Efficacy, Safety, and Tolerability of a New Low-Dose Copper and Nitinol Intrauterine Device

Phase 2 Data to 36 Months

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OBJECTIVE: To assess in parous and nulliparous women, the efficacy, safety, and tolerability of a new, low-dose copper (175 mm²) intrauterine contraceptive with a flexible nitinol frame provided in a preloaded applicator.

METHODS: Institutional review boards at 12 U.S. sites approved this commercially funded project. Patients met standard inclusion and exclusion criteria for a copper-based intrauterine device (IUD), generally consistent with the Centers for Disease Control and Prevention’s U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. Intrauterine device placement occurred at any day in the eligible patient’s menstrual cycle after assuring she was not pregnant. The primary outcome measure assessed efficacy (measured by the Pearl Index) in this 1-year study with a 2-year extension. Secondary outcomes included placement success, ease of placement, safety as measured by adverse events, and tolerability assessed by discontinuation rate and bleeding and spotting patterns.

RESULTS: A total of 286 women provided 5,640 cycles evaluable for pregnancy. Patients averaged 27.1 years of age. Nulliparous women represented 60.8% of the patients. Over 36 months of observation, we identified two pregnancies (Pearl Index 0.46 [95% CI 0.06–1.67]) and 10 serious adverse events; none were study-related. Successful placement occurred in 283 participants (99.0%). Median (range) continuation times were 2.7 years (0–3.4). We identified five expulsions (1.8%), zero uterine perforations, and one report of pelvic inflammatory disease. Adverse events prompted 30 women (10.6%) to discontinue early in the first year of use with 23 (8.1%) discontinuing for issues of bleeding, pain, or both. Altogether, 107 (37.8%) completed 36 months of device use. Mean bleeding days per cycle decreased from 7.6 in cycle 1 to 5.2 in cycle 13.

CONCLUSION: The novel, low-dose copper and nitinol IUD demonstrated high efficacy and safety in this phase 2 U.S. Food and Drug Administration trial and warrants further expanded study in a phase 3 clinical trial.
Women seeking a highly effective, reversible, and hormone-free contraceptive method have one option, a copper intrauterine device (IUD). Although more than 150 million women have used copper IUDs globally,\(^1\) there have not been significant design improvements brought to the U.S. market in more than 35 years. The VeraCept Copper IUD includes several innovations (Fig. 1). The nitinol frame is small \((32 \text{ mm} \times 30 \text{ mm})\) and flexible, able to conform to anatomic variations of the uterus and smaller than the \(32 \text{ mm} \times 36 \text{ mm} \) T380A. This novel low-dose copper and nitinol IUD comes preloaded in an applicator with a tapered, rounded tip and has precut strings \(7.8 \text{ cm}\) in length—innovations not available in any currently available copper IUD outside of the United States. The placement applicator has a narrow diameter \((3.7 \text{ mm})\) compared with the T380A \((4.4 \text{ mm})\). The low-dose copper and nitinol IUD contains \(175 \text{ mm}^2\) of copper placed in strategic locations, close to the internal os of the cervix and at the cornua bilaterally. This permits a copper load of less than half of that in the currently U.S. Food and Drug Administration (FDA)—approved copper T380A, and this is less copper than in any available copper IUD globally. With less than half the copper load of the only current available FDA-approved copper IUD, the lower copper load in the new IUD may decrease copper-associated problems of cramping and bleeding.

Nitinol, a nickel and titanium alloy, is a novel material for an IUD frame. It was chosen for its superelasticity that permits compression in a narrow insertion tube and expansion to fill the space of a vessel or cavity. It is commonly used in interventional radiology for guidewires, stents, and inferior vena cava filters.\(^2\)

Two early clinical studies of this device provide reassuring data. An initial study of 463 parous women supported safety and efficacy. Investigators identified no insertion-related infections or perforations and a single pregnancy for a Pearl Index of 0.3 per 100 woman-years \((95\% \text{ CI 0.1–1.2})\). Expulsions occurred in 2.1% of participants at 6 months \(\text{(Reeves MF, Katz BH, Canela J, Hathaway M, Tal M. Initial evaluation of a novel nitinol, low-dose-copper intrauterine contraceptive [abstract]. Contraception 2014;90:315.)}\).

