Study Design and Critical Appraisal of Randomized Controlled Trials (RCTs)

Canadian Chiropractic Guideline Initiative (CCGI)

Centre for Disability Prevention and Rehabilitation

Systematic Review Workshop 2019

CCGI Workshops

1. Introduction to research questions and the PICO framework
2. Systematic review screening of literature
3. **Critical appraisal/risk of bias assessment of RCTs**
4. Data extraction from studies

Outline of RCT Workshop

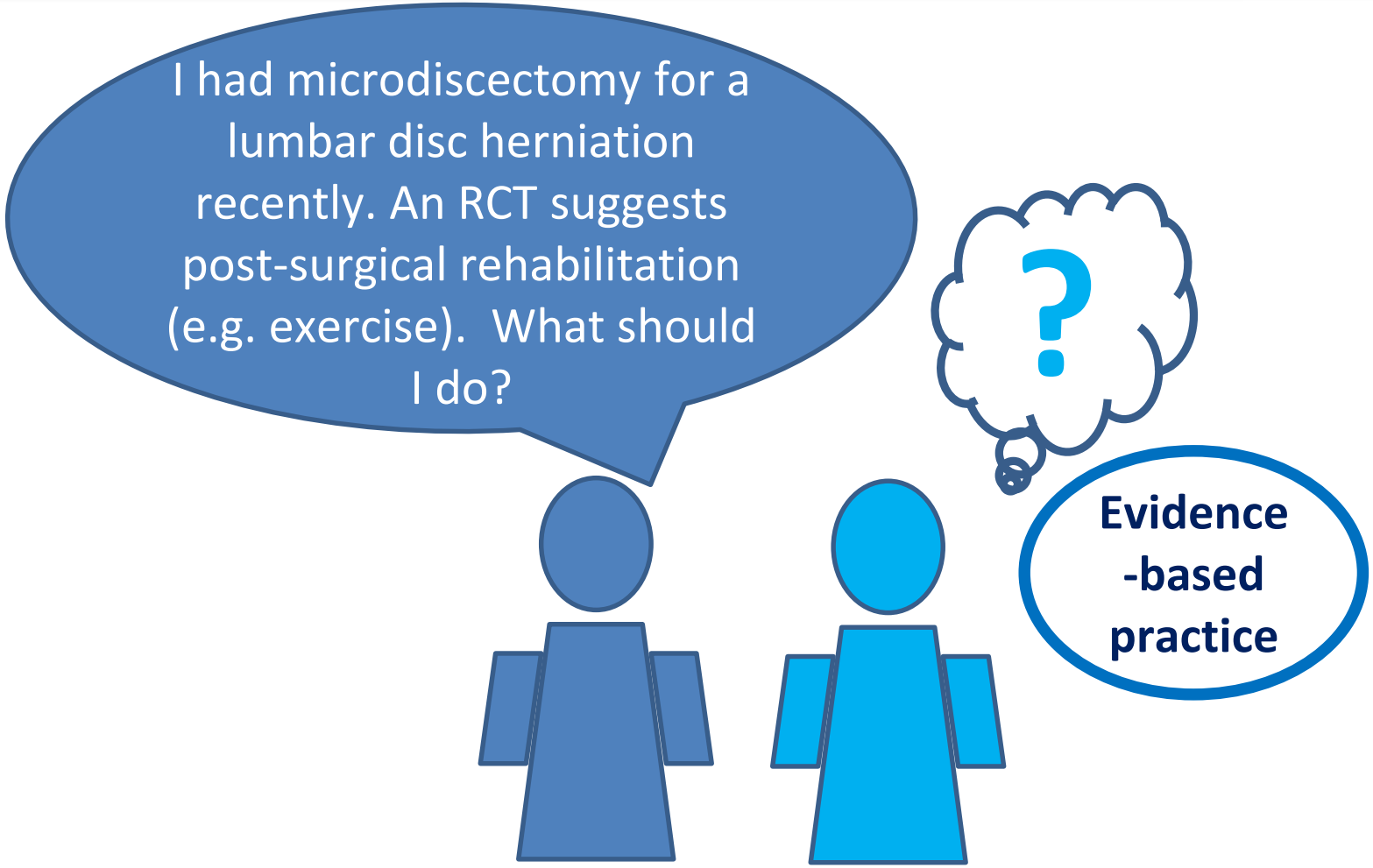
1. Introduction to study design of RCTs
2. Introduction to the SIGN checklist
3. Group learning: critical appraisal of RCTs

Learning Outcomes

At the end of this session, you should be able to:

- Describe the unique features of RCTs
- Critically appraise RCTs using the SIGN checklist
- Reach consensus on individual appraisals

Clinical/Educational Scenario



Randomized Controlled Trials (RCTs)

- Experimental studies (clinical trials)
- Conditions of studies determined by researchers
  - Selection of patients
  - Nature of interventions
  - Duration of study
  - Measurement of outcomes

Randomized Clinical Trials (RCT)

