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Original Research

Ohnut vs waitlist control for the self-management of endometriosis-associated deep dyspareunia: a pilot randomized controlled trial

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Abstract

Background: Deep dyspareunia affects 50% of people with endometriosis. The Ohnut is a set of interlocking rings that fit over the penis/insertive object. One or more rings can be used to limit insertion depth and reduce deep dyspareunia.
Aim: We conducted a pilot, parallel, open-label randomized controlled trial (RCT) to investigate the feasibility of the study design and the acceptability and preliminary efficacy of the Ohnut.
Method: Participants were recruited from a tertiary center for endometriosis. Eligibility criteria were surgically confirmed endometriosis, age 19-49 years, monogamous sexual relationship with a partner willing to participate in the study, and no comorbid superficial dyspareunia, anxiety, or depression. Couples were randomized into an intervention group or a waitlist control group using a 1:1 allocation ratio. All couples had sex as normal during weeks 1 to 4 (baseline period), and couples in the intervention group used the Ohnut with sex during weeks 5 to 10 (intervention period) while controls had sex as normal. Patient participants used daily diaries to record sexual activity and deep dyspareunia score (0-10) for the 10-week study. Intervention group participants completed an acceptability questionnaire at the end of the study.
Outcomes: The primary outcomes were feasibility of the study and acceptability of the Ohnut. We also assessed differences in deep dyspareunia scores in the participants who used the Ohnut compared to the control participants who did not.
Results: We recruited approximately 5 couples per month of active recruitment. Of 864 potentially eligible participants, we successfully contacted 44.7% (n = 386), of whom 8.0% (n = 31) consented, 64.8% (n = 250) were ineligible, and 27.2% (n = 105) declined. Thirty-one couples were randomly assigned to the intervention or control group, and 17 couples completed the study. Intervention group couples used the Ohnut for an average of 72.4% (32.7%) of sexual encounters during the intervention period. The mean acceptability index score for the Ohnut was 0.83 (0.078) among patients and 0.83 (0.049) among partners (index between 0 and 1). After controlling for baseline deep dyspareunia, there was a significant difference in the intervention period mean deep dyspareunia scores between the control and intervention group (4.69 (2.44) vs 2.46 (1.82), $P = .012$).
Clinical Implications: We identified preliminary evidence for the acceptability and efficacy of the Ohnut among both patients and partners, suggesting that the Ohnut may be a useful stand-alone or adjuvant management tool for endometriosis-associated deep dyspareunia.
Strengths and Limitations: Strengths of this study were the "real-world" use of the Ohnut and data collection from both patients and partners. Limitations of the study design included the strict eligibility criteria that affected feasibility and generalizability.
Conclusion: This pilot RCT indicated that the Ohnut may be an acceptable and effective intervention to reduce endometriosis-associated deep dyspareunia. We identified opportunities to improve design for a larger RCT.
Clinical Trial Registration: This clinical trial was registered with clinicaltrials.gov (#NCT04370444).

Keywords: endometriosis; deep dyspareunia; Ohnut; pilot project; randomized controlled trial; patient acceptance of health care; feasibility study.

Introduction

Deep dyspareunia, defined as pain with deep vaginal insertion, is experienced by approximately half of people with endometriosis, a condition characterized by endometrial-like tissue growing outside the uterus.[1] Deep dyspareunia has been attributed to factors including contact with endometriosis lesions on pelvic structures at or near the vaginal apex, stretching of adhesions associated with endometriosis lesions, physical (eg, pelvic floor) and psychological (eg, depression) comorbidities, and nociplastic pain secondary to central nervous system sensitization.[2-4] Regardless of the specific etiology, deep dyspareunia has a significant effect on women with endometriosis and their partners that includes worse quality of life, concerns about future fertility, and relationship difficulties.[5-7]

Treatment of endometriosis may include medical/hormonal therapy to suppress estrogen that stimulates endometriosis, surgical excision or destruction of the endometriosis

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lesions, and allied health interventions (eg, physiotherapy) to manage the symptoms and comorbidites associated with endometriosis. Medical, surgical, and allied health interventions for endometriosis have mixed effects for deep dyspareunia. While medical and surgical options decrease deep dyspareunia, for both of these treatment options the effect appears to be incomplete and may rebound after surgery.[8] Medical/hormonal therapy may negatively impact components of sexual function such as desire, arousal, and lubrication[8]; moreover, these hormonal options are not indicated in women seeking to become pregnant. Allied health interventions, including pelvic floor physiotherapy, mindfulness, and cognitive behavioral therapy, have shown promise[9,10] but have not been fully explored and may be cost prohibitive for some patients.

Given the potentially limited interventions for endometriosis-associated deep dyspareunia, we conducted a pilot randomized controlled trial (RCT) to investigate the Ohnut, a set of up to four polymer rings that fit over the penis or insertive object. The rationale of the Ohnut is to limit depth of insertion, thereby preventing contact with affected pelvic structures at the vaginal apex and reducing deep dyspareunia. Our study asked the following questions: (1) Is the RCT design feasible and is the Ohnut acceptable to both patient and partner? (2) What is the preliminary efficacy of the Ohnut for reducing deep dyspareunia and associated psychological and sexual function outcomes?

Methods

Trial design

A detailed description of the protocol for this study has been previously published.[11] This pilot RCT compared two parallel arms: the intervention group using the Ohnut for vaginal insertion during sexual activity and the waitlist control group engaging in vaginal insertion as usual. The waitlist control group received the Ohnut upon completion of the study.

