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Title: The Effects of Pelvic Floor Muscle Training on the Treatment of Women with Urinary Incontinence: A Meta-Analysis of Randomized Controlled Trials

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Abstract: Background: Although many studies have reported the effectiveness of pelvic floor muscle training for treating female urinary incontinence, the magnitude of the effect and the optimal configuration of the parameters of the training have not been clearly determined.

Objectives: The aims of this meta-analysis were (a) to calculate the effect size of pelvic floor muscle training compared to no-treatment on incontinent episodes, urine leakage amount, and perceived severity of urine loss, and (b) to identify parameters of PFMT and subjects' characteristics influencing on the magnitude of the effects.

Method: The search for relevant literature published from 1980 to 2005 consisted of using several computerized databases, citation searching, and footnote chasing. Twelve studies met the inclusion criteria were reviewed and coded.

Results: The overall mean weighted effect size on incontinent episodes, urine leakage amount, and perceived severity were -0.68 ($Z = 5.89$, $p = .000$), -1.48 ($Z = 2.64$, $p = .008$), and -1.66 ($Z = 1.68$, $p = .092$) respectively. The studies with women having stress urinary incontinence showed a mean weighted effect size of -0.77 ($Z = 7.03$, $p = .000$), whereas studies with women having any type of urinary incontinence showed -0.47 with ($Z = 4.40$, $p = .000$). The mean weighted effect size for studies including subjects over 60

years mean age was -0.54 ($Z = 6.21$, $p = .000$), whereas that of studies in which the average age was younger than 60 years was -0.94 ($Z = 6.58$, $p = .000$).

Discussion: The treatment effect of pelvic floor muscle training on the incontinent episodes may be greater in younger women with only stress urinary incontinence. It appears that the number of daily contractions and the length of training period are not related to effect sizes on condition that training includes at least daily 24 contractions and keeps for at least six weeks.

August 26, 2006

Molly C. Dougherty, PhD., RN

Editor, *Nursing Research*

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Dear Dr. Dougherty:

I am submitting the manuscript titled “The Effects of Pelvic Floor Muscle Training on the Treatment of Women with Urinary Incontinence: A Meta-Analysis of Randomized Controlled Trials” to the *Nursing Research* which we believe will be of interest to *Nursing Research* readers. This manuscript conforms to the format requirements and includes 16 page-long text, one table and seven figures.

My coauthors and I do not have any interests that might be interpreted as influencing the results of the study, and have followed APA ethical standards in conduct of the study. All of the authors agreed to byline order and to submission of the manuscript in this form. We also agreed that I will be serving as the corresponding author for convenience, as I am located in United States and I mentor my coauthors. Dr Choi was a visiting scholar last year and Ms. Park is my doctoral student advisee.

If you have any questions regarding this manuscript, please do not hesitate to contact me by phone or e-mail. Thank you for your time and attention.

Sincerely,

Mary H. Palmer, PhD, RNC, FAAN

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Running Head: META-ANALYSIS OF PELVIC FLOOR MUSCLE TRAINING

The Effects of Pelvic Floor Muscle Training on the
Treatment of Women with Urinary Incontinence:
A Meta-Analysis of Randomized Controlled Trials

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1 Introduction

2 Urinary incontinence (UI), defined by the International Continence Society (ICS) as “the
3 complaint of any involuntary leakage or urine,” is a common but underreported health problem
4 among women (Abrams et al., 2002). The prevalence of female UI varies from 5% to 66%
5 depending on UI definition, methods of measurement, age of women included in the study, and
6 setting (e.g., general or institutionalized population). Evidence exists that UI may seriously affect
7 the physical, psychological, and social well-being of women (Hunskar et al., 2005). UI has
8 substantial impact. The annual direct cost of urinary incontinence in women was estimated to be
9 \$12.4 billion (1995 dollars) as compared to \$3.8 billion (1995 dollars) in men (Glazener et al.,
10 2001). Because of its prevalence and impact on women’s well-being, and its high financial costs,
11 UI is a major health problem that requires serious attention from health professionals.

12 Three major types of female UI treatment are: pharmacological, surgical, and
13 conservative. It is beyond the scope of this paper to discuss pharmacological and surgical
14 treatments and the reader is referred to the 3rd International Consultation on Incontinence for in
15 depth discussions of these topics (Abrams et al., 2005).

16 Conservative treatment, also called behavioral therapy, includes physical therapies,
17 lifestyle interventions, and scheduled voiding regimens (Wilson et al., 2005). A physical therapy
18 intervention, pelvic floor muscle training (PFMT), is a frequently used treatment modality for
19 female UI. Several studies have reported the effectiveness of PFMT for female UI (Berghmans et
20 al., 1998; Hay-Smith et al., 2001; Hay-Smith & Dumoulin, 2006; Holroyd-Leduc & Straus,
21 2004). Their findings are consistent, that is PFMT is an effective treatment for many women with
22 stress UI. Unfortunately almost every published clinical trial has not precisely described all the
23 parameters of PFMT such as the number, frequency, and velocity of pelvic floor muscle (PFM)

1 contractions, the length of training period, and type of instruction provided. In addition,
2 considerable variation exist in outcome measures and whether PFMT was applied as the sole
3 intervention or in combination with other modalities such as biofeedback, electrical stimulation,
4 and bladder training (Hay-Smith & Dumoulin, 2006). Moreover, previously published systemic
5 reviews (Berghmans et al., 1998; Bo, 1996; Bo & Maanum, 1996; Holroyd-Leduc & Straus,
6 2004; Wilson et al., 2002) relied on qualitative synthesis, thus the effect size specific parameters
7 were not reported. For these reasons, the magnitude of the effect for many PFMT protocols and
8 the optimal configuration of the parameters of PFMT have not been clearly determined (Gormley,
9 2002; Hay-Smith et al., 2001; Hay-Smith, Herbison, & Morkved, 2004; Holroyd-Leduc & Straus,
10 2004).

11 In an attempt to remedy this situation, Hay-Smith et al. (2001) tried to calculate effect
12 sizes and to compare the effectiveness of different PFMT protocols with studies published in
13 from 1980 to 2000. These authors calculated effect sizes of PFMT compared with various control
14 treatments on perceived cure/improvement and on incontinent episodes. They did not, however,
15 compare the effect of specific parameters of PFMT protocols on outcomes, no doubt in part due
16 to variability in PFMT protocols used and that relatively few published studies specified which
17 PFMT protocol parameter or combination of parameters were most effective on outcomes.

18 Recognizing the need for this information, Wilson and colleagues (2002) extrapolated
19 evidence from exercise science literature and made recommendation for specific parameters
20 including: minimum daily number, velocity, and frequency of pelvic floor muscle (PFM)
21 contraction and a minimum length of training. To further advance and refine evidence based
22 practice for conservative treatment for female urinary incontinence, we conducted a meta-
23 analysis with published PFMT clinical trials.