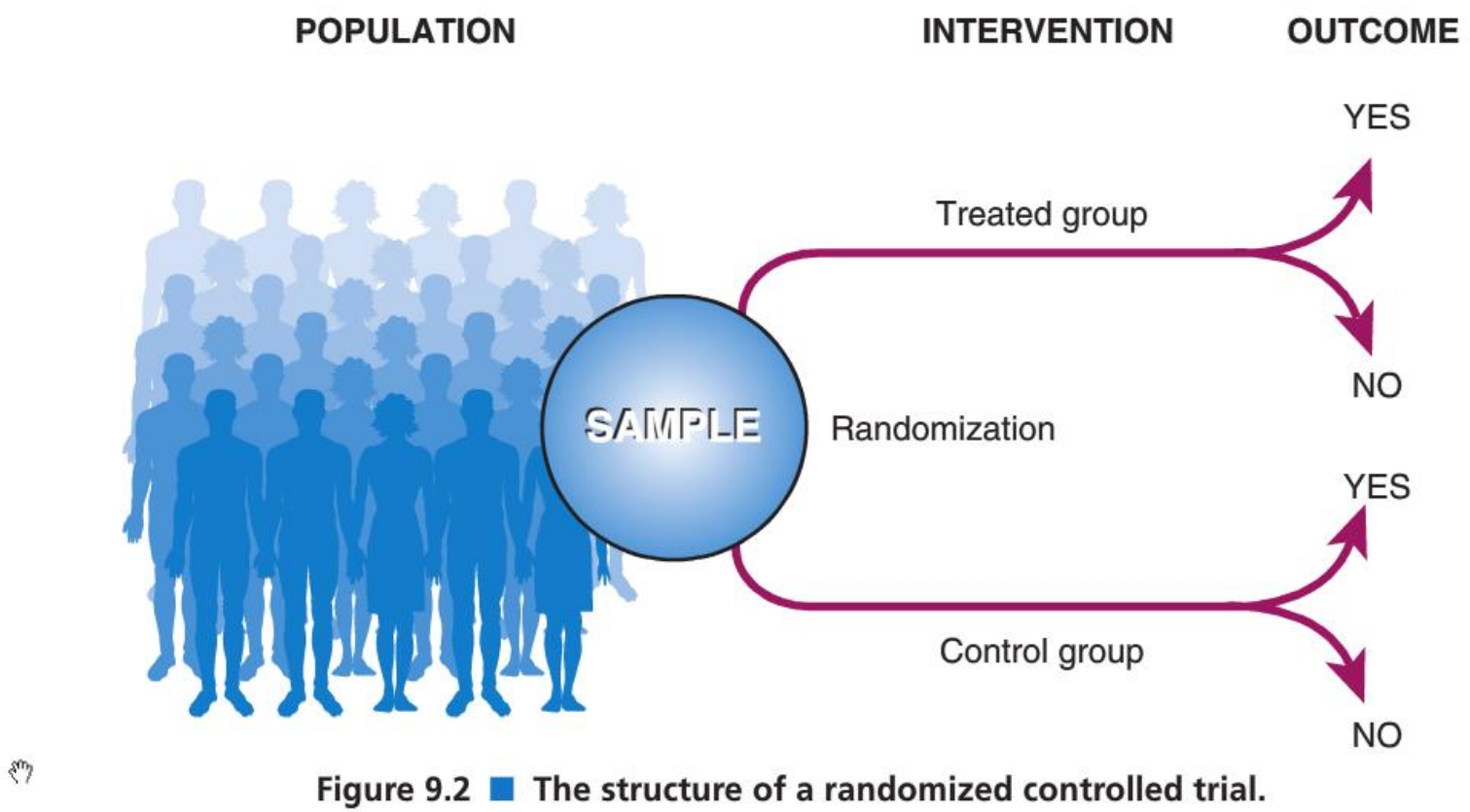


Figure 9.2 ■ The structure of a randomized controlled trial.

Adapted from Fletcher et al. Clinical Epidemiology 5th Edition

Unique Features of RCTs: Random Treatment Allocation

- Randomization of Participants
- To make groups similar at baseline (i.e., similar baseline characteristics)
- To make groups similar with respect to measured and unmeasured confounders

Unique Features of RCTs: Random Treatment Allocation

Adequate Randomization:	Poor Randomization:	Inadequate Randomization (non-random):
-Random Numbers Table -Computer-generated randomization	-Coin flipping -Drawing numbers from a hat	-SIN -Date of birth

