

The Effect of L-Arginine Supplementation on Sexual Function in Diabetic Postmenopausal Women: A Double-Blind Randomized Clinical Trial

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Abstract

The effect of L-arginine supplements on sexual function in diabetic postmenopausal women: a double-blind randomized clinical trial

Background: While evidence suggests that L-arginine may improve sexual function, no study, to our knowledge, has evaluated its simultaneous effects on sexual distress and sexual function in postmenopausal women with diabetes.

Methods: In this double-blind randomized clinical trial, postmenopausal women with diabetes attending the Endocrinology Clinic of Ayatollah Rouhani Hospital, Babol, Iran, were enrolled. Sexual distress and sexual function were assessed using the Female Sexual Distress Scale-Revised and Female Sexual Function Index-6, respectively. Participants were randomly assigned in a 1:1 ratio to receive either L-arginine 2 g/day or placebo for eight weeks. Outcomes were reassessed at weeks 4 and 8. Data were analyzed using SPSS version 27.

Results: A total of 62 women with a mean age of 58.06 ± 5.57 years participated. Baseline demographic and clinical characteristics were comparable between groups. At baseline, sexual distress scores were 29.00 ± 5.60 in the intervention group and 28.26 ± 5.13 in the control group ($p = 0.589$). Sexual function scores were 14.35 ± 3.68 and 15.03 ± 3.36 , respectively ($p = 0.452$). At the end of the study, the between-group difference in mean changes in sexual distress was statistically significant ($p = 0.006$; effect size = 0.121). However, changes in sexual function were not statistically significant ($p = 0.135$; effect size = 0.037).

Conclusion: L-arginine supplementation significantly reduced sexual distress in postmenopausal women with diabetes but did not produce a statistically significant improvement in overall sexual function. Larger trials with higher doses and longer follow-up are warranted to confirm these findings.

Trial Registration Number: IRCT20150630022991N17

2. INTRODUCTION

Sexual activity and the satisfaction derived from it are recognized as among the most important dimensions of human life [1]. Female Sexual dysfunction is a highly prevalent disorder, and previous studies have reported the global prevalence of sexual problems in women to range between 22% and 86% [1]. Sexual dysfunction is a common complaint during menopause and may be associated with decreased levels of estrogen and androgen hormones [2]. Many individuals in this age group have underlying conditions such as diabetes [3], which can also lead to sexual dysfunction [4]. In these individuals, hyperglycemia, infection, vascular complications, neuropathy, and psychogenic factors contribute to the development of sexual dysfunction. In women with diabetes, systemic complications secondary to diabetes result in impaired vaginal and clitoral hemodynamics, lubrication difficulties, reduced genital muscle activity, and loss of genital sensitivity [5, 6].

Among the supplements that have long attracted the attention of researchers, and for which contradictory effects have been reported in various studies, is L-arginine. Arginine, or L-arginine, is an amino acid synthesized in the body [7]. L-arginine tablets, as an amino acid supplement, are used to enhance immune function and to support the improvement of various diseases and conditions. After administration, by increasing nitric oxide levels in the bloodstream, this supplement induces vasodilation, enhances sexual response, and stimulates the sensation of increased oxygenated blood flow to the genital organs. Previous studies have demonstrated that this supplement may improve sexual dysfunction and erectile dysfunction in male patients with diabetes [8, 9]. However, to date, no study has been conducted in postmenopausal women with diabetes. Therefore, the present study was conducted to evaluate the effect of L-arginine supplementation on sexual function in postmenopausal women with diabetes (up to 70 years of age).

3. METHODS

This double-blind randomized clinical trial was conducted among postmenopausal women with diabetes who were referred to the endocrinology clinic or ward of Ayatollah Rouhani Hospital, Babol.

Participants

The inclusion criteria comprised postmenopausal women (up to 70 years of age), married, with a diagnosis of diabetes for at least one year prior to the initiation of the intervention. The exclusion criteria included a diagnosis of major depressive disorder, a history of myocardial infarction within the past year, absence of regular sexual activity between the individual and her partner, asthma and allergies, herpes infection, use of medications such as nitroglycerin and drugs for the treatment of sexual dysfunction (Viagra), presence of an active peptic ulcer, renal failure, and hepatic failure. Individuals who did not adhere properly to their medication regimen during the study period were also excluded.