Participant recruitment

This study was conducted at a tertiary care center for endometriosis and pelvic pain in western Canada. Patient participants were recruited from the Endometriosis and Pelvic Pain Interdisciplinary Cohort if they had an initial or re-referral visit at the center between January 1, 2018, and December 31, 2020.[12] Recruitment was open from April 2021 to October 2021, during which COVID-19 protection measures were in place. To be potentially eligible for this study, the patient participants must have consented to be contacted for future research and have surgically confirmed endometriosis (primary screening). If a patient participant was potentially eligible to participate, the study coordinator contacted them by email or phone and followed up with each participant over the phone to review the full list of eligibility requirements (secondary screening). If the participant met the eligibility requirements, then the study coordinator assessed the eligibility of the participant's partner.

Patient participant eligibility criteria

Inclusion criteria for the patient participants were the following: (1) age 19 to 49 years; (2) assigned female at birth; (3) currently in a monogamous sexual relationship; (4) sexually active or not currently sexually active due to deep dyspareunia; (5) self-reported deep dyspareunia score $\geq$4/10; (6) sexual partner who consents to participate in the study; and (7) willing to engage in insertive sex during the study period.

Exclusion criteria for the patient participants were the following: (1) self-reported superficial dyspareunia score $\geq$4/10, a potentially confounding variable because the Ohnut is not expected to affect introital pain; (2) severe anxiety or depression symptoms in the last 2 weeks (score $\geq$15 for Generalized Anxiety Disorder Scale–7 [GAD-7] or Patient Health Questionnaire [PHQ-9])[13,14]; (3) positive response to the question—"In the last 2 weeks, have you had intense fear/anxiety in anticipation of, during, or as a result of vaginal intercourse?"—which was used to exclude women with comorbid vaginismus and for ethical concerns that participation in this study may potentially worsen participant anxiety; (4) current use of an Ohnut; or (5) inability to complete English-language questionnaires.

Partner participant eligibility criteria

Inclusion criteria for partner participants were the following: (1) 19 years of age or older and (2) any sex and gender. Partners exclusion criteria were the following: (1) currently using a Ohnut or (2) unable to complete English-language questionnaires.

Procedure

After the patient and partner participants provided their consent, the study coordinator randomly assigned the couple to the intervention group or waitlist control group with a 1:1 allocation ratio using the randomization feature on the REDCap platform.[15] All participants continued their regular endometriosis treatments and treatments for other health conditions for the duration of the study. All study procedures were conducted independently by the participants. Both groups received a paper diary to record their daily sexual activity and associated deep dyspareunia scores for a period of 10 weeks.

At baseline, all participants completed a demographic questionnaire and the patient participants also completed the GAD-7 to assess symptoms of anxiety (possible score 0-21),[14] the PHQ-9 to assess depressive symptoms (possible score 0-27),[13] the Female Sexual Function Index (FSFI; possible score 2-36) to assess sexual function among participants who reported having had sexual activity in the previous 4 weeks,[16] and the Female Sexual Distress Scale–Revised (FSDS-R, possible score 0-52) to assess distress during sexual activity.[17] Higher scores on the GAD-7, PHQ-9, and FSDS-R indicate increased anxiety, depression, and sexual distress, respectively; for the FSFI, a higher score indicates higher sexual function.

From weeks 1 to 4, couples from both the intervention and waitlist control group engaged in sex as usual. Patient participants recorded if they had sex (yes/no) and the severity of deep dyspareunia on a single-item measure (possible score 0-10). Sex was defined as follows in the daily diary: "When we ask if you had sex, we are asking specifically if you had penetrative vaginal sex (ie, was something like a penis, fingers, or sex toy inserted inside your vagina?)." At the end of week 4, all patient participants again completed the GAD-7, PHQ-9, FSFI, and FSDS-R questionnaires. During weeks 1 to 4, patient participants who were also enrolled in an embedded substudy concurrently completed tasks to evaluate a vaginal insert for objective testing of deep dyspareunia.[18]

At the start of week 5, the couples in the intervention group received the Ohnut, including the manufacturer's instructions, by mail. From week 5 to 10, the intervention group used the Ohnut during vaginal insertion, and the waitlist control group continued engaging and reporting on their vaginal insertion as usual. For the intervention group, the Ohnut was delivered to participants with manufacturer's instructions (without additional information or counseling). The intervention group recorded if they had sex (yes/no), if they used the Ohnut (yes/no), how many Ohnut rings were used (0-4), if they used lubricant (yes/no), the severity of deep dyspareunia (0-10), and if they had any undesirable experiences when using the Ohnut. Upon the completion of the study, all patient participants submitted their diaries to the study coordinator and completed the GAD-7, PHQ-9, FSFI, and FSDS-R questionnaires for the third time. The participants in the intervention group also completed an acceptability questionnaire, which we adapted from a study of a female condom.[19] The partners' acceptability questionnaire also included a revised version of the International Index of Erectile Function.[20] After week 10, the couples in the waitlist control group received the Ohnut by mail.

Statistical analysis

The demographic characteristics of the sample are reported using means (SD) for continuous variables or frequencies (percentage) for categorical variables. We conducted a pairwise exclusion of the missing data. SPSS Statistics version 25 (IBM corp) was used for analysis.

Feasibility of the RCT design

We defined feasibility as the successful delivery of planned study procedures and processes.[21] To evaluate recruitment and retention, we assessed the proportion of potentially eligible individuals who were successfully contacted by the study team (response rate); the proportion of contacted individuals who were ineligible, declined to participate, and consented; the number of couples enrolled per month of active recruitment (recruitment rate); and the proportion of enrolled participants who completed the study (retention rate). To evaluate protocol adherence, we assessed the proportion of sexual encounters using the Ohnut per couple in the intervention group during the intervention period (intervention fidelity) and the proportion of missing data.

Acceptability of the Ohnut

Acceptability was defined as the suitability of the intervention to patients and their partners.[21] To analyze the acceptability of the Ohnut, we calculated an overall acceptability index score for each patient participant and their partner participant.

