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Increased 1-year continuation of DMPA among women randomized to self-administration: results from a randomized controlled trial at Planned Parenthood

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Abstract

Objectives: Self-administration of subcutaneous depot medroxyprogesterone acetate (DMPA-sc) is feasible, acceptable, and effective. Our objective was to compare one-year continuation of DMPA-sc between women randomized to self-administration versus clinic administration.
Study design: We randomized 401 females ages 15–44 requesting DMPA at clinics in Texas and New Jersey to self-administration or clinic administration in a 1:1 allocation. Clinic staff taught participants randomized to self-administration to self-inject and observed the first injection; participants received instructions, a sharps container, and three doses for home use. Participants randomized to clinic administration received usual care. All participants received DMPA-sc at no cost and injection reminders via text message or email. We conducted follow-up surveys at six and 12 months.
Results: Three hundred thirty-six participants (84%) completed the 12-month survey; 316 completed both follow-up surveys (an 80% response rate excluding eight withdrawals). Participants ranged in age from 16–44. One-year DMPA continuous use was 69% in the self-administration group and 54% in the clinic group (p=.005). There were three self-reported pregnancies during the study period, all occurred in the clinic group; all three women had discontinued DMPA and one reported her pregnancy as intended.

Among the self-administration group, 97% reported that self-administration was very or somewhat easy; 87% would recommend self-administration of DMPA-sc to a friend. Among the clinic group, 52% reported interest in self-administration in the future. Satisfaction was similar between groups. No serious adverse events were reported.
Conclusions: DMPA self-administration improves contraceptive continuation and is a feasible and acceptable option for women and adolescents.
Implications: Self-administration of subcutaneous DMPA can improve contraceptive access, autonomy, and continuation, and is a feasible and acceptable option for women and adolescents. It should be made widely available as an option for women and adolescents.
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1. Introduction

The overall family planning goal for Healthy People 2020 is to *"Improve pregnancy planning and spacing, and prevent unintended pregnancy"* [1]. This in response to estimates that nearly half of all pregnancies in the United States are unintended and one-third are mistimed [2]. The most effective way to reduce unintended pregnancy is to increase consistent use of effective contraception [3].

Data from the National Survey of Family Growth show that approximately 4.5% of U.S. contraceptive users ages 15–44 were relying on injectables as their contraceptive method in 2012, an estimated 1.5 million women [4]. Among Planned Parenthood patients use is higher: 15% of female contraceptive clients were using injectables in 2015, roughly 290,000 women and adolescents [5].

Abbreviations: DMPA, depot medroxyprogesterone acetate; DMPA-IM, intramuscular depot medroxyprogesterone acetate; DMPA-sc, subcutaneous depot medroxyprogesterone acetate.

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Depo-Provera®, the intramuscular (IM) form of depot medroxyprogesterone acetate (DMPA), has been available in the U.S. since 1992. A subcutaneous formulation of depo-subQ provera 104™ (DMPA-sc) became available in 2004, providing the same efficacy with a lower dose and greater ease of administration [6]. Traditionally, patients return to a health center for DMPA administration within 12–14 weeks of the previous injection. For some women the time and expense of a clinic appointment may outweigh the other advantages of DMPA, which may lead them to choose less reliable contraceptive methods. Self-administration of DMPA-sc outside the clinic setting may therefore be an attractive option for some women, offering increased contraceptive access and autonomy and reduced healthcare-related costs.

Self-administration of DMPA-sc is feasible, acceptable, and effective. Beasley et al. (2014) conducted a randomized trial with 137 women to evaluate DMPA-sc self-administration versus clinic administration and confirmed the therapeutic effect by measuring trough serum concentrations [7]. Ninety of 91 women were able to correctly self-inject and continuation rates were 71% in the self-administration group and 63% in the clinic administration group at 12 months. All women had serum concentration in the therapeutic range, confirming their ability to administer injections successfully at home.

A previous single-arm pilot study of self-administered DMPA-sc found a one-year continuation rate of 74% [8]. Eighty-seven percent of women in this study reported self-injection to be easy, and 94% would be likely to recommend it to others. One study included adolescent DMPA users and found that most were interested and able to self-administer successfully [9].

