GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

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SPOTLIGHT: One More Use for Semaglutide: Can It Improve Functionality in HFpEF?

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GEMs GOOD EVIDENCE MATTERS SPOTLIGHT

Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity

Kosiborod MN, Abildstrøm SZ, Borlaug BA, et al. Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. *N Engl J Med.* 2023;389(12):1069-1084. doi:10.1056/NEJMoa2306963

KEY TAKEAWAY: Semaglutide improves physical functionality and symptoms in patients with heart failure with preserved ejection fraction (HFpEF) and obesity.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: The incidence of HFpEF is increasing as it accounts for more than half of heart failure cases in the United States. HFpEF is associated with a significant decrease in quality of life. Many of these patients have comorbid obesity and evidence suggests that obesity may be a significant contributory factor towards disease progression. Currently, there are no FDA-approved medications for HFpEF with comorbid obesity. This study sought to determine whether targeting obesity can improve symptoms and physical capacity.

PATIENTS: Patients with HFpEF and obesity

INTERVENTION: Semaglutide

CONTROL: Placebo

PRIMARY OUTCOME: Overall health, change in body weight

Secondary Outcome: Six-minute walk test, C-reactive protein (CRP) levels

METHODS (BRIEF DESCRIPTION):

- Randomized, double-blind, placebo-controlled trial, involving 96 sites in 13 countries in Asia, Europe, and North and South America.
- Included patients >18 years old with HFpEF (defined as EF ≥45%), New York Heart Association functional class 2–4, Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) score of <90, six-minute walk test of ≥100 m, BMI >30 Kg/m^2, and either elevated left ventricular filling pressures, elevated natriuretic peptide levels plus echocardiographic abnormalities, or hospitalization for heart failure in the last 12 months.
- Patients were excluded if body weight changed more than 5 kg in 90 days before screening or if known history of diabetes (A1c ≥6.5%).
- Randomized 1:1 based on baseline BMI with patients receiving graduated weekly semaglutide dosing with goal dose of 2.4 mg weekly by week 16 of the study
- Patients were observed for 52 weeks, followed by a five-week follow-up period.
- Primary outcomes were measured at baseline and the end of the study
- Overall health was measured by the KCCQ-CSS. Scores range from 0–100 with higher scores indicating better overall health.
- The other primary outcome was the percent reduction in overall body weight.
- The secondary results were an improvement in the six-minute walk distance and a decrease in CRP from baseline to 52 weeks.

INTERVENTION (# IN THE GROUP): 263

COMPARISON (# IN THE GROUP): 266

FOLLOW-UP PERIOD: 57 weeks

RESULTS:

Primary Outcome –

- Semaglutide improved overall health compared to placebo (difference 7.8; 95% CI, 4.8–11).
- Semaglutide increased weight loss compared to placebo (percent change in body weight –11%; 95% CI, –12 to –9.4).

Secondary Outcome –

- Semaglutide improved the six-minute walk distance compared to baseline (difference 20 m; 95% CI, 8.6–32).
- Semaglutide improved CRP levels compared to baseline (treatment ratio 0.61; 95% CI, 0.51–0.72).

LIMITATIONS:

- The study had a low number of non-white patients. In the US cohort, 23% of patients were Black.
- The study did not look at clinical events related to heart failure in any detail to be able to discuss significance.
- The study lasted only one year and did not look at the long-term sustainability of weight loss, symptom

scores, or adverse events of long-term use of semaglutide.

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Reflecting on the Past: How Childhood Experiences Shape Body Image

Adverse Childhood Experiences and Body Dysmorphic Symptoms: A Meta-Analysis

Longobardi C, Badenes-Ribera L, Fabris MA. Adverse childhood experiences and body dysmorphic symptoms: A meta-analysis. *Body Image*. 2022;40:267-284. doi:10.1016/j.bodyim.2022.01.003

KEY TAKEAWAY: Adverse childhood experiences (ACEs), including abuse, neglect, teasing, and bullying, are positively associated with body dysmorphic disorder (BDD) symptomatology.

