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FIT & STRONG! PLUS: DESCRIPTIVE DEMOGRAPHIC AND RISK CHARACTERISTICS IN A COMPARATIVE EFFECTIVENESS TRIAL FOR OLDER AFRICAN-AMERICAN ADULTS WITH OSTEOARTHRITIS

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Abstract

Objectives: The prevalence of osteoarthritis (OA) has increased in the US. We report on a comparative effectiveness trial that compares Fit & Strong!, an existing evidence-based physical activity (PA) program, to Fit & Strong! Plus, which combines the Fit & Strong! intervention with a weight management intervention.

Methods: Participants included 413 overweight/obese (BMI 25–50 kg/m²) adults with lower extremity (LE) OA. The majority of the sample was African-American and female. Both interventions met 3 times weekly for 8 weeks. Primary measures included diet and weight.

Results: The baseline mean BMI for all participants was 34.8 kg/m^2 , percentage of calories from fat was high, and self-reported PA was low.

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Ethical standards: All authors in this manuscript declare that they have no conflicting interest

Discussion: This sample of overweight/obese African-American adults had lifestyle patterns at baseline that were less than healthful, and there were differences between self-report and performance-based measures as a function of age.

Keywords

Weight management; obesity; older adults; physical activity

Purpose

Arthritis and related rheumatic conditions, including osteoarthritis (OA), affect approximately 50 million or 22% of the adult United States (US) population (1), and the majority of affected individuals are older adults. African Americans with OA have higher rates of inactivity and functional limitations than non-Hispanic whites (2–4), and African-American women with OA have approximately twice the rate of disability compared to non-Hispanic whites (5). Risk factors for OA include genetics, female sex, and obesity (6), and obesity is a strong risk factor for the incidence and progression of knee OA (7, 8). Unfortunately, the prevalence of obesity has increased significantly since the 1980s, with African-American women 60 years having the highest rates compared to non-Hispanic white women (57.5% vs. 38.2%) (9–13).

Obese individuals who have OA are usually advised to lose weight (14–16). Several studies support the combination of physical activity (PA) and weight management as central to the reduction of knee pain and limitations in mobility (17, 18), and several randomized controlled trials (RCTs) have tested the combined impact of modest weight loss with regular moderate PA compared to either PA or diet/weight management alone (17, 19–22). These studies highlight a need to test relatively simple, easily replicable evidence-based programs that combine both PA and weight management for adults with OA and to test these interventions with disadvantaged populations that have consistently higher rates of OA and obesity, such as African-American women (1, 23). To address this need, our team developed and is testing Fit & Strong! Plus.

Fit & Strong! Plus combines interventions from two successful RCTs that have shown improvements in PA (Fit & Strong!) and weight management (the Obesity Reduction Black Intervention Trial, ORBIT) (24–26). The Fit & Strong! intervention and its evidence base are described in detail elsewhere (27–29). ORBIT is a 6-month weight loss and PA intervention targeting African-American women that was successful in reducing weight by 3.0 kg in the intervention group, on average (25). In 2012, we received funding to test the comparative effectiveness of customary Fit & Strong! vs. the new Fit & Strong! Plus version using an RCT. The details of the trial design are published elsewhere (30).

Methods

Design

The Fit & Strong! Plus trial is a randomized comparative effectiveness trial that is testing whether Fit & Strong! Plus produces significantly better results than standard Fit & Strong!

on weight, dietary intake, PA, physical performance, OA-associated symptoms of LE pain and stiffness, anxiety / depression, and self-efficacy for weight loss and exercise among overweight / obese adults with OA. The project was approved by the Institutional Review Board at the University of Illinois at Chicago (UIC), and all participants gave written informed consent. The trial is registered at clinicaltrials. gov (NCT03180008).

Setting

Both interventions were conducted at local community sites.

Subjects

Participants were randomly assigned to Fit & Strong! (n = 210) or Fit & Strong! Plus (n = 203) and are being followed for 18 months.