For each patient participant, the questions from the acceptability questionnaire were adapted from the female condom acceptability questionnaire[19] and consisted of 16 questions that were each scored from 1 to 5, summed, and divided by the total possible score of 80 to provide a percentage index for acceptability (higher score indicating greater acceptability).

For each partner participant, the questions from the acceptability questionnaire were adapted from the female condom acceptability questionnaire[19] and International Index of Erectile Function[20] and consisted of 25 questions that were each scored from 1 to 5, summed, and divided by the total possible score of 125 to provide a percentage index for acceptability (higher score indicating greater acceptability).

Preliminary efficacy of the Ohnut

To assess the efficacy of the Ohnut in reducing deep dyspareunia scores, we compared the difference in deep dyspareunia scores from weeks 5 to 10 between the intervention and waitlist control group using the analysis of covariance (ANCOVA) approach. The outcome variable was the mean of the deep dyspareunia scores during the intervention period (weeks 5 to 10), and the independent variable was the intervention group (waitlist control vs intervention) while controlling for the covariate of preintervention (weeks 1 to 4) mean deep dyspareunia scores. We also used ANCOVA modeling for the outcome variables of GAD-7, PHQ-9, FSFI, or FSDS-R at week 10 after the intervention period, with the independent variables being the intervention group (waitlist control vs intervention) while controlling for the covariates of GAD-7, PHQ-9, FSFI, or FSDS-R at baseline and at week 4 (preintervention). We explored the pain domain of the FSFI, which is calculated by taking the sum of the 3 pain questions in the questionnaire $\times$-weighted score of 0.4 (possible range 0-6). We reported partial eta squared (η^2) to assess how large of an effect the intervention had on the outcomes. Effect sizes can be interpreted as $\eta^2 = .01$ is a small effect; $\eta^2 = .06$ is a medium effect; $\eta^2 = .14$ is a large effect.[22] We reported unadjusted means (SD).

The intervention group also recorded any undesirable outcomes or harms experienced while using the Ohnut during sex from this open-ended question: "Did you or your partner have any undesirable experiences when using the Ohnut (eg, loss of erection, pain, irritation)?"

Ethics

Ethics approval for this pilot RCT was provided by the institution. All participants (patients and partners) provided informed consent. This research is registered on ClinicalTrials.gov (#NCT04370444).

Results

Feasibility

Within the recruitment time frame, 2317 new patients attended the tertiary center, of whom 37.3% of patients (n = 864) had a confirmed diagnosis of endometriosis and were between 19 and 49 years old (primary screening for potentially eligible participants) (Figure S1 for CONSORT diagram). The response among these potentially eligible participants was 44.7% (n = 386), of whom 8.0% (n = 31) consented to participate, 64.8% (n = 250) did not meet eligibility criteria (secondary screening), and 27.2% (n = 105) declined to participate. Among participants who did not meet eligibility criteria, 51.6% (n = 129) reported no or minimal deep dyspareunia, 20.8% (n = 52) had no monogamous sexual partner, 8.4% (n = 21) had moderate/severe superficial dyspareunia, 7.6% (n = 19) scored $\geq$15 on the GAD-7 or reported intense fear/anxiety around sexual activity, 5.2% (n = 13) did not have insertive sex, 4.4% (n = 11) had a partner who declined to participate, 1.6% (n = 4) had previously used the Ohnut or a similar intervention, and 0.4% (n = 1) scored $\geq$15 on the PHQ-9. The recruitment rate was approximately 5 participants per month.

Thirty-one couples were enrolled and randomized. Seventeen (54.8%; n = 17/31) of enrolled couples completed the full study, with 19.4% (n = 6) lost to follow up, 16.1% (n = 5)

discontinuing due to stress or situational factors, 6.5% (n = 2) discontinuing due to new pregnancy, and 3.2% (n = 1) discontinuing for mental health reasons.

During weeks 5 to 10, couples in the intervention group used the Ohnut for an average of 72.4% (32.7%) (range 15.38-100) sexual enounters. The proportion of construct-level missingness (ie, omitting an entire questionnaire) was 11.8% (n = 4) among all participants. The proportion of item-level missingness in the daily diaries (ie, omitting responses to certain questions) was 70.6% (n = 12) among patient participants, with 17.6% (n = 3) failing to report deep dyspareunia scores for 1 or more sexual encounters.

Sample demographics

The demographic characteristics of the patient and partner participants who completed the study can be found in Tables 1 and 2, respectively. There were no differences between participants who completed the study (n = 17) and those who did not (n = 14) (see Table S1). All patient participants identified as female and all partner participants identified as male.

Acceptability

Among the 10 couples in the intervention group who completed the entire study period, 9 patient participants and 8 partner participants completed the acceptability questionnaire. The detailed results from the closed-ended responses from the questionnaire are in Table 3. For the patient participants, 16 questions (Q1-5, 7, 8, 10, 12-19 in Table 3) were included to calculate the acceptability index, and for partners 25 questions (Q1-25 in Table 3) were included to calculate the acceptability index. The mean acceptability index score for the patient participants was 0.83 (0.078) and for the partner participants was 0.83 (0.049) (each index being a percentage between 0 and 1, with higher percentage indicating higher acceptability). Most patients (n = 8, 88.9%) and partners (n = 7, 87.5%) found that overall, the Ohnut was somewhat or very comfortable during vaginal sex. Similarly, most patients (n = 7, 77.8%) and partners (n = 6, 75.0%) were somewhat or very satisfied with the feeling of vaginal sex when using the Ohnut. When comparing sex with the Ohnut to vaginal sex before the Ohnut, approximately one-half of the patients (n = 9, 55.6%) and one-third of partners (n = 3, 37.5%) said that sex was somewhat better or much better when using the Ohnut. Most patients (n = 8, 88.9%) and partners (n = 5, 62.5%) said they were somewhat likely or very likely to use the Ohnut again.

