Background: Childhood obesity treatment recommendations promote utilization of screening tools, motivational interviewing, and support staff to facilitate lifestyle behavior change with children and families through a staged approach. While these recommendations are evidence- based and have been in place for over a decade, little research has been done to explore the utilization and effectiveness of the framework in real-world primary care settings. **Objective:** The purpose of the *My Health, My Way!* (MHMW) pilot study was to determine the effectiveness of a primary care practice-based framework for childhood obesity treatment on behaviors related to nutrition, physical activity, sleep, and screen time. **Methods:** Families of pediatric patients at a primary care practice in the Midwest were invited to participate if the child was 5-12 years of age and had a body mass index (BMI) ≥ 85th percentile. Participants were randomized to standard of care (control) or a six-month intervention, which involved monthly health coaching sessions utilizing the Family Nutrition and Physical Activity (FNPA) screening tool. Outcome measures included FNPA score, BMI percentile, and BMI z-score. **Results:** Thirty-five participants enrolled and 28 completed baseline measures. Participants in the intervention group had greater increases in FNPA scores than the control group for those that completed the study, though not significantly different (4.86 ± 6.28 versus 0.38 ± 4.6; $p = 0.135$). However, the effect size ($d = 0.88$) is considered to be large. There was a significantly greater mean change score on the FNPA subscale of family eating practices (intervention 0.57 ± 0.54, control -0.13 ± 0.41; $p = 0.041$). **Conclusions:** A primary care practice-based framework for childhood obesity treatment utilizing health coaching and a behavioral screening tool may be effective for facilitating lifestyle behavior change with children and families. Additional study is needed to examine retention strategies in real-world primary care interventions.

Keywords: Childhood obesity; Motivational interviewing; Behavior change; Patient-centered care; Brief action planning, Health coaching.

Background

In the United States (US), over one-third of children and adolescents experience overweight and obesity [1]. Children with obesity are more likely to become adults with obesity, and may experience co-morbidities including heart disease, stroke, type 2 diabetes, and cancer [2-4]. Recommendations for childhood obesity treatment were released in 2007 by the Expert Committee of the American Medical Association (AMA) and included a staged treatment approach beginning in well-child visits with a primary care provider (PCP) [5]. The first two stages, Stage 1 and Stage 2, focus primarily on behavior change. The staged treatment approach has not been widely studied and PCPs have encountered barriers in addressing behavior change with families such as PCPs' lack of time and resources, as well as patient and family motivation [6,7].

Some strategies for engaging families in behavior change have been examined including motivational interviewing (MI) and brief action planning (BAP), a self-management technique grounded in MI that seeks to build self-efficacy [8]. Christison et al. (2014) piloted a primary care-based intervention utilizing brief MI-enhanced conversations and the Family Nutrition and Physical Activity (FNPA) screening tool formatted to be used as a coaching tool [9]. The FNPA was developed as a result of an Academy of Nutrition and Dietetics (formerly American Dietetic Association) evidence analysis project on pediatric overweight and obesity and includes 20 questions (10 constructs) about behaviors related to overweight and obesity. The FNPA has previously been shown to have construct validity and predictive validity relative to body mass index (BMI) [10,11].

Christison et al. used the FNPA to facilitate goal setting and action planning in single well-child visits for childhood obesity prevention and found the process to have good patient and provider acceptability [9]. Additionally, mean FNPA score significantly increased by 4.2 points from baseline to six months post-intervention. Parents reported success achieving 68% of primary behavior goals at one month and 46% at six months, however there was no significant change in BMI z–score at 6 months. While this pilot study targeted obesity prevention, the model demonstrates potential for application with respect to behavior change for childhood obesity treatment, as well.

The purpose of the *My Health, My Way!* (MHMW) randomized controlled pilot trial was to determine the effectiveness of a practice-based framework for childhood obesity treatment on behaviors related to nutrition, physical activity, sleep, and screen time. We performed this study to examine whether this framework could be an effective design for a potential larger trial. Our hypothesis was that participants in the intervention group would demonstrate significantly greater improvements in obesity-related lifestyle behaviors from baseline to post-intervention.