STUDY DESIGN: Systematic review and meta-analysis of 27 quantitative studies (N=9,167)

LEVEL OF EVIDENCE: STEP 2 (downgraded due to the inclusion of only cross-sectional studies)

BRIEF BACKGROUND INFORMATION: Body dysmorphic disorder profoundly affects individuals' well-being, disrupting their social, academic, and occupational lives. Its etiology is multifaceted, with a potential interplay between predisposing vulnerability factors and environmental stressors, including adverse childhood experiences (ACEs). This study aimed to quantify the association between ACEs and BDD symptomatology in young children and adults, enhancing understanding of early life stressors' role in the disorder.

PATIENTS: Children with ACEs and BDD symptoms

INTERVENTION: Not applicable

CONTROL: Not applicable

PRIMARY OUTCOME: Correlation between ACEs and BDD symptomatology

Secondary Outcome: Moderating factors of the relationship between ACEs and BDD symptomology

METHODS (BRIEF DESCRIPTION):

- Meta-analysis of the relationship between ACEs and BDD was conducted according to PRISMA guidelines.
- Inclusion criteria: Studies had to be published in peer-reviewed journals, present original quantitative investigations, measured ACEs and BDD, examined their relationship, and reported correlation coefficients. There were no restrictions on publication date or participant age.
- Exclusion criteria: Qualitative studies, literature reviews, case series, or studies not assessing ACEs and their relationship with BDD.
- A three-stage meta-analysis of 27 articles with 9,167 participants was conducted to assess the relationship between ACEs and BDD symptomatology.
- Absolute r values of 0.10, 0.30, and 0.50 indicate small, moderate, and large effect sizes, respectively.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Varied from no follow-up to 12 months

RESULTS:

Primary Outcome –

- The relationship between ACEs and BDD symptomatology was low to moderate (r=.29; 95% CI, 0.24–0.34).
- Small to moderate association with BDD symptomatology for:
  - Bullying (r=.28; 95% CI, 0.21–0.35)
  - Abuse (r=.22; 95% CI, 0.17–0.28)
  - Neglect (r=.17; 95% CI, 0.058–0.28)
- Moderate to large association with BDD was found for teasing (r=.42; 95% CI, 0.36–0.48).

Secondary Outcome –

- Stronger associations between ACEs and BDD were observed when:
  - ACEs were measured as teasing (r=.40) in comparison to other ACE types (r=.29 for bullying, r=.23 for past abuse, and r=.16 for neglect).
  - Study participants were children (r=.39) compared to other sample types (r=.26).
  - Studies were conducted in mixed settings (r=.35) or community settings (r=.31) compared to other settings (r=.23) for clinics and (r=.21) for gyms.
- Significant predictors in the Model:
  - Sample Environment: Statistically significant (p=.007), with mixed samples (community and clinical settings) showing stronger correlations.

- Participant Gender: Significant relationship (p=.046), stronger correlations with a higher percentage of females.
- Type of ACE Studied: Highly significant (p<.001), teasing definition associated with larger correlation magnitudes.

LIMITATIONS:

- The majority of the studies included were cross-sectional (25 out of 27), restricting the ability to establish causal relationships between ACEs and BDD symptomatology.
- Delusional and paranoid thinking in individuals with BDD may introduce bias in reporting negative experiences.
- Convenience samples in the majority of the studies (25 out of 27) may limit the generalizability of the findings.
- The lack of comprehensive information about the characteristics of the study participants hinders the exploration of moderating variables that could clarify variations across studies.
- Retrospective assessment of ACEs may lead to inaccuracies in reporting childhood events.

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To Keep or Not to Keep, Aspirin is the Question

Effects of a Polypill, Aspirin, and the Combination of Both on Cognitive and Functional Outcomes: A Randomized Clinical Trial

Bosch JJ, O'Donnell MJ, Gao P, et al. Effects of a Polypill, Aspirin, and the Combination of Both on Cognitive and Functional Outcomes: A Randomized Clinical Trial. *JAMA Neurol*. 2023;80(3):251-259. doi:10.1001/jamaneurol.2022.5088

KEY TAKEAWAY: Treating adults with cardiovascular risk factors with a polypill that contains medications targeting blood pressure and a statin, with or without the addition of aspirin does not significantly reduce the risk of cognitive decline but could reduce functional decline.