Sample size

The sample size was calculated using G*Power software version 3.1.9.2, based on the statistical model of repeated measure, within-between interaction. Considering the results of the study by Torkaman et al. [10], and assuming a moderate effect size of 25% for the effect of L-arginine on sexual function, with a significance level of 0.05, a statistical power of 80%, and three assessment time points, the minimum required sample size was estimated as 28 participants per group. Taking into account a 10% attrition rate, 31 participants were enrolled in each group, resulting in a total sample of 62 individuals.

Study Instruments

In this study, sexual function and sexual distress were assessed using two validated instruments. First, the Female Sexual Function Index–short form (FSFI-6), developed by Isidori et al. based on the original version designed by Rosen et al. [11, 12] and validated in Iran [13], was utilized. This instrument consists of six items corresponding to the domains of desire, arousal, lubrication, orgasm, satisfaction, and pain,

scored on a Likert scale ranging from zero to five. The sum of the domain scores constitutes the total score (maximum 36), with higher scores indicating better sexual function. The scale demonstrates acceptable internal consistency ($\alpha \geq 0.78$) and high test–retest reliability ($r = 0.95$) and is capable of discriminating women with FSD from those with normal function [11, 12]. In the present study, the Persian validated version by Ghasemi et al. was used [14].

Second, the revised Female Sexual Distress Scale (FSDS-R), developed by Derogatis et al. [15], includes 13 items rated on a five-point Likert scale (zero to four). The total score is obtained by summing the item scores, with higher scores indicating greater sexual distress. This instrument also demonstrates adequate internal consistency ($\alpha \geq 0.86$) and acceptable test–retest reliability ($r = 0.74$), with satisfactory diagnostic validity [15]. Its Persian version has been validated in Iran and is considered a reliable tool for assessing sexual distress in Iranian women [16].

Randomization and Blinding

Randomization was performed using permuted block randomization with block sizes of two and four and an allocation ratio of 1:1, ensuring an equal number of drug and placebo assignments within each block. The allocation sequence was generated by the study methodologist using Sealed Envelope software. After generation of the random sequence, a unique code was assigned to each allocation, and this code was labeled on the corresponding drug/placebo package to maintain allocation concealment. Upon enrollment of each participant, the relevant code was communicated to the researcher, and the corresponding product was delivered. Both the researcher and the participants were unaware of the contents of the drug or placebo, and only the allocation code was recorded in the study file. In the event of a severe or intolerable adverse effect, code unblinding was permitted. Data collection was conducted by the researcher through direct attendance at the study site.

To achieve blinding, a contract was established with Karen Pharmaceutical Company for the preparation of the active drug and placebo, and participants did not incur any cost. The drug and placebo were completely identical in terms of shape, color, odor, taste, and packaging method, with no distinguishable differences. The placebo contained one gram of starch and was manufactured to be fully comparable in appearance to the L-arginine tablet.

Intervention

The researcher was present in the research setting (endocrinology clinic or Rouhani Hospital ward) to identify eligible participants. Sampling was conducted using a convenience sampling method. Based on the inclusion and exclusion criteria and the participants' agreement to continue the study for eight weeks, patients in the intervention group received L-arginine supplementation at a dose of two g per day (one g L-arginine tablets manufactured by Karen Pharmaceutical Company, administered twice daily), while the control group received a placebo. After enrollment of eligible individuals, participants were randomly allocated to the intervention or control group. Study questionnaires were completed prior to the intervention. The primary outcome was the assessment of sexual function using the FSFI-6

questionnaire, and the secondary outcome was the assessment of sexual distress using the FSDS-R questionnaire. Eligible participants completed the questionnaires at baseline and at the fourth and eighth weeks after study initiation. To prevent bias, the medications (L-arginine and placebo), following blinding and complete randomization, were provided to the participants by the researcher. Therefore, in addition to the patients and their companions and caregivers, the physician and all evaluators involved in the study were unaware of the type of intervention (drug/placebo).