1 *Purpose, Research Questions, and Variable Definition*

2 The primary aim of this meta-analysis was to calculate the effect size of PFMT
3 compared to no-treatment on two objective outcome measures: incontinent episodes and amount
4 of urine leakage and on one subjective outcome measure: perceived severity of urine loss.

5 Because agreement about what constitutes an effective PFMT protocol does not exist
6 (Berghmans et al., 1998; Hay-Smith et al., 2004; Wilson et al., 2002) a secondary aim was also
7 defined. It is to identify the effect sizes for each parameter and then to determine the most
8 effective configuration of these parameters in treating female UI.

9 The tertiary aim was to identify sample characteristics acting as moderators on the effect
10 of PFMT. Potential sample characteristics moderators include type of UI (McDowell, Burgio,
11 Dombrowski, Locher, & Rodriguez, 1992) because PFMT was originally designed to reduce
12 urine loss from inadequate muscle tone and decreased urethral resistance (DeLancey, 1988). Age
13 is also a very important sample characteristic as conflicting findings related to age appear in the
14 literature. For example, some researchers (Theofrastous et al., 2002; Wyman, Fantl, McClish,
15 Bump, & the Continence Program for Women Research Group, 1998) found that there was no
16 significant relationship between response to PFMT and subject age. Other researchers (Wilson,
17 Al Samarrai, Deakin, Kolbe, & Brown, 1987) reported successful treatment was more likely in
18 younger women. In other study, treatment responders were older than borderline responders (Bo
19 & Larsen, 1992). In recent studies, it was suggested that the effect of PFMT may be greater in
20 younger women, however, no compelling evidence exists that older women benefit less from
21 PFMT (Hay-Smith & Dumoulin, 2006; Wilson et al., 2005). This latter conclusion was based on
22 only a few investigations and effect sizes were not reported, therefore more analysis is required
23 to investigate the association between age and PFMT outcome.

1 “conservative treatment,” “behavioral therapy,” and “women.” These computerized searches
2 revealed 122 studies including 25 dissertations. Two authors reviewed the abstracts of all 122
3 studies independently with following inclusion criteria: (a) study design was randomized
4 controlled trial (RCT), (b) PFMT was used as an UI intervention, (c) control groups limited to
5 only no-treatment groups or placebo PFMT groups, (d) at least one of the selected outcome
6 variables, incontinent episodes, urine leakage amount, and perceived severity was measured. The
7 two authors agreed that 33 abstracts met inclusion criteria. Additional citation searching and
8 footnote chasing added three more original research articles, thus 36 research articles were pulled
9 for complete review.

10 *Selection of Studies*

11 The first and third authors reviewed the 36 studies to independently confirm that they met
12 inclusion criteria. Twenty four studies were excluded with following reasons: (a) five studies
13 applied PFMT as a preventive measure instead of treatment measure, (b) one study (Miller,
14 Ashton-Miller, & DeLancey, 1998) used “The Knack” which was defined as intentionally
15 contracting the PFM before and during a cough instead of usual PFMT, (c) seven studies had
16 control groups that were neither no-treatment groups nor placebo PFMT groups, (d) five studies
17 reported outcomes not using mean and standard deviation which could be used for calculating
18 mean difference effect size and mean weighted effect size (MWES), (e) one study (Glazener,
19 Herbison, MacArthur, Grant, & Wilson, 2005) reported on only six-year follow-up effect of
20 PFMT, (f) one study (Lagro-Janssen, Debruyne, Smits, & van Weel, 1992) was excluded because
21 the sample and reported results substantially overlapped with a study by the same authors already
22 included for this meta-analysis, (g) finally, four studies were excluded because quasi-
23 experimental rather than randomized controlled trial design was used.

1 *Data-Collection Methods*

2 The authors created a codebook on selected variables. Each study was coded for five
3 dimensions: (a) report identification including author, publication year, study setting (country)
4 and coder of study; (b) subjects parameters including sample size, mean and range of age, types
5 of UI, and baseline perceived severity of UI; (c) methodology including assignment of subjects,
6 blindedness, and attrition; and (d) treatment parameters including length of PFM training period,
7 the number of daily PFM contractions, velocity of contractions, holding time in contractions,
8 combined treatment measure with PFMT, and time to outcome measure; and (e) information for
9 effect size including mean and standard deviation. In addition to objectively assess study quality,
10 the criteria for quality of randomized controlled trials developed by Jadad and colleagues (1996)
11 were adopted. These criteria had three scoring items including description of randomization,
12 double blinding and withdrawals/dropouts. Scores for study quality range from 0 to 5.

13 At the beginning of the coding process, the first author and the third author coded two
14 studies concurrently to improve agreement on coding decisions. The next ten studies were coded
15 independently. To measure inter-rater reliability, coder agreement was calculated by the
16 percentage of agreement between the two coders on subjects' characteristics, study methodology,
17 and treatment parameters. The coder agreement was 91% and discrepancies between coders were
18 resolved by discussion.

19 *Statistical Analyses*

20 An effect size and 95% confidence interval (CI) for each outcome variable in each study
21 was calculated using Hedges's *g* defined as the difference between the group means divided by
22 the pooled standard deviation (Rosenthal, 1984).

23 In this meta-analysis, overall MWES for incontinent episodes, urine leakage amount, and

1 perceived severity were calculated weighing for study variance. To test the assumption that the
2 studies share a common population effect size, Q test for homogeneity was used.

3 Sensitivity analysis was performed to identify whether the results of a research synthesis
4 were sensitive to the inclusion or exclusion of low-quality studies because quality can influence
5 the outcome in a clinical trial (Halvorsen, 1984). Subgroup analyses also were performed to
6 examine whether the results varied by parameters of PFMT and subject characteristics.

7 To investigate the possibility of publication bias affecting the results of this meta-analysis,
8 funnel graph and rank correlation test such as Kendall's tau were performed based on
9 standardized effect sizes and sampling variances of all studies reviewed (Begg, 1994). The fail-
10 safe N, another method related to publication bias based on p value, was computed. Statistical
11 analyses were performed using StatsDirect Statistical Software.

12 Results

13 *Characteristics of Studies and Overall Mean Weighted Effect Sizes*

14 The studies were conducted in different countries: five in the United States (41.7%), two
15 in two European countries (16.7%), two in Korea (16.7%), two elsewhere (16.7%), and one not
16 reported (8.3%), see Table 1. Although many parameters of PFMT may have an impact on UI
17 outcomes, only the length of training period and the number of contractions were clearly
18 described in most of the studies. The length of training period ranged from 6 to 24 weeks, and
19 the number of pelvic floor muscle contractions per day ranged from 24 to 200 and varied in each
20 study. Seven of the 12 studies (58.3%) were scored as 3 or higher for study quality (Table 1).

21 In this meta-analysis, a negative effect size meant that the subjects in the intervention
22 groups improved more on each outcome measure than the subjects of the control groups. That is,
23 subjects in the intervention groups showed fewer incontinent episodes, less urine leakage, and

1 less perceived severity.

