GEMs
GOOD EVIDENCE MATTERS

# GEMs of the Week

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## What's in this week's issue?

**Week of September 23 - 27, 2024**

**SPOTLIGHT:**
**Motivating Movement: Does Motivational Interviewing Increase Exercise?**

# Motivating Movement: Does Motivational Interviewing Increase Exercise

**Effectiveness of Behavioral Interventions with Motivational Interviewing on Physical Activity Outcomes in Adults: Systematic Review and Meta-Analysis**

Zhu S, Sinha D, Kirk M, et al. Effectiveness of behavioral interventions with motivational interviewing on physical activity outcomes in adults: systematic review and meta-analysis. *BMJ.* 2024;386:e078713. Published 2024 Jul 10. doi:10.1136/bmj-2023-078713



**KEY TAKEAWAY:** Motivational interviewing may increase physical activity compared to no motivational interviewing and other interventions.

**STUDY DESIGN:** Systematic review and meta-analysis of 97 randomized controlled trials (N=27,811)

**LEVEL OF EVIDENCE:** STEP 2 (downgraded due to high heterogeneity)

**BRIEF BACKGROUND INFORMATION:** Physical inactivity is one of the leading risk factors for non-communicable diseases. Interventions targeting physical inactivity could improve adults' overall health. Motivational interviewing is one way to target physical inactivity in adults. The study aimed to see if motivational interviewing increases overall exercise.

**PATIENTS:** Adults >18 years old

**INTERVENTION:** Motivational interviewing

**CONTROL:** No motivational interviewing or an active comparator

**PRIMARY OUTCOME:** Amount of physical activity

Secondary Outcome: Effectiveness of interviewing over time, effect of treatment duration, moderate to vigorous activity, sedentary time

**METHODS (BRIEF DESCRIPTION):**

- Inclusion in the study required participants to be adults >18 years old and roughly 25% of the participants were generally healthy. The remainder of the participants had a health condition or pre-existing disease.
- The studies that were excluded included interventions that did not include motivational interviewing and the outcome of the study was not a quantitative measure of physical activity.
- Most studies were conducted in high-income countries.
- Individuals participated in motivational interviewing which was conducted in a variety of ways including face-to-face, over the telephone, via mobile app, and a combination of both in-person and remote interviewing.
- Most studies compared with no intervention or minimal control intervention and had an active comparator.
- Overall physical activity levels were device-measured or self-reported.

**INTERVENTION (# IN THE GROUP):** Not available

**COMPARISON (# IN THE GROUP):** Not available

**FOLLOW-UP PERIOD:** Varied (≤3 months to >12 months)

**RESULTS:**

Primary Outcome –

- Motivational interviewing increased overall total physical activity compared to control (76 trials, n=19,732; standardized mean difference [SMD] 0.45; 95% CI, 0.33–0.65; $I^2$=91%).

Secondary Outcome –

- Motivational interviewing increased moderate to vigorous physical activity compared to control (42 trials, n=10,683; SMD 0.45; 95% CI, 0.19–0.71; $I^2$=91%).
- Motivational interviewing reduced sedentary time compared to control (23 trials, n=2,673; SMD –0.58; 95% CI, –1.0 to 0.14; $I^2$=88%).
- The effectiveness of motivational interviewing over time increased in total physical activity compared to control groups until >12 months.
  - Months 0–3 (42 trials, n=3,803; SMD 0.72; 95% CI, 0.51–0.93; $I^2$=92%)
  - Months 4–6 (38 trials, n=7,481; SMD 0.63; 95% CI, 0.34–0.93; $I^2$=96%)
  - Months 7–12 (29 trials, n=15,580; SMD 0.22; 95% CI, 0.05–0.40; $I^2$=95%)
  - There was no statistically significant data between motivational interviewing and the control at >12 months.
- Motivational interviewing had a positive effect on treatment duration until >12 months.
  - Months 0–3 (34 trials, n=2,182; SMD 0.70; 95% CI, 0.46–0.92; $I^2$=79%)

- Months 4–6 (19 trials, n=3,218; SMD 0.99; 95% Cl, 0.49–1.5; $I^2$=94%)
- Months 7–12 (17 trials, n=11,262; SMD 0.26; 95% Cl, 0.06–0.47; $I^2$=90%)
- There was no statistically significant data between motivational interviewing and the control at >12 months.

