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Comparative Effectiveness of Clinical and Community-Based Approaches to Healthy Weight

Lauren Fiechtner, MD, MPH[1,2], **Meghan Perkins, MPH**[1], **Vincent Biggs, MD**[3], **Nancy Langhans, MD**[4], **Mona Sharifi, MD, MPH**[5], **Sarah Price, MPH**[1], **Man Luo, MPH**[1], **Joseph J. Locascio, PhD**[6], **Katherine H. Hohman, DrPH**[7], **Heather Hodge, M.Ed.**[7], **Steven Gortmaker, PhD**[8], **Shioban Torres, DrPH**[9], **Elsie M. Taveras, MD, MPH**[1,9]

[1]Division of General Academic Pediatrics, Department of Pediatrics, MassGeneral Hospital *for* Children, 125 Nashua Street, Suite 860, Boston, MA 02114, USA;

[2]Department of Gastroenterology and Nutrition, MassGeneral Hospital *for* Children, 175 Cambridge St, 5th floor, Boston, MA 02114 USA;

[3]Holyoke Community Health Center, Department of Pediatrics, 230 Maple St, Holyoke, MA 01040, USA;

[4]Greater New Bedford Community Health Center, Department of Pediatrics, 874 Purchase St, New Bedford, MA 02740, USA;

[5]Section of General Pediatrics, Department of Pediatrics, Yale University School of Medicine, 333 Cedar Street, PO Box 208064, New Haven, CT 06520, USA;

[6]Department of Neurology, Massachusetts General Hospital, 55 Fruit Street, Boston, MA 02114, USA;

[7]YMCA of the USA, 101 N Wacker Drive, Chicago, IL, 60606;

[8]Department of Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health, 677 Huntington Avenue, Boston, MA 02115, Bureau of Community Health and Prevention, Massachusetts Department of Public Health, 250 Washington Street, Boston, MA 02108, USA;

[9]Department of Nutrition, Harvard T.H. Chan School of Public Health, 677 Huntington Ave, Boston, MA, 02115 USA

Abstract

Corresponding author: Lauren Fiechtner, MD, MPH, Divisions of Gastroenterology and Nutrition, and General Academic Pediatrics, Massachusetts General Hospital *for* Children. 125 Nashua Street, 8th floor, Boston, MA 02114 USA. Telephone: 617-643-7247. Fax: 617-726-1812. lfiechtner@mgh.harvard.edu.

Contributor's Statement: Drs Fiechtner and Taveras conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript.

Ms. Perkins, Price designed the data collection instruments, collected data and reviewed and revised the manuscript.

Ms. Luo and Dr. Locascio conducted the data analyses and reviewed and revised the manuscript.

Drs Sharifi, Gortmaker and Torres conceptualized and helped design the study and critically reviewed the manuscript for important intellectual content.

Drs Langhans, Biggs and Hohman as well as Ms. Hodge helped with data collection and reviewed and revised the manuscript.

All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Objectives: The objective was to evaluate if two, pediatric weight management interventions delivered to Latino, low-income children: one in a health center, the other in a YMCA were effective in reducing Body Mass Index (BMI). We hypothesized that they would be equally effective.

Methods: Four hundred and seven children ages 6–12 years with a BMI ≥ 85th percentile receiving care at two health centers were randomized to a Healthy Weight Clinic (HWC) at the health center or to a modified Healthy Weight and Your Child (M-HWYC) intervention delivered in YMCAs. Four thousand thirty-seven children receiving care in similar health centers served as the comparison group. First, we completed a non-inferiority test comparing the M-HWYC to the HWC which was supported if the bounds of the 90% CI for the difference in %BMIp$_{95}$ changes did not contain what we considered a minimally clinically important difference, based on previous data (0.87). Then, using linear mixed models, we assessed yearly changes in BMI among intervention participants compared to comparison sites.

Results: The mean difference in %BMIp$_{95}$ between the M-HWYC and the HWC was 0.75 [90% CI: 0.07, 1.43] which did not support non-inferiority. Compared to the comparison sites, per year, children in the HWC had a −0.23 kg/m^2 [95% CI: −0.36, −0.10] decrease in BMI and a −1.03 [−1.61, −0.45] %BMIp$_{95}$ decrease. There was no BMI effect in the M-HWYC.

Conclusions: We were unable to establish non-inferiority of the M-HWYC. The HWC improved BMI, offering an effective treatment for those disproportionately affected.

Trial Registration: NCT03012126

Article Summary:

In this randomized trial in a Latino, low-income population, a PWMI delivered in a healthy weight clinic was effective in improving BMI.

Keywords

Childhood obesity treatment; primary care; community based; randomized trial

Introduction

Childhood obesity represents a major threat to public health.[1] The highest prevalence of childhood obesity in the US is among Latino (25.8%) and non-Latino Black (22.0%) compared to White (14.1%) children and increases as income decreases.[2] The United States Preventive Services Task Force (USPSTF) offers evidence that pediatric weight management interventions (PWMI) that focus on lifestyle changes and deliver ≥ 26 contact hours are important interventions.[3] Evidence suggests that multidisciplinary healthy weight clinics that provide access to a team of a pediatric provider, dietitian and community health worker are effective.[4,5]

Intensive community-based interventions for pediatric weight management offer an alternative to clinical programs. For example, the Mind, Exercise, Nutrition…Do it! (MEND®) Program, a community-based intervention has shown reductions in BMI after eighteen 2-hour group sessions held twice weekly, followed by a 12-week free swimming

pass.[6–8] The MEND program was adapted by the YMCA to a program called Healthy Weight and Your Child (HWYC). The HWYC could provide an additional and potentially less costly option if found to be non-inferior to traditional clinically-based models and allow for treatment to reach families in other settings. Such comparative studies, and in particular those that include low-income, Latino children have not been previously conducted.