In a UK study most health professionals (86%) were comfortable teaching women DMPA-sc self-injection, but 45% were concerned about unintended pregnancies [10]. In this non-randomized study of DMPA users, 80% of self-injections were given on time (and no injections were given beyond the 14-week interval). The majority of women who wanted to use DMPA-sc at home were able to do so; however, 20% reported some difficulty with one or more injections (e.g., resistance to the medication passing through the needle).

Other feasibility studies also confirm women's interest in DMPA self-injection [11,12]. A survey conducted in family planning clinics found that 21% of all patients would be interested in self-administration; interest was higher (40%) among DMPA users [13].

Sayana® Press, a newer subcutaneous DMPA delivery system, is approved in many countries worldwide and is specifically labeled for self-administration in a number of markets in Europe; studies conducted outside of the U.S. show promise for improving access to and continuation of DMPA-sc [14,15]. Sayana® Press is not available in the United States and thus was not available for use in the present study.

Building upon prior studies, we conducted a randomized controlled trial to compare one-year continuation of DMPA-sc between women randomized to self-administration versus clinic administration. Secondary objectives included assessment of feasibility and patient satisfaction.

2. Materials and methods

2.1. Study design

We conducted an open-label, randomized parallel group clinical trial using DMPA-sc (depo-subQ provera 104™) at three Planned Parenthood health centers located in Texas and New Jersey. Female patients ages 15–44 requesting DMPA were randomized to either self-administration or clinic administration in a 1:1 allocation from August 2015–February 2016. We compared method continuation and patient satisfaction between arms based on follow-up surveys at six and 12 months. The study was approved by the Chesapeake Institutional Review Board and registered on clinicaltrials.gov (NCT02509767).

Females ages 15–44 requesting DMPA, including method initiators and continuers, were eligible to enroll in the study. Additional inclusion criteria were: not desiring pregnancy in the next 12 months; understanding spoken and written English or Spanish; willing to consider/attempt self-injection; and willing to be randomized to either self- or clinic administration of DMPA. We excluded women with medical contraindications to DMPA based on the US Medical Eligibility Criteria for Contraceptive Use, enrolling only women in Categories 1 or 2 [16].

2.2. Study procedures

Participants completed a web-based baseline survey in the clinic assessing demographics, sexual activity, reproductive history, and contraceptive use and satisfaction. They received the first DMPA-sc dose in the clinic on the day of enrollment. Those initiating or restarting DMPA followed the QuickStart protocol [17].

The sequence for the 1:1 (self vs. clinic) treatment allocation was determined using a random number generator in blocks of six; individual assignments were placed in sequentially numbered opaque envelopes. Following screening and informed consent, study staff enrolled each willing participant and opened the next envelope in the sequence. Patients ages 18 and over provided informed consent; for those under age 18, both assent and parental consent was required.

Participants were either taught to self-inject or were administered DMPA-sc by qualified clinic personnel. Those randomized to self-administration were taught to self-inject using printed instructions based on the drug packaging insert. If willing, participants then self-administered DMPA-sc under staff supervision. Those who correctly self-administered received three additional doses of DMPA-sc, a self-administration kit

(including alcohol swabs, cotton pads, bandages, mini sharps disposal container), and printed self-administration instructions for the subsequent three injections along with a calendar showing the appropriate injection dates.

Participants who were not interested in self-administration — either after the educational session or after correctly self-administering the medication — were permitted to cross over to the clinic administration group and remain in the study. They were not told of this option ahead of time to discourage enrollment of subjects who were not truly willing to self-administer. Participants returned to the enrollment clinic or performed self-injection every 12–14 weeks, depending on the study arm. Participants received a reminder email and/or text message two weeks before each injection was due. Participants uncomfortable with self-injection at any point could return to the enrollment clinic to receive their injection per usual clinic protocol.

Participants received a link to follow-up surveys via email, text, or both at 26 and 52 weeks following enrollment, and received up to four reminders through email, text, and phone. Study participants were compensated up to $90 for completion of all three surveys, regardless of whether they continued DMPA.