Statistical Analysis

Data were analyzed using SPSS v27. Normality was assessed with the Shapiro–Wilk test, and descriptive statistics (frequency, percentage, mean $\pm$ SD) were reported. Between-group comparisons were performed using an independent t-test, chi-square, or Fisher’s exact test as appropriate, and Pearson correlation was applied for normally distributed quantitative variables. The intervention effect was analyzed using the ITT approach, with missing data assessed by MCAR and imputed via the EM algorithm; per-protocol analysis was also conducted. Repeated Measures ANOVA was used to evaluate pre–post and between-group changes, with a significance level of 0.05.

Ethical considerations

This study was approved by the Ethics Committee of Babol University of Medical Sciences under the code IR.MUBABOL.HRI.REC.1404.015 and was registered in the Iranian Registry of Clinical Trials under the code IRCT20150630022991N17.

4. Patient and Public Involvement

The research question and outcome measures were developed based on existing evidence regarding sexual dysfunction and sexual distress in postmenopausal women with diabetes; patients were not directly involved in this process. Patients were not involved in the design, recruitment strategy, or conduct of the study. Study findings will be disseminated through scientific publication and will be shared with participants upon request. The burden of the intervention (daily supplementation and questionnaire completion over 8 weeks) was not formally assessed by patients; however, no significant difficulties or intervention-related burdens were reported.

5. RESULTS

In this clinical trial, a total of 180 individuals were assessed for eligibility, of whom 62 met the inclusion criteria and were enrolled in the study. The process of participant enrollment and randomization, according to the CONSORT checklist, is presented in Fig. 1. During the study period, two patients in the control group and four patients in the intervention group were excluded despite follow-up due to non-adherence to the study medication.

The demographic characteristics of the participants are presented in Table 1.

Table 1
Baseline demographic characteristics of the study population

Variable	Total Patients (Mean ± SD)	Intervention Group (Mean ± SD)	Control Group (Mean ± SD)	P value ^a
Age (year)	58.06 ± 5.57	57.94 ± 6.02	58.19 ± 5.18	0.857
Age at Marriage (year)	20.39 ± 4.96	20.45 ± 5.08	20.32 ± 4.92	0.920
Duration of Marriage (year)	37.73 ± 8.27	37.61 ± 9.33	37.84 ± 7.21	0.916
Age Difference with Spouse (year)	5.21 ± 3.79	5.00 ± 4.21	5.42 ± 3.37	0.667
Frequency of Intercourse per Week	0.76 ± 0.59	0.77 ± 0.56	0.74 ± 0.63	0.832
Duration of Menopause (year)	7.71 ± 5.64	7.00 ± 5.30	8.42 ± 5.96	0.326
a: T test				

Intention-to-Treat (ITT) analysis

To address missing data, the EM algorithm was applied, and analysis was performed according to the ITT approach (62 patients). At baseline, prior to the intervention, the mean ± standard deviation of the sexual distress score was 29.00 ± 5.60 in the intervention group and 28.26 ± 5.13 in the control group ($p = 0.589$). Regarding sexual function, the mean ± standard deviation score was 14.35 ± 3.68 in the intervention group and 15.03 ± 3.36 in the control group ($p = 0.452$).

Changes in the mean ± standard deviation of sexual distress and sexual function scores were analyzed using repeated measures analysis, and the corresponding results are presented in Table 2. As shown, for the variable of sexual distress, irrespective of group allocation, the mean sexual distress score changed significantly over time ($p > 0.001$ and effect size 0.317). Furthermore, the difference in mean changes between the two groups was statistically significant ($p = 0.006$ and effect size 0.121), with a greater reduction observed in the intervention group compared to the control group.

Table 2

Changes in mean $\pm$ standard deviation of sexual distress and sexual function scores in the intervention and control groups (intention-to-treat analysis)

Variable	Time Point	Intervention (n = 31) Mean ± SD	Control (n = 31) Mean ± SD	P value [⊠] (effect size)	P value [⊠] (effect size)
Sexual Distress	Baseline	29.00 ± 5.60	28.26 ± 5.13	0.006 (0.121)	< 0.001 (0.317)
	Week 4 Follow-up	22.63 ± 6.38	26.72 ± 3.15		
	Week 8 Follow-up	20.25 ± 7.44	26.11 ± 3.59		
Sexual Function	Baseline	14.35 ± 3.68	15.03 ± 3.36	0.135 (0.037)	< 0.001 (0.373)
	Week 4 Follow-up	17.80 ± 2.13	16.44 ± 2.30		
	Week 8 Follow-up	18.41 ± 2.10	16.60 ± 2.25		
⊠ A comparison of mean changes over time between the intervention and control groups using repeated measures analysis.					
⊠ Overall comparison of mean changes over time irrespective of group allocation.					

