

Knee flexor strength recovery following hamstring tendon harvest for anterior cruciate ligament reconstruction: a systematic review

Introduction

weakness.7,8

Anterior cruciate ligament (ACL) reconstructive surgery is performed to correct instability and restore high level function following ACL rupture.^{1,2} Typically, autografts are harvested from the patella or hamstring tendons.³ Bone-patellar tendon-bone (BPTB) grafts provide strong graft fixation to the femur and tibia, and are widely accepted as the gold standard surgical option.^{4,5} However, the use of quadruple strand semitendinosus (4ST) or double strand semitendinosus-gracilis (2ST-2G) grafts in ACL reconstructive surgery is becoming increasingly common.⁶ This is primarily in an effort to combat post-operative anterior knee pain and persistent quadriceps

Concerns regarding post-operative knee flexor weakness following hamstring ACL reconstruction have been raised, particularly when both the gracilis and semitendinosus tendons are harvested (2ST-2G).⁹ Although primarily considered a hip adductor, it has been hypothesized that the gracilis may act to reinforce the action of the hamstrings in deep knee flexion due to biomechanical alteration.¹⁰ This is thought to occur with a change in the line of pull of the muscle, as increasing knee flexion results in an alteration in the position of insertion of the gracilis with respect to the knee joint center.^{11,12} The gracilis may also undergo compensatory hypertrophy in response to semitendinosus graft harvest as well as facilitating more anatomic semitendinosus regeneration.11 These findings appear to suggest gracilis harvest may in fact be detrimental to post-surgical strength outcomes, and support the contention that semitendinosus

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Abstract

The hamstring tendons are an increasingly popular graft choice for anterior cruciate ligament reconstruction due to preservation of quadriceps function and the absence of anterior knee pain post-operatively. Two commonly used hamstring grafts are a quadruple strand semitendinosus graft (4ST) and a double strand semitendinosus-double strand gracilis graft (2ST-2G). It has been suggested that concurrent harvest of the semitendinsous and gracilis tendons may result in sub-optimal hamstring strength recovery as the gracilis may play a role in reinforcing the semitendinosus particularly in deep knee flexion angles. The objective of this systematic review was to synthesize the findings of available literature and determine whether semitendinosus and gracilis harvest lead to post-operative hamstring strength deficits when compared to semitendinosus harvest alone. Seven studies were identified which compared hamstring strength outcomes between the common hamstring graft types. The methodological quality of each paper was assessed, and where possible effect sizes were calculated to allow comparison of results across studies. No differences were reported between the groups in isokinetic hamstring strength. Deficits in hamstring strength were reported in the 2ST-2G groups when compared to the 4ST groups in isometric strength testing at knee flexion angles $\geq 70^{\circ}$, and in the standing knee flexion angle. Preliminary evidence exists to support the hypothesis that harvesting the semitendinosus tendon alone is preferable to harvesting in combination with the gracilis tendon for minimizing post-operative hamstring strength deficits at knee flexion angles greater than 70°. However, due to the paucity of research comparing strength outcomes between the common hamstring graft types, further investigation is warranted to fully elucidate the implications for graft harvest.

operative strength outcome.

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Methods

Search strategy

Relevant articles were obtained through a search of the electronic databases CINAHL, Medline, Embase, The Cochrane Library, SPORTDiscus, PubMed, AMI, AusportMed, APAIS-Health and Meditext. Database entries were searched from the earliest reported date (January 1966 for Medline) to June 2008. Keywords used to produce the search strategy were entered in the database in three groups. Group 1: anterior cruciate ligament, anterior cruciate ligament autograft, semitendinosus graft, gracilis graft, autograft. Group 2: muscle strength, hamstring function, active knee flexion, knee flexor strength, hamstring torque, hamstring muscles. Group 3: isokinetic strength test, isometric strength test, dynamometry, muscle strength, biomechanics. The keywords were searched individually, with the results of each keyword search combined within each group. The results from each of the three groups were then combined between groups to produce the search strategy and final yield. To supplement the electronic database search the reference lists of relevant papers were also cross-checked. Citation tracking was also conducted via the electronic databases PubMed and Web of Science in order to identify any further relevant articles. Details from all studies identified in the literature search were

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harvest alone (4ST) is preferable.

able literature is contradictory.^{9,11,13}

While a large number of studies have compared the post-operative strength outcomes between patients receiving BPTB grafts with those receiving hamstring tendon grafts, few have compared outcomes between the 2ST-2G and 4ST groups. Some of these studies have suggested marked hamstring strength deficits exist at deep knee flexion angles (≥70° knee flexion) in the 2ST-2G group when compared to the 4ST group. However, much of the avail-

Therefore, the aim of this review was to evaluate the literature comparing hamstring strength outcomes in patients following anterior cruciate ligament reconstruction to determine whether concurrent semitendinosus and gracilis (2ST-2G) harvest or semitendinosus (4ST) harvest alone produced optimal post-

exported to EndNote X to allow application of the selection criteria.