We designed the Clinic and Community Approaches to Healthy Weight trial to evaluate the comparative effectiveness of a Healthy Weight Clinic (HWC) delivered in federally qualified health centers (FQHC) and a modified – HWYC (M-HWYC) delivered in YMCAs in two communities in Massachusetts. We hypothesized that the M-HWYC would be 1) non-inferior to the HWC in improving percent change of the 95th percentile (%BMIp$_{95}$) and that 2) both interventions would reduce BMI and %BMIp$_{95}$ compared to eight demographically similar comparison sites.

Methods:

Study Overview

The Clinic and Community Approaches to Healthy Weight trial was a randomized trial conducted in two FQHCs and two YMCAs serving the same two communities. The study design has been previously described (Figure 1).[9] All study activities were approved by the Institutional Review Board at the Massachusetts Department of Public Health. The trial has been recorded in the clinicaltrials.gov national registry of randomized trials (NCT03012126). There were no adverse events.

Eligibility and Recruitment

Eligibility included: 1) child was 6.0–12.9 years at referral 2) child's BMI ≥85th percentile and 3) parent could speak English or Spanish. We excluded: 1) children who did not have at least one guardian who was able to follow study procedures 2) families who planned to leave the FQHC within the study time frame, 3) families for whom the intervention was inappropriate as determined by the primary care clinician, e.g., due to emotional or cognitive difficulties that would not allow them to participate 4) children who were taking medications that substantially interfere with growth and 5) children who had a sibling enrolled.

Recruitment began in December 2016 and continued through February 2018; data collection ended in September 2019. Children were referred to the study by their primary care provider at a visit where a height and weight was obtained. After receiving the referral, research assistants called parents/guardians to confirm eligibility, obtain verbal consent and complete a survey. Participants were randomized at the end of the survey. Families were mailed a $25 gift card for completing each of the baseline, 6 month and 12-month surveys, as well as up to three $25 gift cards as incentives for attending one visit, completing 1/3 and completing 2/3 of the offered visits. The CONSORT flow diagram is displayed on Figure 2.

Randomization and Blinding

We randomized participants using two randomization lists (one for each FQHC) created by the data analyst. Lists were organized into blocks of four to keep the sizes of intervention

groups similar and assignment was concealed in numbered envelopes from those conducting the randomization. Participants were randomized in the order in which their consent was obtained. Follow-up surveys were completed by a different research assistant to ensure those assessing outcomes were blinded to intervention arm assignment.

Power

We had planned to enroll 400 children into the study and were able to enroll 407. We were powered at 91% with N=388 at follow-up to detect a clinically meaningful difference in BMI change.

Common Intervention Components

Children in both interventions were exposed to quality of care improvements in their FQHC which included primary care provider weight management training and text messages to guardians for self-guided behavior change support. Automated text messages were sent 2–3 times per week with tips on how to make lifestyle changes, messages that supported social and emotional wellness, and promoted community resource utilization and resources for mitigating unmet social needs. In addition, we mailed everyone enrolled in the interventions community resources for mitigating unmet social needs.

Healthy Weight Clinic (HWC)

The HWC provided a comprehensive, multidisciplinary team intervention and offered 30 hours of contact to the parent/guardian and child. Siblings were allowed to attend but were not included in the trial analysis. The team included a pediatrician or advanced practice clinician, community health worker and dietitian with access to mental health providers as needed. The HWC team utilized motivational interviewing for counseling and goal setting. For the first six months participants were offered monthly group visits with other families, alternating with monthly individual visits with the multidisciplinary team. Each HWC visit whether individual or group was 1.5 hours in length. The group visit curriculum included: understanding health, healthy eating, healthy drinks choices, physical activity, bullying, sleep and screen time, food label reading and eating outside the home. In the second six months participants were offered monthly individual visits with the multidisciplinary team. Participants received twice-monthly health coaching calls (approximately 10 minutes in duration) from the community health worker or dietitian in the first six months, and monthly health coaching calls in the second six months.

YMCA Modified Healthy Weight and Your Child (M-HWYC)

The YMCA of the USA worked with two local YMCAs to train staff to implement a modified version of the HWYC intervention (M-HWYC) that included 16 weekly sessions, followed by 4 sessions every other week, ending with 5 monthly sessions, for a total of 25 sessions offered to the parent/guardian and child over one year. Siblings were allowed to attend but were not included in the trial analysis. Each session was two hours long. In total the M-HWYC offered 50 contact hours. This modified intervention was different from the HWYC that is being implemented nationally which contains 25 sessions delivered over four months vs. over 12 months as was offered in this intervention. Additionally, the national

HWYC intervention is only offered to children with a BMI ≥ 95th percentile. Two group leaders provided support, education and activities during each session, including: a Family Huddle which incorporates goal setting, a parent discussion, and 60 minutes of physical activity for the children the last 30 minutes of which is for the whole family.