STUDY DESIGN: Randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: There is a large prevalence (around 12–20%) of cognitive decline in adults >65 which often leads to functional decline. However, there is little evidence that interventions can reduce this impairment as most previous studies have focused on decreasing risk factors at the patient level. Given that more than half of adults report a decline in at least one activity of daily living (ADL) or instrumental activities of daily living (IADL) due to cognitive issues, which can significantly impact their quality of life, this study sought to determine whether treating adults with cardiovascular risk factors with a polypill containing blood pressure and cholesterol medications, with or without the addition of aspirin, could reduce this decline.

PATIENTS: Adults ≥65 years old with at least one cardiovascular risk factor

INTERVENTION: Polypill (simvastatin, atenolol, hydrochlorothiazide, ramipril) + aspirin

CONTROL: Double placebo pill

PRIMARY OUTCOME: Composite score of cognitive and functional decline

METHODS (BRIEF DESCRIPTION):

- Data was from the TIPS-3 trial, a double-blind randomized control trial with a 2x2x2 factorial design conducted in 86 centers in eight countries.
- Included patients ≥65 years old with at least one cardiovascular risk factor, but no known cardiovascular disease but intermediate risk on the INTERHEART risk score.
- The study excluded patients with hypotension, already on any of the study medications, who had contraindications to study medications, had chronic liver disease or severe kidney impairment.
- Participants were randomized to four different treatment groups:
    - Polypill + aspirin
    - Polypill + placebo
    - Aspirin + placebo
    - Double placebo.
- The polypill contained simvastatin 40 mg, atenolol 100 mg, hydrochlorothiazide 25 mg, and ramipril 10 mg.
- The aspirin dose used was a 75 mg enteric-coated tablet.
- Assessments of cognition and function were done at the time of randomization, after two years, and at the final visit at five years.
- The primary outcome was a reduction of cognitive and functional decline as indicated by composite scores on several different cognitive and functional assessments including the MoCA, DSST, TMT-B, SAGEA, SAGEA Cog, or the development of dementia.
- Scores were country-standardized to account for differences at the country level given likely cultural and geographic influences.

INTERVENTION (# IN THE GROUP):

- Polypill + aspirin: 598
- Polypill + placebo: 603
- Placebo + aspirin: 563

COMPARISON (# IN THE GROUP): 598

FOLLOW-UP PERIOD: Five years

RESULTS:

Primary Outcome –

- The composite score of functional and cognitive decline was not significantly different at five years compared to the polypill vs placebo group (hazard ratio [HR] 1.1; 95% CI, 0.90–1.2).
- The aspirin vs placebo and polypill + aspirin vs placebo groups had similar results.

Secondary Outcome –

- Cognitive decline was not significantly different at five years on any cognitive assessments (MoCA, DSST, TMT-B, SAGEA) when comparing the polypill, aspirin, or polypill + aspirin vs placebo groups.
- Functional decline was significantly less (based on mean SAGEA scores) in participants assigned the polypill vs placebo (mean country-standardized score 0.06 vs 0.15, *p*=.01) and polypill + aspirin vs double placebo (mean country-standardized score 0.01 vs 0.14, *p*=.01). No significant difference was seen in the aspirin vs placebo group.

LIMITATIONS:

- There was not enough power in the study to detect small or slow changes in cognitive and functional status.
- Responder bias is also possible given that there were participants who were missing but still alive at the end of the study.
- The questionnaires and assessments used to evaluate cognitive and functional status and decline were based on Western studies and may not translate well or be as valid in other populations given that this study included patients from several non-Western countries.
- It is also possible that the questionnaires used did not pick up cognitive decline that was occurring.

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Do Interventions Addressing Social Determinants of Health Reduce Hospitalization and ED Usage?

Acute Care Utilization and Its Associated Determinants Among Patients with Substance-Related Disorders: A Worldwide Systematic Review and Meta-Analysis

Armoon B, Griffiths MD, Mohammadi R, Ahounbar E, Fleury MJ. Acute care utilization and its associated determinants among patients with substance-related disorders: A worldwide systematic review and meta-analysis. *J Psychiatr Ment Health Nurs.* 2023;30(6):1096-1113. doi:10.1111/jpm.12936

KEY TAKEAWAY: By addressing social determinants of health among patients with substance-related disorders (SRDs) use disorders emergency department (ED) utilization and hospitalization can decrease.