**LIMITATIONS:**

- It is hard to isolate motivational interviewing because other behavioral modifying factors were performed at the same time.
- There was high heterogeneity due to multiple different comparators and interventions.
- There was high heterogeneity due to the large inclusion criteria (different populations, interventions, and assessments of outcomes).
- There were multiple assessments used for the outcome.
- Studies included were published in English only.
- The participants were mostly overweight or obese females from high-income countries.

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# Semaglutide: A Game Changer for Heart Failure Related Symptoms

**Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes**

Kosiborod MN, Petrie MC, Borlaug BA, et al. Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes. *N Engl J Med.* 2024;390(15):1394-1407. doi:10.1056/NEJMoa2313917



**KEY TAKEAWAY:** Semaglutide improves heart failure-related symptoms, physical limitations, and weight loss compared to placebo in patients with heart failure with preserved ejection fraction (HFpEF), obesity, and type 2 diabetes (T2DM).

**STUDY DESIGN:** Double-blind, randomized, placebo-controlled trial

**LEVEL OF EVIDENCE:** STEP 2

**BRIEF BACKGROUND INFORMATION:** Obesity and T2DM are common among patients with heart failure with preserved ejection fraction. Currently, there are no approved therapies that specifically address all of these comorbidities.

**PATIENTS:** Adults with HFpEF, obesity, and T2DM

**INTERVENTION:** Semaglutide

**CONTROL:** Placebo

**PRIMARY OUTCOME:** Heart failure symptom burden and physical limitations, body weight

Secondary Outcome: Six-minute walk distance, CRP levels

**METHODS (BRIEF DESCRIPTION):**

- Individuals ≥18 years old with HFpEF, a BMI of ≥30, and diagnosed with T2DM within 90 days before screening with a glycated hemoglobin level of ≤10% were included.
- Participants were blinded and randomly assigned to receive once-weekly subcutaneous semaglutide or placebo for one year.
- The semaglutide treatment group was started at a dose of 0.25 mg once weekly for four weeks. The dose was increased every four weeks until the maintenance dose of 2.4 mg was reached by week 16.
- Symptom burden and physical limitations were quantified using the KCCQ-SS. Scores range from 0–100, with higher scores indicating fewer symptoms and less physical limitations.
- A change in body weight was used as the study's primary endpoint.

**INTERVENTION (# IN THE GROUP):** 310

**COMPARISON (# IN THE GROUP):** 306

**FOLLOW-UP PERIOD:** One year

**RESULTS:**

Primary Outcome –

- Semaglutide improved symptom burden and physical limitations more than placebo (mean difference [MD] 7.3; 95% CI, 4.1–10).
- Semaglutide reduced body weight more than placebo (MD –6.4%; 95% CI, –7.6 to –5.2).

Secondary Outcome –

- Semaglutide improved the six-minute walk distance more than placebo (MD 14 m; 95% CI, 3.7–25).
- Semaglutide reduced CRP levels more than placebo (estimated treatment ratio 0.67; 95% CI, 0.55–0.80).

**LIMITATIONS:**

- The percentage of non-white participants in the study was lower than observed in the general population.
- The study was not designed to look at hospitalizations or urgent visits for heart failure.
- Follow-up duration was limited to one year.
- Data was missing for some participants. For the primary endpoints, the semaglutide group had 29 participants missing data for the KCCQ-CSS and 24 participants missing data for body weight. The placebo group had 34 participants missing data for the KCCQ-CSS and 28 missing data for body weight.

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# Reduced Alcohol Use Following Mobile Chat-Based Support

**A Brief Intervention with Instant Messaging or Regular Text Messaging Support in Reducing Alcohol Use: A Randomized Clinical Trial**

Chau SL, Luk TT, Wong BYC, et al. A Brief Intervention With Instant Messaging or Regular Text Messaging Support in Reducing Alcohol Use: A Randomized Clinical Trial. *JAMA Intern Med.* 2024;184(6):641-649. doi:10.1001/jamainternmed.2024.0343



**KEY TAKEAWAY:** An alcohol-brief intervention followed by three months of electronic chat-based support reduces alcohol consumption among university students at risk of alcohol use disorder.