Random Number Table

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
1	8	0	9	4	2	5	2	5	8	2	4	7	1	3	4	7	7	4	3	3	3	6	2	0	1	8	9	7	2	1	3	4
2	3	5	6	3	2	1	9	8	8	2	1	1	9	0	4	5	2	6	1	8	2	7	5	1	2	6	2	7	1	0	9	5
3	1	3	3	0	6	3	3	1	3	7	5	3	9	6	9	3	8	7	3	8	6	8	1	5	1	5	3	8	8	5	4	3
4	3	5	6	5	0	0	1	6	2	2	4	3	6	4	3	2	4	7	9	6	6	0	9	5	5	2	8	3	1	6	2	0
5	7	8	5	0	5	9	2	5	5	5	6	8	7	3	1	1	2	1	9	2	4	5	4	5	3	5	3	0	5	5	8	9
6	4	4	9	0	5	4	1	7	9	7	2	7	6	1	5	3	5	9	0	1	4	8	7	8	9	9	8	0	9	8	7	7
7	6	5	4	5	9	1	0	4	9	3	1	8	8	8	1	9	7	5	3	7	2	7	8	5	9	3	7	3	2	4	4	5
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13	5	6	4	1	1	4	1	7	1	4	1	9	7	4	3	4	8	1	6	5	7	3	6	8	1	2	1	8	5	0	3	9
14	7	4	4	4	9	2	0	0	8	8	4	0	5	8	8	2	4	3	9	8	3	9	0	4	9	1	9	9	9	3	3	6
15	8	2	7	9	3	0	1	9	4	6	7	2	3	7	4	3	3	9	7	9	4	6	8	9	9	0	2	1	6	9	9	0
16	0	1	6	1	7	6	1	7	1	0	2	4	2	3	8	7	2	8	9	1	6	6	7	7	1	5	8	5	2	4	8	2
17	7	3	8	8	9	7	5	9	7	5	5	5	6	6	2	4	9	9	7	7	2	0	0	8	5	5	9	6	9	7	4	0
18	7	8	3	0	4	7	1	4	3	8	9	5	2	9	1	9	1	8	0	4	4	0	4	4	1	0	3	4	2	5	9	7
19	9	8	8	7	4	2	1	6	6	5	2	6	4	5	3	5	8	4	3	0	5	2	7	0	9	8	0	5	0	7	8	8
20	1	2	6	1	2	5	1	6	8	5	6	9	2	3	1	0	3	9	3	9	8	7	0	3	9	8	4	1	0	3	5	3
21	3	9	4	7	4	9	3	7	7	6	3	4	2	5	4	3	6	2	3	9	7	4	5	5	2	0	5	5	7	7	9	5
22	4	5	5	0	8	1	0	3	1	2	5	0	2	3	0	4	1	1	3	8	9	7	8	8	9	1	4	4	4	5	2	6
23	1	3	4	4	9	6	9	7	2	3	8	3	6	9	7	6	6	2	5	1	4	2	0	1	2	0	3	8	6	5	5	2
24	8	9	7	6	5	8	2	3	8	4	8	7	0	4	5	0	3	1	0	6	9	1	6	6	2	7	1	7	7	6	0	1
25	7	7	1	0	9	9	4	3	6	9	7	8	8	2	7	3	9	7	1	4	9	7	0	0	1	5	6	6	2	8	8	9
26	6	9	5	9	6	0	0	8	8	4	4	2	2	2	8	2	1	5	2	4	2	5	1	7	5	8	1	8	0	0	8	1
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28	2	2	8	4	0	8	9	6	9	1	0	7	5	5	4	2	7	3	1	9	3	7	8	2	1	0	6	8	9	5	7	4
29	9	5	9	4	7	4	1	6	8	3	6	5	6	0	4	5	1	1	8	3	5	9	1	6	9	5	9	9	1	1	4	3
30	4	6	1	3	8	5	4	9	6	3	6	9	3	2	0	8	5	1	0	9	9	6	8	0	1	1	6	8	6	1	3	3

Use Random Number Table

Example: to randomly assign 20 participants into two groups (interventions A and B) and each group has 10 participants

	1	2	3	4	5	6	7	8	9	10
1	56	99	20	20	52	05	78	58	50	62
2	86	52	11	88	31	60	26	13	69	74
3	80	71	48	73	72	17	60	58	21	55
4	59	06	67	02	66	75	99	34	22	56
5	73	08	46	58	39	65	76	64	26	90

- Intervention A: odd numbers
- Intervention B:even numbers

Computer Generated Randomization

https://www.randomizer.org/

Unique Features of RCTs: Allocation Concealment

- Concealment of the allocation sequences
- Examples
  - Sealed opaque envelopes
  - Centralized allocation/telephone service
  - Randomization performed electronically as participants present

Unique Features of RCTs: Blinding

- Related to treatment and follow-up of participants

- Who can be blinded?
  - Participants and providers
  - Assessors
  - Person in data analysis

Design a RCT

To evaluate LLLT for shoulder pain

- Population, Interventions, Blinding, Outcomes
- Population: shoulder pain
- Randomization
  - LLLT + usual care
  - placebo LLLT + usual care
- Blinding: patients, treatment providers, outcome assessors and biostatisticians
- Outcomes: pain and function

Additive effects of low-level laser therapy with exercise on subacromial syndrome: a randomised, double-blind, controlled trial

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Abstract The subacromial syndrome is the most common source of shoulder pain. The mainstays of conservative treatment are non-steroidal anti-inflammatory drugs and exercise therapy. Recently, low-level laser therapy (LLLT) has been popularized in the treatment of various musculoskeletal disorders. The aim of this study is to evaluate the additive effects of LLLT with exercise in comparison with exercise therapy alone in treatment of the subacromial syndrome. We conducted a randomised clinical study of 80 patients who presented to clinic with subacromial syndrome (rotator cuff and biceps tendinitis). Patients were randomly allocated into two groups. In group I (n=40), patients were given laser treatment (pulsed infrared laser) and exercise therapy for ten sessions during a period of 2 weeks. In group II (n=40), placebo laser and the same exercise therapy were given for the same period. Patients were evaluated for the pain with visual analogue scale (VAS) and shoulder range of motion (ROM) in an active and passive movement of flexion, abduction and external rotation before and after treatment. In both groups, significant post-treatment improvements were achieved in all parameters (P=0.00). In comparison between the two groups, a significant improvement was noted in all movements in group I (P=0.00). Also, there was a substantial difference between the groups in VAS scores (P=0.00) which showed significant pain reduction in group I. This study indicates that LLLT combined exercise is more effective than exercise therapy alone in relieving pain and in improving the shoulder ROM in patients with subacromial syndrome.

Keywords Exercise therapy · Low-level laser therapy · Shoulder pain · Subacromial syndrome

The SIGN checklist for Randomized Controlled Trials

SIGN Checklist

- Scottish Intercollegiate Guidelines Network
- Widely used standardized instrument
- Facilitates judgement of study methodology
- 2 sections:
  - Section 1: Internal Validity (10 individual questions)
  - Section 2: Overall Assessment

Section 1: Internal Validity

Response options:

- Yes
- No
- Can’t say
- Not applicable

Question 1.1

- The study addresses an appropriate and clearly focused question

- P = Population
- I = Intervention
- C = Comparison
- O = Outcome

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Abstract.
BACKGROUND: Lumbar open laser microdiscectomy has been shown to be an effective intervention and safe approach for lumbar disc prolapse. However early post-operative physical disability affecting daily activities have been sporadically reported.
OBJECTIVE: To evaluate the feasibility of using early individualised manipulative rehabilitation to improve early post-operative functional disability following lumbar discectomy.
METHODS: Randomised controlled pilot trial. Setting at a major metropolitan spine surgery hospital. Twenty-one patients aged 25–69 years who underwent lumbar microdiscectomy were randomised to either the manipulative rehabilitation treatment group or the active control group. Rehabilitation was initiated 2–3 weeks after surgery, twice a week for 4 weeks. Each session was for 30 minutes. Primary outcomes were the Roland-Morris disability questionnaire and the visual analogue pain scale. Outcome measures were assessed at baseline and post-intervention.
RESULTS: Early post-operative physical disability was improved with a 55% reduction by early individualised manipulative rehabilitation, compared to that of control care with a 5% increase. Early post-operative residual leg pain decreased with rehabilitation (55%) and control care (9%).
CONCLUSION: This pilot study supports the feasibility of a future definitive randomised control trial and indicates this type of rehabilitation may be an important option for post-operative management after spinal surgery.

Keywords: Lumbar disc surgery, micro-discectomy, early post-operative disability, early post-operative residual pain, manipulative treatment, rehabilitation

1. Introduction

Low back pain has a lifetime prevalence ranging from 11–84% and is reviewed as one of the main causes of disability worldwide [1,2]. Lumbar disc prolapse or herniation accounts for less than 5% of all causes of low back pain, but lumbar disc surgery has been one of the most commonly performed op-

Among the health professions dealing with low back pain and physical disability, osteopathic medicine with the osteopathic diagnosis and treatment has been used for the management of low back pain. Especially, the efficacy of osteopathic manipulative treatment (OMT) with an individualised assessment on the physical disability due to acute or chronic low back pain has been reviewed by recent consensus guidelines and meta-analysis [22–26]. However, scant evidence supports the use of OMT in post-operative rehabilitation to optimise the outcomes of spinal surgery.

The aim of this pilot study was to evaluate the feasibility of using early individualised manipulative rehabilitation whether the early post-operative disability and residual pain after lumbar open laser microdiscectomy can be improved, compared with active control care.

2. Methods

This was a randomised controlled pilot trial assessing the post-operative rehabilitation of patients who recently underwent lumbar microdiscectomy. This study was conducted in the setting of a rehabilitation centre at a specialised hospital for spinal surgery, where two spinal surgeons and an osteopath participated in patient recruitment and screening assessment. The in-

cation concealment. We considered it ethical to reduce the size of the active control group (50% of the rehabilitation intervention group size), because there was less chance for clinical improvement compared with the rehabilitation group [27] (Fig. 1).

2.2. *Intervention*

The patients allocated to OMT rehabilitation visited the hospital for baseline measurement and to receive the intervention between 2 and 3 weeks after surgery (post-operative days 15.4 ± 3.4, mean ± standard deviation (SD)). The OMT rehabilitation consisted of eight individualised sessions for four weeks within the treatment protocol (each session for 30 minutes long twice weekly). At each visit for the intervention, the patients were individually assessed and treated by the same practitioner who was allocated to the study during the entire sessions. All assessments and treatment processes were documented and reviewed by the surgeons and research osteopath allocated to the study. The practitioner chose and used a combination of the techniques in the standardised OMT rehabilitation protocol after an individual physical assessment. Although the techniques are standardized (Fig. 2), the intensity and sequence of the treatment were individualised to each patient's tolerance level and the post-operative conditions at each visit. Spinal manipulation directly

Question 1.2

- The assignment of subjects to treatment groups is randomized.

- Randomization procedure
- Equal probability of allocation to each group
- Examples:
  - Random number table
  - Computer generated randomization

post-operative physical disability affecting daily activities and residual leg pain, have been sporadically reported [7–10]. Therefore, the post-operative rehabilitation has been considered important to reduce the post-operative outcomes.

To optimise the early post-surgical outcomes, the early use of rehabilitation individualised to the post-operative conditions of the patient would be important. The variability in early post-operative complications has been reviewed to associate with various predisposing factors rather than the failure of surgery itself [11–15]. The predisposing factors such as dysfunctional patterns of recruitment of spinal muscles can be exacerbated by the open discectomy since the role of the spinal muscles and fascia partially damaged by the surgery for back pain and back stability has been reviewed [13–19]. Additionally, restrictions on post-operative physical activities by common medical recommendations for periods of time may induce the lack of use of spinal muscles and fasciae, which stabilise the lumbar segments [20,21].

Among the health professions dealing with low back pain and physical disability, osteopathic medicine with the osteopathic diagnosis and treatment has been used for the management of low back pain. Especially, the efficacy of osteopathic manipulative treatment (OMT) with an individualised assessment on the physical disability due to acute or chronic low back pain has been

2.1. Selection of patients

We recruited 59 eligible patients 25–69 years old who were undergoing lumbar discectomy after screening and individual interview, which were performed by research surgeons. Exclusion criteria were patients with any spinal deformity, planned revision surgery, or a serious systemic medical condition including diabetic neuropathy, cancer, and cardiovascular disease. We also excluded patients with pregnancy or mental illness precluding any intervention. Of these 59 patients, 38 were excluded (37 patients were unwilling and unavailable, and one was undergoing revision surgery). The remaining 21 patients who completed the baseline evaluation were randomly allocated to one of two groups by a research physiotherapist at the hospital who was not involved in the intervention or measurement – fourteen patients in the OMT group and seven in the control group. We used simple randomisation and sealed envelopes with sequential numbers for allocation concealment. We considered it ethical to reduce the size of the active control group (50% of the rehabilitation intervention group size), because there was less chance for clinical improvement compared with the rehabilitation group [27] (Fig. 1).