Methods

Participants

For this parallel-group randomized controlled pilot trial, participants were recruited and enrolled over a one-year period (between March 2017 and February 2018), and the duration of the study once enrolled was six months. We sought to enroll up to 60 participants (30 per group) during the one-year period based on sample size calculations utilizing data from a previous study by one of the study authors [9].The sample size also accounted for 25% attrition.

Families of patients at a pediatric primary care clinic in the Midwest were invited to participate in the MHMW study if the child was 5-12 years of age, had a BMI ≥ 85th percentile, had no co-morbidities requiring follow-up with a specialist, and they were English-proficient. The pediatrician introduced the study opportunity to families with children meeting eligibility criteria that were scheduled for a visit to the clinic and when a health coach for the study was available to enroll the families. If families indicated interest in participating in the study, the pediatrician invited the health coach into the exam room to share additional study information and to obtain written consent from the parent/guardian and assent from the child.

Participants were randomized (card in sealed envelope) to intervention and control (standard of care) groups using permuted block randomization to promote even distribution of subjects between groups, with an equal randomization to groups of 1:1. Randomization was completed in blocks of ten, with each block containing five assignments to intervention and five assignments to control, and each block of envelopes was shuffled. As per standard of care at this clinic, control families had follow-up growth checks with the pediatrician every three months (i.e., three months and six months from enrollment) (Table 1). Standard of care at this clinic involved assessing lifestyle behaviors using the 5-2-1-0 Healthy Habits Questionnaire [12] at well-child visits and follow-up growth checks, as well as setting a behavioral goal with the pediatrician who utilized MI. This study was approved by the UnityPoint Health Des Moines Institutional Review Board (Study Number: IM2017-001).

Table 1. *My Health, My Way!* study design.

<table>
<tr><th>Month</th><th>Control</th><th colspan="2">Intervention</th></tr>
<tr><td>0</td><td>Meet with Pediatrician
(in-person)</td><td colspan="2">Meet with Pediatrician & Health Coach (in-person)</td></tr>
<tr><td>1</td><td rowspan="2"></td><td colspan="2">Talk with Health Coach (phone)</td></tr>
<tr><td>2</td><td colspan="2">Talk with Health Coach (phone)</td></tr>
<tr><td>3</td><td>Meet with Pediatrician
(in-person)</td><td colspan="2">Meet with Pediatrician & Health Coach (in-person)
<u>Continue Stage 1</u> <u>Stage 2</u></td></tr>
<tr><td>4</td><td rowspan="3"></td><td rowspan="2">Talk with Health Coach (phone)</td><td>Talk with Health Coach (phone)</td></tr>
<tr><td>Talk with Health Coach (phone)</td></tr>
<tr><td>5</td><td rowspan="2">Talk with Health Coach (phone)</td><td>Talk with Health Coach (phone)</td></tr>
<tr><td>6</td><td>Meet with Pediatrician
(in-person)</td><td colspan="2">Meet with Pediatrician & Health Coach (in-person)</td></tr>
</table>

MHMW Intervention

The intervention protocol was based on the Expert Committee staged treatment approach and intervention families began with Stage 1 treatment (Prevention Plus). The intervention included the same schedule of visits with the pediatrician as the control participants (i.e., every three months) to promote behavior change related to items included in the FNPA screening tool.

After enrollment, intervention families scheduled a time to return to the clinic for the initial visit with a health coach, typically within a week of the pediatrician visit. Two health coaches were available to support the intervention in the clinic. Health coaches were professional support staff that had previous training and experience in utilizing MI with patients. The health coaches also attended the same health care professional training on BAP. To facilitate the intervention, health coaches followed standardized processes and scripts, as well as a statement of coaching fidelity.