The second study used a randomized controlled design to compare the method to the copper T380S IUD \(\text{(a modification of the Copper T380A in which the copper sleeves on the IUD’s arms terminate at the end of the IUD’s plastic arms).}\) The novel device was associated with statistically significant lower pain scores at placement.\(^3\) In addition, low-dose copper and nitinol IUD users had greater continuation rates, fewer expulsions, and fewer removals for pain and bleeding complaints at 12 months compared with copper T380S users. These results founded the basis for an FDA phase 2 study to assess over 36 months the efficacy, safety, tolerability, and discontinuation rates of this new, low-dose copper IUD.

### ROLE OF THE FUNDING SOURCE

Sebela Pharmaceuticals, Inc, funded this study, and the research team includes Sebela employees who participated in data interpretation, as well as review, approval of, and decision to submit this manuscript. The authors had access to relevant aggregated study data and other information \(\text{(such as study protocol, analytic plan and report, validated data table, and clinical study report)}\) required to understand and report research findings. The authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately. The role of the sponsor in the design, execution, analysis, reporting, and funding is fully disclosed. The authors’ personal interests, financial or nonfinancial, relating to this research and its publication have been disclosed.
METHODS
We conducted this single-arm, phase 2 FDA trial at 12 sites in the United States. All investigators had experience placing IUDs. Participating site IRBs approved this study. Here, we report outcomes from the original 1-year study and through the end of study, to 3 years of use. Participants completed the informed consent process before study participation and agreed to continue into the 2-year extension. Study enrollment began in June 2015 and data collection finished in March 2019. The investigators followed Good Clinical Practice guidelines and the Declaration of Helsinki. The study sponsor, Sebela Pharmaceuticals Inc, designed the study and oversaw its conduct.

Enrollment began in June 2015 and concluded in March 2016. Participants were between 18 and 40 years of age at study initiation, healthy, with regular menstrual cycles of (28±5 days) for the 3 months before enrollment, premenopausal, nonpregnant, sexually active, and at risk for pregnancy in an established relationship of 1 year expecting coital frequency of at least once per month through study participation. In addition, participants agreed to use the study contraceptive as their sole method to prevent pregnancy and accepted the risk of pregnancy. This study excluded people at low risk of pregnancy, including those breastfeeding without having had two consecutive normal menses, having used depo medroxyprogesterone acetate within the previous 10 months, using exogenous hormones, and those less than 6 weeks postpartum. We excluded those with prior IUD complications; heavy or painful menses; suspected or known abnormalities of the cervix, uterus, or ovaries; and those with known intolerance to nickel or copper, including Wilson’s disease. Infection-related exclusions included any pelvic infection of the cervix, uterus, or fallopian tubes within the previous 3 months; mucopurulent cervicitis at the time of IUD placement; high risk of sexually transmitted infections (eg, multiple sexual partners); or acquired immunodeficiency syndrome (AIDS). We anticipated enrolling 25 women aged 36–40 for whom we would only assess safety data. All participants had testing for Chlamydia trachomatis and Neisseria gonorrhoea within 1 month of or at the time of IUD placement. We assured normal cervical cytology on Pap testing within the 2012 ASCCP guidelines or a result of atypical squamous cells of undetermined significance with negative high-risk human papilloma virus testing before IUD placement.

The study sponsor trained and certified each of the investigators, limited to two per site, in insertion technique. Placement occurred any cycle day consistent with Centers for Disease Control and Prevention guidelines. Placement technique employed tenaculum placement, sounding, and prescribed placement of the study IUD as directed by the study sponsor (Sebela Pharmaceuticals, Inc). All site investigators performing IUD placements received one-on-one training and direct observation by a single expert in use of the IUD inserter. Site clinical investigators used cervical dilation and pain medication at their discretion and confirmed IUD placement by transvaginal ultrasound scan immediately after placement. Site principal investigators made management decisions based on ultrasound findings independently or in conjunction with a central ultrasound reader if needed. If the initial placement attempt failed, a second attempt could be performed within 7 days. Participants reported baseline bleeding information. A research assistant assessed pain at IUD placement using a 5-point Likert scale (no pain, some pain, painful, moderately painful, and very painful). Investigators rated IUD ease of placement as very easy, easy, neither easy or hard, hard, or very hard.

