Practical session and discussion

Isabelle Boutron, Jonathan Sterne, Lucy Turner

Effects of Tai Chi Exercise on Pain, Balance, Muscle Strength, and Perceived Difficulties in Physical Functioning in Older Women with Osteoarthritis: A Randomized Clinical Trial

RHAYUN SONG, EUN-OK LEE, PAUL LAM, and SANG-CHEOL BAE

Selection bias

sion criteria for this study (below). Those who agreed to participate and signed the consent form were randomly assigned to either the tai chi exercise group or the control group; this random process was conducted by a hospital coordination center using a random table with no involvement of the research team. The control group was expected to receive the routine

Sequence generation: low risk of bias
Allocation concealment: low risk of bias

Blinding of patients and personnel

- **Who is blinded?**
  - Patients: **No**
  - Care providers: **No**
- **Is the outcome likely to be influenced by lack of blinding?**
  - **Outcomes**
    - WOMAC
    - Physical performance

Blinding of patients and personnel

- **Blinding of patients and personnel:**
  - Unclear risk of bias
    - Co-interventions?
    - Contamination?

Blinding of outcome assessment

Data collection procedure. All subjects attended the sports center of a university hospital for pre- and post-test measurements of balance, muscle strength, and cardiovascular functioning by exercise physiologists using blind procedures. A standardized measurement set (Takei Kiki Kogyo, Tokyo, Japan) was used for all tests. An interview was conducted for filling out the questionnaires on demographic characteristics, OA symptoms, and physical functioning.

Blinding of outcome assessment

- **<u>WOMAC</u>**:
  - Outcome assessor: patient, not blinded
  - Outcome subjective: yes
  - **High risk of bias**

Blinding of outcome assessment

- **<u>Physical performance:</u>**
  - Outcome assessor: exercise physiologists, blinded, using a standardized measurement set
  - Blinding procedure: questionable
  - **High risk of bias**

Attrition bias

= 0.51, SD 0.7). A total of 72 female patients gave consent for the study: 38 were randomly assigned to the experimental group and 34 to the control group. The study dropout rates were 43% and 39% for the experimental and control groups, respectively, so that both pre- and post-test data for 12 weeks of tai chi exercise were available from 22 patients and 21 controls. The main reasons for dropouts were readmission to the hospital for surgery, moving to another city, family commitments, becoming homebound due to falls or traffic accidents, and failure to complete either the survey or the fitness measures. Additional analysis was conducted to compare demo-

Attrition bias

Table 3. Mean group comparisons in change scores of K-WOMAC, balance, muscle strength, and cardiovascular functioning in groups between pre-test and post-test.

Variable	Exercise (n = 22), mean* (SD)	Control (n = 21), mean* (SD)	t	p
Joint pain	–2.45 (3.9)	0.61 (5.1)	–2.19	0.034
Joint stiffness	–0.91 (1.6)	0.23 (1.8)	–2.13	0.039
Physical functioning†	–11.09 (12.0)	–1.33 (10.6)	–2.81	0.008
Balance, seconds	7.50 (7.8)	–1.00 (8.7)	3.34	0.002
Abdominal muscle strength, n/30 seconds	1.95 (2.7)	0.09 (1.5)	2.77	0.009
Knee muscle strength, degrees/second	6.75 (8.9)	4.25 (6.6)	1.03	0.306
Knee muscle endurance, degrees/second	7.69 (19.0)	1.46 (5.1)	1.44	0.155
Flexibility, cm	1.19 (3.2)	1.32 (3.3)	–0.12	0.903
Body mass index, kg/m^2	–0.20 (0.5)	–0.08 (1.1)	–0.44	0.662
Cardiovascular functioning, ml/kg/min	1.64 (6.0)	0.91 (4.2)	0.45	0.653

* Mean scores were computed as differences between the post-test and the pre-test. ** Measured by difficulties in ADL: higher score reflects worse physical functioning.