**STUDY DESIGN:** Randomized controlled trial

**LEVEL OF EVIDENCE:** STEP 2

**BRIEF BACKGROUND INFORMATION:** Alcohol-brief interventions (ABIs) via short messaging services (SMS) have been shown to effectively reduce alcohol consumption in adults with alcohol use disorder (AUD). Studies on smoking have found that instant messaging apps reduce smoking among young adults. This study evaluated the efficacy of an instant messaging supplemented ABI for alcohol reduction.

**PATIENTS:** University students at risk of AUD

**INTERVENTION:** ABI supplemented by personalized instant messaging support focused on alcohol reduction

**CONTROL:** ABI followed by SMS support on general health topics

**PRIMARY OUTCOME:** Alcohol consumption

Secondary Outcome: Risk of AUD, weekly alcohol unit consumption, drinking frequency, binge, and heavy drinking

**METHODS (BRIEF DESCRIPTION):**

- This study included male and female students, ≥18 years old, from eight universities in Hong Kong, and at risk of AUD based on their AUDIT score.
  - AUDIT scores range from 0–40, with 0 indicating no risk and ≥15 indicating moderate to severe risk.
- Participants were randomized 1:1 using a permuted block technique into one of the following groups:
  - ABI + chat-based instant messaging support on alcohol reduction
    - The intervention group received 26 push messages over three months, on alcohol reduction in a tapering schedule.
    - Every Friday through Sunday, the intervention group received personalized, chat-based support from a nurse before happy hours (2 pm to 7 pm), tailored to their AUDIT score and guided by behavioral change techniques. Participants consistently interacted with the same nurse.
  - ABI + SMS text messaging support on general health topics
    - The control group received SMS messages on general health topics on a similar schedule.
- ABI consisted of personalized feedback, based on individual AUDIT risk, delivered in person or by virtual meeting.
- Blinded research assistants assessed participants via phone call at six months from baseline.
- Outcomes were measured by a questionnaire that consisted of the following:
  - Alcohol consumption in grams per week
  - Weekly alcohol unit consumption
  - Engaged in binge drinking (4+ drinks for females, 5+ drinks for males)
  - Engaged in heavy drinking (8+ drinks for females, 15+ drinks for males)
  - Drinking frequency in the past 30 days
- Outcomes were statistically analyzed and reported as unstandardized coefficient *B.*
- The AUDIT was repeated at follow-up.

**INTERVENTION (# IN THE GROUP):** 386

**COMPARISON (# IN THE GROUP):** 386

**FOLLOW-UP PERIOD:** Six months

**RESULTS:**

Primary Outcome –

- The intervention group had a reduction of alcohol consumption by 11 g, or about one alcoholic drink per week, compared to the control group (*B* −11; 95% CI, −19 to −3.6).

Secondary Outcome –

- The intervention group had a lower risk of AUD compared to the control group (*B* –1.2; 95% CI, –1.6 to –0.34).

- The intervention group had lower weekly alcohol unit consumption compared to the control group (*B* −1.1; 95% CI, −1.9 to −0.36).
- No significant differences were found in frequency, binge, or heavy drinking between the intervention and control groups.

**LIMITATIONS:**

- Incomplete follow-up could introduce selection bias. 60 participants in the intervention group were lost to follow-up and 58 in the control group.
- The data is self-reported and therefore susceptible to social desirability bias.
- The instant messaging services were only offered during work-day office hours.
- The intervention may not apply to people with lower levels of technological literacy.

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# Put Your Mind to It: Mindfulness-Based Therapies in Individuals with Prehypertension and Hypertension

**Effect of Mindfulness-Based Intervention on People with Prehypertension or Hypertension: A Systematic Review and Meta-Analysis of Randomized Controlled Trials**

Chen Q, Liu H, Du S. Effect of mindfulness-based interventions on people with prehypertension or hypertension: a systematic review and meta-analysis of randomized controlled trials. *BMC Cardiovasc Disord.* 2024;24(1):104. Published 2024 Feb 14. doi:10.1186/s12872-024-03746-w



**KEY TAKEAWAY:** Mindfulness-based interventions (MBIs) may be a positive addition to hypertension and prehypertension management.