There were three open-ended questions in the acceptability questionnaire. First, we asked both the patient participants and partner participants what they liked about the Ohnut for vaginal sex. Many participants reported that using the Ohnut did reduce pain during vaginal sex and that it gave the opportunity for the couples to engage in vaginal insertion without focusing on manually controlling depth. Patient participant 8 said, "lessened pain and partner enjoyed this better than trying to use my hand as a buffer." Common responses from the partner participants included appreciating that the Ohnut made vaginal sex more comfortable for the patient participant.

Second, we asked the couples what they disliked about the buffer. One couple described how the Ohnut would slip off the partner during vaginal sex and another couple described disliking the color of the Ohnut. One couple described experiencing heat while using the Ohnut and requiring frequent lubricant to prevent friction burn. Additionally, penile piercings were mentioned—Patient participant 7 said: "It doesn't work well with penile piercings. Having to take them out prior makes using it more of a deterrent." Some participants mentioned that it was difficult to be romantic while putting on the Ohnut and that it was a bit awkward. Also, one partner participant who said it was very difficult to put on the buffer commented that the Ohnut was "hard to install before sex."

Last, we asked the couples to comment on what they would change about the Ohnut to improve their experiences. Some participants and partners described altering the Ohnut's color, width, length, and grip to optimize the look and fit of the Ohnut. Patient participant 6 said, "If it was wider (external diameter) I would feel more confident that it wouldn't just slide inside me (which would really hurt I imagine)." Additionally, multiple participants mentioned wanting extra rings.

Preliminary efficacy of the Ohnut

Table 4 displays the mean deep dyspareunia scores for the waitlist control and intervention group from weeks 1 to 4 and 5 to 10 of the study. We performed an intention-to-treat analysis and found that after controlling for preintervention (weeks 1 to 4) deep dyspareunia scores, there was a statistically significant difference in the intervention period (weeks 5 to10) mean deep dyspareunia scores between the waitlist control and intervention group ($F[1,14] = 8.310$, $P = .012$, partial eta square = 0.37; a large effect size). The change in the deep dyspareunia score (0-10) was +0.18 in the control group (worsening by 0.18/10), and -2.67 in the intervention group (improving by 2.67/10) (Table 4).

The mean scores on the PHQ-9, GAD-7, FSFI, and FSDS-R in the intervention group and waitlist control group are shown in Table 4. There were no statistically significant differences in the mean PHQ-9 ($F[1,11] = 3.295$, $P = .097$, partial eta squared = .231; a large effect size), GAD-7 ($F[1,11] = 0.024$, $P = .880$, partial eta squared = 0.002; a small effect size), FSFI ($F[1,11] = 0.254$, $P = .625$, partial eta squared = 0.025; a small effect size) or FSDS-R ($F[1,11] = 1.674$, $P = .222$, partial eta squared = 0.132; a large effect size) scores between the waitlist control and intervention group after the intervention period (week 10) when controlling for the preintervention scores at baseline and week 4. However, the effect sizes for PHQ-9 and for FSDS-R were clinically significant (partial eta squared = 0.231 and 0.132, respectively). Moreover, for the FSFI pain domain, there was a clinically significant effect size between the waitlist control and intervention group but it did not reach statistical significance ($F[1,10] = 3.060$, $P = .111$, partial eta-squared = 0.234; a large effect size) (Table 4).

The prospective number of sexual events during weeks 1 to 4 was 4 (IQR = 4.5) in the intervention group and 4 (IQR = 6) in the control group and during weeks 5 to 10 was 7 (IQR = 8.75) in the intervention group and 8 (IQR = 11) in the control group.

Potential harms

A few participants described issues with irritation (n = 1), loss of erection at the start of intercourse (n = 1), Ohnut rings feeling too tight (n = 1), and concerns about safety with penile piercings (n = 1).

Table 1. Demographic characteristics of the patient participants in the control and intervention group.

Variable	Control (N = 7) No. (%) or Mean (SD)	Intervention (N = 10) No. (%) or Mean (SD)
Age, y	36.9 (7.5)	32.1 (6.3)
Gender identity		
Female	7 (100%)	10 (100%)
Sexual orientation		
Heterosexual	6 (85.7%)	10 (100%)
Bisexual	1 (14.3%)	0 (0.0%)
Race		
White	6 (85.7%)	10 (100%)
Other	1 (14.3%)	0 (0%)
Highest level of education		
High school (completed grade 12)	0 (0.0%)	2 (20.0%)
2-y college or university program	2 (28.6%)	3 (30.0%)
4-y college or university program (including professional degrees)	3 (42.9%)	4 (40.0%)
Graduate program	2 (28.6%)	1 (10.0%)
Relationship status		
Dating	0 (0.0%)	3 (30.0%)
Common-law	4 (57.1%)	3 (30.0%)
Married	3 (42.9%)	4 (40.0%)
Length of current relationship[a]		
Not in a relationship	1 (14.3%)	0 (0.0%)
2-5 mo	1 (14.3%)	1 (10.0%)
6-12 mo	0 (0.0%)	2 (20.0%)
1-2 y	0 (0.0%)	1 (10.0%)
3-5 y	2 (28.6%)	2 (20.0%)
>5 y	3 (42.9%)	4 (40.0%)
Most recent engagement in penetrative vaginal sex		
Within the last wk	5 (71.4%)	8 (80.0%)
Within the last 3 mo	0 (0.0%)	2 (20.0%)
Within the last y	2 (28.6%)	0 (0.0%)
Number of times the participant engaged in penetrative vaginal sex in the past mo		
0-7	5 (71.4%)	6 (60.0%)
8-14	2 (28.6%)	3 (30.0%)
15-21	0 (0.0%)	1 (10.0%)
Ever given birth via vaginal delivery?		
Yes	1 (14.3%)	0 (0.0%)
No	6 (85.7%)	10 (100.0%)
Ever given birth via Caesarean section?		
Yes	0 (0.0%)	1 (10.0%)
No	7 (100.0%)	9 (90.0%)
Currently trying to get pregnant		
Yes	1 (14.3%)	2 (20.0%)
No	6 (85.7%)	8 (80.0%)
Deep penetrative pain score during sexual activity in the past 3 mo		
0-4	2 (28.6%)	1 (10.0%)
5-10	3 (42.9%)	9 (90.0%)
Did not have penetration	2 (28.6%)	0 (0.0%)
Menstrual pain score while bleeding in the past 3 mo		
0-4	0 (0.0%)	2 (20.0%)
5-10	3 (42.9%)	5 (50.0%)
Did not bleed	4 (57.1%)	3 (30.0%)
Bowel movement pain score in the past 3 mo		
0-4	3 (42.9%)	6 (60.0%)
5-10	4 (57.1%)	4 (40.0%)
Back pain score in the past 3 mo		
0-4	3 (42.9%)	5 (50.0%)
5-10	4 (57.1%)	5 (50.0%)
Vaginal insert tenderness (0-10 Likert scale)		
Bladder	3.1 (2.3)	3.1 (1.3)
Cervix uterus	5.6 (2.3)	5.3 (1.9)
Cul-de-sac	4.9 (2.0)	4.9 (2.6)
Right pelvic floor	4.2 (2.4)	3.3 (3.0)
Left pelvic floor	4.6 (3.5)	4.0 (2.6)
Highest tenderness score across the 5 anatomic sites	7.1 (1.2)	7.1 (1.5)