Number randomised: n = 72

Attrition bias

- Incomplete outcome data: **High risk of bias**

Example

ORIGINAL CONTRIBUTION

Surgical vs Nonoperative Treatment for Lumbar Disk Herniation

The Spine Patient Outcomes Research Trial (SPORT): A Randomized Trial

James N. Weinstein, DO, MSc
Tor D. Tosteson, ScD
Jon D. Lurie, MD, MS

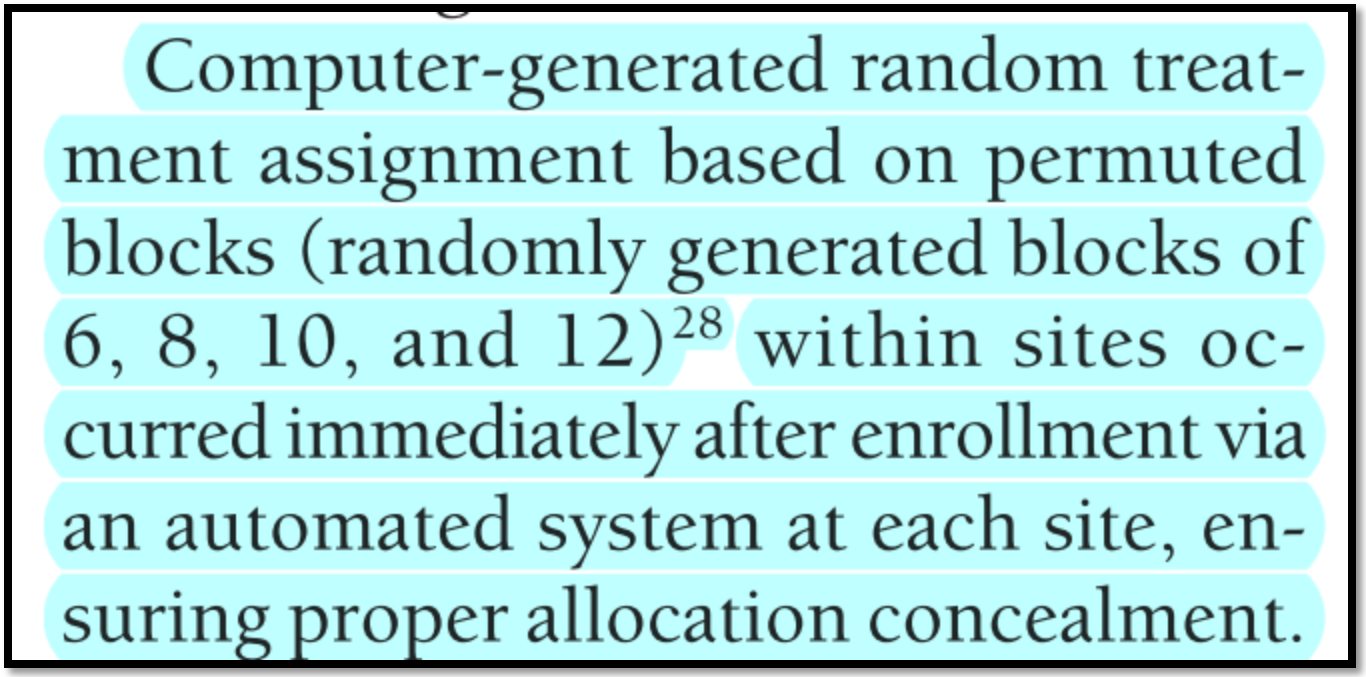
Context Lumbar diskectomy is the most common surgical procedure performed for back and leg symptoms in US patients, but the efficacy of the procedure relative to nonoperative care remains controversial.

- Aim: to assess the efficacy of Surgical vs nonoperative treatment for lumbar disk herniation
- Design: randomized clinical trial
- Primary outcome measure: changes from baseline in the Medical Outcomes Study 36-item Short-Form Health Survey bodily pain and physical function scales
- No blinding

Selection bias

Computer-generated random treatment assignment based on permuted blocks (randomly generated blocks of 6, 8, 10, and 12)[28] within sites occurred immediately after enrollment via an automated system at each site, ensuring proper allocation concealment.