2 *Incontinent Episodes*

3 Ten studies (Aksac et al., 2003; Bo, Talseth, & Holme, 1999; Burgio et al., 1998; Burns
4 et al., 1993; Dougherty et al., 2002; Ghoneim et al., 2005; Lagro-Janssen, Debruyne, Smits, &
5 van Weel, 1991; McDowell et al., 1999; Subak, Quesenberry, Posner, Cattolica, & Soghikian,
6 2002; Sung, Hong, Choi, Baik, & Yoon, 2000) were analyzed for incontinent episodes.

7 One study (Glazener et al., 2001) was excluded from incontinent episodes analysis
8 because the outcome variables reported was the percentage of women who had at least one
9 weekly incontinent episode. The means and standard deviations (SD) of experimental and control
10 groups of Lagro-Janssen et al. (1991) and Bo et al. (1999) were taken from the meta-analysis
11 performed by Hay-Smith and Dumoulin (2006) as the original articles reported only confidence
12 interval (CI), rather than SD. With Ghoneim et al. (2005) study, we estimated the SD from the
13 published CI. All of the other studies with the exception of Sung and colleagues' (2000)
14 measured incontinent episodes using bladder records, and time intervals varied from 24 hours to
15 two weeks.

16 The sample sizes of the included studies ranged from 30 to 147, with a mean of 85 ($SD =$
17 35.20), and a total of 849 subjects. The subjects' age ranged from 18 to over 90 years.

18 Effect sizes ranged from -1.71 to -0.42. The overall MWES was -0.68 with a 95%
19 confidence interval of -0.91 to -0.46 ($Z = 5.89$, $p = .000$) (Figure 1). The homogeneity test
20 showed $Q = 22.59$ ($df = 9$, $p = .006$), indicating that the studies varied in effect size.

21 *Urine leakage amount*

22 Five studies (Aksac et al., 2003; Bo et al., 1999; Dougherty et al., 2002; Sung et al.,
23 2000; Yoon, Song, & Ro, 2003) were reviewed for this outcome. Six leakage outcome measures

1 were included in calculating overall MWES as Bo and her colleagues (1999) measured urine
2 leakage amount with two different methods: stress pad test and 24-hour pad test. Most of the
3 measurements used for urine leakage amount involved various types of pad tests, such as 24
4 hours, one-hour, 30 minutes, and stress-pad test. The sample sizes of these studies ranged from
5 25 to 147, with a mean sample size of 62 ($SD = 44.09$) and a total of 372 subjects. The subjects'
6 age ranged from 18 to over 80 years.

7 The effect sizes on urine leakage amount ranged from -12.29 to 0.09. The MWES was
8 -1.48 with a 95% CI of -2.58 to -0.38 ($Z = 2.64, p = .008$) (Figure 2). Subjects in the intervention
9 groups, therefore, showed significantly smaller amounts of urine leakage than the subjects in the
10 control groups after finishing PMFT. The result of Q statistics was 95.63 ($df = 5, p = .000$) and
11 was significantly heterogeneous among studies.

12 *Perceived severity*

13 Perceived severity related to urine loss was examined in four studies (Dougherty et al.,
14 2002; Glazener et al., 2001; Sung et al., 2000; Yoon et al., 2003). Measurement of this outcome
15 varied greatly in the reviewed studies. For example, Yoon and colleagues (2003) measured
16 perceived severity with eighteen 5-point scales while the authors of the other 3 studies used
17 different single-items. The sample sizes ranged from 25 to 284, with a mean of 129 ($SD =$
18 115.36) and total of 516 subjects. The participants' ages for calculating overall MWES of PFMT
19 on perceived severity also ranged from 18 to over 80 years.

20 The four included studies had effect sizes of perceived severity ranging from -4.43 to
21 -0.33. The MWES was -1.66 and a 95% CI was from -3.59 to 0.27 with $Z = 1.68$ and $p = .092$
22 (Figure 3). The heterogeneity test had a result of $Q = 191.79$ ($df = 3, p = .000$).

1 *Result of Sensitivity Analysis*

2 Sensitivity analysis based on the study quality rating was limited only to incontinent
3 episodes due to the low number of studies available to calculate MWES for urine leakage
4 amount and for perceived severity.

5 Among 10 studies measured incontinent episodes, six studies scoring 3 or higher were
6 assigned a high quality rating whereas the remaining four studies were assigned a low quality
7 rating. The MWES on incontinent episodes of high quality studies were -0.68, with a 95% CI of -
8 0.85 to -0.50 ($Z = 7.54, p = .000$), and MWES of the studies rated less than 3 was -0.55 with a
9 95% CI of -0.77 to -0.32 ($Z = 4.71, p = .000$). The MWES on incontinent episodes for both
10 groups were statistically significant, however, there were no significant differences between the
11 MWESs of two study groups ($Q_{BET} = 0.81, df = 1, p = .368$).

12 *Results of Subgroup Analysis*

13 This meta-analysis also examined the effectiveness of PFMT on incontinent episodes by
14 the number or magnitude of two specific PFMT parameters and two subject characteristics: (a)
15 the length of training period; (b) the number of PFM contractions; (c) subjects' type of UI, and
16 (d) subjects' age (Figure 4). Sub-analyses were not possible for urine leakage amount and
17 perceived severity because so few studies were available.

18 *Length of training period*

19 The same 10 studies used in analyzing incontinent episodes reported training-period
20 durations with a range of 6 to 24 weeks. The studies were divided based on eight weeks of
21 training period because muscle hypertrophy begins only after regular and intense strength
22 training for more than eight weeks (Dinubile, 1991). The overall MWES for the four studies that
23 used PFMT for more than eight weeks was -0.66 with a 95% CI of -0.88 to -0.44 ($Z = 5.91, p$

1 = .000). The overall MWES for the six studies that used PFMT for eight weeks or less was -0.61
 2 with a 95% CI of -0.79 to -0.43 ($Z = 6.60, p = .000$). However, there was no heterogeneity in
 3 these two study groups ($Q_{BET} = 0.13, df = 1, p = .718$).

4 *Number of PFM contractions*

5 Eight studies reported the number of daily contractions from a minimum of 24 to a
 6 maximum of 200. These studies were then divided into two subgroups on the basis of Wilson and
 7 colleagues' (2002) suggestion that the PFMT should include three sets of 8 to 12 slow-velocity
 8 and maximal-strength pelvic floor muscle contractions daily. The overall MWES of three studies
 9 that used a minimum of 24-36 daily contractions was -0.68 with a 95% CI of -0.98 to -0.37 ($Z =$
 10 $4.32, p = .000$). The overall MWES of five studies that used at least 45 daily PFM contractions
 11 was -0.68 with a 95% CI of -0.87 to -0.50 ($Z = 7.26, p = .000$). The MWESs of two study groups
 12 were not heterogeneous ($Q_{BET} = 0.00, df = 1, p = .995$).