**STUDY DESIGN:** Systematic review and meta-analysis of 12 randomized control trials (N=715)

**LEVEL OF EVIDENCE:** STEP 2 (downgraded due to significant heterogeneity, some studies with small sample size, and moderate to high risk of bias)

**BRIEF BACKGROUND INFORMATION:** Hypertension and prehypertension are recognized as key drivers of mortality worldwide. Mindfulness-based therapies may improve blood pressure as well as mental health. The magnitude of the effect of mindfulness-based intervention on blood pressure and mental health has not been explored. This study aimed to further elucidate the impact of mindfulness-based interventions on pre-hypertension and hypertension.

**PATIENTS:** Patients with pre-hypertension or hypertension

**INTERVENTION:** Mindfulness-based interventions

**CONTROL:** Waitlist, treatment as usual, or other intervention

**PRIMARY OUTCOME:** Systolic blood pressure (SBP) and diastolic blood pressure (DBP)

Secondary Outcome: Anxiety, depression, perceived stress

**METHODS (BRIEF DESCRIPTION):**

- Studies published before May 24, 2023 were identified by searching 10 databases and two grey databases.
- Pregnant or lactating women or those with previous experience in mindfulness or medication techniques were excluded from the study.
- Participants included men and women ≥18 years old, and those with pre-hypertension or hypertension (SBP ≥120 mmHg and/or DBP ≥80 mmHg) with or without prescribed antihypertensive medication.
  - Only one study included patients with grade II hypertension
  - Average age ranged from 43–74 years old.
- Studies included mindfulness-based interventions.
  - 10 studies adopted eight weekly sessions of mindfulness-based stress reduction.
  - One study applied eight weekly sessions of mindfulness-based cognitive therapy.
  - One study applied six weekly sessions of mindful awareness practice.
  - All activities were done in a group setting ranging from 45 minutes to 2.5 hours
  - Home practices were included in seven studies.
- Comparisons included a wait list, an active control group (defined as a group who received an intervention other than mindfulness), or treatment as usual.
- The primary outcome was measured via a pooled analysis of the reduction of SBP and DBP, reported as a mean difference (MD).
- Secondary outcomes included the standard mean difference (SMD) of anxiety, depression, and perceived stress

**INTERVENTION (# IN THE GROUP):** 368

**COMPARISON (# IN THE GROUP):** 347

**FOLLOW-UP PERIOD:** Varied from immediately post-intervention to three months post-intervention

**RESULTS:**

Primary Outcome –

- MBIs reduced SBP more than control (12 studies, n=688; MD –9.1; 95% CI, –12 to –6.1; $I^2$=92%).
- MBIs reduced DBP more than control (12 studies, n=688; MD –5.7; 95% CI, –8.9 to –2.4; $I^2$=97%).

Secondary Outcome –

- MBIs reduced anxiety more than control (4 studies, n=261; SMD –4.1; 95% CI, –6.5 to –1.7; $I^2$=98%).
- MBIs reduced depression more than control (4 studies, n=261; SMD –1.7; 95% CI, –3.0 to –0.44; $I^2$=94%).

- MBIs reduced perceived stress more than control (4 studies, n=208; SMD –1.5; 95% CI, –2.6 to –0.26; $I^2$=92%).

**LIMITATIONS:**

- There is significant heterogeneity in the primary and secondary outcomes.
- Many included studies had small sample sizes and moderate to high levels of risk of bias.
- The safety of the intervention was not analyzed.

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# From Food to Mood: Do Ultra-Processed Foods Feed Depression?

**Adherence to the Ultra-Processed Dietary Pattern and Risk of Depressive Outcomes: Findings from the NutriNet Brasil Cohort Study and an Updated Systematic Review and Meta-Analysis**

Werneck AO, Steele EM, Delpino FM, et al. Adherence to the ultra-processed dietary pattern and risk of depressive outcomes: Findings from the NutriNet Brasil cohort study and an updated systematic review and meta-analysis. *Clin Nutr.* 2024;43(5):1190-1199. doi:10.1016/j.clnu.2024.03.028



**KEY TAKEAWAY:** Higher consumption of ultra-processed foods is associated with a greater risk of developing depressive symptoms/depression compared to low consumption of ultra-processed foods.