Selection bias



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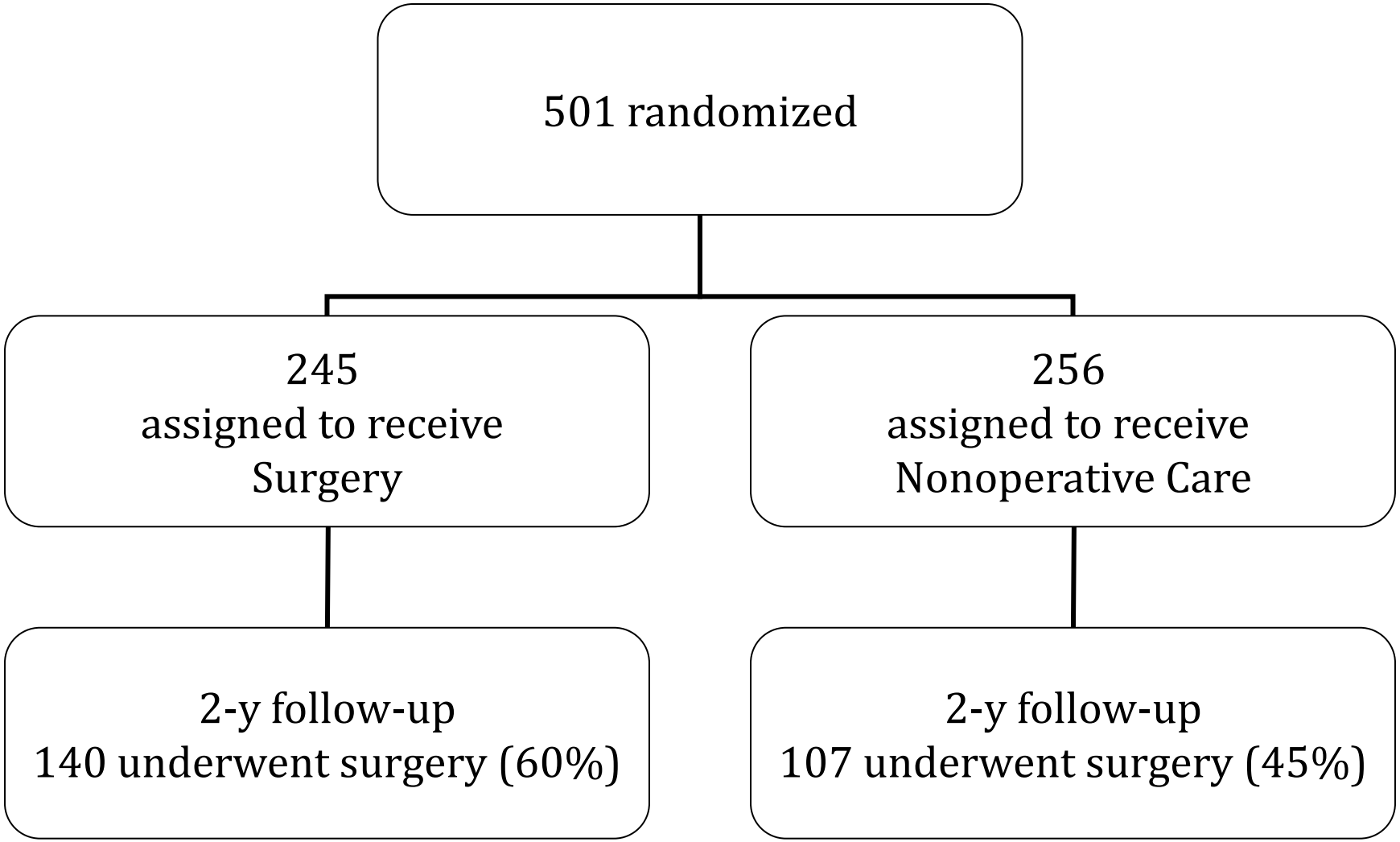
Sequence generation: low risk of bias
Allocation concealment: low risk of bias

Blinding of patients and personnel

- **Who is blinded?**
  - Patients: **No**
  - Care providers: **No**
- **Is the outcome likely to be influenced by lack of blinding?**
  - **Outcome:** SF36

Flow Diagram of the SPORT Randomized Controlled Trial of Disk Herniation: Exclusion, Enrollment, Randomization, and Follow-up



Weinstein, J. N. et al. JAMA 2006;296:2441-2450.