[a] An individual could have a monogamous sexual partner but not be in a relationship.

Table 2. Demographics of the partner participants in the control and intervention group.

Variable	Control (N = 7) No. (%) or Mean (SD)	Intervention (N = 10) No. (%) or Mean (SD)
Age, y	42.7 (8.2)	33.9 (5.9)
Gender identity		
Male	7 (100.0%)	10 (100.0%)
Sexual orientation		
Heterosexual	7 (100.0%)	10 (100.0%)
Ethnicity		
White	6 (85.7%)	10 (100.0%)
Other	1 (14.3%)	0 (0.0%)
Highest level of education		
High school (completed grade 12)	1 (14.3%)	2 (20.0%)
Trade school	2 (28.6%)	1 (10.0%)
2-y college or university program	1 (14.3%)	3 (30.0%)
4-y college or university program (including professional degrees)	1 (14.3%)	4 (40.0%)
Graduate program	2 (28.6%)	0 (0.0%)
Relationship status		
Dating	0 (0.0%)	3 (30.0%)
Common-law	4 (57.1%)	3 (30.0%)
Married	3 (42.9%)	4 (40.0%)
How would you rate your confidence that you could get and keep an erection?		
Very low	0 (0.0%)	0 (0.0%)
Low	0 (0.0%)	0 (0.0%)
Moderate	0 (0.0%)	1 (10.0%)
High	2 (28.6%)	3 (30.0%)
Very high	5 (71.4%)	6 (60.0%)
When you had erections with sexual stimulation, how often were your erections hard enough for penetration?		
Almost never/never	0 (0.0%)	0 (0.0%)
A few times (much less than half the time)	0 (0.0%)	0 (0.0%)
Sometimes (about half of the time)	0 (0.0%)	1 (10.0%)
Most times (much more than half the time)	0 (0.0%)	0 (0.0%)
Almost always/always	7 (100.0%)	9 (90.0%)
During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?		
Almost never/never	0 (0.0%)	0 (0.0%)
A few times (much less than half the time)	0 (0.0%)	0 (0.0%)
Sometimes (about half of the time)	0 (0.0%)	1 (10.0%)
Most times (much more than half the time)	0 (0.0%)	0 (0.0%)
Almost always/always	7 (100.0%)	9 (90.0%)
During intercourse, how difficult was it to maintain your erection to completion of intercourse?		
Extremely difficult	0 (0.0%)	0 (0.0%)
Very difficult	0 (0.0%)	0 (0.0%)
Difficult	0 (0.0%)	0 (0.0%)
Slightly difficult	0 (0.0%)	0 (0.0%)
Not difficult	7 (100.0%)	10 (100.0%)
When you attempted intercourse, how often was it satisfactory for you?		
Almost never/never	0 (0.0%)	0 (0.0%)
A few times (much less than half the time)	0 (0.0%)	0 (0.0%)
Sometimes (about half of the time)	1 (14.3%)	0 (0.0%)
Most times (much more than half the time)	1 (14.3%)	3 (30.0%)
Almost always/always	5 (71.4%)	7 (70.0%)
Stretched penile length, cm	13.5 (3.3); range (8.0-17.0)	12.7 (4.5); range (4.5-18.5)

Discussion

In this pilot RCT, we examined the feasibility, acceptability, and preliminary efficacy and found that the Ohnut was acceptable overall to individuals with deep dyspareunia due to endometriosis and their partners. There was also evidence of preliminary efficacy, with a significant reduction in deep dyspareunia in the intervention group.