Comparison Sites

Eight demographically matched comparison community health centers in Massachusetts were chosen. All BMI data from children ages 5.1–14.1 years was obtained from these health centers from December 2015 – September 2019 (N=4037). This mirrored the ages and date ranges of EHR BMI measurements we obtained for our intervention participants.

Outcome Measures

Primary Outcomes: The primary outcomes were change in BMI and %BMIp$_{95}$ per year calculated based on the CDC growth curves. Height and weight were collected by clinical staff per their clinical protocols at routine visits. We extracted age and longitudinal BMI data from the electronic records of all ten health centers for 4425 children, ages 5.1–14.1 years, who received their primary care at these health centers. This provided a BMI trajectory pre-intervention for both the intervention participants and the comparison sites.

Secondary Outcomes: Secondary outcomes included lifestyle changes including changes in screen time, physical activity, sleep duration and sugary beverages for those enrolled in either the HWC or M-HWYC at baseline and 1-year.[10–16]

Covariates: Race/ethnicity for intervention participants was collected via survey for comparison sites and any intervention participants missing race/ethnicity on the survey it was collected from their EHR data. Income and parent BMI were collected via self-report on the baseline survey.

Statistical Analysis

Non-Inferiority Analysis—We performed a two-tailed upper bound 90% CI noninferiority test of child %BMIp$_{95}$ to examine if %BMIp$_{95}$ change difference for the M-HYWC was appreciably inferior to that of the standard HWC intervention.[9] Non-inferiority was supported if the bounds of the 90% CI for the difference in %BMIp$_{95}$ changes did not contain what we considered a minimally clinically important difference, based on previous data (0.87).[17] We stratified these results by severe obesity vs. overweight/obesity.

Changes in BMI and %BMIp$_{95}$ in the HWC and M-HWYC vs. Comparison Sites—We then examined changes in BMI and %BMIp$_{95}$ and compared changes among each intervention arm to the comparison sites. To assess changes per year in BMI and %BMIp$_{95,}$ we used indicator variables for time and intervention arm (HWC, M-HWYC or comparison site). We performed an intention to treat analysis for children enrolled in the interventions with BMI measurements at follow-up N= 388 (95%). We used the MIXED procedure in SAS 9.4 (SAS Institute, Cary NC) to fit mixed linear regression models with random intercepts and slopes. The models accounted for clustering of observations within individuals and within sites. There was a larger prevalence of Latino patients and higher

baseline BMIs in the intervention groups compared to the comparison sites so models were adjusted for these covariates. Given the increased prevalence of severe obesity enrolled in the intervention groups compared to the comparison sites, we examined severe obesity as an interaction term which was significant and thus, we present stratified results.

Lifestyle Change—We examined changes in lifestyle change from baseline to 1-year for those enrolled in the intervention arms for those who completed the follow-up survey N=330 (81%). We examined guardian reported change in sugary beverage, fast-food intake, sleep duration, screen time, and physical activity assessed via survey at baseline and 1-year. Models were adjusted for community, self-reported parent BMI category (lean or overweight/obesity) and household income (≤$20,000 vs. >$20,000).

Results:

Participant Characteristics

Figure 2 shows the participant flow of the study. Clinicians referred 770 children; we attempted to contact 673 children. We enrolled 407 children, 201 to the HWC and 206 to the M-HWYC. At follow-up we obtained BMI from 388 (95%) of children. 4037 children were identified from the comparison sites as detailed above. Table 1 shows baseline characteristics of the study sample. Parental BMI and income were not balanced at randomization between the HWC and M-HWYC. Compared to children in the comparison sites, those in the intervention groups had a higher percentage of Latino children and children with severe obesity.

Outcomes

Non-Inferiority—The mean difference in $\%BMIp_{95}$ between the M-HWYC and the HWC (considered the standard intervention) was 0.75 (90% CI: 0.07, 1.43). Because the CI contained 0.87, we were unable to establish non-inferiority. When examining stratified data by overweight or obesity vs. severe obesity category, we were again unable to establish non-inferiority for the M-HWYC for those with overweight or obesity, but for those with severe obesity the M-HWYC was non-inferior (Figure 3 and Table 2).

BMI Effectiveness Results—Table 3 shows participants unadjusted and covariate-adjusted changes per year in BMI and $\%BMIp_{95}$. In the fully adjusted model, HWC participants' BMI decreased by −0.23 kg/m^2 (95%CI: −0.36, −0.10) per year and $\%BMIp_{95}$ decreased by −1.03 (95% CI: −1.61, −0.45) per year compared to the comparison sites. In the fully adjusted model the M-HWYC participants' BMI increased by 0.02 kg/m^2 (95%CI: −0.11, 0.16) per year and $\%BMIp_{95}$ decreased by −0.22 (95% CI: −0.83,0.38) per year compared to the comparison sites.