At the initial in-person visit with the health coach, families completed the FNPA screening tool. Using a standardized script, health coaches reviewed the FNPA with the family and then used the FNPA as a menu for change in facilitating BAP. Families identified a change they were interested in making as a goal and then determined specific details to create an action plan (i.e., what, when, where, how often/much). Families then rated their confidence in achieving the plan they had created on a scale of zero to ten. Participants were considered confident in achieving their plan if confidence was rated as seven or greater. If confidence was rated lower than a seven, follow-up discussion addressed potential barriers or challenges. After further discussion, the action

plan was revised to a level the participants were confident they could achieve. Goal sheets were used to document action plans and included a calendar that could be used for self-monitoring. A time to follow-up approximately one month later by phone was documented, as well.

During months one and two, health coaches conducted phone calls with intervention families once per month, typically lasting 15 minutes or less. During these sessions, families reflected on their action plans and then determined if they would like to continue with the same action plans, modify the action plans, or create new action plans. Health coaches again facilitated BAP to create the action plans, assessed confidence, and scheduled a time to follow-up the next month. At month three, participants had a follow-up growth check in the clinic with the pediatrician and an in-person visit with the health coach. Families completed the FNPA and height and weight were measured to assess BMI percentile. Participants who improved their FNPA score from baseline (or decreased BMI percentile) continued monthly health coaching visits by phone for an additional two months. Participants with no change in FNPA score increased the frequency of health coach visits by phone to twice monthly for two months (Stage 2 treatment). At month six, participants had a follow-up growth check in the clinic with the pediatrician, an in-person visit with the health coach, and repeated baseline measures.

Outcome Measures

The primary outcome measure was the FNPA score, which was completed by the parent at baseline, three months, and six months. Secondary outcome measures included BMI percentile-for-age and BMI z-score. BMI percentile was documented from the electronic health record at baseline, three months, and six months. BMI z-score was determined using the Centers for Disease Control and Prevention (CDC) 2000 growth charts and published age- and sex-specific LMS (lamda-mu-sigma) parameters [14]. Parent health literacy was assessed at baseline using the Newest Vital Sign (NVS) [13] to characterize the participants. Incentives such as water bottles and jump ropes were provided at three months and six months, but were intentionally kept to a minimum to simulate resources available in real-world primary care settings.

Data Analysis

Baseline participant characteristics were summarized by group with means ± standard deviation (SD) for continuous variables and frequency distributions for categorical variables. Independent samples t-tests and Mann-Whitney *U* tests were conducted to determine if the groups were significantly different at baseline. Mean ± SD was determined for the number of health coaching sessions completed by the intervention group. Change scores were calculated for the FNPA (total score and ten subscale scores), BMI percentile, and BMI z-scores from baseline to six months. Independent samples t-tests were conducted to examine the differences between intervention and control participants that completed the study. Effect size was calculated according to Cohen [15]. Differences between groups were considered to be significant at $p < 0.05$. Data analysis was completed using SPSS (IBM Corp. Released 2016. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

Results

A total of 203 children with a BMI $\geq 85^{th}$ percentile and who were English-proficient were further assessed for meeting inclusion criteria (Figure 1) over the course of the planned one-year recruitment period (March 2017 and February 2018). Sixty children were excluded, 51 families declined to participate, and 57 did not enroll for other reasons (e.g., cancelled/no-show to appointment, expressed interest but did not enroll upon follow-up). Thirty-five families enrolled in the MHMW pilot study and 28 families (14 intervention, 14 control) completed all baseline measures. None of the participant characteristics were significantly different between groups at baseline (Table 2).