**STUDY DESIGN:** Prospective cohort study

**LEVEL OF EVIDENCE:** STEP 3

**BRIEF BACKGROUND INFORMATION:** One of the most prevalent worldwide causes of disability in people who seek medical care is major depressive disorder, with a global incidence of >4%. Previous studies have suggested a potential detrimental effect of these ultra-processed diets, characterized by high levels of additives and low nutritional value, on mental health, particularly depression. This study aimed to investigate and review data from the NutriNet Brazil Cohort to asses the prospective risk between depressive symptoms and its association with adherence to a diet high in ultra-processed foods.

**PATIENTS:** Adults without depressive symptoms

**INTERVENTION:** High consumption of ultra-processed foods

**CONTROL:** Low-consumption of ultra-processed foods

**PRIMARY OUTCOME:** Depressive symptoms

Secondary Outcome: Depressive symptoms adjusted for dietary mediators

**METHODS (BRIEF DESCRIPTION):**

- This study utilized the "NutriNet Brasil" cohort program— a research agency largely supported by the Brazilian Ministry of Health to investigate the relationship between dietary choices and chronic diseases in Brazil.
- Adults aged 18 and above from all Brazilian regions who decided to participate in the NutriNet Brasil cohort study were included.
- All study participants were recruited through online questionnaires.
  - Questionnaires assessed factors such as alcohol and tobacco consumption, physical activity, self-reported weight, and previous chronic health conditions.
- Participants were excluded if they had a previous history of depression or depressive symptoms.
  - Individuals were also excluded if they developed depressive symptoms during the first six months of the study
- All participants were split into quartiles based on the percentage of their diet that consisted of ultra-processed foods.
- The extent of ultra-processed foods was assessed using the Nova24h, a validated online dietary recall that helps to classify foods and the amount eaten including the energy and nutrient content. It then classified the foods into four quartiles with Q1 being the least processed foods and Q4 being the ultra-processed foods.
- Individuals were also split into two Cox regression models for analysis which are:
  - Model 1 included the primary outcome and was adjusted for characteristics such as gender, age, education, and ethnicity.
  - Model 2 included the secondary outcome which was adjusted for dietary mediators.
- Dietary mediators included the amount of sodium, fiber, trans fats, and added sugar within foods as well as the intake of fruits and vegetables in the diet.
- Individuals were assessed after 14 months, 20 months, 26 months, 32 months, and 38 months.
- Development of depressive symptoms was assessed using PHQ-2 and PHQ-9 questionnaires. A score of ≥9 indicated a positive screen for depressive symptoms/depression.
- The primary and secondary outcomes were both twofold in the data that was presented.

- In the first data set, both outcomes of the study included all cases of depressive symptoms compared to the total participants (2,373 cases of depression out of 15,960 participants.)
- In the second data set, the study excluded those who developed symptoms within the first six months of follow-up (1,251 cases of depression out of 14,838 participants).

**INTERVENTION (# IN THE GROUP):** 14,838

**COMPARISON (# IN THE GROUP):** Not available

**FOLLOW-UP PERIOD:** 14–38 months

**RESULTS:**

Primary Outcome –

- Consumption of ultra-processed foods was associated with depression or depression symptoms compared to a diet consisting of low consumption of ultra-processed foods (hazard ratio [HR] 1.1; 95% CI, 1.0–1.1).
- After excluding participants who had depressive symptoms within six months, high consumption of ultra-processed foods was associated with depression or depressive symptoms compared to a diet low in ultra-processed foods (HR 1.1; 95% CI, 1.1–1.2).

Secondary Outcome –

- After adjusting for dietary mediators, consumption of ultra-processed foods was associated with depression or depressive symptoms compared to eating a diet low in ultra-processed foods (HR 1.1; 95% CI, 1.0–1.1).
- After excluding participants who had depressive symptoms within six months and adjusted for dietary mediators, consumption of high amounts of ultra-processed diets was associated with depression or depressive symptoms compared to consuming a diet low in ultra-processed foods (HR 1.1; 95% CI, 1.0–1.1).