Stratified BMI results by Baseline BMI category—Table 4 presents the unadjusted and covariate-adjusted BMI changes per year stratified by baseline BMI category. In fully adjusted models BMI decreased by −0.28 (95% CI: −0.51, −0.05) for those with overweight, −0.36 (95% CI: −0.56, −0.16) for those with obesity, and increased by 0.04 (95%CI −0.23, 0.32) for those with severe obesity in the HWC compared to the comparison sites. We saw

similar findings for %BMIp$_{95}$ change for those in the HWC. In the M-HWYC program, BMI stratified results for change in BMI and %BMIp$_{95}$ were not statistically significant.

Lifestyle Change—Supplemental Table 1 outlines the changes in lifestyle from baseline to 1-year. For those in the HWC in fully adjusted models, sugary beverage intake decreased by −2.59 servings/week (95% CI −3.68, −1.50), fast-food intake/week decreased by −0.61 servings/week (95% CI: −0.91, −0.31), sleep duration increased by 0.53 hours/ day (95% CI: 0.24,0.82), screen time decreased by −1.11 hours/day (95%CI: −1.67, −0.55), and being physically active for 60 minutes or more per day increased by 1.01 days/week (95% CI: 0.56, 1.46) from baseline to 1-year. For the participants in the M-HWYC intervention in fully adjusted models participants decreased their sugary beverages per week (−2.12 servings; 95% CI: −3.10, −1.14), and increased the frequency of being physically active for 60 minutes or more per day (0.74 days (95% CI: 0.29, 1.20).

Discussion

We found that a PWMI delivered in HWCs resulted in improvements in BMI, %BMIp$_{95}$ when compared to 8 comparison sites, and sugary beverage and fast-food intake, sleep, screen time and physical activity among a predominantly Latino and low-income population. We were unable to establish non-inferiority in %BMIp$_{95}$ change for the M-HWYC overall and for those with overweight or obesity, but participants in the M-HWYC did show improvements in sugary beverage intake and physical activity. When BMI and %BMIp$_{95}$ results were stratified by weight category neither intervention was effective in reducing BMI for children with severe obesity.

In the USPSTF evidence report and systematic review, two PWMIs reviewed offered 26–51 contact hours and reported BMI change.[17–19] The magnitude of BMI effect in the HWC compared to comparison sites in our study per year was −0.23 kg/m^2 (95%CI: −0.36, −0.10) which was lower but was significant as compared to the Kalarchian, et. al study which saw a 12-month BMI change of (SE) −0.61 kg/m^2 (0.31) (p=0.11) compared to usual care.[20] Our BMI change was more modest than was found by Nemet, et. al. who demonstrated a −1.7 +/− 2.3 kg/m^2 vs. 0.6 +/− 0.9 kg/m^2 in usual care. However, this study had only 46 children enrolled.[19] Compared to our previous HWC intervention change %BMIp$_{95}$ was more robust in this current study in the HWC group and decreased by −1.03 (95% CI: −1.61, −0.45) compared to our previous finding of a %BMIp$_{95}$ −0.87 (95% CI: −1.82, 0.09) change.[17] Our estimate was larger than the median changes found in the Pediatric Obesity Weight evaluation Registry sites for 6–11 year olds of %BMIp$_{95}$ of −0.16 (IQR, −1.40, 0.87) at 12 months.[21] Finally, any decrease in BMI is likely of clinical benefit and a strength of our study is that we saw this BMI decrease preserved up to 2 years post-intervention.

This study was designed with the hypothesis that the M-HWYC intervention would be non-inferior to the HWC in reducing %BMIp$_{95}$. Our findings did not support this and there are several potential reasons. First, the M-HWYC was delivered at a different intensity and length compared to the original MEND® program. The YMCA has returned to this shorter more intense model. Second, it is possible that the presence of a pediatric medical provider in the HWC plays a role, as past work has shown that lifestyle change is often improved

when supported by a pediatrician.[22,23] In addition, both HWCs had access to mental health which may have improved outcomes. Our clinician champions at the HWCs played a large role in the implementation of the HWC: participated in every two-week technical assistance calls to share lessons learned and adapted the intervention collaboratively. The M-HWYC may have led to other health benefits that weren't measured such as quality of life or other cardiometabolic effects as has been seen in other successful YMCA programs.[25,26] It's also possible that if there had been more engagement in the M-HWYC we would have seen a BMI effect as has been shown in previous YMCA interventions.[25,26] Finally, the comparison sites sample had a lower baseline BMI and proportion of Latino patients served compared to our intervention sites.