Interventions

Both Fit & Strong! and Fit & Strong! Plus are conducted in 90-minute sessions 3 times per week over an 8-week period. The first 60 minutes of both interventions consist of stretching, low-impact aerobics, and strengthening exercises with a consistent focus on lower extremity muscles. The interventions diverge in the 30-minute health education component at the end of the session. The health education component of Fit & Strong is designed to build self-efficacy (SE) related to managing pain and OA symptoms through PA, while Fit & Strong! Plus also incorporates SE for dietary weight management behaviors.

Measures

Anthropometrics: Height was measured using a portable stadiometer (Seca, United Kingdom), and weight was measured using a calibrated digital scale (Tanita Worldwide). Both height and weight were measured twice. If the two measurements were > 0.5 cm or > 0.2 kg apart, a third measurement was taken, and the mean of the two closest measurements was used. BMI was calculated as weight (kg) divided by height (m) squared. To assess body composition change, we measured waist circumference twice using a Gulick 150-centimeter anthropometric tape (Country Technology, Inc.; Gays Mills, WI, USA). If the two waist measurements were > 1 cm apart, a third measurement was taken, and the mean of the two closest measurements was used.

Dietary intake

We used the Block 2005 Food Frequency Questionnaire (FFQ) to assess dietary intake. The FFQ, which inquires about approximately 110 food items, was designed to estimate habitual intake of an array of nutrients and food groups (31). Using data from the FFQ, participants' diet quality was calculated using the Healthy Eating Index-2010 (HEI) (32), which measures adherence to the 2010 Dietary Guidelines for Americans (DGA).

Physical Activity

PA was assessed using the Physical Activity Scale for the Elderly (PASE) (33), a valid and reliable self-report measure for older adults, with a higher score indicating greater self-reported physical activity.

Performance measures

Lower extremity (LE) strength was measured using the 30-second Chair Stand, which tests the number of full stands from a seated position a person can complete in 30 seconds with folded arms (34). Mobility was assessed using the 6-minute Walk Test, which measures functional exercise capacity (35–37).

OA Symptoms

The Western Ontario and McMaster Universities Arthritis Index (WOMAC) was used to assess OA symptoms of stiffness and pain in the hip and knee joints during daily activities and the degree to which physical functioning is affected by arthritis.

Depression and anxiety

These outcomes were measured using the GERI-AIMS, a version of the Arthritis Impact Measurement Scale that was adapted for use with an elderly population (38).

Self Efficacy

We assessed weight-related SE using the Weight Efficacy Lifestyle Questionnaire (WEL), a 20-item measure that assesses confidence to manage eating in an array of situations (39).

Statistical Analyses

We tested for differences in participant characteristics between randomization groups at baseline using t-tests for most continuous variables, Wilcoxon rank tests for income and number of chronic conditions, and chi-square tests for categorical variables. We also examined differences in anthropometrics, diet, physical activity, performance measures, WOMAC OA index, anxiety/depression, and self-efficacy by age (<70 vs 70 years) using t-tests and chi-square tests. We explored associations with diet quality, PA, and physical performance using linear regression models with multiple covariates. SAS v 9.4 was used for all analyses.

Primary Results

This study met its target recruitment goal of 400 subjects. We randomized 413 individuals: 203 to standard Fit & Strong! and 210 to Fit & Strong! Plus. Table 1 reflects the baseline demographic characteristics. As we anticipated in designing the study, our sample was primarily African-American and representative of the racial and ethnic distribution of older adults in the neighborhoods surrounding the participating Chicago Park District sites. As measured by the Block 2005 FFQ, participants reported a mean energy intake of 1579 (SD = 710) calories, the mean percentage of calories from fat was 39.9 (SD = 6.9%), and the mean HEI total score was 66.3 out of a possible 100, which is in the "needs improvement" range, but is consistent with the HEI-2010 total score reported by the USDA for a nationally representative sample of adults that were 65 years and older (https://www.cnpp.usda.gov/sites/default/files/healthy_eating_index/HEI89-90report.pdf; https://www.cnpp.usda.gov/sites/default/files/healthy_eating_index/HEI-2010-During-2011-2012-Oct21-2016.pdf).