The primary study outcome was one-year DMPA continuous use by self-report (defined as reporting two additional doses on the six-month survey and at least one additional dose on the 12-month survey, i.e. 1 year of continuous contraceptive coverage). For 12-month continuation, we defined continuous use as reporting three post-enrollment injections within 42 weeks of enrollment (36+6 weeks allowing for a 2-week window period per shot). We therefore classified those with a final study dose beyond the 42-week period as discontinued. Secondary outcomes included patient-reported satisfaction with DMPA; satisfaction with home use; and barriers associated with contraceptive care.

2.3. Statistical analysis

We hypothesized higher continuation with self-administration compared to standard care. A sample size of 400 was calculated to detect an estimated 13% difference between groups (80% power; one-sided α=0.05; allowing for 15% loss-to-follow-up). We conducted all statistical analyses on an intent-to-treat basis using chi-square and *t* tests as appropriate.

To assess our primary hypothesis of improved continuation in the self-administration group, we used chi-square analysis and calculated risk differences and 95% confidence intervals for six- and 12-month continuation (i.e., the absolute increase in continuation at both time points). We also examined differences by age group and DMPA user status at enrollment and conducted several sensitivity analyses for the primary study outcome. We performed all analyses using STATA version 13 (StataCorp: College Station, TX).

3. Results

A total of 401 participants were randomized. Of those, 336 participants (84%) completed the 12-month survey; 316 completed both six- and 12-month surveys (an 80% complete response rate excluding eight subjects who withdrew from the study). Response rates and loss-to-follow-up were similar between study arms (82% responded to both follow-up surveys in the clinic group vs. 79% in the self-administration group, p=.44). Four participants crossed over from the self-administration to clinic arm before giving the first injection; two crossed over later and eight withdrew from the study (Fig. 1).

3.1. Sample characteristics

The self- and clinic administration groups were well balanced at enrollment, with similar distributions of age, race/ethnicity, nativity, education, employment, parity, income, and insurance status. Participants ranged in age from 16–44 with a mean of 26 years. Only 2% (*n*=8) were under age 18. Approximately half self-identified as Hispanic (51%); 27% identified as Black and 18% as White. Forty-five percent had health insurance at enrollment, approximately half of which was Medicaid. Fifty percent of participants reported having trouble paying for medical care in the last 6 months, and 26% had difficulty paying for transportation. Over half (56%) were current or past DMPA users (Table 1).

3.2. Continuation

One-year DMPA continuous use was 69% in the self-administration group and 54% in the clinic group (risk difference [RD] 15%, 95% CI 5–26%; p=.005). A similar difference was observed at 6 months (87 vs. 69%; RD 18%, 95% CI 9–27%; p = <.0001) (Table 2).

We examined group differences in 12-month continuation by age group and DMPA user status at enrollment. Continuation was similar by age group (67% in ≤19 y vs. 60% in ≥20 y, p=.46), and was slightly higher among current DMPA users (68%) than new users (56%) and past users (53%) (p=.06).

We also calculated the proportion of participants in each group who reported receiving at least four shots during the study period, regardless of dose intervals. Using this relaxed definition of continuation, 78% of the self-administration group had received four shots compared to 64% of the clinic group (p=.008).

Sensitivity analyses for the 12-month continuation outcome included per-protocol and as-treated analyses. First, for 20 women assigned to self-administration, a study nurse from one site administered the first injection after training the subject to self-inject. We ran a per protocol sensitivity analysis removing these subjects; this showed a consistent direction and magnitude of the self-administration effect. For an as-treated analysis, we re-assigned the treatment group of the self-administration subjects who crossed over to the clinic administration group (*n*=6) and found a similar effect: 68% in the self-administration group versus 54% in the clinic group (RD 14%, 95% CI 4–25%].