Study feasibilty

Participant retention was a challenge, with almost half of enrolled couples discontinuing participation. Discontinuation was primarily due to pregnancy or situational factors not related to the study. Six couples were lost to follow-up, possibly due to the long study period (10 weeks) and time commitment (daily diary). Strategies to support retention included the open, waitlist-controlled design, as well as frequent reminders from a study coordinator. Offering monetary incentives may improve retention in a larger definitive trial.[23]

Protocol adherence varied among participants. Some couples used the Ohnut in every sexual encounter whereas others used it irregularly; this finding may reflect "real-world" implementation of the intervention (eg, using the Ohnut on days when endometriosis-associated pain is more severe). Although

Table 3. Results from the closed-ended responses in the Ohnut acceptability questionnaire.[a]

Q#	Variable	Patient responses (N = 9) No. (%) or Mean (SD)	Partner responses (N = 8) No. (%) or Mean (SD)
	Mean acceptability index (percentage between 0 and 1)	0.83 (0.078)	0.83 (0.049)
	Did you engage in penile-vaginal intercourse with the subject in this study?		
	Yes	—	8 (100%)
	No	—	0 (0%)
1	How easy was it to follow the manufacturer's instructions?		
	Very difficult	0 (0%)	0 (0%)
	Somewhat difficult	0 (0%)	1 (12.5%)
	Neutral	0 (0%)	0 (0%)
	Somewhat easy	0 (0%)	0 (0%)
	Very easy	9 (100%)	7 (87.5%)
2	How easy was it to handle the buffer?		
	Very difficult	0 (0%)	0 (0%)
	Somewhat difficult	0 (0%)	0 (0%)
	Neutral	0 (0%)	0 (0%)
	Somewhat easy	1 (11.1%)	5 (62.5%)
	Very easy	8 (88.9%)	3 (37.5%)
3	How easy was it to put the buffer on?		
	Very difficult	0 (0%)	1 (12.5%)
	Somewhat difficult	0 (0%)	0 (0%)
	Neutral	0 (0%)	1 (12.5%)
	Somewhat easy	5 (55.6%)	3 (37.5%)
	Very easy	4 (44.4%)	3 (37.5%)
4	How easy was it to apply the buffer after lubricant?		
	Very difficult	0 (0%)	1 (12.5%)
	Somewhat difficult	0 (0%)	0 (0%)
	Neutral	1 (11.1%)	0 (0%)
	Somewhat easy	0 (0%)	3 (37.5%)
	Very easy	8 (88.9%)	4 (50.0%)
5	How easy was it to remove the buffer?		
	Very difficult	0 (0%)	0 (0%)
	Somewhat difficult	0 (0%)	0 (0%)
	Neutral	0 (0%)	0 (0%)
	Somewhat easy	3 (33.3%)	1 (12.5%)
	Very easy	6 (66.7%)	7 (87.5%)
6	How comfortable was it to put on the buffer?		
	Very uncomfortable	—	0 (0%)
	Somewhat uncomfortable	—	0 (0%)
	Neutral	—	0 (0%)
	Somewhat comfortable	—	7 (87.5%)
	Very comfortable	—	1 (12.5%)
7	How comfortable was the material of the buffer?		
	Very uncomfortable	0 (0%)	0 (0%)
	Somewhat uncomfortable	0 (0%)	0 (0%)
	Neutral	0 (0%)	0 (0%)
	Somewhat comfortable	2 (22.2%)	2 (25.0%)
	Very comfortable	7 (77.8%)	6 (75.0%)
8	Overall, how comfortable was the buffer during vaginal sex?		
	Very uncomfortable	0 (0%)	0 (0%)
	Somewhat uncomfortable	1 (11.1%)	0 (0%)
	Neutral	0 (0%)	1 (12.5%)
	Somewhat comfortable	5 (55.6%)	2 (25.0%)
	Very comfortable	3 (33.3%)	5 (62.5%)
9	How comfortable was it to remove the buffer?		
	Very uncomfortable	—	0 (0%)
	Somewhat uncomfortable	—	0 (0%)
	Neutral	—	2 (25.0%)
	Somewhat comfortable	—	4 (50.0%)
	Very comfortable	—	2 (25.0%)
10	How did the penis (or penetrating object) look once the buffer was in place?		
	Very bad	0 (0%)	0 (0%)
	Somewhat bad	1 (11.1%)	1 (12.5%)
	Neutral	4 (44.4%)	4 (50.0%)
	Somewhat good	1 (11.1%)	1 (12.5%)
	Very good	3 (33.3%)	2 (25.0%)

(continued)