There are several reasons why neither intervention was effective in reducing BMI or $\%BMIp_{95}$ for children with severe obesity. First, we may be underpowered for this subgroup. Furthermore, the net daily energy intake decrease necessary for children with severe obesity to achieve a healthy BMI is likely larger than what can be delivered in a primary care-based model.[24] Earlier referral to a HWC when a child has a BMI in the overweight/obese range or to a tertiary center for children with severe obesity may be preferable. From our estimates it appears that children with severe obesity in all three groups (HWC, M-HWYC and comparison sites) had flattening of their BMI suggesting that they were receiving more weight management care from their pediatrician or elsewhere. Children with severe obesity may need to be in the program longer, receive a higher dose or additional social supports given the higher prevalence among Latino and Black populations who suffer from issues associated with racial inequity.[27]

As with any study, this one is subject to limitations. First, our population was largely Latino and our results may not be generalizable, however, this study appropriately focuses on those who are disproportionately affected. Finally, none of our participants met the recommended 26 hours of contact: HWC participants received a mean (SD) of 4.8 (5.7) hours and the M-HWYC participants received a mean (SD) of 9.9 (12.7) hours. It is possible that if adherence had been higher, effects would have been more robust.[28]

Conclusion

A comprehensive HWC PWMI that included a pediatric provider, dietitian and community health worker with text messages and community resource support resulted in improved BMI and $\%BMIp_{95}$ for a low-income largely Latino population. We were unable to establish non-inferiority for the M-HWYC. Obesity is a complex disease that requires investment in high quality interventions and the HWC may offer a solution for children disproportionately affected.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations:

PWMI	Pediatric weight management interventions
BMI	body mass index
FQHC	federally qualified health center
HWC	Healthy Weight Clinics
M-HWYC	modified Healthy Weight and Your Child
USPSTF	United States Preventive Services Task Force
MEND®	Mind, Exercise, Nutrition…Do it!
%BMIp_{95}	95th percentile
SD	standard deviation
EHR	electronic health record
CI	confidence interval

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What's Known?

Pediatric weight management interventions (PWMI) that offer ≥ 26 contact hours have been found to be effective in improving body mass index (BMI). However, few studies have compared the effectiveness of treatment approaches that optimize the care of vulnerable children.

What this Study adds:

In this randomized trial in a largely Latino, low-income population, a PWMI delivered in a healthy weight clinic was effective in improving BMI. The noninferiority of a PWMI delivered in a community setting was not established.

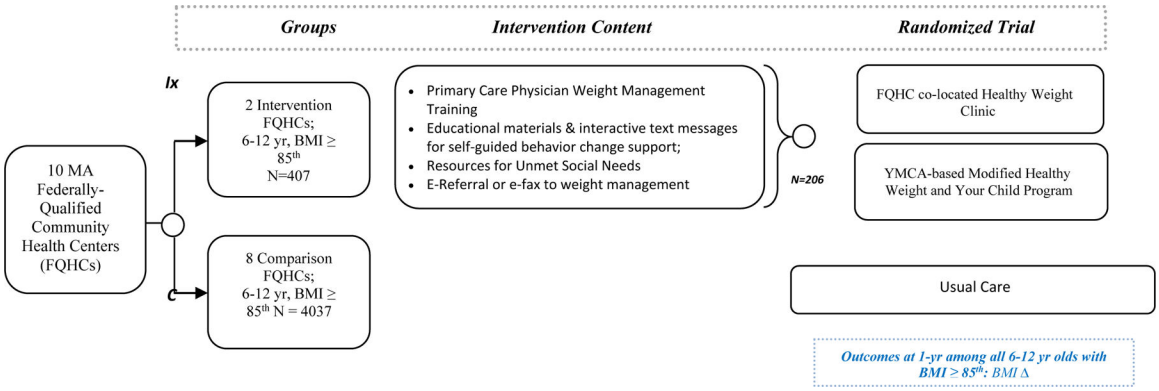


Figure 1.

Study design of the Clinic and Community Approaches to a Healthy Weight Trial (Ix=Intervention; C=Comparison)