With respect to sexual function, irrespective of group allocation, the mean sexual function score changed significantly over time ($p > 0.001$ and effect size 0.373). However, as indicated in Table 2, the difference in mean changes between the two groups was not statistically significant ($p = 0.135$ and effect size 0.037).

Per-protocol analysis

A per-protocol analysis was conducted to evaluate changes among participants who completed the trial (56 patients). Changes in the mean $\pm$ standard deviation of sexual distress and sexual function scores were examined using repeated measures analysis, and the results are presented in Table 3. For the variable of sexual distress, irrespective of intervention or control group, the mean sexual distress score changed significantly over time ($p > 0.001$ and effect size 0.321). Additionally, the difference in mean changes between the two groups was statistically significant ($p = 0.007$ and effect size 0.127).

Table 3
Changes in sexual distress and sexual function scores in the intervention and control groups (per-protocol analysis)

Variable	Time Point	Intervention (n = 27) Mean ± SD	Control (n = 29) Mean ± SD	p value [⊠] (effect size)	p value [⊠] (effect size)
Sexual Distress	Baseline	29.19 ± 5.94	27.97 ± 5.03	0.007 (0.127)	< 0.001 (0.321)
	Week 4 Follow-up	22.30 ± 6.77	26.76 ± 3.23		
	Week 8 Follow-up	19.67 ± 7.81	26.28 ± 3.66		
Sexual Function	Baseline	13.93 ± 3.70	15.03 ± 3.46	0.209 (0.029)	< 0.001 (0.402)
	Week 4 Follow-up	17.81 ± 2.28	16.38 ± 2.36		
	Week 8 Follow-up	18.48 ± 2.24	16.52 ± 2.30		
⊠ A comparison of mean changes over time between the intervention and control groups using repeated measures analysis.					
⊠ Overall comparison of mean changes over time irrespective of group allocation.					

Regarding sexual function, irrespective of group allocation, the mean score changed significantly over time ($p > 0.001$ and effect size 0.402). However, as shown in Table 3, there was no statistically significant difference between the intervention and placebo groups in terms of sexual function score ($p = 0.209$ and effect size 0.029).

6. DISCUSSION

This double-blind randomized clinical trial demonstrated that daily administration of two g of L-arginine for eight weeks in postmenopausal women with diabetes significantly reduced sexual distress compared with placebo. However, although an improvement in sexual function was observed, the between-group difference did not reach statistical significance. To our knowledge, this is the first study to evaluate L-arginine monotherapy in this specific population.

Previously, the efficacy of L-arginine in improving male sexual function has been reported [17, 18]. In women, Torkaman et al. demonstrated improvements in lubrication, orgasm, and mood among patients with depression [10]. Furthermore, a 2021 systematic review indicated that L-arginine-containing products (such as ArginMax) may improve the total FSFI score or certain domains; six out of seven studies reported favorable outcomes, and no significant adverse events were observed [19].

Nevertheless, most previous investigations have used combination formulations, and there is a lack of evidence regarding the efficacy of L-arginine as monotherapy [20–22]. Therefore, definitive attribution of the therapeutic effect to L-arginine alone remains challenging [19].

In the ArginMax formulation, approximately 77% of the composition consists of L-arginine and 23% includes Korean ginseng, Ginkgo biloba, and damiana. Since some of these components also influence the nitric oxide (NO) pathway, a potential synergistic effect has been proposed; however, the doses of ginseng and damiana are lower than those evaluated for Hypoactive Sexual Desire Disorder (HSDD), and the evidence regarding Ginkgo is inconsistent [23–25]. In contrast, the Lady Prelox formulation contains L-arginine in combination with L-citrulline and French maritime pine bark extract, which may exert effects through improvement of endothelial function [20, 22]. Despite these findings, the relative contribution of each component remains unclear, and none of the administered doses have been associated with serious adverse events [19]. The present findings, based on monotherapy, reinforce the importance of evaluating L-arginine independently.