**LIMITATIONS:**

- The sample of participants was not randomized and possibly excluded those with lower socioeconomic status and those who may have limitations with the internet, like older adults.
- The study occurred during the worst stage of the COVID-19 pandemic so the incidence of depressive symptoms may be underestimated.
- Social desirability bias may have led to underreporting of dietary share of foods.
- The study had a relatively short follow-up period.
- Participants who self-reported moderate-to-severe depressive symptoms would need to be formally diagnosed with depression by a registered physician.
- The potential for reverse causality could not be excluded even though previous cases of documented depression/depressive symptoms were not incorporated

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# Low Back Pain Relief with Sustained McKenzie than Repetitive McKenzie

**Sustained vs Repetitive Standing Trunk Extension Results in Greater Spinal Growth and Pain Improvement in Back Pain: A Randomized Clinical Trial**

Harrison JJ, Brismée JM, Sizer PS Jr, Denny BK, Sobczak S. Sustained versus repetitive standing trunk extension results in greater spinal growth and pain improvement in back pain: A randomized clinical trial. *J Back Musculoskelet Rehabil*. 2024;37(2):395-405. doi:10.3233/BMR-230118



**KEY TAKEAWAY:** Sustained standing trunk extension (STE) may help alleviate low back pain and improve spine growth in adults compared to repetitive standing trunk extension (RTE).

**STUDY DESIGN:** Randomized, single-blind, controlled trial

**LEVEL OF EVIDENCE:** STEP 3 (downgraded due to small sample size and utilization of per protocol analysis)

**BRIEF BACKGROUND INFORMATION:** Low back pain is one of the most common patient complaints in primary care. The standing McKenzie method can be used for the management of low back pain, however, the effect on spinal height and clinical outcomes, including pain reduction and functional outcomes remains unknown. This study aimed to evaluate standing extension postures, specifically sustained vs repetitive, on spinal height, pain, symptoms centralization, and function.

**PATIENTS:** Adults with low back pain

**INTERVENTION:** McKenzie sustained standing trunk extension

**CONTROL:** McKenzie repetitive standing trunk extension

**PRIMARY OUTCOME:** Spinal height growth

Secondary Outcome: Pain reduction, symptoms centralization, function

**METHODS (BRIEF DESCRIPTION):**

- Male and female participants 18–80 years old with low back pain and directional preference in back extension with an ability to stand for five minutes and the ability to sit for 10 minutes were included.
- Subjects attended two physical therapy sessions with 10 minutes of trunk unloading in a supine position followed by respective interventions involving four stadiometric measurements.
    - Group one underwent sustained standing trunk extension of five sets of 45 seconds with 15-second rest breaks between sets.
    - Group two underwent repetitive standing trunk extension at a rate of 10 per 45 seconds, repeated five times, with 15-second rest breaks between sets.
- Follow up between the two sessions was two-weeks
- A two-by-three mixed design was used to evaluate the effects of STE and RTE in primary and secondary outcomes.
    - Two (between subject groups) by three (time period within subject groups, before vs after vs 2 weeks after)
- Pain was assessed through a scale ranging from 0–10 with higher scores indicating greater pain.

**INTERVENTION (# IN THE GROUP):** 15

**COMPARISON (# IN THE GROUP):** 15

**FOLLOW-UP PERIOD:** Two weeks

**RESULTS:**

Primary Outcome –

- STE resulted in more spinal height growth than RTE in the first session (4.5 vs 2.1 mm, respectively; effect size 1.7; $p<.001$).
- STE resulted in more spinal growth compared to RTE two weeks later in the second session (3.9 vs 2.4 mm, respectively; effect size 0.8; $p=.02$).
- STE resulted in more spinal height growth than RTE in the first session (4.5 vs 2.1 mm, respectively; effect size 1.7; $p<.001$).
- STE resulted in more spinal growth compared to RTE two weeks later in the second session (3.9 vs 2.4 mm, respectively; effect size 0.8; $p=.02$).

Secondary Outcome –

- STE reduced pain more than RTE between session one and session two (5.4 to 2.6 vs 5.8 to 4.2, respectively, effect size 0.2; $p<.001$).
- There was no difference between the STE and RTE groups in symptom centralization and functional outcomes.

**LIMITATIONS:**

- The sample size of the study was small (n=30), potentially increasing the odds of type one error

- Four participants out of the 34 who met the inclusion criteria were excluded from the final analysis. Three participants experienced increased pain several days after the first session and one participant did not follow the protocol. The study analysis was conducted as per-protocol effects, potentially over-estimating the effects of the intervention outcome
- Participants had low initial current pain levels and the effect of pain reduction from the two methods may be inconsiderable.
- There was a slight difference in the mean age between the two groups compared.
- The follow-up period was only two weeks and long-term benefits remain unknown.

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