Table 3. Continued

Q#	Variable	Patient responses (N = 9) No. (%) or Mean (SD)	Partner responses (N = 8) No. (%) or Mean (SD)
11	How is the general fit of the buffer on the penis (or penetrating object)?		
	Very bad	—	0 (0%)
	Somewhat bad	—	0 (0%)
	Neutral	—	1 (12.5%)
	Somewhat good	—	5 (62.5%)
	Very good	—	2 (25.0%)
12	How much noise did the buffer make during use?		
	Too much noise	0 (0%)	0 (0%)
	Somewhat noticeable amount of noise	0 (0%)	0 (0%)
	Neutral	0 (0%)	4 (50%)
	Somewhat unnoticeable amount of noise	1 (11.1%)	0 (0%)
	Unnoticeable amount of noise	8 (88.9%)	4 (50.0%)
	How was the length of the buffer?		
	Too short	1 (11.1%)	0 (0%)
	Somewhat short	1 (11.1%)	0 (0%)
	Just right	6 (66.7%)	7 (87.5%)
	Somewhat long	1 (11.1%)	1 (12.5%)
	Too long	0 (0%)	0 (0%)
	How was the width of the buffer?		
	Too narrow	0 (0%)	0 (0%)
	Somewhat narrow	1 (11.1%)	0 (0%)
	Just right	7 (77.8%)	6 (75.0%)
	Somewhat wide	1 (11.1%)	2 (25.0%)
	Too wide	0 (0%)	0 (0%)
	How was the thickness of the buffer?		
	Too thin	0 (0%)	0 (0%)
	Somewhat thin	0 (0%)	1 (12.5%)
	Just right	9 (100%)	6 (75.0%)
	Somewhat thick	0 (0%)	1 (12.5%)
	Too thick	0 (0%)	0 (0%)
	How did the buffer feel during vaginal sex?		
	Too cool	0 (0%)	0 (0%)
	Cool	0 (0%)	2 (25.0%)
	Just right	8 (88.9%)	2 (25.0%)
	Warm	1 (11.1%)	4 (50.0%)
	Too warm	0 (0%)	0 (0%)
13	How does the buffer smell?		
	Very unpleasant	0 (0%)	0 (0%)
	Somewhat unpleasant	0 (0%)	1 (12.5%)
	Neutral	8 (88.9%)	7 (87.5%)
	Somewhat pleasant	0 (0%)	0 (0%)
	Very pleasant	1 (11.1%)	0 (0%)
14	How was sensitivity/stimulation during use of the buffer compared with no use?		
	Much worse	1 (11.1%)	1 (12.5%)
	Somewhat worse	2 (22.2%)	2 (25.0%)
	Neutral	5 (55.6%)	4 (50.0%)
	Somewhat better	0 (0%)	1 (12.5%)
	Much better	1 (11.1%)	0 (0%)
15	How satisfied are you with the stability of the buffer during use?		
	Very dissatisfied	0 (0%)	0 (0%)
	Somewhat dissatisfied	0 (0%)	1 (12.5%)
	Neutral	0 (0%)	1 (12.5%)
	Somewhat satisfied	4 (44.4%)	3 (37.5%)
	Very satisfied	5 (55.6%)	3 (37.5%)
16	How satisfied are you with the feeling of vaginal sex when using the buffer?		
	Very dissatisfied	0 (0%)	0 (0%)
	Somewhat dissatisfied	2 (22.2%)	1 (12.5%)
	Neutral	0 (0%)	1 (12.5%)
	Somewhat satisfied	3 (33.3%)	3 (37.5%)
	Very satisfied	4 (44.4%)	3 (37.5%)
17	In general, how did sex using the buffer compare to vaginal sex before using the buffer?		
	Sex was much worse with the buffer	0 (0%)	0 (0%)
	Sex was somewhat worse	2 (22.2%)	3 (37.5%)
	Sex was about the same as without the buffer	2 (22.2%)	2 (25.0%)
	Sex was somewhat better	3 (33.4%)	2 (25.0%)
	Sex was much better with the buffer	2 (22.2%)	1 (12.5%)

(continued)

Table 3. Continued

Q#	Variable	Patient responses (N = 9) No. (%) or Mean (SD)	Partner responses (N = 8) No. (%) or Mean (SD)
18	In general, how did sexual satisfaction using the buffer compare to vaginal sex before using the buffer?		
	Much less sexual satisfaction	1 (11.1%)	0 (0%)
	Somewhat less sexual satisfaction	1 (11.1%)	3 (37.5%)
	Neutral	3 (33.4%)	3 (37.5%)
	Somewhat more sexual satisfaction	2 (22.2%)	2 (25.0%)
	Much more sexual satisfaction	2 (22.2%)	0 (0%)
19	How likely are you to use the buffer again the next time you have sex?		
	Not likely at all, I would never use the buffer again	0 (0%)	0 (0%)
	Somewhat unlikely	1 (11.1%)	1 (12.5%)
	Neutral, I'm not sure	0 (0%)	2 (25.0%)
	Somewhat likely	5 (55.6%)	3 (37.5%)
	Very likely, I would definitely use the buffer again	3 (33.3%)	2 (25.0%)
20	How do you rate your confidence that you could get and keep an erection while using the Ohnut?		
	Very low	—	0 (0%)
	Low	—	0 (0%)
	Moderate	—	1 (12.5%)
	High	—	1 (12.5%)
	Very high	—	6 (75.0%)
21	When you had erections with sexual stimulation, how often were your erections hard enough to put on the Ohnut?		
	Almost never	—	0 (0%)
	A few times (less than half of the time)	—	0 (0%)
	Sometimes (about half of the time)	—	0 (0%)
	Most times (much more than half the time)	—	0 (0%)
	Almost always/always	—	8 (100%)
22	During sexual intercourse, how often were you able to maintain your erection after you had put on the Ohnut?		
	Almost never	—	0 (0%)
	A few times (less than half of the time)	—	0 (0%)
	Sometimes (about half of the time)	—	0 (0%)
	Most times (much more than half the time)	—	1 (12.5%)
	Almost always/always	—	7 (87.5%)
23	During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?		
	Almost never	—	0 (0%)
	A few times (less than half of the time)	—	0 (0%)
	Sometimes (about half of the time)	—	0 (0%)
	Most times (much more than half the time)	—	0 (0%)
	Almost always/always	—	8 (100%)
24	During intercourse, how difficult was it to maintain your erection to completion of intercourse?		
	Extremely difficult	—	0 (0%)
	Very difficult	—	0 (0%)
	Difficult	—	0 (0%)
	Slightly difficult	—	0 (0%)
	Not difficult	—	8 (100%)
25	When you attempted intercourse with the Ohnut, how often was it satisfactory for you?		
	Almost never	—	0 (0%)
	A few times (less than half of the time)	—	0 (0%)
	Sometimes (about half of the time)	—	1 (12.5%)
	Most times (much more than half the time)	—	2 (25.0%)
	Almost always/always	—	5 (62.5%)

Abbreviation: Q, question. [a]Patient acceptability index is calculated using Q1-5, 7, 8, 10, 12-19 (16 Qs total). Partner acceptability index is calculated using Q1-25 (25 Qs total; Q20-25 are revised from the IIEF questionnaire).

most participants completed questionnaires delivered by email, a larger proportion of patient participants did not complete items in the paper daily diary. A definitive trial could integrate an electronic hand-held device to collect daily diary information.[24]

Ohnut acceptability

The overall acceptability of the Ohnut was high among patient participants and their partners, with some dislikes related to size and comfort reported. Although acceptability results were similar between patient and partner participants, some

Table 4. The mean deep dyspareunia scores, psychological variables, and sexual function variables across the waitlist control and intervention group according to the study period.