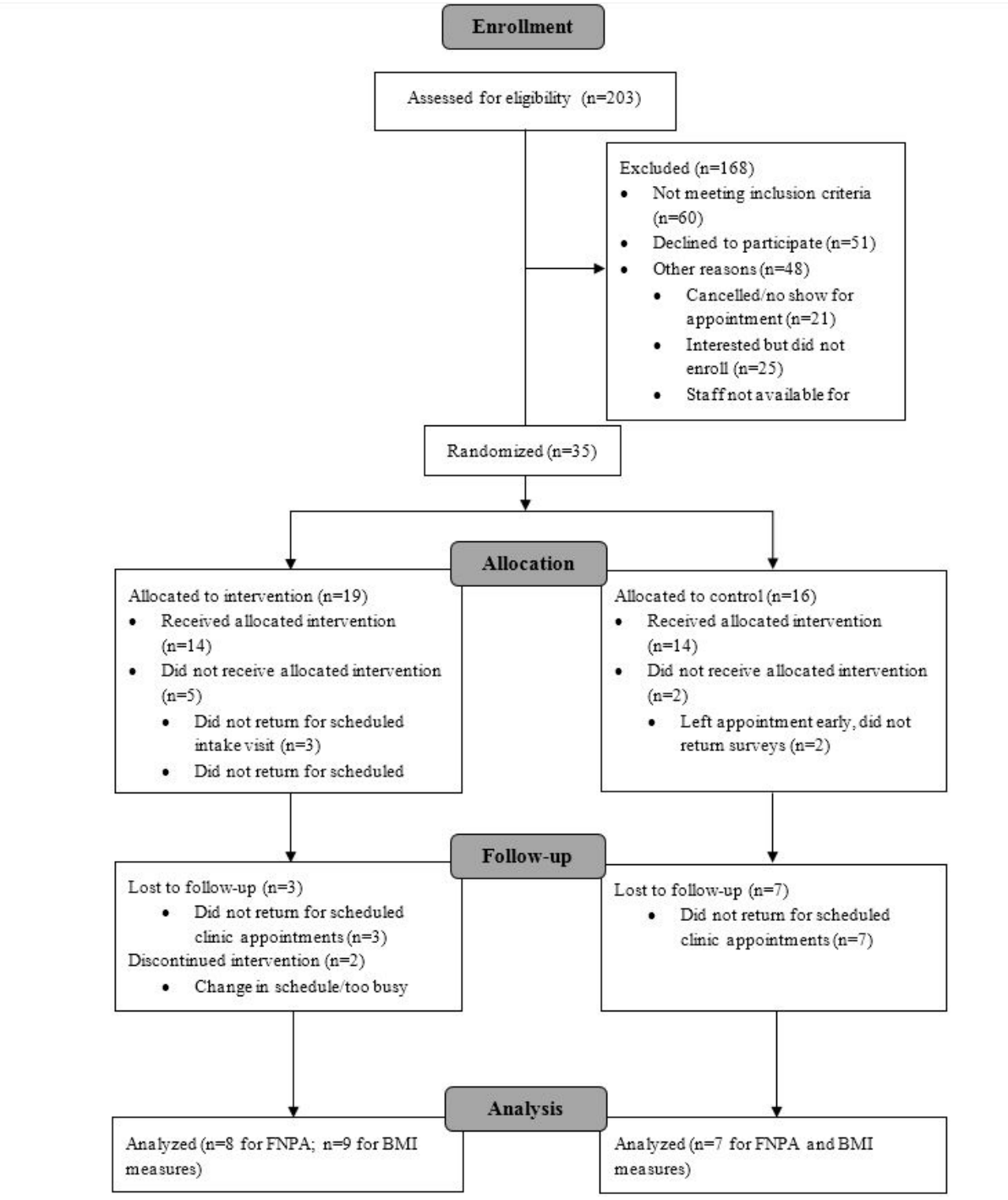


Figure 1: CONSORT diagram of participant flow from enrollment through analysis.

Table 2. Participant characteristics at baseline by group.