13 *Subjects' type of UI*

14 The ten studies involved identified UI type are as follows: six had women with stress UI
 15 and mixed UI with dominant stress symptoms; three had women with any kind of UI; and one
 16 had women with urge UI and mixed UI with dominant with urge symptoms. The studies with
 17 women having stress UI and mixed UI with dominant stress symptoms showed an overall
 18 MWES of -0.77 with a 95% CI of -0.98 to -0.55 ($Z = 7.03, p = .000$). Studies of subjects with
 19 any type of UI showed an overall MWES of -0.47 with a 95% CI of -0.68 to -0.26 ($Z = 4.40, p$
 20 $= .000$). As a result of the heterogeneity test, Q_{BET} was 3.99 ($df = 1, p = .046$).

21 *Subject's age*

22 The participants of five studies used for these analyses (Burgio et al., 1998; Burns et al.,
 23 1993; Dougherty et al., 2002; McDowell et al., 1999; Subak et al., 2002) were women aged 55

1 years and older. The mean age was 63.37 years. The overall MWES of studies with an average
2 age over 60 years was -0.54 with a 95% CI of -0.71 to -0.37 ($Z = 6.21, p = .000$). The overall
3 MWES of studies in which the average age was younger than 60 years was -0.94 with a 95% CI
4 of -1.21 to -0.66 ($Z = 6.58, p = .000$). The heterogeneity test showed that Q_{BET} was 5.98 ($df = 1,$
5 $p = .015$).

6 *Publication Bias*

7 The results of Funnel graph on incontinent episodes, urine leakage amount and
8 perceived severity were showed at Figure 5, 6, 7 respectively. The results of Kendall's tau on
9 each outcome were -0.42 ($p = .073$), -0.73 ($p = .017$) and 0 ($p = .75$) respectively. The fail-safe N
10 (N_{FS}) for incontinent episodes was 210 and much greater than the reasonable guideline 60
11 computed from the formula with 10 studies. Inadequate number of studies prohibited testing fail-
12 safe N for urine leakage amount, and perceived severity.

13 Discussion

14 Calculating the MWES of PFMT compared to no treatment was the one of the goals of
15 this meta-analysis. Ten RCT for incontinent episodes, five RCT for urine leakage amount, and
16 four RCT for perceived severity were reviewed.

17 The results of Q test for homogeneity on each outcome measure showed that the
18 variances in MWES were not homogeneous. Hence, inclusion of other variables may be
19 necessary to more fully explain the variance in these effect sizes. Therefore, the MWESs of the
20 random effects model on each outcome were reported because the model is more conservative in
21 the presence of unexplained heterogeneity than the fixed model (Shadish & Haddock, 1984).

22 The overall MWES of PFMT on the incontinent episodes was -0.68 indicating that
23 PFMT was effective in reducing incontinent episodes compared to no treatment. This effect size

1 is considered a medium effect size (Cohen, 1988). Both the MWESs on urine leakage amount
2 and perceived severity, -1.44 and -1.66 respectively, are considered very large (Cohen, 1988).
3 However, the MWESs on urine leakage amount and perceived severity must be interpreted with
4 caution. In the case of the MWES on urine leakage amount, funnel graph and the results of
5 Kendall's tau showed that the publication bias is likely to be present. The MWES on perceived
6 severity that was calculated from only four studies had the statistic Z which did not exceed the
7 1.96 critical value at $\alpha = .05$, therefore, it is possible to conclude PFMT has no significant effect
8 on subjects' perceived severity.

9 Had most studies precisely reported on all PFMT parameters and sample characteristics,
10 more subgroup analyses could have been performed. In this case, the only subgroup analyses we
11 were able to perform were length of training period, number of daily contraction, type of UI, and
12 age. Because the number of studies and the variation in each parameter were very limited, an
13 analysis of variance for effect sizes with one factor model was used instead of multiple
14 regression analysis for effect sizes (Hedges, 1984).

15 The result of subgroup analysis by length of training period showed that the MWESs of
16 both study groups, one with more than eight weeks training period and the other with eight
17 weeks or less, were statistically significant in reducing incontinent episodes and that the
18 difference between MWESs of the two groups was not statistically significant.

19 Three possible reasons for the lack of difference between these groups might be
20 considered. First, the small variation among training periods could be a reason. In this meta-
21 analysis, two subgroups were used. One subgroup consisted of two studies with 6-week training
22 periods and four studies with 8-week training periods. Another subgroup consisted of three
23 studies that used 12-week training periods and one study that used a 6-month training period.

1 A second possible reason might be that the outcome variable for this analysis was
2 incontinent episodes rather than muscle strength. Empirical studies (Burgio et al., 1998; Burns et
3 al., 1993; Subak et al., 2002; Wyman et al., 1998), which analyzed the timing of response to
4 training, showed that reduction in incontinent episodes begins immediately after starting PFMT
5 and the degree of this reduction decreased with time. It is necessary, however, for women to
6 attain PFM hypertrophy to maintain reduced incontinent episodes or to reach a continent state,
7 and they attain PFM hypertrophy by repeated contractions over time. Thus maintaining a
8 regimen of performing PFM contractions regularly and repeatedly until at least achieving PFM
9 hypertrophy is important. Future studies that measure both visible PFM hypertrophy and
10 incontinent episodes over time are needed to determine the ideal length of training period.

11 Patients' adherence to PFM contractions may also confound the effect of PFMT because
12 PFMT requires at least several weeks of maintaining regular contractions. Most of the included
13 studies in this meta-analysis did not measure or report the level of adherence, even though some
14 studies applied specific methods for increasing adherence to PFMT programs.

15 As Wilson et al. (2002) noted, the studies investigating the effects of PFMT should
16 precisely describe specific parameters of PFMT such as the number, the velocity, and the
17 strength of the contractions, and length of training period. Most studies, however, have poorly
18 reported those parameters of the PFMT. Only two studies (Bo, et al., 1999; Lagro-Janssen, et al.,
19 1991) in this meta-analysis reported using close to the maximum strength contractions
20 recommended to increase muscle volume (Miller, Kasper, & Sampelle, 1994). Two other studies
21 (Burns et al., 1993; Ghoniem et al., 2005) reported on the velocity of contractions.

22 The number of contractions was used in subgroup analyses as eight studies reported the
23 number of daily contractions. The studies were divided into two groups, one including studies

1 using daily minimum contractions within the range of 24 to 36 as suggested by Wilson and
2 colleagues (2002) and the other subgroup included studies with at least 45 contractions daily. The
3 result indicated that the PFMT has significant effect on incontinent episodes in both groups and
4 no variation in effect size across studies with different number of daily PFM contractions. Thus
5 no statistically significant relationship between the number of contractions and effect size on
6 incontinent episodes was found.