Research staff provided participants with paper diaries used during the first 52 weeks of participation to record daily absence or presence of menstrual or other bleeding (none, spotting, normal, or heavy), use of menstrual bleeding products, IUD expulsion, use of additional birth control methods, presence of abnormal pain or cramping, and all days on which intercourse occurred. Research staff did not instruct participants to check IUD string length but they advised them to return for concerning bleeding or cramping suggestive of expulsion.

In-person follow-up appointments occurred at 6, 13, 26, and 52 weeks in the first year. At each visit, investigators confirmed correct IUD placement by speculum or digital examination and transvaginal ultrasound scan when the IUD strings were not seen or palpated. These visits also included a pregnancy test, a physical examination, diary review and an interview to identify any potential adverse events and concomitant medications. Phone contact occurred monthly to confirm daily diary completion to week 52. When no information on intercourse or backup contraception was available for some cycles for a given participant, mostly after week 52, when diary collection ceased, we assumed the rate of evaluable cycles for that participant would be the same as the cycles with information provided on intercourse and backup contraception. For example, if a participant provided information on 13 cycles in the first year and 10 of the cycles were evaluable, that evaluable rate of 76.9%
(10/13) would be used for future cycles. So, if she continued to participate for eight more cycles, we estimated that 6.2 cycles (76.9%) were evaluable. Participant compensation varied by site. The maximum compensation for attending all study visits ranged from $175 to $745.

We informed participants requesting IUD discontinuation of the need to use an alternative method of contraception for 2 weeks after removal and provided a package of progestin-only birth control pills if desired. We followed those requesting IUD removal for desire of pregnancy with monthly phone contact for 6 months. At the 52-week visit, an investigator assessed IUD placement by transvaginal ultrasound examination and offered participants continued use of the IUD until 3 years with end of 28-day cycle contacts and in-person follow-up every 6 months. Participants extending use beyond 1 year did not systematically collect diary data. Discontinuation visits occurred when participants desired discontinuation, or reported an expulsion or pregnancy. We defined expulsion as partial or complete, with the study device moving respectively part way into the vagina or all the way out of the body.

We chose the sample size to provide an estimate on pregnancy and adverse effects consistent with the goals of an FDA phase 2 study. The primary outcome measure was effectiveness, evaluated as the pregnancy rate at 12 months measured by the Pearl Index. We also assessed pregnancy rates by life-table analysis and assessed pregnancy rates by both methods annually up to 3 years. Secondary outcomes included rates of placement success, expulsion, discontinuation rates, reason for discontinuation, adverse events, serious adverse events, and bleeding and spotting patterns. A medical monitor conducted monthly reviews assessing safety concerns and pregnancies. Formation of a clinical events committee was planned if there was more than one pregnancy in the first 12 months of use among all participants. The evaluable for pregnancy population included those 18–35 years of age at enrollment, with at least one report of pregnancy status after enrollment,

**Table 1. Demographics of Participants Enrolled in a Phase 2 Study of a Low-Dose Copper Intrauterine Device**

| Age Range (y) | 18–35 (n=261) | 36–40 (n=25) | Total (N=286) |
|---------------|---------------|---------------|---------------|
| Age (y)       | 26.1±4.4      | 37.4±1.7      | 27.1±5.8      |
| Ethnicity     |               |               |               |
| Hispanic or Latina | 44 (16.9) | 4 (16) | 48 (16.8) |
| Race          |               |               |               |
| American Indian or Alaska Native | 3 (1.1) | 0 (0) | 3 (1.0) |
| Asian         | 19 (7.3)      | 0 (0)         | 19 (6.6)      |
| Black or African American | 63 (24.1) | 6 (24) | 69 (24.1) |
| Native Hawaiian or other Pacific Islander | 2 (0.8) | 0 (0) | 2 (0.7) |
| White         | 163 (62.5)    | 19 (76)       | 182 (63.6)    |
| Other         | 4 (1.5)       | 1 (4)         | 5 (1.7)       |
| Education     |               |               |               |
| High school graduate or less | 56 (21.6) | 2 (8) | 58 (20.3) |
| Some college  | 85 (32.7)     | 5 (20)        | 90 (31.6)     |
| College graduate or more | 119 (45.8) | 18 (72) | 137 (47.9) |
| Partner status|               |               |               |
| Married       | 58 (22.2)     | 13 (52)       | 71 (24.8)     |
| Pregnancy history |         |               |               |
| Nulligravid   | 141 (54.0)    | 8 (32)        | 149 (52.1)    |
| Nulliparous   | 163 (62.4)    | 11 (44)       | 174 (60.8)    |
| BMI (kg/m²)   |               |               |               |
| Less than 18.5| 10 (3.8)      | 0             | 10 (3.5)      |
| 18.5–24.9     | 110 (42.1)    | 9 (36)        | 119 (41.6)    |
| 25.0–29.9     | 51 (19.5)     | 5 (20)        | 56 (19.6)     |
| 30 or higher  | 90 (34.5)     | 11 (44)       | 101 (35.3)    |