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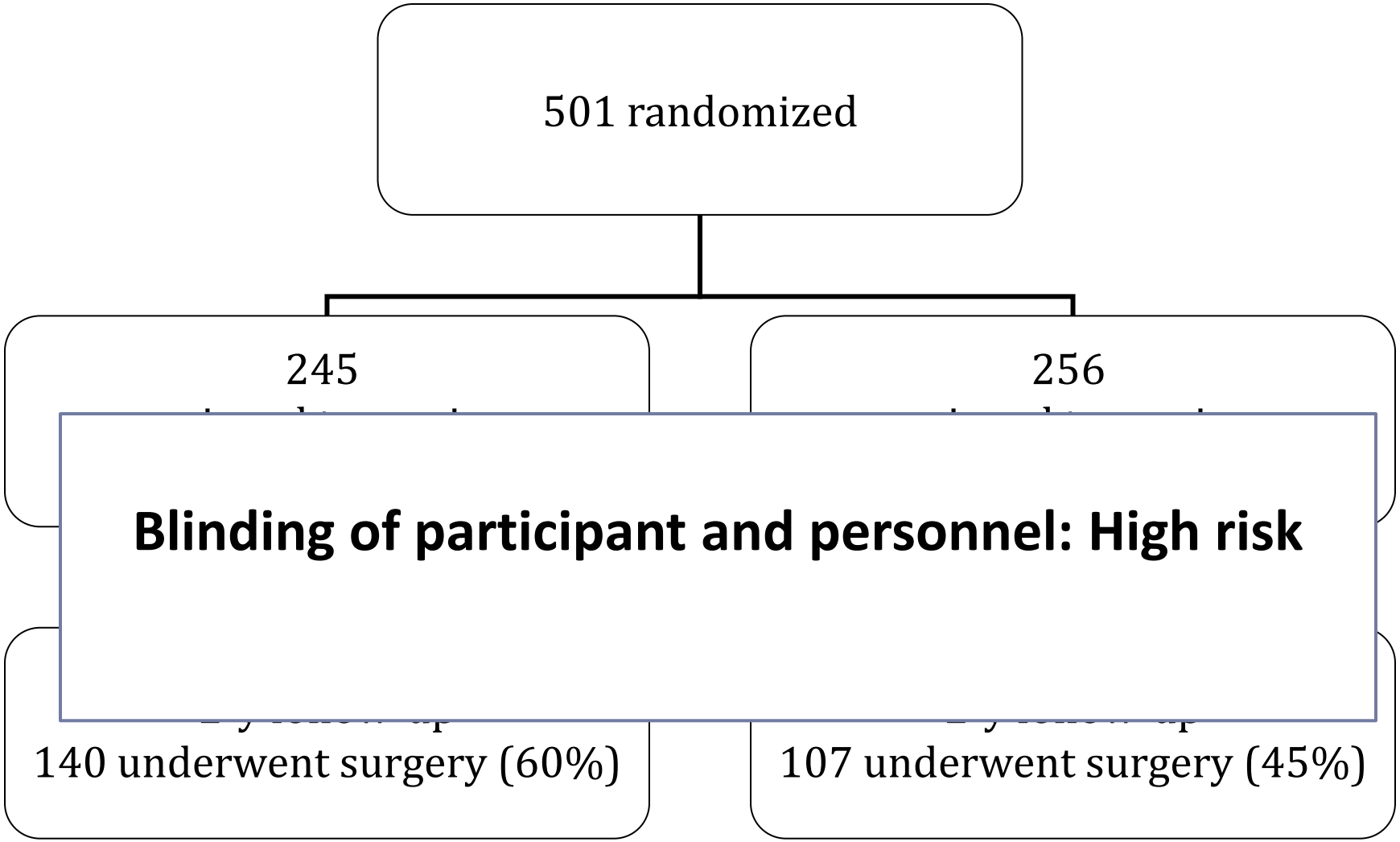