2.2. Intervention

Question 1.3

- An adequate concealment method is used.

- Allocation to group is concealed
- Examples:
  - Sealed opaque envelopes
  - Central telephone service
  - Randomization preformed
  - as participants arrive

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2.2. *Intervention*

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Question 1.4

- Subjects and investigators are kept ‘blind’ about treatment allocation.

- Blinding can involve:
  - Subjects
  - Treatment providers
  - Outcome assessors
  - Biostatisticians

tients who received this osteopathic manipulative rehabilitation reported considerable improvement in the primary outcome measure of post-operative functional disability (55% reduction) and early residual post-operative leg pain (55% reduction), and in the secondary outcome of medication use (93% reduction).

Active rehabilitation such as physical fitness programmes is commonly recommended option for post-operative management in spinal surgery [27]. However, the low rate of referrals by spinal surgeons for the active rehabilitation was reported in the national audit [34] and post-surgical active restrictions for short period of time was commonly recommended by the surgeons although necessity and duration are still controversial [20,21]. We used a passive rehabilitation gently applied to the whole body including the local spinal area. The OMT rehabilitation aimed to reduce the mechanical pressure applied to the lumbar spine by structurally and functionally improving the adjacent and distant joints (Fig. 2).

Most of the patients undergoing lumbar discectomy expect early restoration with less disability for early able to patients on what they can do post-operatively may not produce optimal outcomes after surgery. Thus, we decided, in this preliminary study, to start early rehabilitation 2 to 3 weeks post-operatively, and we found that it influenced early improvement in post-operative functional disability.

This study has several limitations. We decided against using a placebo group or no treatment but had a minimal active intervention control owing to the ethical consideration. In the pragmatic study design, it was not possible to blind the patients from the intervention, because we explained the type of rehabilitation being used when they inquired. Blinding the practitioners was neither possible in the pragmatic setting. The patients completed outcome measures based on the questionnaire. However, we used self-reported questionnaire responses to evaluate outcomes and the envelopes were gathered. The unavailability of fully trained osteopaths but student osteopaths for OMT intervention in the study was also a limitation. Two students had been trained for two years at an osteopathic institute by fully registered osteopaths to apply the osteopathic

Question 1.5

- The treatment and control groups are similar at the start of the trial.

- Important to consider:
  - Meaningful differences (not just statistical)
  - Impact on results
- >5% differences between groups
- Baseline characteristics (often Table 1)

Rehabilitation Protocol
Manipulative Techniques
Joint mobilisation and soft tissue release
Myofascial Release
Neuromuscular Technique
Muscle Energy Technique
Structures applied
To cervical spine and paraspinal muscles
To thoracic spine and paraspinal muscles
To sacroiliac joints and pelvic muscles
To illiotibial band and tensor fascia lata
To thoracolumbar fascia
To quadratus lumborum
To transverse abdominis
To psoas muscles
Rationale for Use
For functional improvement of lumbar spine
For releasing fascial restriction over lumbar spine
For improving coactivation of lumbar paraspinal

Table 1
Baseline characteristics of the study participants

Characteristics*	Rehabilitation	Control
Age, yr	45.7 ± 12.4	54.9 ± 6.7
Sex, no (%)		
Male	5 (36)	5 (71)
Female	9 (64)	2 (29)
Surgical Level, n (%)		
L3-4	0 (0)	1 (14)
L4-5	6 (43)	3 (43)
L5-S1	5 (36)	2 (29)
Multi-levels	3 (21)	1 (14)

Note: *There were no statistically significant differences between the groups.

the post-intervention evaluation (Fig. 1). At baseline, there were no clinically or statistically significant differences between the groups in baseline characteristics, including age, sex, and level(s) of lumbar segment for surgery (Table 1), and between the post-operative outcomes before each intervention (Table 2). Similar results were shown when the data obtained from the patients who lost to follow-up were not analysed.

Table 2
Clinical parameters pre- and post-intervenitons

Measure	Rehabilitation	Control	P value
Primary outcome			
Diability Score (RDQ)			
Pre intervention	6.5 ± 5.7	6.6 ± 5.5	> 0.05[a]
Post intervention	2.9 ± 2.9	6.9 ± 3.1	
Change scores	3.6 ± 5.3	−0.3 ± 4.2	0.005[b]
Low Back Pain (VAS)			
Pre intervention	31.1 ± 27.9	30.0 ± 20.8	> 0.05[a]
Post intervention	16.4 ± 12.2	17.1 ± 13.8	
Change scores	14.6 ± 24.8	12.9 ± 19.8	0.87[b]
Leg Pain (VAS)			
Pre intervention	35.0 ± 24.4	32.9 ± 24.3	> 0.05[a]
Post intervention	15.7 ± 12.2	30.0 ± 18.3	
Change scores	19.3 ± 25.6	2.9 ± 13.8	0.029[b]
Secondary outcome			
Life Quality (SF-36 PCS)			
Pre intervention	40.4 ± 6.9	36.5 ± 10.0	> 0.05[a]
Post intervention	43.5 ± 9.1	41.9 ± 7.0	
Change scores	3.1 ± 7.9	5.3 ± 10.7	0.97[b]
Medication use (weekly)			
Pre intervention	13.7 ± 1.1 (14)	14 (14)	> 0.05[a]
Post intervention	1.0 ± 3.7 (0)	8.7 ± 6.4 (12)	
Change scores	12.7 ± 3.8 (14)	5.3 ± 6.4 (2)	0.004[b]

Note: RDQ, Roland-Morris Disability Questionnaire (0–24, 0 = no physical disability); VAS, the visual-analogue pain scale (0–100, 0 = no pain); SF-36 PCS, Physical component score (higher scores denote better health); Medication use, number of times consumed weekly (0–14, 0 = no use); P value[a], Student's t-test or the Mann-Whitney U test; P value[b], ANCOVA with baseline values as covariates; Plus-minus values are means ± SD or median in the brackets.