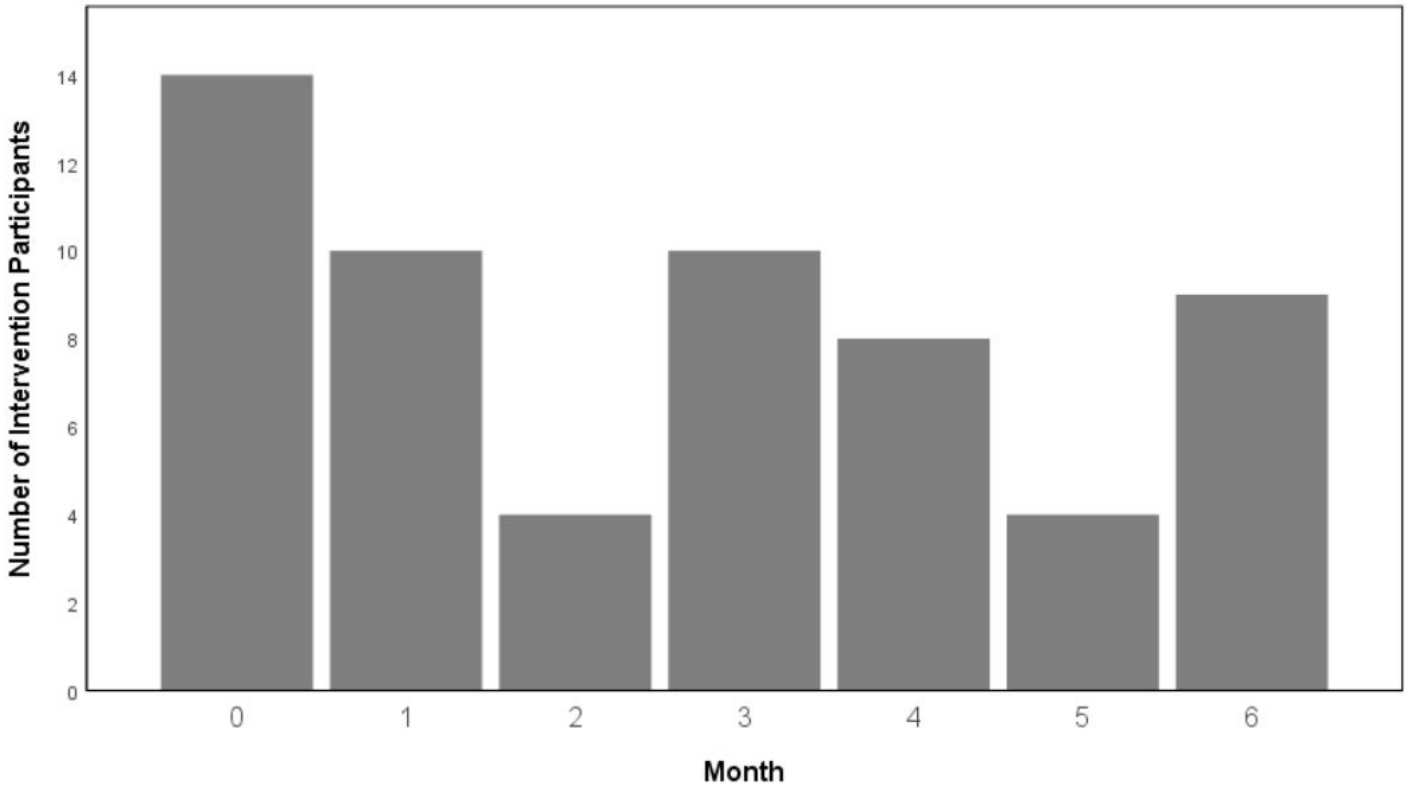
		Intervention (*n* = 14)			Control (*n* = 14)		
		Mean	SD	*n*	Mean	SD	*n*
Age (years)		8.8	2.0		9.4	2.1	
Sex	Male			5			5
	Female			9			9
BMI Category	Overweight			4			4
	Obesity			10			10
BMI Percentile		96.4	3.2		95.8	3.7	
BMI z-score		2.0	.5		1.9	.5	
FNPA Score		58.6	8.6		56.0	7.3	
Newest Vital Sign Category	High Likelihood of Limited Literacy			3			2
	Possibility of Limited Literacy			1			2
	Adequate Literacy			10			10

No significant differences at baseline.