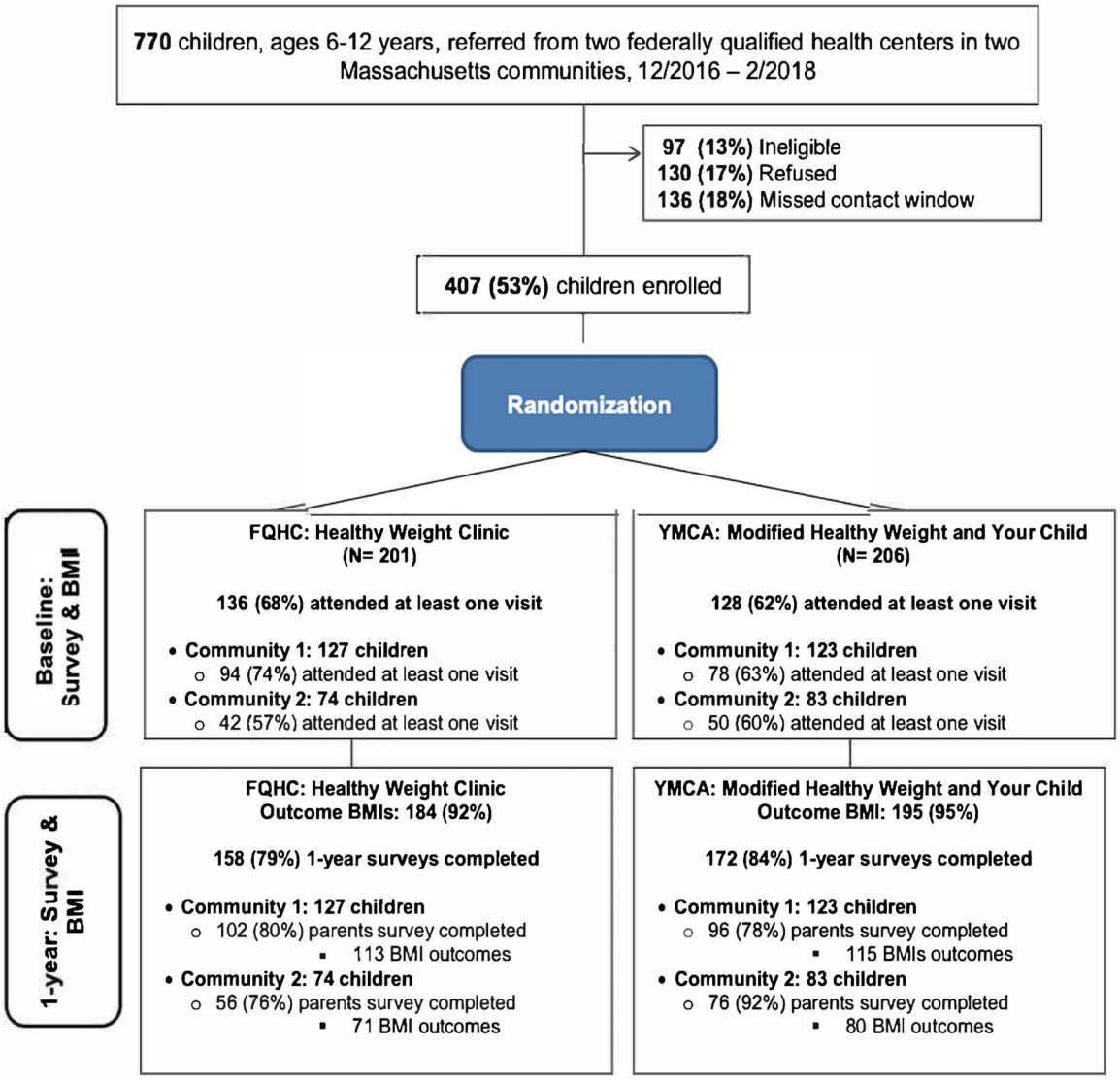
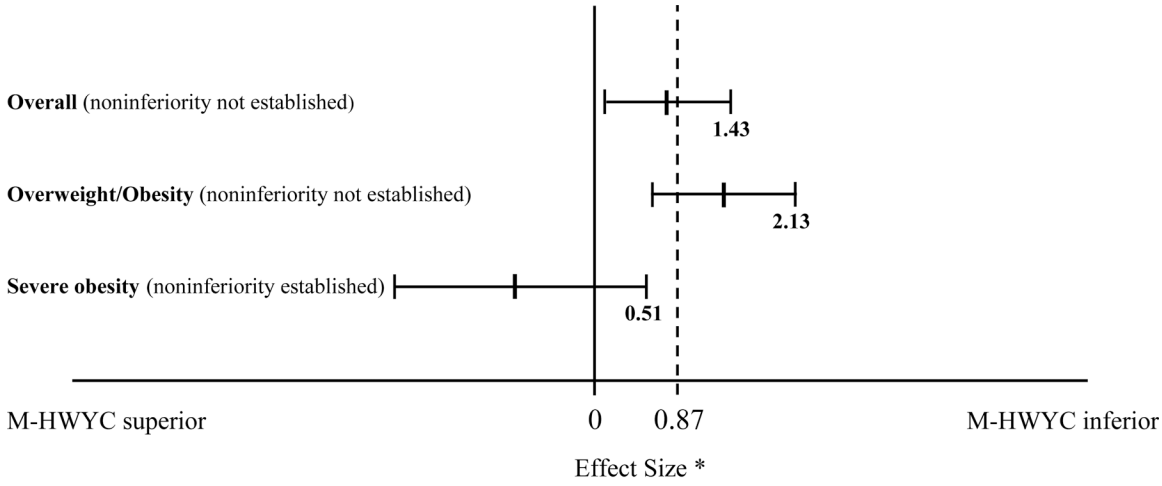


Figure 2.
CONSORT Participant Flow for the Clinic and Community Approaches to Healthy Weight Trial



*Regression coefficient of interaction of Treatment X Time.

Figure 3.

Non-inferiority Test in Overall Sample and Stratified by Baseline BMI category Comparing Upper Bounds of the 90%CIs with Minimally Clinically Important Margin (0.87)

Table 1.

Baseline Characteristics of Participants in the Clinic and Community Approaches to a Healthy Weight Trial with 1-year BMI (N=388) and subjects from 8 Comparison Sites, by Intervention Assignment