The mean score on the PASE (33) was 97.2 (SD = 61.3), which is lower than the mean scores of 169.3 (SD = 88.2) reported by Skou and colleagues (40) and 131.4 (SD = 71.1) by Martin and colleagues (41) in work with older adult samples. Participants had a low mean score of 8.7 (SD = 3.6) on the 30-second chair stand as well as a low mean score of 356.3 meters (SD = 97.1) on the six-minute walk test. On the WOMAC, participants had a mean of (SD = 4.0) on the pain subscale, 3.2 (SD = 1.7) on the stiffness subscale and 18.0 (SD = 12.9) on the physical functioning subscale, indicating a moderate amount of OA-related impairment at baseline. The mean score for anxiety/depression measured by the GERI-AIMS was low at 2.5 (SD = 1.7). Mean overall score on weight-related self-efficacy was 134.1 (SD = 32.9), which is higher than reported for other samples of overweight/obese non-Hispanic white samples (5, 42). Mean self-efficacy for exercise was also relatively high: 7.6 (SD=2.0) on a 1–10 scale.

Differences by Age

As shown in Table 2, we tested for differences between younger (60–69 years) and older (70 years) participants on a number of measures. Younger participants had a higher mean BMI (35.3 vs. 33.6 kg/m², p = .003), and 23% of younger participants had Class III obesity (40 kg/m²) compared to 12% of older participants. Consistent with their lower BMI, older participants also scored significantly higher on the HEI (mean=68.4 vs. 65.4, p = .009) and consumed more fiber (10.6 vs. 9.6 g/1000 kcal, p = .02). Mean scores on the self-reported WOMAC showed that younger participants perceived more OA-related impairment than older participants. This was evident across the pain (6.1 vs. 4.6, p < .001), stiffness (3.3 vs. 2.7, p = .002), and physical functioning subscales (19.1 vs. 15.6, p = .01). However, on the performance-based six-minute walk, younger participants had a better mean score than older participants (363.9 m vs. 338.8 m, p = .02).

Finally, we used linear regression models with multiple covariates to explore possible predictors of diet quality, PA, and performance measures at baseline (Table 3). The chosen predictors explained a relatively small percentage of the variance for the HEI-2010 (R^2 =0.06) and self-reported PA (R^2 =0.07), somewhat more for chair stands in 30 seconds (R^2 =0.12) and a substantial percentage for six-minute walk distance (R^2 =0.29). None of the selected predictors were significantly associated with the HEI-2010 score at baseline. However, increased age was associated with lower self-reported PA (b=-1.69, p = .002), a shorter 6-minute walk distance (b=-3.38, p < .001), and fewer chair stands in 30 seconds (b=-0.08, p = .01). A higher BMI predicted a shorter 6-minute walk distance (b=-4.70, p < .001) and fewer chair stands (-0.08, p =.02). Married participants had higher self-reported PA (b=18.44, p=.009), but did not have significantly higher performance scores. A higher score on the WOMAC (more severe OA symptoms) predicted a shorter 6-minute walk distance (b=-1.16, p < .001) and fewer chair stands (b=-0.04, p < .001).

Discussion

OA is a leading cause of pain and disability among older adults in the US (43). The primary aim of this comparative effectiveness trial is to assess whether Fit & Strong! Plus is more successful than Standard Fit & Strong! for producing positive dietary changes at post-

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intervention (2 months) and producing a 5% or greater weight loss at 6 months that is maintained at 18 months among older adults who both have OA and are overweight or obese. The secondary aim is to assess whether Fit & Strong! Plus will produce superior outcomes for this population in self-reported PA and physical performance, lower extremity (LE) pain, stiffness, function, anxiety/depression, and self-efficacy at 2 months that are maintained at 6, 12, and 18 months.

Dietary intake is a central aspect of weight management, and high fat consumption is a key contributor to the obesity epidemic (44, 45). Overall, participants in our study consumed more than the recommended amount of fat and less than the recommended amount of fiber (46). Although clinical guidelines recommend PA as a central tenet of treating OA, PA in this population is low, with less than 50% meeting current recommended activity levels (47–49). In addition, a number of articles demonstrate that African Americans are less likely to meet PA guidelines than non-Hispanic whites (50, 51), and that African-American women, in particular, are among those reporting the lowest levels of PA (52–54).