STUDY DESIGN: Systematic review and meta-analysis of 32 studies (N=133,469,809), 16 cross-sectional studies (N=1,007,451), and 16 cohort studies (N=132,481,151).

LEVEL OF EVIDENCE: STEP 2 (downgraded due to sample not being local)

BRIEF BACKGROUND INFORMATION: ED utilization and hospital admissions can cause large financial burdens. Patients with lower socioeconomic standing or other related determinants and SRDs have a higher ED usage rate than the general population. Understanding the social determinants amongst those with SRDs that lead to higher utilization can help develop more services to decrease ED utilization.

PATIENTS: Individuals with substance use disorders

INTERVENTION: Sociodemographic and clinical determinants leading to ED use or hospitalization

CONTROL: Patients with substance use disorder who do not use ED for care or have hospitalization

PRIMARY OUTCOME: Usage of ED or hospitalization in the past 12 months

METHODS (BRIEF DESCRIPTION):

- Included studies published between January 1, 1995, to December 1, 2022, with the selection of studies based on PRISMA guidelines.
- 63% of participants were male with a mean age of 39 years old.
- Drug use type factors included polysubstance, cannabis, cocaine, and heroin.
    - Frequency, dosing, and severity were not available.
- Sociodemographic factors included medical insurance and education level. A lower education level was defined as not completing high school.
- Clinical characteristic factors included mental health disorders (MHDs) and chronic physical illness (CPI).
    - No definitions were provided for qualifying characteristics to meet the definition of MHD or CPI.
- The primary outcome was measured as ED usage or hospitalization, assessed using odds ratios.
    - Comparison of drug use, sociodemographic factors, clinical characteristics, and pooled groups.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Mean 4.2 years

RESULTS:

Primary Outcome –

- Patients with health insurance and SRDs were 1.4 times more likely to use the ED for care than those without insurance (2 studies, odds ratio [OR] 0.36; 95% CI, 0.26–0.46).
- Patients with health insurance and SRDs were 1.6 times more likely to be hospitalized (7 studies, OR 0.41; 95% CI, 0.21–0.61).
- Low education levels and SRDs led to 1.2 times more ED usage compared to those with higher education (3 studies, OR 1.2; 95% CI, 1.0–1.5).
- SRDs related to heroin use along with methamphetamine led to 1.6 times more ED usage or hospitalization than heroin alone (4 studies, OR 1.6; 95% CI, 1.5–1.6).
- SRDs related to heroin use along with cocaine led to 2.3 times more ED usage or hospitalization than heroin alone (4 studies, OR 2.3; 95% CI, 1.3–4.2).
- Patients with SRDs and MHDs were 1.5 times more likely to use the ED for care (11 studies, OR 1.5; 95% CI, 1.2–2.0).
- Patients with SRDs and MHDs were 1.4 times more likely to be admitted to the hospital (11 studies, OR 1.4; 95% CI, 1.1–1.8).
- Patients with SRDs and CPI were 1.3 times more likely to use the ED for care (7 studies, OR 1.3; 95% CI, 1.2–1.5).

- Patients with SRDs and CPI were 1.3 times more likely to be admitted to the hospital (9 studies, OR 1.3; 95% CI, 1.2–1.5).

LIMITATIONS:

- Results were gathered through patient self-report.
- Ability to create causal and temporal connections due to the inability to determine cause and effect in the included cross-sectional studies.
- The number of available surveys meeting topic criteria was limited.

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Is Telephone-Based CBT for Weight Loss, Disordered Eating, and Psychological Distress in the Post-Bariatric Surgery Period Beneficial?