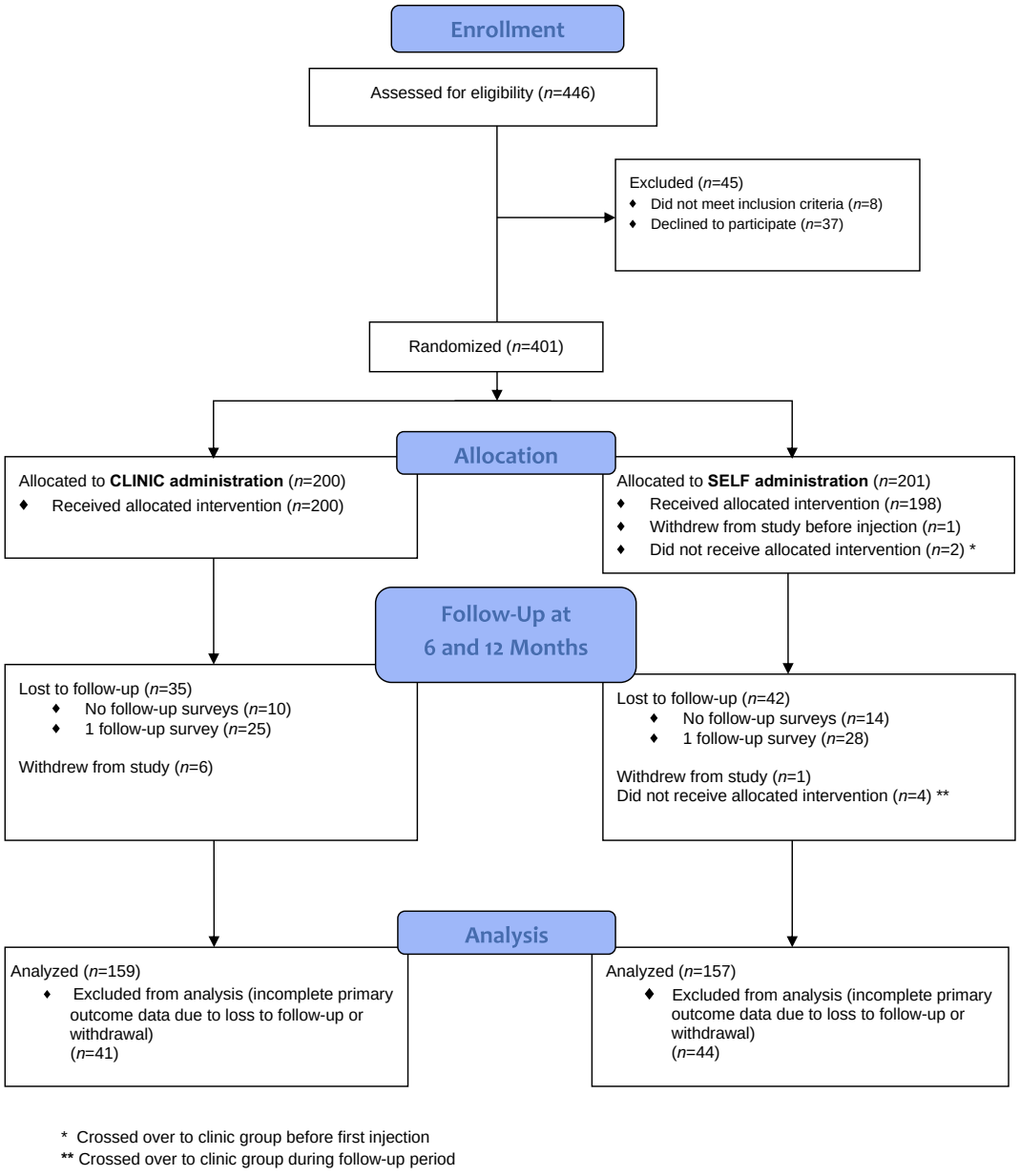

Fig. 1. CONSORT diagram.

We also re-calculated 12-month continuation classifying those who withdrew or were lost-to-follow-up as discontinued and found a similar effect in direction and magnitude.