Inclusion criteria

The following criteria were applied to the final yield. All criteria must have been fulfilled to be included in the review:

- English language report;
- human subjects;
- comparison of outcomes between groups having either a quadruple strand semitendinosus autograft (4ST) or a double strand semitendinosus-double strand gracilis autograft (2ST-2G) for their ACL reconstruction;
- graft harvest from the ipsilateral limb to the ACL injury;
- knee flexor strength of the harvest limb measured.

Exclusion criteria

- review studies;
- studies that did not report new data.

Studies were limited to English language reports due to translation costs. Human subjects were required as the review aimed to produce evidence to guide graft selection in humans undergoing ACL reconstruction.

Quality assessment

The included studies were assessed using Downs and Black's¹⁴ revised checklist for measuring study quality, which is appropriate for determining the quality of both randomized and non-randomized studies. The revised checklist for measuring study quality demonstrates high test-retest reliability $(r = 0.88)$ and good inter-rater reliability $(r = 0.75)^{14}$ The revised checklist for measuring study quality comprises 27 items all of which are

applicable to comparative studies, and a maximum score of 27 is obtained if all criteria are met (see Appendix for item definitions).

Data extraction and synthesis

Data were obtained from each study using a data extraction form developed specifically for this review. The data extraction was conducted in order to assist collation of results across studies, allowing comparisons to be made between demographic data, methods and strength outcomes. A meta-analysis was not performed due to heterogeneity in the reporting of results and in study design and method. Effect sizes and 95% confidence intervals for the strength outcome measures (concentric knee flexion peak torque and standing knee flexion angle data) were determined where means and standard deviations were reported, using the G*Power web-based calculator.¹⁵ These results are presented in forest plots. The formula used to calculate effect size was:

 $d = M_1 - M_2 / \sigma_{pooled}$ where $\sigma_{pooled} = \sqrt{[(\sigma_1^2 + \sigma_2^2)]}$ / 2] ($M =$ mean and $\sigma =$ standard deviation)

Results

The literature search yielded 1,045 potential articles. Following deletion of duplicates the final yield was 928 articles. The title and abstract of each article were analyzed by the principal researcher (CLA) according to the inclusion and exclusion criteria, allowing immediate exclusion of 911 articles that did not fit the criteria. Full copies of articles were obtained where their appropriateness for inclusion was not able to be determined following review of the title and abstract. Eighteen articles were obtained in full for further evaluation by two reviewers (CLA and KEW). Following this evaluation eleven studies were excluded, leaving seven papers for full review. Figure 1 provides an outline of the process of study identification.

Study quality

Overall the median quality assessment score was 21 out of a possible 27 (Table 1), with five out of the seven studies reviewed

Table 1. Downs and Black's revised checklist for measuring study quality14 (scores by paper).

 $l = \text{ves: } \theta = \text{no.}$ or not determinable from the information reported.

scoring 20 or above. No studies fulfilled the criteria assessing double blinding and reporting of statistical power. Allocation of participants to treatment groups may have been biased in five studies where allocation was conducted according to graft thickness or date of surgery.4,7,9,12,16 Description of the population from which their subjects were recruited was inadequate in all studies. Table 2 provides an overview of the allocation methods, length of follow-up and outcome measures employed by each study.

Surgical procedure and post-operative rehabilitation

Six of the seven studies included for review described the use of a single incision arthroscopically guided procedure performed by the same surgeon for ACL reconstruction. The surgical procedure described by Lipscomb *et al.*¹³ was not arthroscopically assisted. This is likely due to the year the study was conducted (1982). The post-operative rehabilitation programs were comprehensively described in all studies. The post-operative rehabilitation protocol described by Lipscomb *et al.*¹³ is of note as it had a much longer period of knee joint immobilization (six weeks) when compared to

the other studies in this review (usually one day). This difference also likely reflects the year the study was conducted.