7 Other contraction characteristics may have an impact on incontinent episodes; therefore,
8 more research is needed to test combinations of number, strength, and velocity of contractions to
9 determine the ideal configuration of a PFMT protocol for female UI.

10 In recent years, PFMT has been applied for the behavioral management of urge UI with
11 the understanding that PFMT can inhibit unstable bladder contractions (Burgio et al., 1998;
12 Wyman et al, 1998). Generally PFMT has been used to manage stress UI based on the rationale
13 that PFMT enhances urethral resistance and PFM strength, thus to prevent leaking urine during
14 times of sudden, episodic increased intravesical pressure (DeLancey, 1988).

15 In this meta-analysis, studies were divided two UI type groups. One group included
16 studies with only women with stress UI alone and the other group included studies with
17 incontinent women regardless of the UI type. Bladder training (BT) was used in the latter group
18 as an additional intervention. Significant treatment effects on reducing incontinent episodes were
19 reported although no analyses were conducted on the effectiveness of PFMT and BT for each
20 type of UI. The result of this subgroup analysis, however, showed that the PFMT is more
21 effective on women with stress UI alone, although the PFMT was effective to both groups on
22 reducing incontinent episodes. Research is still needed to explore the specific mechanism by
23 which PFMT effects stress and urge UI.

1 Age is often viewed as a risk factor for incontinence due to increased prevalence of UI
2 with aging. No causal relationship has been found. For subgroup analysis, the studies were
3 divided into two study groups including studies with mean ages younger than and older than 60
4 years. The result of this subgroup analysis implies that the effect of PFMT in the younger group
5 was significantly greater than that for the older group, although PFMT was significantly effective
6 in reducing incontinent episodes in both groups. This result confirms earlier findings that
7 although the effect is greater in younger women, older women can benefit from PFMT. Future
8 studies should explore different methods of training such as individualized and graded PFMT
9 regimen and determine the effect of age may play.

10 One limitation of this meta-analysis is the limited number of eligible studies especially,
11 those reporting measured urine leakage amount and perceived severity as outcomes. This small
12 number of studies also prevented us from using multifactor models in subgroup analysis. We did
13 not contact authors of unpublished studies to include in this meta-analysis. In addition, the
14 authors of included studies were not contacted to provide supplemental information to conduct
15 analyses thus it is possible more information may have been available.

16 In conclusion, the treatment effect of PFMT on the incontinent episodes may be greater
17 in younger women with stress UI alone, though PFMT is also effective for all women with UI. It
18 appears that the number of daily PFM contractions and the length of training period as
19 parameters of PFMT treatment are not related to effect sizes on incontinent episodes on the
20 condition that PFMT includes at least daily 24 PFM contractions and the regime is maintained
21 for at least six weeks. To advance evidence based interventions for incontinent women,
22 researchers must include detailed reports of parameters used in PFMT regimes and to test
23 configuration of these parameters to devise the ideal protocol to effectively treat incontinence.

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Figure Caption

Figure 1. Effect Size of Each Study (study number 1, 2, 3, 4, 5, 6, 8, 9, 10, 11) and Overall Mean Weighted Effect Size on Incontinent Episodes

Figure Caption

Figure 2. Effect Size of Each Study (study number: 1, 2, 5, 11, 12) and Overall Mean Weighted Effect Size on Amount of Urine Leakage.

Figure Caption

Figure 3. Effect Size of Each Study (study number 5, 7, 11, 12) and Overall Mean Weighted Effect Size on Perceived Severity

Figure Caption

Figure 4. Subgroup Analysis on Incontinent Episodes by Study Quality, Length of PFMT, Number of Daily Contraction, Type of UI, and Mean Age of Subjects

Figure Caption

Figure 5. Funnel Graph of Ten Studies for Incontinent Episodes

Figure Caption

Figure 6. Funnel Graph of Six Studies for Urine Leakage Amount

Figure Caption

Figure 7. Funnel Graph of Four Studies for Perceived Severity

Table 1

Characteristics of the Randomized Clinical Trials Included in the Meta-analysis

	Authors (Year)	Study setting	Sample size ^a	Age		Type of UI	Number of PFM contractions (daily)	Length of training (weeks)	Study quality
				Range	Mean				
1	Aksac et al. (2003)	N/R	30	N/R	53	Stress	30	8	1
2	Bo et al. (1999)	Norway	55	24 ~ 70	51	Stress	24 ~ 36	24	4
3	Burgio et al. (1998)	US	114	55 ~ 92	67	Urge	45	8	3
4	Burns et al. (1993)	US	82	55 and older	63	Stress	200 ^c	8	3
5	Dougherty et al. (2002)	US	147	55 ~ 95	68	All	45 ^d	12	2
6	Ghoneim et al. (2005)	Netherlands, UK, US	79	18 ~ 75	53	Stress	50	12	2
7	Glazener et al. (2001)	UK, NZ	284	N/R	30	All	80 ~ 100	16	2
8	Lagro-Janssen et al. (1991)	Netherlands	66	20 ~ 65	45	Stress	50 ~ 100	12	3
9	McDowell et al. (1999)	US	93 ^b	60 ~ 97	77	All	30 ~ 45	8	4
10	Subak et al. (2002)	US	123	55 and older	69	All	N/R	6	3

11	Sung et al. (2000)	KOREA	60	18 and older	N/R	Stress	N/R	6	1
12	Yoon et al. (2003)	KOREA	25	N/R	N/R	N/R	60	8	4

Note. N/R = not reported.

^a Sample size was based on data extracted for meta-analysis; therefore, it may be different from sample size of original study.

^b Less than 10 male participants were included in this sample.

^c Beginning with 4 set of 20 contractions and increased by 10 per set over 4 weeks until daily maximum of 200 contractions

^d Beginning with 15 contractions per day and increased by 15 every 3 weeks to 45 contractions per day

Incontinent episodes analysis: studies 1, 2, 3, 4, 5, 6, 8, 9, 10, 11 were included