Mean age of child participants was 8.8 ± 2 years in the intervention group and 9.4 ± 2.1 years in the control group. Mean BMI percentile was 96.4 ± 3.2 in the intervention group and 95.8 ± 3.7 in the control group. Groups were evenly distributed by sex (five males and nine females per group) and by BMI category (four with overweight and ten with obesity per group). Baseline mean FNPA scores were 58.6 ± 8.6 for intervention participants and 56 ± 7.3 for control participants. Most parent participants (71%) demonstrated adequate health literacy.

The study ended in June 2018 after follow-up data collection with the final participants enrolled was complete. Sixteen participants completed six-month BMI measurements (9 intervention and 7 control). However, only 15 participants completed the six-month FNPA (8 intervention and 7 control). Of the 14 intervention participants that completed baseline measures, the mean health coaching sessions completed prior to six months was 3.8 ± 1.7 sessions. Intervention participant engagement in the program was higher at month 3 and month 6 (in-person visits at the clinic) compared to months one, two, four and five (Figure 2).

Figure 2: Number of intervention participants engaged in sessions by month.



Among participants who completed six-month measures, the mean FNPA change score was 4.86 ± 6.28 in the intervention group and 0.38 ± 4.6 in the control group, but was not significantly different (p = 0.135) (Table 3). However, the effect size (d = 0.88) was estimated to be large based on Cohen's definition [15]. There was a significantly greater mean change score on the FNPA subscale of family eating practices (intervention 0.57 ± 0.54, control -0.13 ± 0.41; p = 0.041). Change in BMI z-score was not significantly different between groups at six months (intervention -0.007 ± 0.093, control -0.063 ± 0.14; p = 0.33).

Table 3. Mean FNPA change scores from baseline to six months by group.

	Group			
	Intervention (A)		Control (B)	
	Mean	SD	Mean	SD
FNPA Score	4.86	6.28	.38	4.60
Family Meals Score	.29	.95	.13	.99
Family Eating Practices Score	.57 B	.53	-.13	.64
Food Choices Score	.14	.69	.12	1.25
Beverage Choices Score	.71	.76	.38	1.69
Restriction/Reward Score	.57	1.13	.50	.93
Screen Time Score	1.14	1.77	-.13	1.25
Healthy Environment Score	.43	1.72	.62	.92
Family Activity Score	.43	1.62	-.50	1.07
Child Activity Score	.00	.58	-.38	1.41
Family Schedule/Sleep Routine Score	.57	.98	-.25	1.28

Results are based on two-sided tests assuming equal variances. For each significant pair, the key of the smaller category appears in the category with the larger mean.

Significance level for upper case letters (A, B, C): .05[1]

1. Tests are adjusted for all pairwise comparisons within a row of each innermost subtable using the Bonferroni correction.

Conclusion

While the change in FNPA score from baseline to six months was not significantly different between intervention and control, the estimated effect size (d = 0.88) is considered to be large. The intervention group mean change in FNPA score from baseline to six months of 4.86 ± 6.28 was similar to findings of Christison et al. (4.2 ± 5.7) from baseline to six months during a childhood obesity prevention pilot study [9]. Tucker et al. (2014) also found similar FNPA change scores (5.4 ± 6.9) after a seven week Stage 2 treatment intervention [16].

No significant change was observed in BMI percentile or BMI z-score between groups at 6 months. However, a significant change was not anticipated due to the duration and total contact time of the study. The 2017 United States Preventive Services Task Force (USPSTF) recommendation statement on screening obesity suggests ≥ 26 contact hours may be necessary to have an impact on weight status in children and adolescents 6 years of age and older [17]. Estimated total contact time of the MHMW intervention would be five hours or less over the course of six months. However, the main focus of this pilot study was lifestyle behavior change, as opposed to change in weight or BMI, which is recommended by the Expert Committee for Stage 1 and Stage 2 treatment in primary care [5].