The study by Menafrá et al. in men with erectile dysfunction showed that although a significant improvement in severity classification was observed, only a proportion of patients achieved normal functional levels [17]. In the current study, severity of dysfunction was not analyzed categorically; therefore, subgroup analyses were not feasible, and severity-based analyses might yield different results.

Considering potential genetic differences, laboratory assessment of L-arginine levels and its metabolites in patients may provide useful guidance for more accurate evaluation. If baseline levels of various L-arginine metabolites had been measured, a clearer perspective on treatment trajectory could have been obtained. It has been suggested that an integrated evaluation of arginine and its related catabolic products may potentially contribute to predicting susceptibility to major depressive disorder [26].

Although the prevalence of sexual dysfunction has been reported to be higher in women than in men, the distribution of research in this field is unbalanced, with most studies focusing on men with erectile dysfunction. In contrast, evidence regarding the efficacy of L-arginine in women with sexual dysfunction remains limited. Increasing awareness of HSDD and related conditions highlights the need for targeted therapeutic strategies for women; however, the lack of precise understanding of the underlying biological mechanisms complicates the identification of specific pharmacological targets and may partly explain the limited availability of dedicated pharmacotherapies in this area. Most available treatments focus on modifying underlying factors such as psychological disturbances or hormonal imbalances. Moreover, demographic factors, including race, may influence the experience and reporting of sexual dysfunction; a study found that the prevalence of sexual dysfunction was higher among Black women than among White women [27]. Additionally, the study populations in some previous trials were predominantly White, and in several investigations, ambiguous or restrictive inclusion criteria (such as favorable social or occupational status) were applied [20, 21], potentially limiting generalizability and external validity. In this context, the present study, focusing on L-arginine monotherapy in postmenopausal women with diabetes, represents a step toward addressing this research gap and underscores the necessity for larger, more diverse, and methodologically rigorous studies to clarify the role of this supplement in the treatment of female sexual dysfunction.

Limitation

With respect to measurement instruments, although the FSFI and FSDS-R are considered among the most validated tools for assessing sexual function and sexual distress, they do not encompass all psychological, social, and cultural dimensions influencing HSDD [19]. In addition, the absence of serum measurements of L-arginine and its metabolites limited a more precise interpretation of the biological response to treatment. From a comparative evidence perspective, the lack of adequately powered randomized controlled trials and the absence of studies specifically evaluating L-arginine monotherapy in women with HSDD make direct comparison of findings challenging. Moreover, due to limited availability of high-dose L-arginine formulations in the Iranian pharmaceutical market, the minimum effective dose reported in previous studies was used in order to maintain treatment acceptability. Cultural considerations also posed challenges in the recruitment process. The eight-week follow-up period restricted assessment of long-term effects, and the single-center design may have limited the generalizability of the findings.

Conclusion

Given the low incidence of reported adverse effects, L-arginine supplementation may improve sexual distress, sexual function, and orgasm in postmenopausal women with diabetes. Future studies are required to evaluate the effects of higher doses, longer intervention durations, and larger populations of postmenopausal women with diabetes in order to confirm these findings.

Declarations

Statement of authorship:

Fatemeh Fakheri contributed to the conception and design of the study, acquisition of data, and drafting of the manuscript. Neda Meftah contributed to the conception and design of the study, acquisition of data, and critical revision of the manuscript for important intellectual content. Marjan Moudi contributed to the conception and design of the study, acquisition of data, and critical revision of the manuscript for important intellectual content. Hoda Shirafkan contributed to the analysis and interpretation of the data and critical revision of the manuscript for important intellectual content. All authors reviewed and approved the final version of the manuscript, and no other person made a substantial contribution to the paper.

Ethics approval and consent to participate

The study was registered in the Iranian Registry of Clinical Trials (IRCT) under the registration number IRCT20150630022991N17 on June 10, 2025, and was approved by the Ethics Committee of Babol University of Medical Sciences (Approval No. IR.MUBABOL.HRI.REC.1404.015). The study was conducted in accordance with the principles of the Declaration of Helsinki, and informed written consent was obtained from all participants before enrollment in the study.