Urine leakage amount analysis: studies 1, 2, 5, 11, 12 were included

Perceived severity analysis: studies 5, 7, 11, 12 were included

Figure1

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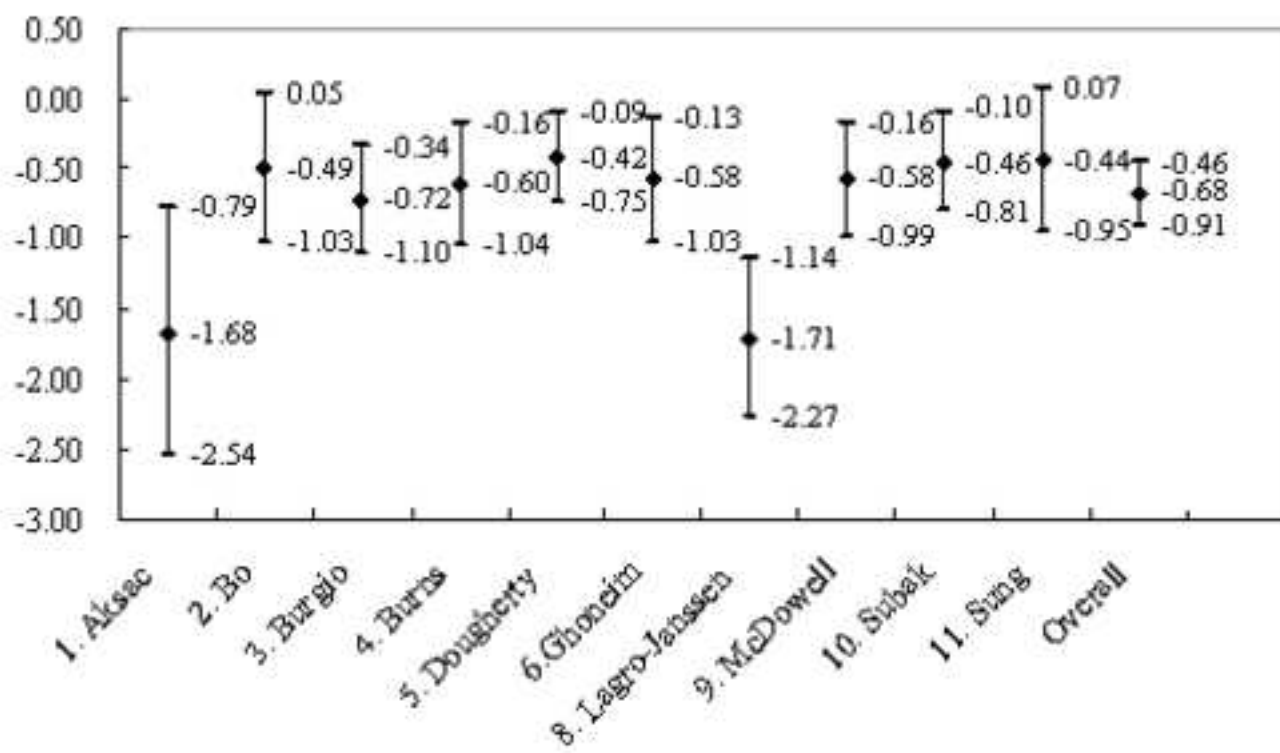


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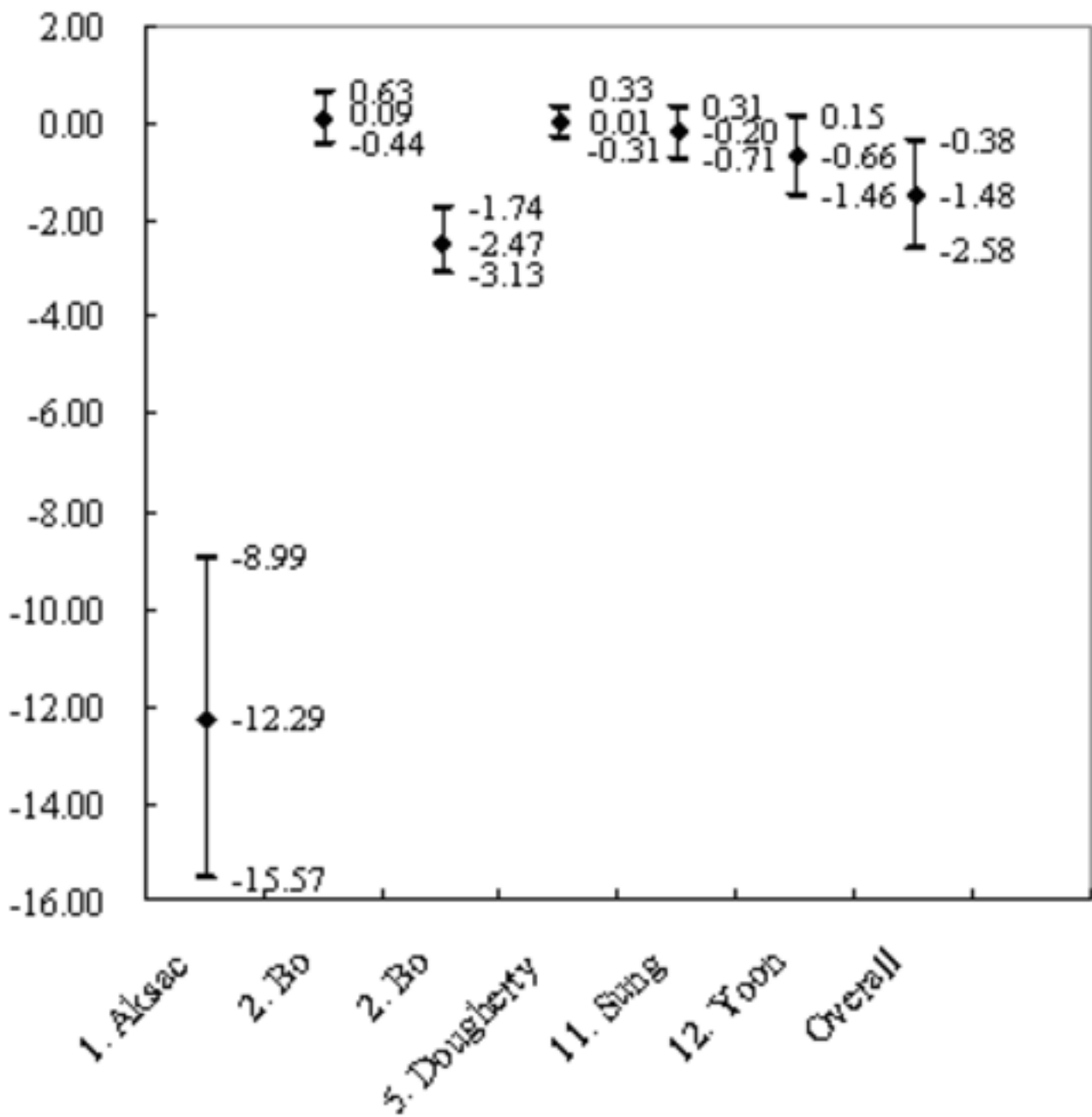