Last, though not a primary study outcome, we calculated the proportion of participants who reported receiving five DMPA injections (i.e., an additional post-study shot), regardless of dosing intervals. We identified participants who reported two post-enrollment doses on the six-month survey and two additional doses on the 12-month survey (i.e., five total doses): 64% of the self-administration group compared to 52% of the clinic group (p=.02). It is important to acknowledge that we do not know who gave this fifth injection or where it was received because it was outside of study conditions.

There were three self-reported pregnancies during the study period, all in the clinic group; all three women had discontinued DMPA, and one reported her pregnancy as intended.

3.3. Feasibility and satisfaction

At enrollment, all participants assigned to self-administration who attempted to self-inject (*n*=178) were successful. At 12 months, 97% of participants in the self-administration group reported that it was very or somewhat easy to administer the injection; 87% would recommend self-administration to a friend. Participants reported few problems with self-administration: difficulty giving the shot (*n*=7), pain (*n*=2), and bruising at the

Table 1
Baseline characteristics of study participants (N=400)[a]

	All participants (n=400)		Clinic (n=200)		Self-administration (n=200)		p-Value for difference between study arms
	n or mean	% or SD	n or mean	% or SD	n or mean	% or SD	
Study site							
Texas (Site 1)	200	50.0	100	50.0	100	50.0	–
New Jersey (Site 2)	100	25.0	50	25.0	50	25.0	
New Jersey (Site 3)	100	25.0	50	25.0	50	25.0	
Age							
Mean and SD	26.2	6.3	26.0	6.2	26.4	6.5	.60
15–19 years	51	12.8	26	13	25	12.6	.76
20–24 years	136	34.1	68	34	68	34.2	
25–29 years	103	25.8	56	28	47	23.6	
30–34 years	60	15.0	26	13	34	17.1	
35–44 years	49	12.3	24	12	25	12.6	
Race/ethnicity							
Hispanic	204	51.4	106	53.0	98	49.8	.12
Non-Hispanic White	71	17.9	31	15.5	40	20.3	
Non-Hispanic Black	107	27.0	51	25.5	56	28.4	
Asian/Pacific Islander	8	2.0	6	3.0	2	1.0	
Other	7	1.8	6	3.0	1	0.5	
Highest grade completed							
Less than high school	52	13.1	25	12.5	27	13.6	.26
High school degree or GED	107	26.9	46	23.0	61	30.8	
Some college or vocational school	129	32.4	64	32.0	65	32.8	
Vocational school certificate/degree	36	9.1	23	11.5	13	6.6	
Associate's or 2-year degree	37	9.3	20	10.0	17	8.6	
Bachelor's degree or higher	37	9.3	22	11.0	15	7.6	
Employment status							
Employed	274	69.7	131	66.5	143	73.0	.37
Unemployed	107	27.2	59	29.9	48	24.5	
Other	12	3.1	7	3.6	5	2.5	
Annual income							
Less than $10,000	89	22.5	42	21.3	47	23.6	.90
$10,000–19,999	70	17.7	32	16.2	38	19.1	
$20,000–29,999	54	13.6	26	13.2	28	14.1	
$30,000–39,999	38	9.6	18	9.1	20	10.1	
$40,000–49,999	30	7.6	17	8.6	13	6.5	
$50,000 or more	39	9.1	21	10.7	18	9.1	
Don't know	76	19.9	41	20.8	35	17.6	
Difficulty paying for…							
Medical care or medications	105	50.0	52	51.5	53	48.6	.68
Transportation	55	26.1	28	27.7	27	24.8	.63
Housing/rent	97	46.2	42	41.6	55	50.5	.20
Food	59	28.1	31	30.7	28	25.7	.42
Current health insurance coverage							
Yes	181	45.4	93	46.5	88	44.2	.52
No	214	53.6	104	52.0	110	55.3	
Don't know	4	1.0	3	1.5	1	0.5	
Parity							
Nulliparous	178	44.6	88	44	90	42.2	.81
Parous	221	55.4	112	56	109	54.8	
Depo-Provera use							
Current user	171	43.0	88	44.2	83	41.7	.88
Past user	53	13.3	26	13.1	27	13.6	
New user	174	43.7	85	42.7	89	44.7	

[a] There was one immediate withdrawal from the self-administration group for whom we do not have baseline data.

injection site (n=2). No serious adverse events were reported. Among the clinic group, 52% reported that they would be interested in self-administration in the future and 21% said 'maybe'. Satisfaction with DMPA at 12 months was similar between the self-administration and clinic groups (87% and 92% very/somewhat satisfied, respectively, p=.47).