Baseline Participant Characteristics	**Overall N=4425**	**HWC N= 191**	**M-HWYC N= 197**	**p-value[c]**	**Comparison Sites N = 4037**	**p-value[d]**
Age at baseline[a], years, mean (SD)	9.60 (2.22)	9.52 (1.90)	9.52 (1.77)	0.98	9.60 (2.25)	0.77
Male, n (%)	2314 (52.29)	104 (54.45)	107 (54.31)	0.98	2103 (52.09)	0.69
Race/ethnicity, n (%) (n=278 missing)						
White, non-Hispanic/Latino	677 (16.33)	4 (2.09)	2 (1.02)	0.62	671 (17.85)	**<.0001**
Hispanic/Latino	2106 (50.78)	178 (93.19)	185 (93.91)		1743 (46.37)	
Black, non-Hispanic/Latino	1078 (25.99)	8 (4.19)	10 (5.08)		1060 (28.20)	
Asian	87 (2.10)	1 (0.52)	0 (0)		86 (2.29)	
Other, non-Hispanic/Latino	199 (4.80)	0 (0)	0 (0)		199 (5.29)	
Baseline[a] BMI, kg/m^2, mean (SD)	23.79 (4.49)	24.96 (4.82)	24.91 (4.63)	0.91	23.68 (4.45)	**<.0001**
Baseline[a] %BMIp$_{95}$, mean (SD)	107.64 (16.80)	113.32 (18.66)	113.36 (18.90)	0.98	107.09 (16.50)	**<.0001**
Baseline[a] BMI Category, n (%)						
Overweight	1818 (41.08)	53 (27.75)	53 (26.90)	0.98	1712 (42.41)	**<.0001**
Obesity	1736 (39.23)	81 (42.41)	84 (42.64)		1571 (38.92)	
Severe Obesity	871 (19.68)	57 (29.84)	60 (30.46)		754 (18.68)	
Average #of EHR BMI measurements before enrollment date, mean (SD)	2.38 (1.42)	3.98 (2.40)	3.99 (2.19)	0.98	2.23 (1.19)	**<.0001**
Average # of EHR BMI measurements ≥ 6 months after enrollment, mean (SD)	2.33 (1.74)	4.23 (2.92)	3.81 (2.35)	0.12	2.17 (1.54)	**<.0001**
Avg years of follow-up HER BMI measurements, mean (SD)	1.66 (0.51)	1.79 (0.47)	1.79 (0.46)	0.96	1.65 (0.51)	**<.0001**
Randomized Trial Only (N=388)						
	Overall N=388	**HWC N= 191**	**M-HWYC N= 197**			
Average HWC or M-HWYC visits attended	4.16 (5.34)	3.20 (3.68)	5.09 (6.44)	<.0001	N/A	
Community						
Community 1	235 (60.57)	118 (61.78)	117 (59.39)	0.63	N/A	
Community 2	153 (39.43)	73 (38.22)	80 (40.61)		N/A	
Parent age[b]	35.13 (7.65)	34.86 (7.52)	35.40 (7.77)	0.49	N/A	
Born outside US[b] (n=1 missing)	142 (36.69)	73 (38.22)	69 (35.20)	0.54	N/A	
Education levels combined[b] (n=4 missing)						
Some high school or less	171 (44.53)	81 (43.09)	90 (45.92)	0.50	N/A	
High school degree	128 (33.33)	68 (36.17)	60 (30.61)		N/A	

Some college or higher	85 (22.14)	39 (20.74)	46 (23.47)		N/A	
Parent BMI Category[b] (n=32 missing)						
Underweight	4 (1.12)	2 (1.16)	2 (1.09)	0.07	N/A	
Normal weight	57 (16.01)	29 (16.86)	28 (15.22)		N/A	
Overweight	94 (26.40)	57 (33.14)	37 (20.11)		N/A	
Class 1 Obesity	87 (24.44)	39 (22.67)	48 (26.09)		N/A	
Class II Obesity	67 (18.82)	25 (14.53)	42 (22.83)		N/A	
Class III Obesity	47 (13.20)	20 (11.63)	27 (14.67)		N/A	
Income (Dichotomous)[b] (n=88 missing)						
$20,000 or less	205 (68.33)	93 (62.84)	112 (73.68)	**0.04**	N/A	
More than $20,000	95 (31.67)	55 (37.16)	40 (26.32)		N/A	
Parental Depression[b]	139 (35.82)	81 (42.41)	58 (29.44)	**0.01**	N/A	
Food Insecure[b]	189 (48.71)	87 (45.55)	102 (51.78)	0.22	N/A	
Housing Insecure[b]	112 (28.87)	54 (28.27)	58 (29.44)	0.80	N/A	

[a]Baseline *is defined as the visit associated with enrollment date.*

[b]These fields were collected from survey data which were not administered to the comparison sites

[c]p-values were calculated with ANOVA for continuous variables and Chi-square test for categorical variables

[d]p-values were calculated with ANOVA for continuous variables and Chi-square test for categorical variables

Table 2.

Non-inferiority effect estimates for the Participants in the Clinic and Community Approaches to a Healthy Weight Trial with 12-month BMI (N=388). M-HWYC compared to HWC, stratified by severe obesity. Unadjusted for covariates.

	%BMIp$_{95}$ Mean Difference β (90% CI)
Overall (N=388)	0.75 (0.07, 1.43)
Overweight/Obesity (N=271)	1.35 (0.57, 2.13)
Severe Obesity (N=117)	−0.82 (−2.15, 0.51)

Table 3.