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Author Contribution

N.M and F.F. contributed to the conception and design of the study, acquisition of data, and drafting of the manuscript. M.M. contributed to the conception and design of the study, acquisition of data, and critical revision of the manuscript. H.S. contributed to the statistical analysis and interpretation of the data and critically revised the manuscript. All authors reviewed and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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Data Availability

The datasets generated and/or analyzed during the current study are not publicly available due to privacy and confidentiality considerations but are available from the corresponding author on reasonable request.

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Figures

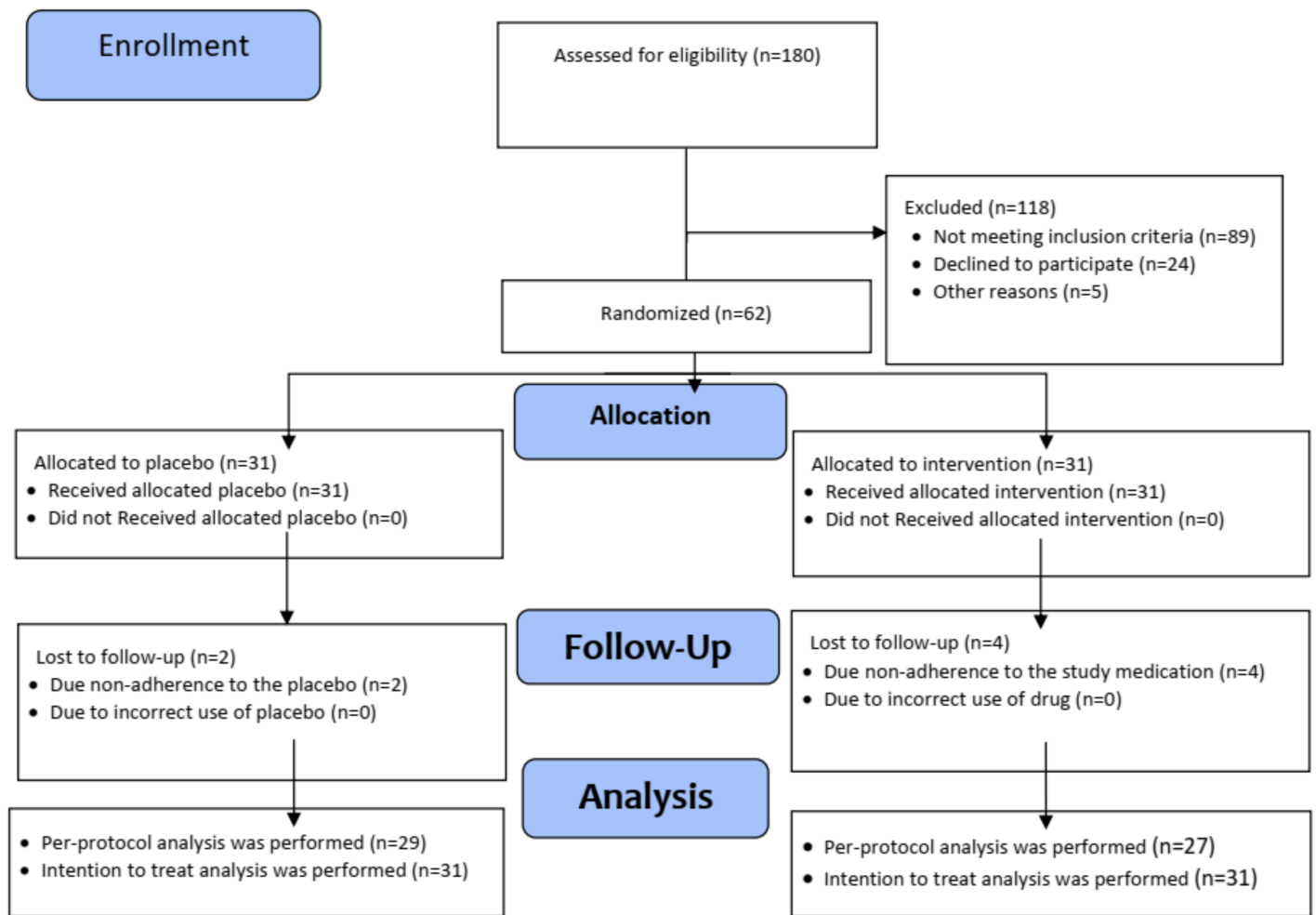


Figure 1

Consort flowchart of the participants