The most common reported reasons for discontinuation among the clinic group were weight changes (36%) and

Table 2
DMPA-sc continuation at 6 and 12 months (n=316)*

	All		Clinic		Self-administration			
	n	%	n	%	n	%	Absolute difference in continuation[a] (95% CI)	chi-square p-value
6-mo Continuation[b]	316	78.2	159	69.2	157	87.3	18.1 (9.2, 26.9)	<.0001
12-mo Continuation[c]	316	61.1	159	53.5	157	68.8	15.3 (4.7, 25.9)	.005

[a] Risk difference (RD).
[b] Defined as two additional doses reported on the 6-month survey.
[c] Defined as two additional doses reported on 6-month survey and at least one additional dose on the 12-month survey within 42 weeks of enrollment.
* Only includes the 316 participants who had complete primary outcome data for both the 6- and 12-month surveys.

irregular bleeding (32%). Among the self-administration group, the most common reasons were irregular bleeding (30%) and mood changes (13%).

4. Discussion

We observed increased continuation of DMPA-sc among women randomized to self-administration at both 6 and 12 months post-enrollment. Previous studies found trends in this direction, but none had adequate statistical power to detect this effect. Similar to other studies, we found that women randomized to self-administration were able to successfully self-inject and they found it easy to do so. Women were largely satisfied with self-administration, wished to continue, and would be likely to recommend this option to a friend. Furthermore, many women in the clinic group (52%) said they would be interested in self-injection in the future, and 21% might be interested. Upadhyay et al. found that 40% of DMPA users were interested in self-administration [13]. That our finding is higher is not surprising given that women in the present study were willing to enroll and to be randomized to either condition.

We found that 69% of those in the self-administration group were continuing DMPA at 1 year; this compares to 74% found by Prabhakaran and Sweet and 71% by Beasley et al., although these studies measured continuation in slightly different ways [7,8]. Fifty-four percent of the clinic group in this study continued DMPA for one year, similar to the St. Louis CHOICE Project (57%), where DMPA was also provided at no cost [18]. One-year continuation rates in studies where DMPA was not necessarily provided for free are similar or lower [19,20]. A survey study found that women who had difficulty obtaining or refilling a prescription in the past year were almost twice as likely to be interested in self-administration compared to those without such difficulty, suggesting that self-administration has potential to reduce barriers and disparities in access to effective contraception [13]. It is important to note, however, that potential barriers related to insurance coverage and reimbursement will need to be identified and addressed for self-administration to be successfully put into practice.

A limitation of the current study is that participants may have over-reported continued DMPA use; however, Beasley et al. previously found that all women who reported having received injections did indeed have therapeutic levels of DMPA [7]. The current study provided DMPA at no cost, thus reducing its external validity. We cannot rule out potential effects of providing no-cost contraception. The study also included injection reminders for all participants, which may be common practice among some provider networks and not others. This additional contact could have itself influenced participant behaviors, as could participation in a research study more generally.

While younger adolescents were reportedly interested in self-administration, they were not willing or able to take the additional steps required to secure parental consent for participation in our research study. All participants in our study who attempted self-injection at enrollment, including adolescents, did so successfully. Williams et al. similarly found that adolescents were both interested in and able to perform DMPA self-administration [9].

Despite these limitations, this is the largest study of this topic to date and the only randomized controlled trial with adequate statistical power to detect increased continuation between women randomized to self- versus clinic administration of DMPA. Despite few young adolescents enrolled, the study was also the first randomized trial to include teens. The study included a diverse population of women from two different states.

In sum, the findings of this study demonstrate that DMPA self-administration improves continuation and is both feasible and acceptable to patients, and should therefore be made widely available as an option for women and adolescents.

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