BMI, body mass index.
Data are mean±SD or n (%).
Data are based on all enrolled participants (N=286) before intrauterine device placement.
Participants can report more than one race, so totals may exceed the total number of participants. Category totals for race and education are less than the total number expected owing to some participants not reporting these variables.
having at least one cycle with intercourse reported without use of any other contraceptive method, or became pregnant with the IUD in place.

Investigators at each study site assessed adverse event severity and their relationship to IUD use. We employed the Medical Dictionary for Regulatory Activities in reporting adverse events in accordance with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. Statisticians conducted analyses using SAS 9.4.

RESULTS

Table 1 presents the demographic characteristics of the 286 enrollees after screening 417 potential participants. This includes 261 participants aged 18–35 years who comprise the population evaluated for efficacy. We enrolled an additional 25 participants aged 36–40 who contributed only to the safety outcome data. Participants had a mean age of 27.1 (SD±5.28) with 41 participants (14.3%) in the 18–21 range and 25 (8.7%) in the 36–40 range. The majority (60.8%) reported nulliparity. Figure 2 reports participant flow over the 36-month study period. Success with first placement attempt occurred for 267 participants, and 19 required a second attempt. Three enrollees did not have successful placement and one of those did not have a second attempt. Investigators dilated the cervix at placement for 41 (14.5%) participants. No perforations occurred. A minority of participants reported the placement to be moderately painful (42, 14.8/%) or very painful (12, 4.2%). Investigators reported ease of placement at first attempt as “very easy” for 173 participants (61.1%) and “easy” for 86 (30.4%). Thirty-six participants received prophylactic ibuprofen for IUD insertion and 168 reported use of

![Fig. 2. Participant flowchart for low-dose copper and nitinol intrauterine device (IUD).](Turok. Low-Dose Copper IUD Phase 2. Obstet Gynecol 2020.)
nonsteroidal antiinflammatory drugs for bleeding, cramping, or both. Chlamydia testing before IUD placement was positive for 0 of 284 participants. Only two participants were tested at the time of placement. Investigators identified one intrauterine pregnancy in year 1 and an ectopic pregnancy in year 3. The primary outcome of 1-year Pearl Index was 0.52 (95% CI 0.01–2.87) and was 0.46 (95% CI 0.06–1.67) over 3 years. Table 2 presents the number of treatment cycles, Pearl Indices, and life-table pregnancy rates by year and cumulatively. Throughout the study, 36% of cycles were “assumed evaluable,” and all of those occurred in years 2 and 3.

Five expulsions occurred over 36 months (1.8%); three occurred in year 1, of which two were in nulliparous women. In the first year, 30 participants (10.4%) discontinued for adverse events related to the study drug (Table 3). In years 2 and 3, the corresponding figures were 14 (7.9%) and four (2.9%). In the first year of use, nine participants reported discontinuations for bleeding, seven for pain or cramping, and seven for a combination of bleeding and pain or cramping. Mean bleeding days per cycle decreased from 7.6 in cycle 1 to 5.2 in cycle 13. In total, early discontinuation in the first year occurred for 23 (8.1%) participants owing to issues related to bleeding or discomfort and 38 (10.6%) participants for all other reasons. Over the 3-year course of the study, discontinuation occurred for 48 (17.0%) participants for adverse events, 34 (12.0%) withdrew consent, 30 (10.6%) were lost to follow-up,