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Blinding of outcome assessment

- **SF36**:
  - Outcome assessor: patient, not blinded
  - Outcome subjective: yes
  - **High risk of bias**

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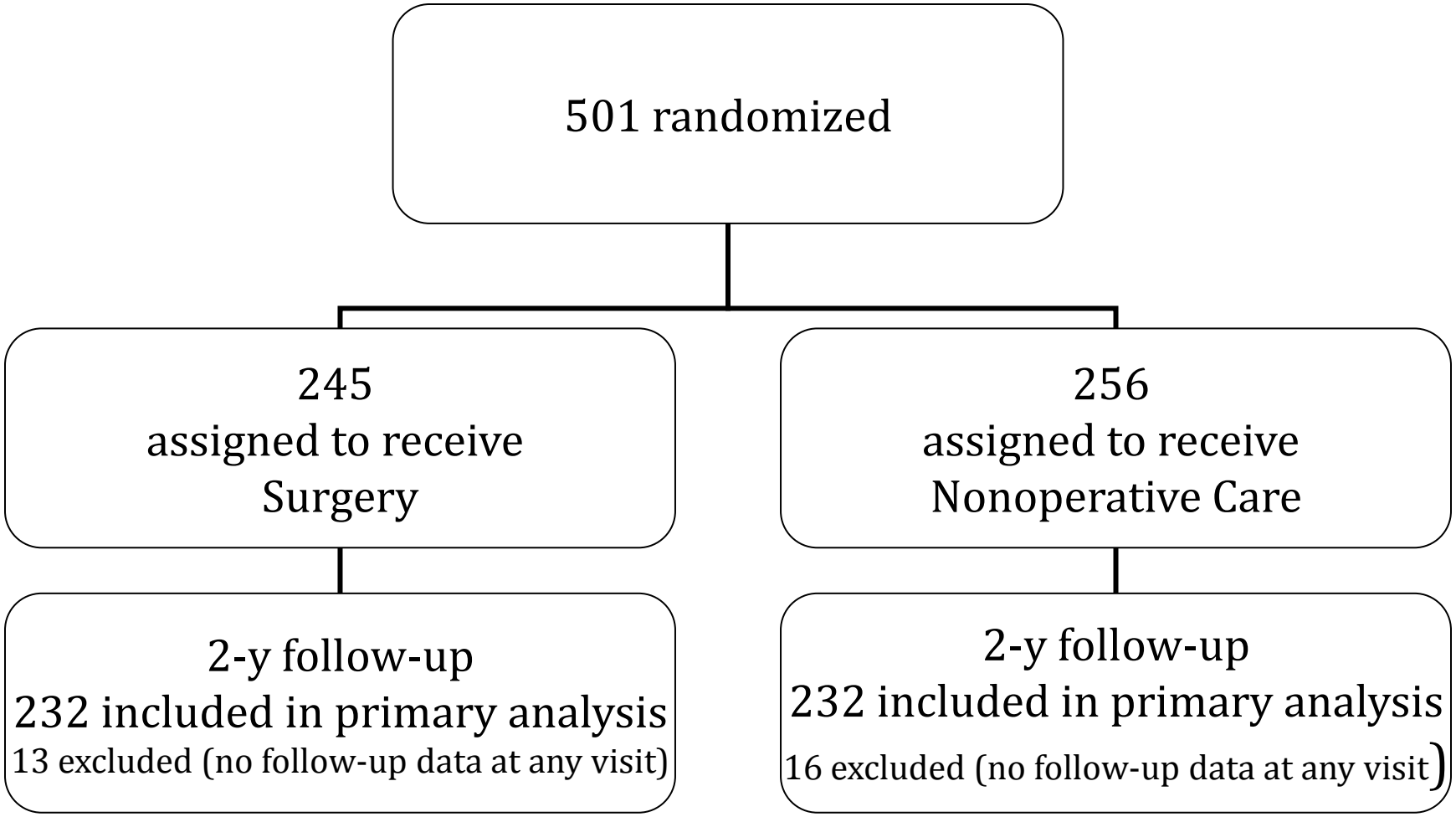