We also administered the performance-based six-minute walk test. The mean score in our sample was 356.3 meters, which was lower than reports from other samples comprising individuals with OA (55).

Measuring lower body strength is vital when evaluating the functional performance of older adults with OA (34, 56) The 30-second chair stand test provides a reliable and valid indication of lower body strength and function (57). In our study, the mean score on this test was 8.7 (SD = 3.6), which is lower than the 13.1 reported in another study of healthy older adults (mean = 70.5 years) (34), and importantly, it was also lower than a score of 10.0 reported in a study of older adults (mean = 56.3 years) with OA(55).

Overall, OA-related pain and functional limitations are known to be higher among African Americans compared to non-Hispanic whites (58, 59). On the WOMAC, we observed both commonalities and differences between our sample and other older adult samples. For example, pain and physical function scores were 6.5 and 24.2 in the Messier IDEA trial respectively (20), compared to our scores of 5.6 and 18.0. Wilcox and colleagues (55) reported lower scores than our sample on the pain subscale (4.6–4.9), but higher scores on the stiffness subscale (5.1–5.5 vs. 3.2 in our sample). A prior study of customary Fit & Strong! that included approximately 47% African Americans (42) reported similar scores on the pain and stiffness subscales but a higher score on physical function (42).

The differences between our older and younger participants are striking for the WOMAC. On all subscales, younger participants (60–69 years) reported more pain, stiffness, and disability than older participants (70 years). This could reflect societal changes in how people think about their health, with younger groups of older adults having higher expectations for their health [60].

Limitations.

The current study has several limitations. It is limited to individuals who are overweight and obese (BMI = $25-50 \text{ kg/m}^2$) and will not provide information on how Fit & Strong! Plus

could benefit those with a BMI < 25 or > 50. We also did not clinically confirm OA, but instead used self-reported LE pain and stiffness. Additionally, our sample consisted of primarily lower-income adults with a median income of \$25,000.

Conclusions.

This study adds to the limited literature on combined PA and diet and weight management studies with older African-American adults with OA. Our results highlight some differences in self-reported versus performance-based functioning in our study sample at baseline and also documents differences between younger and older individuals within our older adult sample. Our findings regarding increased BMI and poorer self-reported function agree with findings from several recent longitudinal studies on aging that document disturbing trends of increased disability related to overweight/obesity in younger cohorts of aging adults (61, 62). These findings illustrate the need for additional research and ongoing refinement of interventions for this population that is both high-risk and growing rapidly.

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Table 1

Participant characteristics at baseline

	F&S! Plus	s N=203	F&S! N	=210	All N=	413 ^{<i>a</i>}
	Mean or %	SD or N	Mean or %	SD or N	Mean or %	SD or N
Age, y	67.7	6.0	68.1	5.8	67.9	5.9
Sex						
Female	87%	177	85%	178	86%	355
Male	13%	26	15%	32	14%	58
Race						
Black or African American, not Hispanic	92%	187	92%	193	92%	380
White, not Hispanic	4%	8	4%	9	4%	17
Hispanic	1%	3	1%	2	1%	5
Multiracial/other	2%	5	3%	6	3%	11
Education, y	14.3	1.9	14.1	2.0	14.2	1.9
Not HS graduate	4%	9	7%	15	6%	24
HS graduate/GED	13%	27	16%	34	15%	61
Some college or technical school	45%	91	40%	84	42%	175
College graduate	37%	76	37%	77	37%	153
Employed full or part-time	15%	30	11%	23	13%	53
Marital status						
Married or member of unmarried couple	26%	52	26%	54	26%	106
Divorced or separated	34%	70	39%	82	37%	152
Widowed	24%	48	20%	43	22%	91
Never married	16%	33	15%	31	16%	64
Income, median	25,000		25,000		25,000	
Health insurance ^b						
Medicare	67%	136	70%	147	69%	283
Medicaid	16%	33	18%	38	17%	71
Private/supplemental	44%	89	40%	83	42%	172
Chronic conditions, of 17^c	2.8	1.6	3.0	1.7	2.9	1.6
Weight, kg	93.0	16.6	93.5	16.0	93.3	16.3
BMI, kg/m ²	34.7	5.7	34.9	5.4	34.8	5.5
BMI category						
Overweight $(25 - <30 \text{ kg/m}^2)$	21%	43	19%	39	20%	82
Obesity class I (30– <35 kg/m ²)	36%	73	35%	74	36%	147
Obesity class II (35–<40 kg/m ²)	24%	48	26%	54	25%	102
	24% 19%	48 39	20% 20%	43	23% 20%	82
Obesity class III (40 kg/m ²)						
Waist circumference, cm	114.0	14.1	112.3	12.9	113.1	13.5
Height, cm	163.8	7.8	163.6	7.8	163.7	7.8
Energy, kcal	1606	700	1553	721	1579	710
Fat, g	72.8	34.4	68.7	36.3	70.7	35.4