Participants

In total, the seven studies reviewed evaluated 519 participants, 265 of whom had a 4ST graft, and 216 who had a 2ST-2G graft. Male participants numbered 246 over the six studies that reported the gender of their participants, while 167 female participants were evaluated. The age range of the participants in the six studies that reported this characteristic was 15-45 years, and the mean age of the participants was 24.8 years. Demographic data for all studies are presented in Table 3.

Isokinetic strength testing

Significant variability existed in the strength testing protocols, particularly among the angular velocities and torque parameters used, and the ranges of motion through which strength was assessed. All studies considered isokinetic strength outcomes measured using a Cybex (Lumex, Ronkonkoma, New York) or Biodex (Shirley, New York) dynamometer.

Six studies included in this review measured concentric knee flexion peak torque at the 60° s⁻¹ angular velocity^{4,7,9,12,13,17} and five studies recorded peak torque results at 180° s–1. 4,9,12,16,17 Tashiro *et al.*¹² reported a statistically significant reduction in peak torque at six months in the 2ST-2G group at the 180° s⁻¹ angular velocity, compared to the 4ST group. However, this difference had resolved at the later 12 and 18 month reviews, and was not apparent at the 60° s⁻¹ angular velocity. No further significant differences were observed in peak torque between the 4ST and 2ST-2G groups in any of the other six studies, at the 60° s⁻¹ or 180° s⁻¹ test conditions. The isokinetic peak torque results and effect sizes from final follow-up at all angular velocities are presented in Table 4.

Effect sizes and 95% confidence intervals for the four studies that presented standard deviation data for peak torque, $4,7,9,16$ are presented in Figure 2. These results demonstrated that the differences between the groups were not statistically significant, although there was a trend in favor of the 4ST graft.

Nakamura *et al.9* also assessed the torque produced at 90° knee flexion at both angular velocities, and found no differences between groups. In contrast, Tashiro *et al.*¹² obtained torques at 70°, 90° and 110° knee flexion from the torque curves recorded at 60° s⁻¹, and

Table 2. Summary of research method by paper.

Author	Allocation	Follow-up	Outcome measures
Adachi et al. $(2003)^4$	Non-random; if ST <7mm, G harvested to increase graft thickness	Mean: 35 months (24-58 months)	Knee laxity (KT-2000 knee arthrometer) Active and passive knee flexion angle Isokinetic strength testing (Cybex dynamometer)
Gobbi et al. $(2005)^{17}$	Random number generator	Examined by surgeon and physiotherapist at 3, 5 and 12 months post-operatively. Examined by independent, blinded examiner at mean 36 months post-operatively	Pre-operative questionnaire, IKDC form, Noyes, Tegner, Lysholm scores; satisfaction and return to sport with Single Assessment Numeric Evaluation (SANE) Clinical knee examination: crepitus, pain, sensation, ROM, kneeling Knee laxity (OSI CA4000) Isokinetic strength testing (Biodex dynamometer) Single leg hop, single leg vertical jump
Carter & Edinger $(1999)^{16}$	Every third patient consecutively had either PT, ST or ST and G harvest	24 weeks (24-28 weeks)	Isokinetic strength testing (Cybex dynamometer)
Lipscomb et al. $(1982)^{13}$	Patients recalled at random from a sample of 482 who had an ACL reconstruction between 1975 and 1980	$4ST = 34.6$ months $(18-52$ months) $2ST-2G = 17.4$ months (12-26 months)	Isokinetic strength testing (Cybex dynamometer)
Nakamura et al. $(2002)^9$	Non-random, if ST <7mm, G harvested to increase graft thickness	24 months	IKDC form Knee laxity (KT-1000 knee arthrometer) Isokinetic strength testing (Cybex dynamometer) Maximum standing knee flexion angle
Segawa et al. $(2002)^7$	Non-random; if ST <7mm, G harvested to increase graft thickness	24 months	IKDC form, Lysholm scores Knee laxity (KT-1000 knee arthrometer) Isokinetic strength testing (Cybex dynamometer)
Tashiro et al. $(2003)^{12}$	Random; according to date of surgery	$0, 6, 12, 18$ months	IKDC form Knee laxity (KT-1000 knee arthrometer) Isokinetic and isometric strength testing (Cybex dynamometer)

ST = semitendinosus tendon; G = gracilis tendon; PT = patellar tendon.

Table 3. Demographic data.