**Table 2. Pregnancy Rate Through 36 Months With Estimated Number of Cycles (18–35-Year-Old Women)**

| Months | Cumulative No. of 28-d Cycles | No. Participating at Time Point (%)* | Cumulative No. of Pregnancies [Total (Ectopic)] | Pearl Index for 12-mo Period | Cumulative Pearl Index | Life-Table Pregnancy Rate (%) |
|--------|------------------------------|------------------------------------|-----------------------------------------------|----------------------------|------------------------|-------------------------------|
| 12     | 2,522                        | 250 (78.4)                         | 1 (0)                                         | 0.52 (0.01–2.87)           | 0.52 (0.01–2.87)       | 0.5 (0.0–1.5)                 |
| 24     | 4,297                        | 134 (47.3)                         | 1 (0)                                         | 0                           | 0.30 (0.01–1.69)       | 0.5 (0.0–1.5)                 |
| 36     | 5,640                        | 107 (37.8)                         | 2 (1)                                         | 0.97 (0.02–5.39)           | 0.46 (0.06–1.67)       | 1.4 (0.0–3.4)                 |

* This table includes data only for participants who reported intercourse during at least one menstrual cycle without use of any other method of contraception.

| AEs Occurring in the First 12 mo of Use | No. Reporting (n=283) | No. Reporting That Led to Early Discontinuation (n=283) |
|----------------------------------------|-----------------------|--------------------------------------------------------|
| No. with at least 1 AE                 | 253 (89.4) [85.2–92.7] | 30 (10.6) [7.3–14.8]                                   |
| Dysmenorrhea                           | 142 (50.2) [44.2–56.2] | 6 (2.1) [0.4–6.4]                                     |
| Procedural pain                        | 105 (37.1) [31.5–43.0] | 3 (1.1) [0.2–3.1]                                     |
| Menorrhagia                            | 73 (25.8) [20.8–31.3]  | 13 (4.6) [2.5–7.7]                                    |
| Nasopharyngitis                        | 61 (21.6) [16.9–26.8]  | 0 (0) [0–1.3]                                         |
| Abdominal pain                         | 44 (15.5) [11.5–20.3]  | 2 (0.7) [0.1–2.5]                                     |
| Metrorrhagia                           | 39 (13.8) [10.0–18.4]  | 3 (1.1) [0.2–3.1]                                     |
| Pelvic pain                            | 39 (13.8) [10.0–18.4]  | 2 (0.7) [0.1–2.5]                                     |
| Headache                               | 38 (13.4) [9.7–18.0]   | 0 (0) [0–1.3]                                         |
| Upper respiratory infection            | 37 (13.1) [9.4–17.6]   | 0 (0) [0–1.3]                                         |
| Back pain                              | 33 (11.7) [8.2–16.0]   | 0 (0) [0–1.3]                                         |
| Bacterial vaginosis                    | 32 (11.3) [7.9–15.6]   | 2 (0.7) [0.1–2.5]                                     |
| Urinary tract infection                | 31 (11.0) [7.6–15.2]   | 1 (0.4) [<0.1–2.0]                                   |
| Uterine spasm                          | 26 (9.2) [6.1–13.2]    | 2 (0.7) [0.1–2.5]                                     |
| Vulvovaginal mycotic infection         | 25 (8.8) [5.8–12.8]    | 1 (0.4) [<0.1–2.0]                                   |
| Abdominal pain lower                   | 23 (8.1) [5.2–12.0]    | 1 (0.4) [<0.1–2.0]                                   |
| Dyspareunia                            | 21 (7.4) [4.7–11.1]    | 1 (0.4) [<0.1–2.0]                                   |
| Postprocedural hemorrhage              | 21 (7.4) [4.7–11.1]    | 0 (0) [0–1.3]                                         |
| Vaginal discharge                      | 18 (6.4) [3.8–9.9]     | 1 (0.4) [<0.1–2.0]                                   |
| Nausea                                 | 15 (5.3) [3.0–8.6]     | 0 (0) [0–1.3]                                         |

AE, adverse effect. Data are n (%) [95% CI].
and 18 (6.4%) for other reasons (including 10 desiring pregnancy). Figure 3 reports the Kaplan-Meier curve for continuation over the 36-month study.