Weinstein, J. N. et al. JAMA 2006;296:2441-2450.

Attrition bias

- **Low risk of bias**

2 years. To adjust for the possible effect of missing data on the study results, the analysis of mean changes for continuous outcomes was performed using maximum likelihood estimation for longitudinal mixed-effects models under "missing at random" assumptions and including a term for treatment center. Comparative analyses were performed using the single imputation methods of baseline value carried forward and last value carried forward, as well as a longitudinal mixed model controlling for covariates associated with missed visits.[30]

ORIGINAL ARTICLES

Wound healing with honey – a randomised controlled trial

Ronald Ingle, Jonathan Levin, Krijn Polinder

Objectives. To compare honey and IntraSite Gel as wound- not significant ($p = 0.94$, 95% CI: -5.72; 6.15.4). Of patients

Ingle R, Levin J, Polinder K.

South African Medical Journal. 2006: 96(9). 831-835.

Random sequence generation

- **Description:**
  - « Enrolled subjects were stratified by wound type, HIV status and the presence of slough, then randomised (using random permuted blocks of size 10) […] »

- **Judgment:**
  - Unclear
    - No reference to a random number table, computer random number generator, coin tossing etc

Allocation concealment

- **Description**
  - « Enrolled subjects were stratified by wound type, HIV status and the presence of slough, then randomised (using random permuted blocks of size 10) to treatment with either honey or Intrasite gel to produce approximate balance of the 3 possible prognostic factors »
- **Judgment**
  - Unclear
    - No reference to a central allocation, sequentially numbered drug containers of identical appearance, sequentially numbered, opaque sealed envelopes

Blinding of participants and personnel

- **Description**
  - « A prospective randomised, **double-blind** controlled trial was carried out by one of the author »
  - The two agents evaluated were
    - natural monofloral aloe honey, creamed by crushing and not heated. […] Honey was then applied with prepacked wooden spatula, using a fresh spatula for each application
    - Intrasite gel, a hydrogel wound-care product manufactured by … [...]IntraSite Gel was expressed from steril sachets.
    - Patients did not know which agent was being used

Blinding of participants and personnel

- **Outcome**: healing time

- **Judgment**
  - **Unclear**
  - Blinding of participants and personnel attempted, but important doubt on the success of blinding as the treatments were clearly different
  - Unclear whether the outcome could be influence by the lack of blinding, however
    - Standardization of co-interventions (supplement, cleaning once daily)
    - No contamination
    - Amount of treatment used monitored (table 4)

Blinding of outcome assessment

- **Outcome**: Healing time (subjective outcome)
- **Description**
  - KP evaluated each wound on the day of entry to the trial, without knowing which agent would be applied. When the healing endpoint was approaching he measured the surface area daily, still blinded, the applied agent from the previous day having being washed off with normal saline
- **Judgment**
  - High risk of bias
    - Blinding of outcome assessment ensured but it is likely that the blinding could have been broken
    - The PI is doing the assessment
    - The outcome is subjective

Incomplete outcome data

- **Outcome**: healing time
- **Description**: Of the 87 patients enrolled 5 were excluded from the analysis:
  - 4/44 in honey arm vs 1/43 gel arm
  - 1 wound being misjudged as being an abrasion but there was complete skin loss; 1 misjudged as being a shallow wound but there were islands of healing, 1 withdraw after 2 days for personal reasons and 2 wounds were dressed with both agents in errors

- **Judgment**
  - Low risk of bias

Questions?