For improving coactivation of lumbar paraspinal muscles

Note: * Spinal manipulation directly appled to the segments of lumbar spine associated with lumbar discectomy was not used in the protocol.

Fig. 2. A summary of individualised manipulative rehabilitation.

between-group differences of the outcome measures obtained at the final evaluation with respect to the baseline using an analysis of covariance (ANCOVA) with baseline values as covariates. Outcome measures were analysed using the intension-to-treat principle. Continuous data were analysed using the Student's t-test or the Mann-Whitney test, and categorical data were analysed using the chi-square test or Fisher's exact test and regression to account for baseline variations. Numerical variables were summarised as means ± SD or medians. SPSS statistical software, version 12.0 (SPSS Inc., Chicago, IL, USA) was used for the analyses. Two-sided tests and a significance level of 5% were used for all statistical analyses.

3. Results

3.2. Primary outcomes

Early post-operative functional disability was more improved by individualised rehabilitation with OMT than active control with self-home exercise (55% vs. −5%, $P < 0.05$). There was similar improvement in early post-operative low back pain in both groups with a 47% reduction by the OMT rehabilitation and a 43% reduction by control care. However, early post-surgical leg pain was more decreased by OMT rehabilitation with a 55% reduction than active control care with a 9% reduction (Table 2).

3.3. Secondary outcomes

Life quality associated with physical activity measured by SF-36 PCS was slightly improved in both groups with a 8% increase by OMT rehabilitation and a 15% increase by control care. All patients in both groups reduced the frequency of medication use; 93% reduction in the OMT rehabilitation group and 38% in the control group. No neurological or other complications after each post-operative care in both groups were observed.

Question 1.6

- The only difference between groups is the treatment under investigation.

- Important to consider:
  - Treatments outside of study
  - Adherence to intervention
  - Extraneous factors (e.g. interaction with provider)

Question 1.7

- All relevant outcomes are measured in a standard, valid and reliable way.

- Examples of valid and reliable outcomes:
  - Pain: NRS, VAS
  - Disability: NDI, ODI, RMDQ, DASH, LEFS
  - Quality of life: SF-36, SF-12
  - Recovery: Global Perceived Effect

ability of the lumbar spine [14,15,28–31]. Patients allocated to the active control group visited the hospital for baseline measurement between 2 and 3 weeks after surgery (post-operative days 14.1 ± 1.1, mean ± SD). Each patient in the control group received a home exercise booklet with verbal instruction and performed the home exercise programme for four weeks. The home exercise included trunk rotation in standing position by putting hands on the pelvis; trunk flexion with the flexed legs while lying supine. The active home exercise was recommended to perform twice a week for four weeks, each for half an hour. All patients in both groups were prescribed anti-inflammatory medication, analgesics, and muscle relaxants by their surgeons and were not restricted in any daily physical activity after surgery.

2.3. *Outcome measures*

The baseline measurement was assessed at the first visit for the intervention, and the final evaluation was conducted a week after the 4-week intervention. The primary outcome measures evaluated disability and pain, and secondary outcomes measures were quality of life and use of medication using self-reported questionnaires. The Roland-Morris disability questionnaire (RDQ) is a 24-point scale ranging from 0–24 that evaluates disability; higher numbers indicate increasing severity of the disease [32]. The visual analogue scale (VAS) evaluates pain in the low back and legs, and ranges from 0–100, with 0 being no pain and 100 being the worst pain. For quality of life evaluation, the physical component score (PCS) of the 36-item Short-Form (SF) was used, and each score ranges from 0–100, with higher scores corresponding to better health status [33]. These outcome measures were assessed before and after the 4-week intervention.

2.4. *Statistical analysis*

Baseline measures were summarised using descriptive statistics and analysed for comparability. The Shapiro-Wilk test was used to assess normality of distribution of the data. Primary analyses compared

Question 1.8

- What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?

- Important to consider:
  - Relatively similar between groups
  - Reasons for drop out
- Less than 20%