Unadjusted and adjusted BMI changes per year of participants in the Clinic and Community Approaches to a Healthy Weight Trial with 1-year BMI compared to subjects from 8 Comparison Sites, by intervention assignment (N=4425)

	Unadjusted β (95% CI)	**Model 1[a] β (95% CI)**	**Model 2[b] β (95% CI)**	**Unadjusted β (95% CI), N=4425**	**Model 1[a] β (95% CI), N=4147**	**Model 2[b] β (95% CI), N=4147**
BMI (kg/m2) within group change				**BMI (kg/m2) comparison sites as reference**		
HWC	**−0.39 (−0.53, −0.25)**	**−0.39 (−0.54, −0.25)**	**−0.32 (−0.46, −0.19)**	**−0.18 (−0.31, −0.05)**	**−0.18 (−0.31,−0.04)**	**−0.23 (−0.36, −0.10)**
M-HWYC	**−0.26 (−0.42, −0.09)**	**−0.26 (−0.42, −0.09)**	−0.16 (−0.32, 0.003)	0.02 (−0.12, 0.15)	0.02 (−0.12, 0.16)	0.02 (−0.11, 0.16)
Comparison Sites	**−0.10 (−0.15, −0.05)**	**−0.11 (−0.16, −0.05)**	**0.07 (0.02, 0.12)**	Reference	Reference	Reference
%BMIp$_{95}$ within group change				**%BMIp$_{95}$ comparison sites as reference**		
HWC	**−2.24 (−2.87, −1.60)**	**−2.24 (−2.87, −1.60)**	**−2.15 (−2.79, −1.52)**	**−1.01 (−1.60, −0.43)**	**−1.00 (−1.58,−0.42)**	**−1.03 (−1.61, −0.45)**
M-HWYC	**−1.66 (−2.40, −0.92)**	**−1.66 (−2.40, −0.92)**	**−1.65 (−2.39, −0.92)**	−0.18 (−0.79, 0.42)	−0.17 (−0.78, 0.44)	−0.22 (−0.83, 0.38)
Comparison Sites	**−0.88 (−1.11, −0.65)**	**−0.90 (−1.14, −0.66)**	**−0.75 (−0.99, −0.52)**	Reference	Reference	Reference

[a] Adjusted for Hispanic vs. Non-Hispanic (N=278 missing Race and Ethnicity)

[b] Adjusted for Hispanic vs Non-Hispanic and BMI at baseline

Table 4.

Unadjusted and adjusted BMI changes per year of participants in the Clinic and Community Approaches to a Healthy Weight Trial with 12-month BMI compared to subjects from 8 Comparison Sites, by intervention assignment, stratified by baseline BMI category

	Unadjusted β (95% CI), N=1818	**Model 1 β (95% CI), N=1693**	**Model 2 β (95% CI), N=1693**
Overweight Baseline BMI Category			
BMI (kg/m2)			
HWC, n=53	**−0.23 −0.46, −0.01)**	**−0.25 (−0.48, −0.02)**	**−0.28 (−0.51, −0.05)**
M-HWYC, n=53	0.15 (−0.10, 0.40)	0.14 (−0.11, 0.39)	0.13 (−0.12, 0.37)
Comparison Sites, n=1712	Reference	Reference	Reference
%BMIp $_{95}$			
HWC, n=53	**−1.29 (−2.29, −0.30)**	**−1.34 (−2.34, −0.34)**	**−1.35 (−2.35, −0.35)**
M-HWYC, n=53	0.55 (−0.53, 1.63)	0.51 (−0.58, 1.59)	0.50 (−0.59, 1.58)
Comparison Sites=1712	Reference	Reference	Reference
Obesity Baseline BMI Category			
	Unadjusted β (95% CI), N=1736	**Model 1 β (95% CI), N=1637**	**Model 2 β (95% CI), N=1637**
BMI (kg/m2)			
HWC, n=81	**−0.32 (−0.52, −0.12)**	**−0.31 (−0.51, −0.11)**	**−0.36 (−0.56, −0.16)**
M-HWYC, n=84	−0.08 (−0.29, 0.13)	−0.07 (−0.28, 0.14)	−0.08 (−0.29, 0.13)
Comparison Sites n=1571	Reference	Reference	Reference
%BMIp $_{95}$			
HWC, n=81	**−1.54 (−2.42, −0.66)**	**−1.48 −2.36, −0.60)**	**−1.52 (−2.40, −0.64)**
M-HWYC, n=84	−0.48 (−1.40, 0.45)	−0.43 (−1.36, 0.50)	−0.48 (−1.41, 0.45)
Comparison Sites, n=1571	Reference	Reference	Reference
Severe Obesity Baseline BMI Category			
Main Outcome	**Unadjusted β (95% CI), N=871**	**Adjusted for Model 1 β (95% CI), N=817**	**Model 2 β (95% CI), N=817**
BMI (kg/m2)			
HWC, n=57	0.07 (−0.22, 0.35)	0.09 (−0.20, 0.37)	0.04 (−0.23, 0.32)
M-HWYC, n=60	0.04 (−0.24, 0.32)	0.06 (−0.23, 0.34)	0.07 (−0.20, 0.35)
Comparison Sites, n=754	Reference	Reference	Reference
%BMIp $_{95}$			
HWC, n=57	0.36 (−0.88, 1.60)	0.43 (−0.80, 1.66)	0.43 (−0.80, 1.66)
M-HWYC, n=60	−0.01 (−1.25, 1.23)	0.07 (−1.16, 1.30)	0.06 (−1.16, 1.29)
Comparison Sites, n=754	Reference	Reference	Reference