Efficacy of Telephone-Based Cognitive Behavioral Therapy for Weight Loss, Disordered Eating, and Psychological Distress After Bariatric Surgery: A Randomized Clinical Trial

Sockalingam S, Leung SE, Ma C, et al. Efficacy of Telephone-Based Cognitive Behavioral Therapy for Weight Loss, Disordered Eating, and Psychological Distress After Bariatric Surgery: A Randomized Clinical Trial. *JAMA Netw Open*. 2023;6(8):e2327099. Published 2023 Aug 1. doi:10.1001/jamanetworkopen.2023.27099

KEY TAKEAWAY: Tele-CBT 1-year post-bariatric surgery vs. standard post-bariatric care did not show a significant change in weight outcomes but did demonstrate improvements in disordered eating and psychological distress.

STUDY DESIGN: Randomized, unblinded, controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Obesity is a global health concern. Bariatric surgery is the most effective method of obesity treatment. However, disordered eating and psychological distress are well-documented risk factors associated with weight regain after bariatric surgery. Telephone-based cognitive behavioral therapy at specific intervals may improve weight loss and psychosocial functioning following bariatric surgery.

PATIENTS: Adults with a post-operative BMI ≥40 or ≥35 with at least one obesity-related comorbidity

INTERVENTION: Tele-CBT

CONTROL: Standard postoperative bariactric care

PRIMARY OUTCOME: Change in weight

Secondary Outcome: Change in disordered eating, psychological distress

METHODS (BRIEF DESCRIPTION):

- Participants one year after bariatric surgery who were fluent in English had access to telephone and internet, and without active suicidal ideation or poorly controlled psychiatric illness were selected.
- This was an unblinded study. Allocation was not concealed.
- Six-weekly one-hour tele-CBT sessions occurred at the one-year mark after bariatric surgery plus a booster session one month later.
- The postoperative percentage of total weight loss was calculated using the patient's self-reported weight at baseline rather than pre-surgery weight to determine tele-CBT intervention efficacy.
- The total time interval was 12 weeks between the baseline and postintervention questionnaire and 24 weeks between the baseline and follow-up questionnaire.

INTERVENTION (# IN THE GROUP): 152

COMPARISON (# IN THE GROUP): 154

FOLLOW-UP PERIOD: 12 weeks and 24 weeks post-intervention (15 months and 18 months post-bariatric surgery)

RESULTS:

Primary Outcome –

- Tele-CBT post-bariatric surgery did not improve weight outcomes compared to standard postoperative care alone at 15 months (T2) and 18 months (T3) post-operatively ($F_{1,160.61} = 2.1$; P=.15).
  - Tele-CBT group:
    - T2 mean weight loss: 1.4%
    - T3 mean weight loss: 1.1%
  - Control group:
    - T2 mean weight loss: 1.1%
    - T3 mean weight loss: 0.9%

Secondary Outcome –

- Tele-CBT significantly decreased the following compared to standard postoperative care:
  - Binge eating ($F_{2,527.32} = 18$; P<.001)
  - Emotional eating ($F_{2,530.67} = 11$; P<.001)
  - Depression ($F_{2,529.93} = 18$; P <.001)
  - Anxiety ($F_{2,535.16} = 15$; P<.001)

LIMITATIONS:

- Energy intake and expenditure were not collected as part of the intervention. There was no caloric-restricted dietary intervention used.
- Baseline BMI was higher in the intervention group (35 vs 32) after randomization.
- The study duration of one year to 18 months post-bariatric surgery may be too short to adequately analyze long-term outcomes.
- In this study, the bariatric centers included post-surgery behavioral health support from a dietitian, social worker, psychologist, and psychiatrist that

was received by the control group. This interprofessional team is not standard across the globe and may have attenuated the weight loss outcome difference between the tele-CBT and control groups.

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The Patella's Great Escape and the Quest for Stability

A Randomized Controlled Trial Comparing a Patella-Stabilizing, Motion-Restricting Knee Brace vs a Neoprene Nonhinged Knee Brace After a First-Time Traumatic Patellar Dislocation

Honkonen EE, Sillanpää PJ, Reito A, Mäenpää H, Mattila VM. A Randomized Controlled Trial Comparing a Patella-Stabilizing, Motion-Restricting Knee Brace Versus a Neoprene Nonhinged Knee Brace After a First-Time Traumatic Patellar Dislocation. *Am J Sports Med.* 2022;50(7):1867-1875. doi:10.1177/03635465221090644

KEY TAKEAWAY: For first-time traumatic patellar dislocation, a motion-restricting knee brace does not significantly lower re-dislocation rates compared to a neoprene brace. The motion-restricting brace may cause more quadricep atrophy, decreased knee mobility, and worse functional outcomes in the first six months.