	F&S! Plus	s N=203	F&S! N	=210	All N=4	413 ^{<i>a</i>}
	Mean or %	SD or N	Mean or %	SD or N	Mean or %	SD or N
Fat, % kcal	40.6	6.6	39.2	7.2	39.9	6.9
Fiber, g	15.2	7.8	15.2	7.6	15.2	7.7
Fiber, g/1000 kcal	9.7	3.5	10.1	3.7	9.9	3.6
Healthy Eating Index-2010	65.9	9.8	66.7	11.1	66.3	10.5
HEI-2010 category						
Poor (0–50)	6%	11	10%	21	8%	32
Needs improvement (51-80)	89%	176	82%	166	86%	342
Good (81–100)	5%	10	8%	16	7%	26
PASE physical activity score ^d	97.3	59.7	97.0	62.9	97.2	61.3
Six-minute walk, m	358.8	94.0	353.9	100.1	356.3	97.1
Chair stands in 30 sec	8.7	3.4	8.8	3.7	8.7	3.6
WOMAC global score $(0-96)^e$	26.3	17.7	27.3	17.1	26.8	17.4
Pain subscale (0–20)	5.4	3.9	5.8	4.1	5.6	4.0
Stiffness subscale (0–8)	3.0	1.8	3.3	1.7	3.2	1.7
Physical functioning subscale (0-68)	17.8	12.9	18.2	12.8	18.0	12.9
Anxiety/depression $(0-10)^{f}$	2.5	1.7	2.5	1.7	2.5	1.7
Weight efficacy lifestyle (WEL) total score $(0-180)^g$	137.0	32.3	131.2	33.3	134.1	32.9
Self-efficacy for exercise $(1-10)^g$	7.7	1.9	7.6	2.0	7.6	2.0

^a.N=345 for income, N=411 for waist. For diet data, N=400; records with estimated energy <500 or >5000 were excluded from the analysis (N=13: 6 in F&S Plus, 7 in F&S). N=409 for physical activity score and 6-minute walk, and N=412 for chair stands

b. Percentage of participants reporting each type of insurance; some participants reported more than one type of insurance

^{c.}Chronic conditions: Number of self-reported conditions currently affecting health (of 17): arthritis, high BP, heart disease, mental illness, diabetes, cancer, alcohol or drug abuse, lung disease, kidney disease, liver disease, stomach disease, blood disease, stroke or other neurologic problems, vascular disease, vision problems, hearing problems, thyroid

d. A higher score indicates greater physical activity

e. A higher score indicates greater difficulties due to OA

f. A higher score indicates greater anxiety/depression

g. A higher score indicates greater self-efficacy.