Author	Participants	Gender (M:F)	Age $(M \pm SD)$
Adachi et al. $(2003)^4$	$n=58$ $4ST=26$ $2ST-2G=18$	15:11 12:6	27.7 ± 10.5 yrs 25.6 ± 8.9 yrs
Carter & Edinger $(1999)^{16}$	$n = 106$ $4ST = 33$ $2ST-2G=35$	Not reported	Not reported
Gobbi et al. $(2005)^{17}$	$n = 115$ $4ST = 50$ $2ST-2G=47$	31:19 26:21	Mean: 31.0yrs Mean: 28.8yrs
Lipscomb et al. $(1982)^{13}$	$n = 51$ $4ST=26$ $2ST-2G=25$	45:6	Mean: 20.3yrs Mean: $19.5yrs(15-45yrs)$
Nakamura <i>et al.</i> $(2002)^9$	$n=74$ $4ST=49$ $2ST-2G=25$	28:21 6:19	Mean: 24.3yrs Mean: 25.7yrs
Segawa et al. $(2002)^7$	$n=62$ $4ST = 32$ $2ST-2G=30$	19:13 15:15	Mean: 20.8yrs (14-41yrs)
Tashiro <i>et al.</i> $(2003)^{12}$	$n=90$ $4ST=49$ $2ST-2G=36$	51:39 30:19 19:17	24.5 ± 7.7 yrs $24.8 + 6.4$ yrs

Table 4. Isokinetic concentric knee flexor peak torque percentage strength deficit (involved/non-involved limb) and effect size for graft type comparison.

Gobbi et al. did not report isokinetic knee flexor strength data therefore results are not included in Table 4. Data from the Adachi et al. (2003) study4 are results from the 24 month follow-up. Effect sizes are presented for papers reporting standard deviations.

Adachi (2003) 60°/s 12 mth Adachi (2003) 60°/s 35 mth Nakamura (2002) 60°/s 24mth Segawa (2002) 60°/s 12mth Adachi (2003) 180°/s 12mth Adachi (2003) 180°/s 35mth Carter (2002) 180°/s 6mth Nakamura (2002) 180°/s 24mth

Figure 2. Concentric knee flexion peak torque, comparison of 4ST and 2ST-2G groups (involved limb; side-to-side ratio).

found significant hamstring weakness (80% of contralateral in the 2ST-2G group vs. 90% in the 4ST group at 70°; 75% of contralateral in the 2ST-2G group vs. 85% in the 4ST group at 90°; 70% of contralateral in the 2ST-2G group vs. 82% in the 4ST group at 110°) in the 2ST-2G group at all angles at the 18-month review, compared to the 4ST group $(p<0.05)$. The effect sizes and 95% confidence intervals were not able to be calculated as standard deviations for these data were not reported.

Isometric strength testing

Tashiro *et al.*¹² were the only authors to consider isometric strength. They measured maximum isometric knee flexion torque at 70° and 90° in both seated and prone positions. Muscle strength was reported as a percentage of the contralateral limb for each group. The 2ST-2G group was significantly weaker than the 4ST group at 18 months, at angles of 70° (70% of contralateral in the 2ST-2G group vs. 80% in the 4ST group) and 90° (60% of contralateral in the 2ST-2G group vs. 75% in the 4ST group) in prone, and at 70° (80% of contralateral in the 2ST-2G group vs. 90% in the 4ST group) in sitting $(p<0.05)$.

Maximum standing knee flexion angle

Adachi et al.⁴ and Nakamura et al.⁹ recorded post-operative active knee flexion range of motion (ROM). Measurements were taken in standing with the hip in neutral flexion/extension and the ankle in maximum plantarflexion. This testing position was chosen in an attempt to minimize the influence of the gastrocnemius and iliopsoas muscle on knee ROM. The authors hypothesized that this measure provided an indirect assessment of strength deficits in higher knee flexion angles.

Adachi *et al.*⁴ found a significant difference in the loss of active knee flexion angle compared to the contralateral limb between the groups at 12 months (8.9° deficit in the 4ST group vs. 16.7° deficit in the 2ST-2G group; $p<0.05$), and at 35 months (7.7° deficit in the

4ST group vs. 17.1° deficit in the 2ST-2G group; *p*<0.05) in the 2ST-2G group when compared to the 4ST group. Nakamura *et al.*⁹ also reported a significant deficit in the loss of standing knee flexion angle compared to the contralateral in the 2ST-2G group (5.0° deficit in the 4ST group vs. 9.0° deficit in the 2ST-2G group; $p=0.01$) when compared to the 4ST group at 24 months. The effect sizes for the data presented in Figure 3 demonstrate the significant deficit in standing knee flexion angle with 2ST-2G harvest.