STUDY DESIGN: Randomized, single-blind, controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to lack of patient blinding, small sample size, and high drop-out rate)

BRIEF BACKGROUND INFORMATION: Traumatic lateral patellar dislocations, common in young people, are often treated nonoperatively with various knee braces due to the lack of definitive guidelines. This research evaluates the efficacy of a motion-restricting, patella-stabilizing brace vs a non-hinged neoprene brace for initial treatment.

PATIENTS: Skeletally mature patients with a first-time traumatic patellar dislocation

INTERVENTION: Patella-stabilizing, motion-restricting brace

CONTROL: Neoprene non-hinged brace

PRIMARY OUTCOME: Rate of recurrent patellar dislocations

Secondary Outcome: Instability symptoms, time to re-dislocation, pain severity, physical activity level, symptoms and functionality, range of motion, quadricep atrophy, brace issues, knee stiffness and weakness at 12 months, and medial patellofemoral ligament (MPFL) reconstruction.

METHODS (BRIEF DESCRIPTION):

- Men and women (≥15 years old), with a first traumatic patellar dislocation were included.
    - Patients were excluded if they had significant ligament injuries, large osteochondral fractures, a history of patellar instability, or if patients refused to wear the prescribed brace.
- Patients were randomly assigned to one of the following four-week treatments, unblinded:
    - Patella-stabilizing brace limiting knee flexion to 0–30 degrees.
    - Non-hinged neoprene brace with unrestricted movement.
- Both participant groups could use crutches, bear weight as tolerated, and follow a specified physical therapy protocol.
- Two orthopedic surgeons with knee injury expertise managed patient follow-ups.
- Blinded orthopedic surgeons and radiologists performed MRI evaluations to ensure unbiased assessments.
- Follow-up appointments occurred at four weeks, three, six, 12, 24, and 36 months.
- The visual analog scale quantifies pain on a 100 mm line, with positions closer to one indicating more severe pain.
- Range of motion for the affected knee was measured at each visit using a goniometer.
- Quadriceps muscle atrophy was visually evaluated as present or absent.
- The Kujala Score evaluates patellofemoral symptoms and function from 0 (worst) to 100 (best), with higher scores indicating better knee function and fewer symptoms.
- The Tegner Activity Scale measures physical activity from 0 (unable to perform activities due to knee issues) to 10 (high-level competitive sports), with higher values indicating more intense activity.
- The frequency of patellar stabilization surgeries after the study shows the need for surgical intervention following initial conservative management.

INTERVENTION (# IN THE GROUP): 38

COMPARISON (# IN THE GROUP): 41

FOLLOW-UP PERIOD: 36 months

RESULTS:

Primary Outcome –

- There were no significant differences in the rates of recurrent patellar dislocation between the motion-restricting knee brace and the neoprene non-hinged brace (34% vs 38%, respectively; *p*=.79).

Secondary Outcome –

- The motion-restricting knee brace reduced ROM compared to the neoprene brace at four weeks (90° vs 115°, respectively; *P*<.001) and three months (125° vs 133°, respectively; *P*=.028), but not at six months.
- The motion-restricting knee brace increased quadriceps muscle atrophy compared to the neoprene brace at four weeks (75% vs 50%, respectively; *P*=.048).
- There were no differences in time to redislocation, subjective symptoms, functionality, activity levels, pain, weakness, stiffness, and surgical intervention rates between the motion-restricting knee brace and the neoprene brace.

LIMITATIONS:

- Lack of blinding affects participants' recovery perceptions and treatment adherence.
- Self-reported compliance with brace use and therapy introduces bias.
- A 19% dropout rate impacts outcomes, reflecting intervention efficacy or adverse effects.
- The Kujala score may not fully capture patellar dislocation impacts.
- The study had a small sample size. Only 32 participants per group were followed for three years.

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