Variable	Control Group (N = 7) Mean (SD)	Intervention Group (N = 10) Mean (SD)
Deep dyspareunia (0-10)		
Preintervention period mean deep dyspareunia score [wk 1-4]	4.51 (1.97)	5.13 (1.91)
Intervention period mean deep dyspareunia scores [wk 5-10]	4.69 (2.44)	2.46 (1.82)
PHQ-9 (0-27)		
Baseline	4.14 (2.61)	6.40 (4.01)
Wk 4	6.83 (1.94)	6.10 (2.89)
Wk 10	6.00 (3.70)	8.11 (6.81)
GAD-7 (0-21)		
Baseline	5.29 (5.09)	8.10 (5.36)
Wk 4	6.00 (2.00)	7.10 (4.65)
Wk 10	4.29 (2.50)	6.11 (4.96)
FSFI (2-36)[a]		
Baseline	27.82 (0.88)	25.40 (5.70)
Week 4	27.04 (1.85)	24.18 (6.06)
Week 10	28.22 (2.09)	26.78 (5.94)
FSDS-R (0-52)		
Baseline	25.29 (12.04)	22.20 (13.99)
Wk 4	18.67 (5.43)	17.70 (13.41)
Wk 10	23.43 (10.47)	16.11 (14.68)
FSFI pain domain (weighted; 0-6)[a]		
Baseline	3.36 (1.00)	2.98 (1.56)
Wk 4	3.44 (1.22)	2.49 (1.09)
Wk 10	3.52 (1.58)	3.60 (1.11)

Abbreviations: FSDS-R, Female Sexual Distress Scale–Revised; FSFI, Female Sexual Function Index; GAD-7, Generalized Anxiety Disorder Scale–7; PHQ-9, Patient Health Questionnaire–9. [a] N = 14 (5 controls and 9 intervention) after removing participants who indicated on the FSFI that they did not have sexual activity within the last 4 weeks.

partner participants reported slightly more difficulty in putting on the buffer and less sexual satisfaction. A larger sample size in a future trial with longer duration and multiple acceptability assessments should be done to further explore potential differences in acceptability between patients and their partners, and if over time more use would improve acceptability for partner participants. Beyond recruiting a larger sample, a future trial should consider the tradeoffs between an acceptability measure that evaluates specific attributes of the intervention (ie, the measure we used in this study) and more global assessments of acceptability (ie, the Treatment Acceptability and Preferences Measure[25]).

Preliminary efficacy of study outcomes

Our analysis indicated that the Ohnut significantly reduces the severity of endometriosis-associated deep dyspareunia. In the intervention group, the was a 2.67 reduction (on a 0-10 scale) in deep dyspareunia; a change score of 2 out of 10 has been suggested to be clinically significant.[26] This change in deep dyspareunia was noted even with the "real-world" nature of the trial, whereby subjects could continue other current treatments that could reduce treatment effects. We were unable to detect a statistically significant effect of the intervention on psychological and sexual function outcomes, although large effect sizes were seen for PHQ-9, FSDS-R, and the FSFI pain domain. Lack of statistical significance may be attributable to the small sample size. Also, the effect sizes for the FSFI overall were smaller than for the FSFI pain domain specifically, suggesting that a decrease in pain was not associated with any changes in sexual response. Additionally, the 6-week intervention period may have been insufficient to allow for meaningful improvements in these outcomes, since learning to use the Ohnut could initially cause distress (eg, feelings of embarrassment using the Ohnut) and interrupt sexual function (eg, loss of erection while putting on the Ohnut). A plan for a definitive trial should consider a longer intervention period; for example, a systematic review of couple-based dyadic interventions for breast cancer patients and their intimate partners found a median intervention duration of 3 months.[27] A larger trial could loosen eligibility criteria to include participants with a wider range of clincal profiles (eg, with concurrent moderate-to-severe superficial dyspareunia, or with high anxiety), and could further explore the frequency of sexual events between groups.

Strengths and limitations

This pilot RCT of the Ohnut identified strengths of the study design as well as opportunities to refine the approach for a future definitive trial. Strengths included the delivery of the Ohnut per manufacturer's instructions (ie, without additional information or counseling), which enhanced the ecological validity of the intervention, as well as the collection of both patient and partner acceptability data. Effect sizes for efficacy can be used to power a future randomized clinical trial. Limitations include the sample size and retention. Opportunities to adapt the design in a future RCT include opening eligibility criteria (eg, including participants with anxiety about insertive sex), increasing the intervention duration, having additional measures of acceptability, and incorporating digital health innovations for daily pain reporting. The effectiveness of the Ohnut may generalize to deep dyspareunia resulting from, for example, cancer treatment, menopause, or interstitical cystitis/painful bladder syndrome; future research could explore the impact of the Ohnut in these conditions.

Conclusion

This pilot RCT provides preliminary evidence of the acceptability and efficacy of the Ohnut and supports the use of the Ohnut for endometriosis-associated deep dyspareunia as an adjuvant to surgical, medical, or other treatments or as a stand-alone strategy for those awaiting treatment or for whom other treatments are not indicated.

Previous presentation of the research

Preliminary results from this study were presented as poster presentations at the Annual Meeting of the International Society for the Study of Women's Sexual Health (ISSWSH) in March 2022 and 2023, as well as the UBC OBGYN Academic Day in 2022.

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Author contributions

Kate Wahl and Natasha L. Orr are co-first authors and contributed equally. In addition, they had full access to all the data in the study and take responsibility for the integrity of data and accuracy of the data analysis.

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Supplementary material

Supplementary material is available at *Sexual Medicine* online.

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Conflicts of interest

R.F. is co-owner of Teumo Health Technologies Inc, a digital health company in sexual medicine.

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