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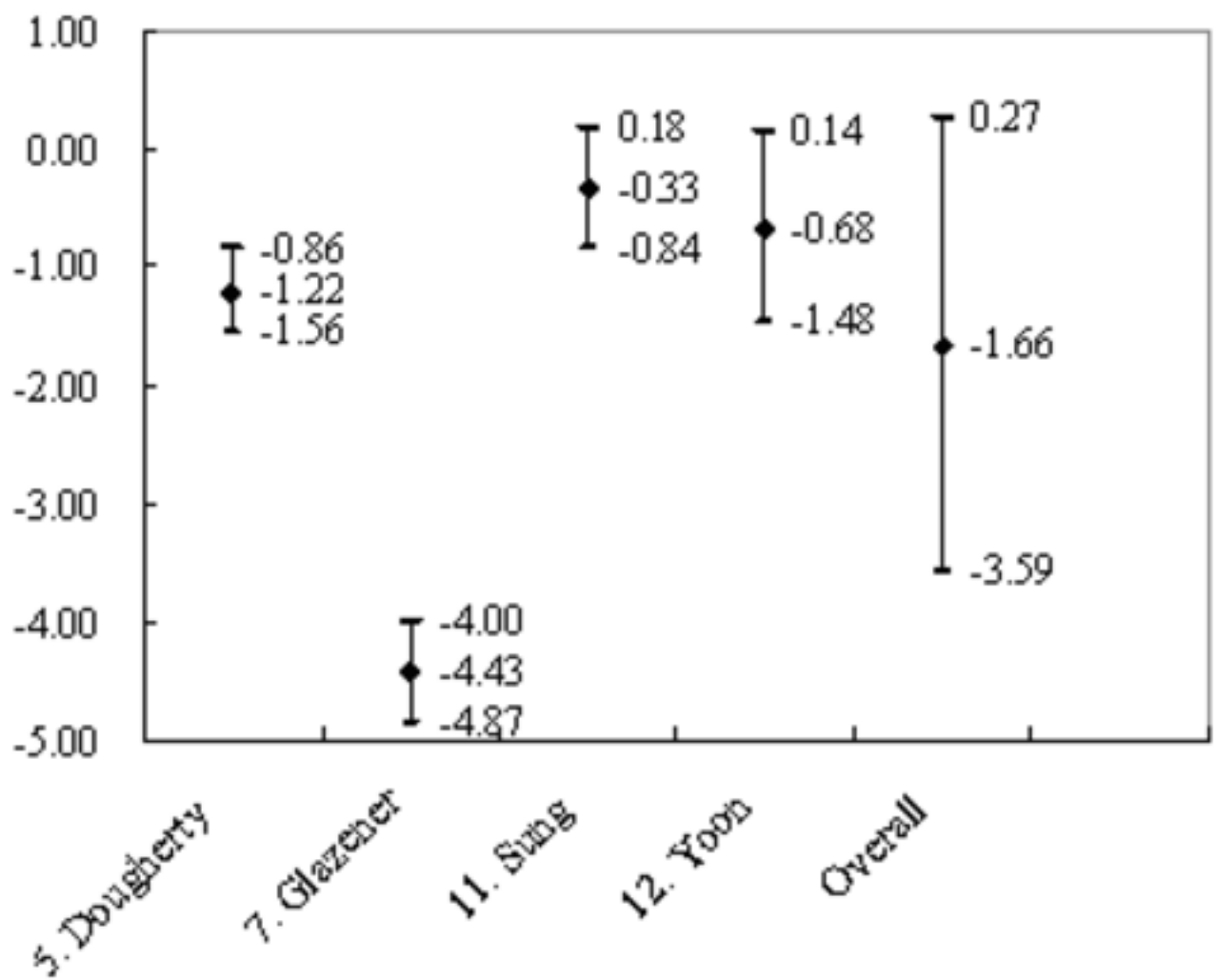


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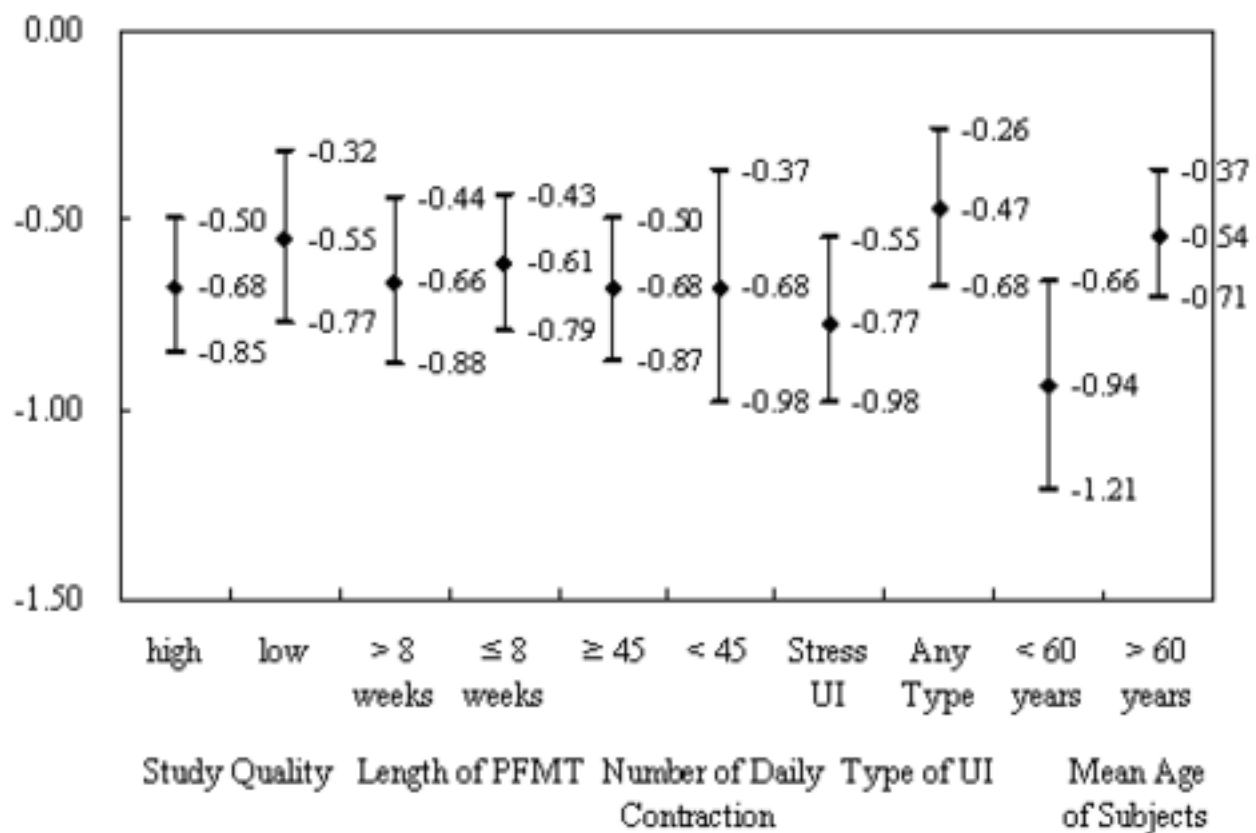