Clinical evaluation

Subjective outcome measures, post-operative knee laxity and the results of functional testing were reported in six of the included stud-
ies. $47,9,12,13,16$ The International Knee The International Knee Documentation Committee subjective knee form (IKDC form) was the most commonly used post-operative subjective outcome measure. Gobbi *et al.*¹⁷ also reported Single Assessment Numeric Evaluation (SANE) method scores where participants were asked to evaluate their function and symptoms against their contralateral limb. No significant differences between groups were found in subjective outcome. Five studies measured post-operative knee laxity.4,7,9,12,17 No study reported significant differences in knee laxity between groups. Gobbi *et al.17* measured each participant's functional ability with a single leg hop and a single limb vertical jump test. The authors found no significant differences between groups. Gobbi *et al.*¹⁷ and Segawa *et al.*⁷ also evaluated functional outcome using either the Noyes, Tegner or Lysholm scales. Again, no differences were found between the groups.

Discussion

Overall, the results from this review provide preliminary evidence that harvesting both the semitendinosus and gracilis tendons for ACL

reconstruction may produce knee flexion strength deficits at deep knee flexion angles when compared to hamstring grafts where the semitendinosus tendon is harvested alone. Studies reporting no post-operative hamstring strength deficits were those that only examined concentric knee flexion peak torque. This variable has tended to be the most widely reported outcome measure used to evaluate post-operative hamstring strength in this literature. However, this approach may have produced a misleading means of strength evaluation as the knee flexion peak torque is typically generated at shallow knee flexion angles (around 15-30° into the flexion range), and is thought to be primarily a result of biceps femoris contraction.¹¹ Strength testing protocols which assess this parameter in isolation are, therefore, unlikely to find differences in hamstring strength between groups as strength at deeper knee flexion angles, where there is thought to be a predominance of semitendinosus and gracilis activity, is not examined.

One study, 12 reported significant isometric hamstring strength deficits in the 2ST-2G group in prone testing at 70° and 90° knee flexion. However, this study was the only study identified which evaluated post-operative isometric hamstring strength. Two studies^{4,9} have reported deficits in the 2ST-2G group when compared to the 4ST group in the standing knee flexion angle. Both the prone isometric strength and standing knee flexion angle testing protocols require the hip to be in the neutral position. The results of these studies appear to support the contention of Tashiro *et al.*¹² that the semitendinosus and gracilis muscles may play a greater role in knee flexion while the hip is extended. Additionally, when the hip is in a relatively extended position, the biarticular hamstring muscles are approaching active insufficiency as they contract concentrically to simultaneously flex the knee. This may account for the significant differences report-

Figure 3. Comparison of maximum standing knee flexion angle between graft types.

ed between the groups in prone isometric strength and the standing knee flexion angle, despite no differences being observed in seated isokinetic strength where testing is performed with the hip in approximately 90° flexion. The position of the hip for isokinetic testing, therefore, may increase the mechanical advantage of the hamstrings as they are positioned in a range more conducive to maximal contraction. The gender implications of hamstring weakness in deep knee flexion angles, particularly when the hip is extended, are at present unclear. No study evaluated differences between genders in post-operative hamstring strength. As such, this is an issue requiring further investigation.

Carofino and Fulkerson¹¹ suggest the standing knee flexion angle is sensitive to hamstring strength deficits post-ACL reconstruction. The standing knee flexion angle measure may allow an indirect measure of hamstring strength to be more readily obtained in the clinic without the need for time-consuming isokinetic testing. Furthermore, the results of the standing knee flexion angle may prove useful in guiding the prescription of appropriate post-operative hamstring rehabilitation programs. However, caution is required when interpreting the results of such a measure based on the evidence of two studies, in addition to the absence of evidence validating its sensitivity. It is possible the standing knee flexion angle may be measuring changes occurring due to alterations in the soft tissue architecture that result from tendon harvest and subsequent regeneration.^{8,18} Subsequently, this measure may not provide an accurate representation of post-operative hamstring strength recovery. The studies reporting significant differences between the groups appear to agree that the deficits observed in deeper angles of knee flexion may influence performance in sports where knee flexion strength is required at deep flexion angles, including gymnastics, judo and wrestling.^{4,9} Other authors¹⁸ have also raised concerns regarding the harvest of 2ST-2G grafts from athletes involved in these sports. Despite this, no study was identified that specifically examined the effects of hamstring tendon harvest in these sporting populations.