The report of adverse events dramatically dropped with time. Over the entire 3 years of follow-up, participant report of dysmenorrhea and pelvic pain occurred for 120 (42.4%) and pelvic pain for 35 (12.4%). However, only eight (2.8%) and five (1.8%) participants reported these symptoms in the second year. Of the 10 serious adverse events, investigators determined seven to be nonrelated to the study drug and the remaining three to be unlikely related to the study drug including one ectopic pregnancy, one hemorrhagic cyst, and one case of pelvic inflammatory disease diagnosed 119 days after IUD placement. The participant with pelvic inflammatory disease had negative results on \textit{C trachomatis} and \textit{N gonorrhea} screening 3 months before IUD placement but tested positive for \textit{N gonorrhea} at the time of diagnosis.

**DISCUSSION**

This phase 2 FDA study of the low-dose copper and nitinol IUD demonstrates the method effectively prevented pregnancy in a group of largely nulliparous users over 3 years. This is the first U.S. study of the product. Our findings demonstrate efficacy and safety data as expected for a highly effective, reversible method and are consistent with point estimates for other recent FDA studies of intrauterine contraceptives.\textsuperscript{6,7} The low expulsion rate, 1.1% in the first year when expulsions are most common, may be the result of the flexible frame design.

The data presented compare favorably with historic data for the Copper T380A, the only currently available, FDA-approved copper IUD in the United States. The low-dose copper and nitinol IUD design with less copper caused fewer discontinuations for bleeding and cramping compared with a T380S.\textsuperscript{3} In this study, the lack of comparator group precludes a direct comparison. However, comparing 1-year outcomes for the low-dose copper and nitinol IUD between this study and the prior randomized controlled trial, the expulsion rate trended lower in this study (1.1% vs 5.0%) and the discontinuation rate for bleeding and pain trended higher (8.1% vs 3.5%). We did not assess the effect of other novel IUD design features including preloaded IUD and precut strings that simplify IUD placement.

Strengths of the study include scientific rigor with 100% source validation of the data and a low loss-to-follow-up rate. The diverse study population from 12 geographically distinct U.S. sites supports external validity. With nulliparous women comprising the majority of participants, the data support safety and efficacy in this group of users. As a phase 2 trial, the inclusion and exclusion criteria were more rigid and the follow-up more extensive than expected in general use. Study weaknesses include the expected limitations of an FDA phase 2 study, including the sample size, which precludes subanalyses based on characteristics and lack of a comparator. This novel, low-dose copper contraceptive demonstrated high efficacy and safety in this phase 2 FDA trial supporting initiation of a phase 3 study.

**REFERENCES**

1. d’Arcangues C. Worldwide use of intrauterine devices for contraception. Contraception 2007;75(6 suppl):S2–7.
2. Morgan NB. Medical shape memory alloy applications—the market and its products. Mater Sci Eng 2004;378:16–23.

3. Reeves MF, Katz BH, Canela JM, Hathaway MJ, Tal MG. A randomized comparison of a novel nitinol-frame low-dose-copper intrauterine contraceptive and a copper T380S intrauterine contraceptive. Contraception 2017;95:544–8.

4. Massad LS, Einstein MH, Huo WK, Katki HA, Kinney WK, Schiffman M, et al. 2012 updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. Obstet Gynecol 2013;121:829–46.

5. Curtis KM, Jatlaoui TC, Tepper NK, Zapata LB, Horton LG, Jamieson DJ, et al. U.S. selected practice recommendations for contraceptive use, 2016. MMWR Recomm Rep 2016;65:1–66.

6. Eisenberg DL, Schreiber CA, Turok DK, Teal SB, Westhoff CL, Creinin MD, et al. Three-year efficacy and safety of a new 52-mg levonorgestrel-releasing intrauterine system. Contraception 2015;92:10–6.

7. Nelson AL. Levonorgestrel-releasing intrauterine system (LNG-IUS 12) for prevention of pregnancy for up to five years. Expert Rev Clin Pharmacol 2017;10:833–42.

Authors’ Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

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