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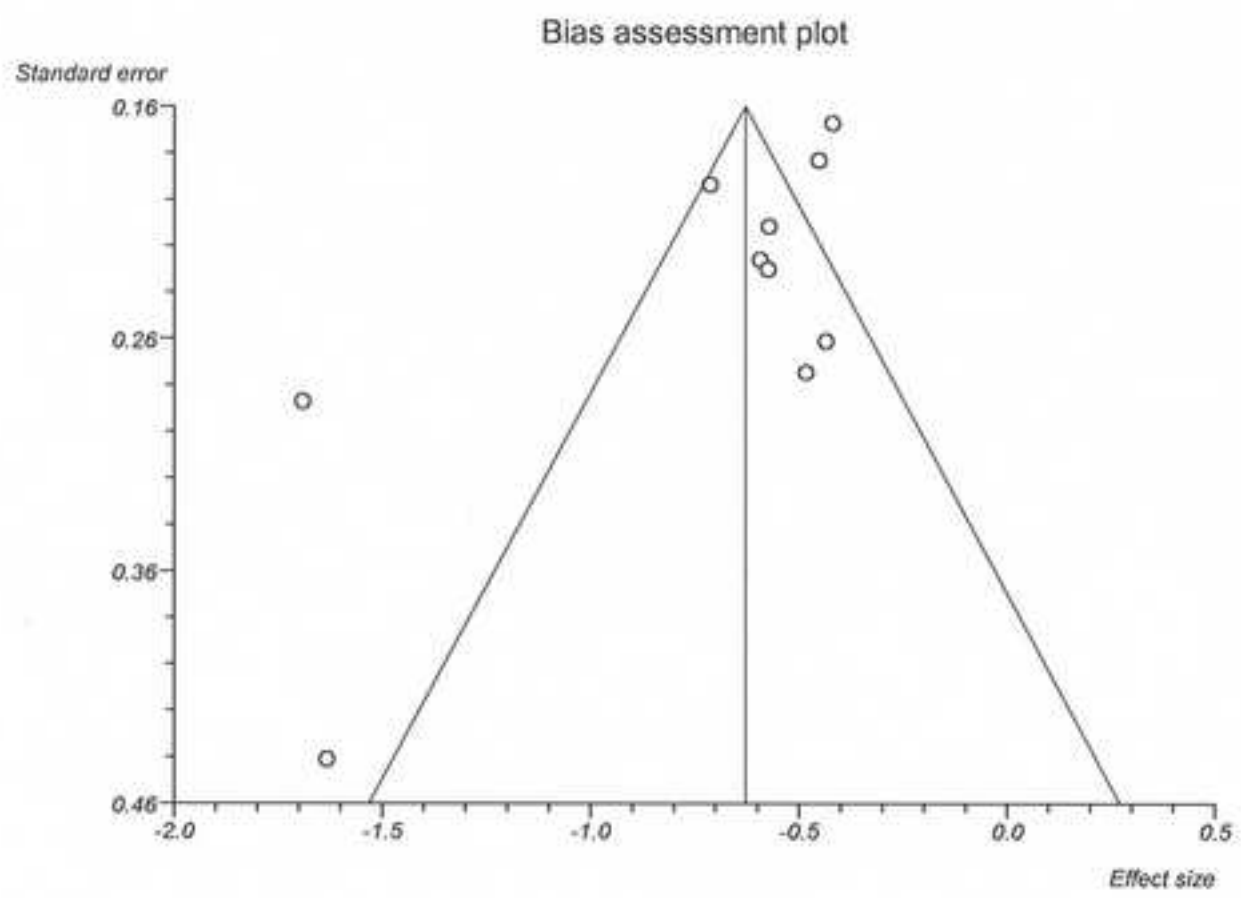


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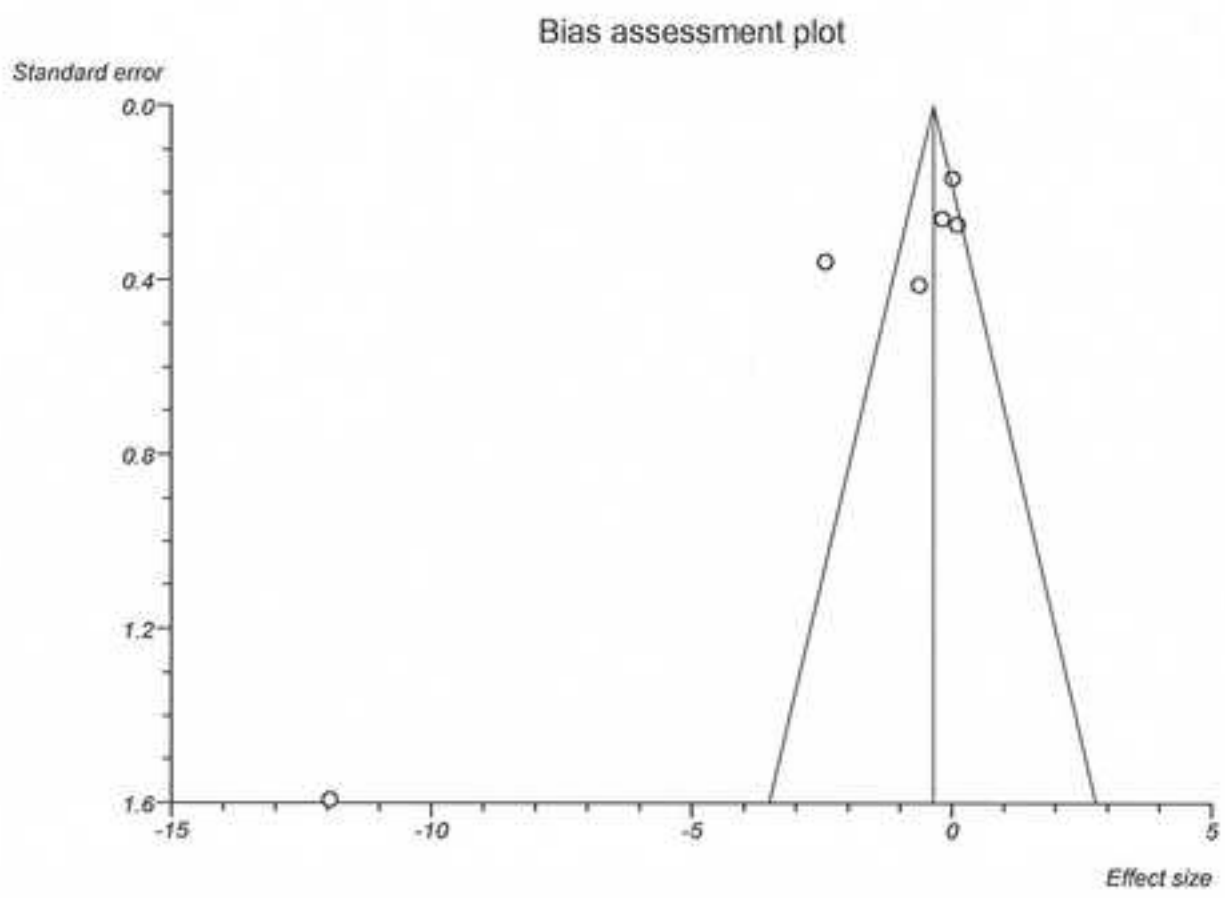


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