Participants in the intervention group completed more in-person sessions (i.e., baseline, three months, and six months) compared to phone sessions (i.e., months one, two, four, and five). It is not known whether this difference is a result of the format of the session (in-person *vs* phone) or perhaps involvement of the pediatrician during sessions in the clinic. Previous research by Lupi et al. (2014) suggested parents believe pediatricians have a central role in identifying and managing childhood obesity [18]. For

instance, families in that study noted they would be willing to work with a Registered Dietitian Nutritionist (RDN) if the pediatrician recommended it, but were concerned about the additional time commitment. Hence, PCP's involvement in childhood obesity treatment may be important for retention of patients, even if PCPs do not have significant time to conduct the treatment and instead need to partner with other health care professionals. However, it may also be possible participants in the MHMW study were motivated to return to the clinic to fulfill more acute needs, such as completing a school physical, receiving vaccinations, updating prescriptions, or discussing concerns with the pediatrician.

This pilot study has a few limitations. First, this study is limited by the sample size. Of the potential participants that were approached about enrolling in the study, 51 declined to participate and 25 said they were interested but never enrolled (Figure 1). In previous research providers have suggested a barrier to childhood obesity treatment is that patients and families are not interested in making lifestyle changes [19-21]. Additionally, as participants in this study were English-proficient, generalizability to other languages should be considered.

The attrition of participants (40%) from enrollment to six months was greater than anticipated. However, similar and even greater levels of attrition (27-73%) have been seen in other childhood obesity treatment studies [22]. Most attrition was due to patients lost to follow-up (i.e., not returning to the clinic for scheduled sessions and not returning phone calls to reschedule sessions). Unfortunately, several intervention participants were lost to follow-up before completing baseline measures (i.e., FNPA and NVS), which were completed at the first health coaching session approximately one week after enrollment.

Due to both low enrollment and attrition of participants, we were not able to examine any differences when participants advanced to Stage 2 treatment versus those that continued with Stage 1 treatment. However, in this pilot study we sought to conduct an intervention in a real-world primary care setting that would likely have limited resources in terms of incentives for patients participating, as well as limited professional staff available to support a treatment intervention. Previous research has documented similar findings of low enrollment and high attrition in real-world childhood obesity treatment settings and identified a great need for additional research in these settings [22-25].

Another factor likely influencing observed outcomes and level of participant engagement in the intervention was the clinic's current standard of care, which may be a higher standard of care than at other primary care clinics. The pediatrician in this primary care practice already regularly assessed lifestyle behaviors, utilized MI for counseling, and facilitated goal setting with interested patients, all of which are practices recommended by the 2007 Expert Committee recommendations. Previous literature has documented, however, that most PCPs are not tracking/following patient lifestyle behaviors [7] and may not utilize MI due to low self-efficacy [26]. Therefore exploring the MHMW practice-based framework with a larger sample and in additional clinics will be important to determine if the observed effect is representative of actual target populations or an artifact of a non-representative sample.

The findings of this study suggest that a primary care practice-based framework for childhood obesity treatment utilizing health coaching, brief action planning, and a behavioral screening tool may be effective for facilitating lifestyle behavior change. Although, low enrollment and high attrition of participants in this pilot study make it challenging to determine the potential effectiveness of this framework.

The 2007 Expert Committee recommendation for staged treatment remains an aspirational approach for elevating patients to appropriate levels of intervention in order to facilitate lifestyle behavior change and weight maintenance with growth. However, retaining engaged patients in entry-level treatment (Stage 1) in primary care settings would be necessary prior to advancing patients to higher levels of treatment (Stages 2, 3, and 4) in the recommended stepwise approach. Further study in multiple clinics with novel strategies to engage and retain patients in real-world primary care interventions is necessary to (1) promote behavior change and long-term improvement of health status in children with overweight and obesity and (2) implement frameworks within health systems to facilitate the staged treatment approach.

Statement of Author Contributions: All authors contributed to study conception and design. MW, JG, and JRK collected the data. MW wrote the first draft with contributions from LLF. All authors reviewed, revised, and gave final approval of the manuscript.

Conflict of Interest Disclosure

- Maren Wolff – no conflicts of interest
- Jennifer Groos – no conflicts of interest
- Julia Richards Krapfl – no conflicts of interest
- Amy Christison – no conflicts of interest
- Lorraine Lanningham-Foster – no conflicts of interest

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