Considerable methodological variability exists within the reviewed literature regarding blinding, allocation of patients to intervention groups and inclusion criteria used. Adachi *et al.*⁴ and Gobbi *et al.*¹⁷ were the only authors to report assessment of participants by blinded assessors. Gobbi *et al.*¹⁷ and Lipscomb *et al.*¹³ also randomly allocated patients to groups; however, the remaining five studies allocated patients according to graft thickness^{4,7,9} or date of surgery.12,16 The non-random methods of group allocation introduce a selection bias which may restrict result comparability. Bias

also arises with differences in the inclusion criteria for patients with concurrent knee pathology. Preferably, only patients with isolated unilateral ACL insufficiency would be included, to eliminate extraneous variables arising from differences in surgical and rehabilitation management. Five of the reviewed studies4,9,12,13,17 excluded patients with history of previous knee injury or knee surgery; however, five studies7,9,12,16,17 included those with concomitant meniscal injury, or failed to adequately report the inclusion criteria applied.

There are three main concerns with the current literature on hamstring tendon harvest for ACL reconstruction. The first is that only one study has reported a direct measure of a reduction in hamstring muscle strength at deep knee flexion angles in a 2ST-2G group when compared to a 4ST group.12 There is a need to replicate these results to further clarify the effects of hamstring graft harvest on post-operative hamstring strength. The second issue is the use of the standing knee flexion angle as a surrogate measure of hamstring strength. It is yet to be determined whether this measure can be used to represent the construct of strength. Thus there is the need for further investigation to explore the association between the standing knee flexion angle and direct measures of hamstring strength obtained from fixed dynamometry. Third, while concern has been raised regarding 2ST-2G graft harvest on the post-operative hamstring strength recovery of patients participating in sports such as gymnastics, judo and wresting, no study has specifically examined these populations. Therefore, a sport-specific analysis of hamstring strength recovery is required to guide graft selection in these patient groups.

Conclusion

This review highlights the limited evidence available to guide hamstring graft selection where preservation of hamstring strength is a priority. Preliminary evidence has been identified to support the harvest of a single semitendinosus tendon rather than in combination with the gracilis tendon where hamstring strength in deep knee flexion angles (≥70° knee flexion) is required. There are a limited number of studies comparing post-operative hamstring strength outcomes obtained between groups following hamstring tendon ACL reconstruction using either a 4ST graft or a 2ST-2G graft. Most of these studies have focused on measuring isokinetic knee flexion peak torque as the main outcome. However, it is likely that this method of evaluation is biased toward assessment of strength in the biceps femoris and semimembranosus muscles, not the semitendinosus and gracilis mus-

cles. Thus the impact of hamstring tendon harvest for ACL reconstruction on post-operative recovery of hamstring muscle strength has not been resolved. In addition, two studies have attempted to use the standing knee flexion angle as a representation of post-operative hamstring strength deficit. While it is possible that this measure may in fact represent a surrogate measure of hamstring strength, its association with hamstring strength is still yet to be determined.

Appendix

Item description for Downs and Black's revised checklist for measuring study quality.14

- Item Description
- 1 Aims clearly described
- 2 Outcomes clearly described
- 3 Subject characteristics clearly described
- 4 Interventions clearly described
- 5 Distribution of principal confounders clearly defined
- 6 Main findings clearly described
- 7 Estimates of variability provided for main outcomes
- 8 Important adverse effects reported
- 9 Characteristics of subjects lost to follow-up reported
- 10 Actual probabilities reported
- 11 Source population identified
- 12 Included subjects representative of source population
- 13 Intervention representative of that used in source population
- 14 Subjects blinded to intervention
- 15 Assessors blinded to groups
- 16 Use of 'data dredging' made clear if used
- 17 Same length of follow-up for all subjects
- 18 Appropriate statistical tests used
- 19 Reliable compliance with intervention
- 20 Main outcome measures reliable and valid
- 21 Subjects recruited from same population
- 22 Subjects recruited over same time
- 23 Subjects randomized to intervention groups
- 24 Randomization concealed until recruitment complete
- 25 Adequate adjustment for confounding 26 Losses of subjects to follow-up accounted for
- 27 Power analysis conducted

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