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Table 2

Participant characteristics at baseline by age

	Age 60–69	N=286 ^a	Age 70 I	N=127 ^a	p ^b
	Mean or %	SD or N	Mean or %	SD or N	
Weight, kg	95.4	16.2	88.5	15.6	<.001
BMI, kg/m ²	35.3	5.6	33.6	5.3	.003
BMI category					.008
Overweight (25-<30 kg/m ²)	16%	47	28%	35	
Obesity class I (30-<35 kg/m ²)	36%	104	34%	43	
Obesity class II (35-<40 kg/m ²)	24%	68	27%	34	
Obesity class III (40 kg/m ²)	23%	67	12%	15	
Waist circumference, cm	114.7	13.3	109.6	13.4	<.00
Energy, kcal	1607	755	1515	593	.23
Fat, % kcal	40.2	7.2	39.3	6.3	.22
Fiber, g/1000 kcal	9.6	3.6	10.6	3.6	.02
Healthy Eating Index-2010	65.4	10.3	68.4	10.6	.009
HEI-2010 category					.12
Poor (0-50)	9%	25	6%	7	
Needs improvement (51-80)	86%	240	84%	102	
Good (81–100)	5%	14	10%	12	
PASE physical activity score	99.9	64.6	90.9	52.8	.17
Six-minute walk, m	363.9	94.5	338.8	101.0	.02
Chair stands in 30 sec	8.8	3.4	8.5	4.0	.40
WOMAC global score $(0-96)^{C}$	28.5	17.7	22.9	16.1	.002
Pain subscale (0-20)	6.1	4.0	4.6	3.8	<.00
Stiffness subscale (0-8)	3.3	1.7	2.7	1.8	.002
Physical functioning subscale (0-68)	19.1	13.1	15.6	12.0	.01
Anxiety/depression (0–10) ^e	2.6	1.7	2.2	1.7	.01
Total WEL score $(0-180)^{f}$	130.7	34.9	141.5	26.7	.002
Self-efficacy for exercise $(1-10)^{f}$	7.6	2.0	7.8	1.9	.19

a. Ns differ for some variables due to missing data; see Table 1

b. From t-tests with pooled variance for continuous variables and chi-square tests for categorical variables

^{C.} A higher score indicates greater difficulties due to OA

d. A higher score indicates greater physical activity

e. A higher score indicates greater anxiety/depression

f. A higher score indicates greater self-efficacy.

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Table 3

Predictors of diet quality, physical activity, and performance measures

	HEL	HEI-2010 (K ⁴ =0.06)	(0 0 ,0)=-			(CIIAII SUAILUS (N -0.12)	
	q	SE	d	В	SE	þ	q	SE	b	q	SE	d
Intercept	59.3	9.7	<0.001	218	53	<0.001	723	73	<0.001	17.5	3.0	<0.001
Male	-3.00	1.56	0.05	-0.13	9.13	0.99	4.24	12.59	0.74	0.64	0.52	0.22
Age, y	0.13	0.10	0.19	-1.69	0.55	0.002	-3.38	0.76	<0.001	-0.08	0.03	0.01
BMI, kg/m ²	-0.19	0.11	0.08	-0.69	0.59	0.24	-4.70	0.82	<0.001	-0.08	0.03	0.02
College graduate	0.97	1.10	0.38	-8.40	6.46	0.19	-5.11	8.89	0.57	-0.05	0.36	0.88
Married or unmarried couple	-0.36	1.20	0.77	18.44	6.99	0.009	14.27	99.66	0.14	0.51	0.40	0.20
Chronic conditions, of 17	0.63	0.36	0.08	-0.07	2.12	0.97	-4.84	2.91	0.10	-0.04	0.12	0.74
WOMAC global score ^b	-0.04	0.04	0.28	-0.36	0.21	0.0	-1.16	0.29	<0.001	-0.04	0.01	<0.001
Anxiety/depression ^{c}	-0.33	0.35	0.35	-1.16	2.08	0.58	1.16	2.86	0.69	-0.07	0.12	0.56
Total WEL score ^d	0.02	0.02	0.25	0.12	0.10	0.22	-0.21	0.14	0.12	0.00	0.01	0.63
Self-efficacy for exercise ^d	0.27	0.31	0.39	1.14	1.78	0.52	11.54	2.46	<0.001	0.21	0.10	0.04
Six-minute walk, m	0.00	0.01	0.82	I	ł	1	I	I	I	1	1	1
HEI-2010	ł	1	I	0.08	0.30	0.79	0.09	0.41	0.82	-0.01	0.02	0.39

For diet data, N=400; records with estimated energy <500 valk

 $\boldsymbol{b}_{\mathrm{A}}$ higher score indicates greater difficulties due to OA

 $c_{\cdot}\mathbf{A}$ higher score indicates greater anxiety/depression

 $d_{\rm A}$ higher score indicates greater self-efficacy.