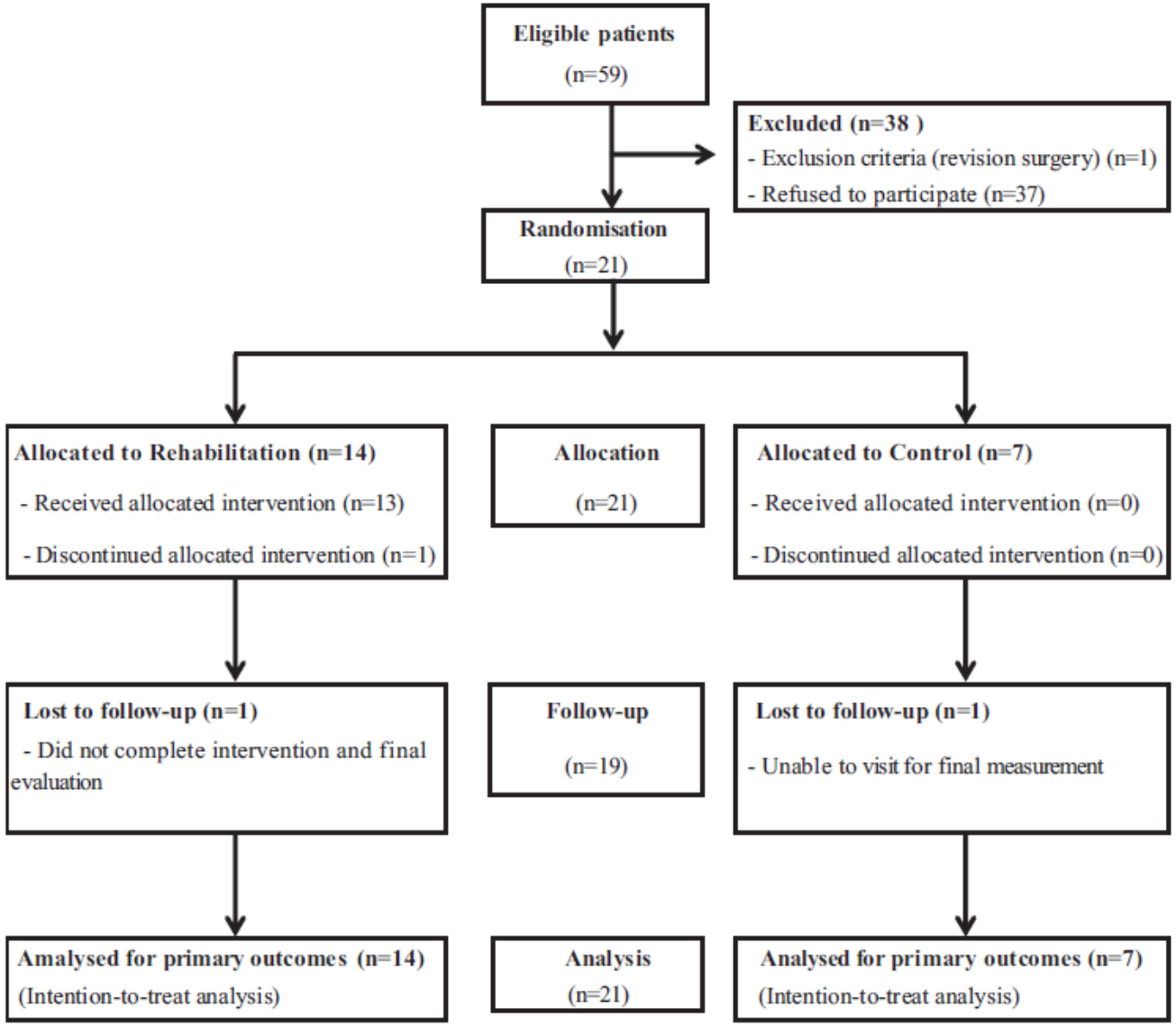


Fig. 1. The flow of participants throughout the study.

Question 1.9

- All the subjects are analyzed into the groups to which they were randomly allocated (often referred to as intention to treat analysis).

- Intention to treat analysis performed
  - Cross-over between groups
  - Retain strengths of randomization
  - Conservative estimate of treatment effect

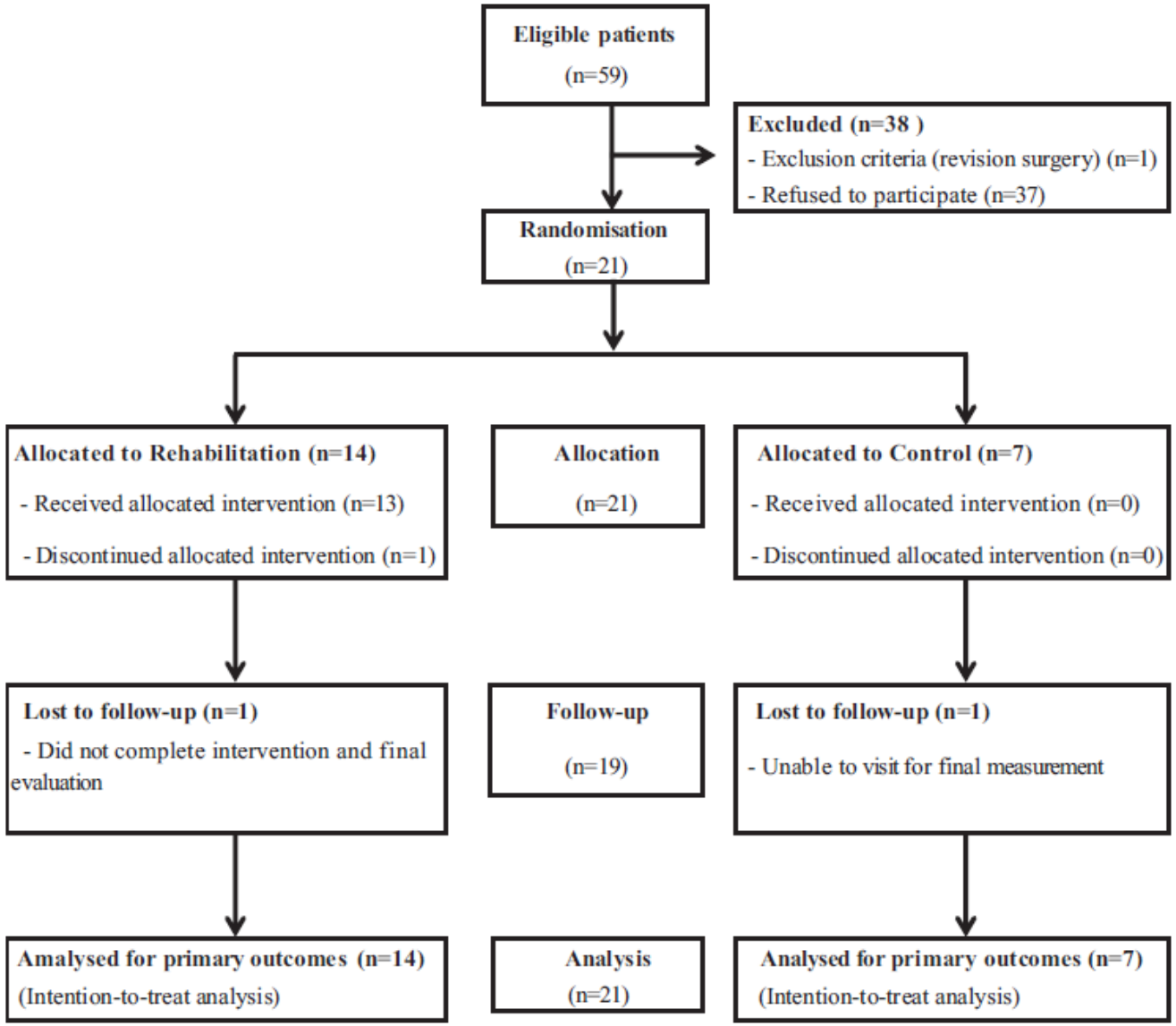


Fig. 1. The flow of participants throughout the study.

Question 1.10

- Where the study is carried out at more than one site, results are comparable for all sites.

- For multi-site trials (i.e. treatment in one group is given at more than one site)

2. Methods

This was a randomised controlled pilot trial assessing the post-operative rehabilitation of patients who recently underwent lumbar microdiscectomy. This study was conducted in the setting of a rehabilitation centre at a specialised hospital for spinal surgery, where two spinal surgeons and an osteopath participated in patient recruitment and screening assessment. The institutional review board of the University of Korea approved the study protocol, and all participants provided written informed consent.

ing the entire sessions. All assessments and treatment processes were documented and reviewed by the surgeons and research osteopath allocated to the study. The practitioner chose and used a combination of the techniques in the standardised OMT rehabilitation protocol after an individual physical assessment. Although the techniques are standardized (Fig. 2), the intensity and sequence of the treatment were individualised to each patient's tolerance level and the post-operative conditions at each visit. Spinal manipulation directly applied to the lumbar segments was not allowed. The structures and areas where the techniques were applied are associated with low back pain and functional dis-

Section 2: Overall Assessment

- How well was the study done to minimize bias?

- High quality (++)
- Acceptable (+)
- Unacceptable – reject

Section 2: Overall Assessment

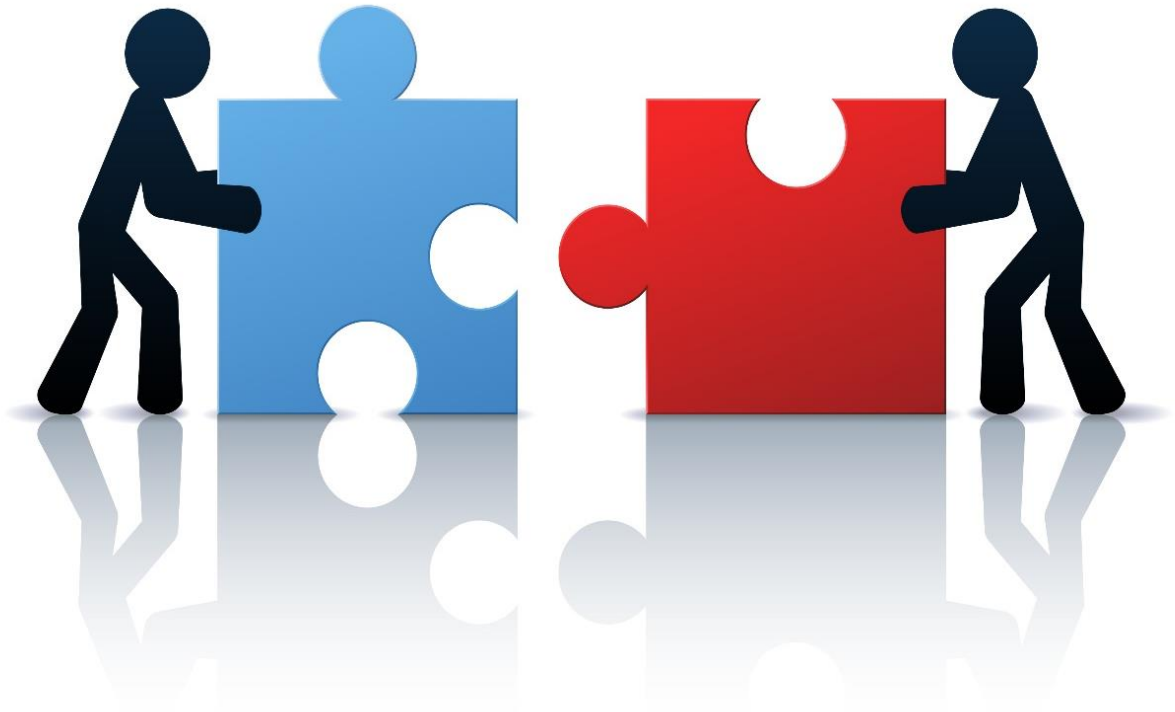
- Are you certain that the overall effect is due to the study intervention?
  - Consider internal validity

- Are the results of this study directly applicable to the patient group targeted by this guideline?
  - Consider external validity (e.g. PICO)

SIGN Checklist and Notes

https://www.sign.ac.uk/checklists-and-notes.html

Group Exercise



Key Messages

- RCTs use randomization and allocation concealment in aims to achieve similar groups at baseline
- Valid outcome measures and acceptable attrition rate also need to be considered
- Tt is important to critically appraise an RCT before using the findings to inform patient care

Thank You

Certificate of completion (for CE)

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