GEMs of the Week

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What's in this week's issue?

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SPOTLIGHT: Addition of SGLT2i to Prevent Progression of Kidney Disease

Addition of SGLT2i to Prevent Progression of Kidney Disease

Impact of Diabetes on the Effects of Sodium Glucose Co-Transporter-2 Inhibitors on Kidney Outcomes: Collaborative Meta-Analysis of Large Placebo-Controlled Trials

Nuffield Department of Population Health Renal Studies Group; SGLT2 inhibitor Meta-Analysis Cardio-Renal Trialists' Consortium. Impact of diabetes on the effects of sodium glucose co-transporter-2 inhibitors on kidney outcomes: collaborative meta-analysis of large placebo-controlled trials. *Lancet*. 2022;400(10365):1788-1801. doi:10.1016/S0140-6736(22)02074-8

KEY TAKEAWAY: Sodium-glucose co-transporter-2 inhibitors (SGLT2i's) reduce the risk of kidney disease progression, the incidence of acute kidney injury (AKI), and risk of cardiovascular death in adults with and without type 2 diabetes mellitus (DM).

STUDY DESIGN: Systematic review and meta-analysis of 13 RCTs (N=90,413)

LEVEL OF EVIDENCE: STEP 1

BRIEF BACKGROUND INFORMATION: Chronic kidney disease (CKD) affects millions of people and can progress in severity leading to renal failure and death. Multiple studies have assessed the renal and cardiovascular protective effects of SGLT2 inhibitors in those with diabetes. However, fewer studies examine the effect of SGLT2 inhibitors on renal function in patients with CKD without underlying diabetes. Currently, few interventions exist to stop or slow the progression of CKD not due to diabetes. This study assesses the intervention of SGLT2 inhibitors in CKD in patients with and without DM as well as analyzes other outcomes such as AKI and cardiovascular death.

PATIENTS: Adults with and without diabetes

INTERVENTION: SGLT2i's

CONTROL: Placebo

PRIMARY OUTCOME: Kidney disease progression, AKI, cardiovascular death

METHODS (BRIEF DESCRIPTION):

- Included trials assessed SGLT2i's, were double-blinded and placebo-controlled, consisted of >500 participants, and were longer than six months.
- 74,804 participants had diabetes and 15,605 did not.
- CKD trials (sustained decrease in eGFR >50%) subgroups consisted of diabetic kidney disease or nephropathy, ischemic and hypertensive kidney disease, glomerular disease, and other/unknown kidney disease.
- Kidney disease progression was defined as a decrease in eGFR of >50% from randomization, a sustained low eGFR, end-stage kidney disease, or death from kidney disease.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Six months to four years

RESULTS:

Primary Outcome –

- SGLT2i's reduced kidney disease progression by 37% compared to placebo (relative risk [RR] 0.63; 95% CI, 0.58–0.69).
- In patients with diabetic kidney disease, SGLT2i's decreased kidney disease progression by 40% compared to placebo (RR 0.60; 95% CI, 0.53–0.69).
- In patients with non-diabetic causes of CKD, SGLT2i's reduced the risk of CKD compared to placebo (RR 0.69; 95% CI, 0.57–0.82).
- SGLT2i's reduced AKI incidence by 23% compared to placebo (RR 0.77; 95% CI, 0.70–0.84).
  - Patients with DM: RR 0.79 (95% CI, 0.72–0.88)
  - Patients without DM: RR 0.66 (95% CI, 0.54–0.81)
- SGLT2i's reduced the risk of cardiovascular death or hospitalization by 23% (RR 0.77; 95% CI, 0.74–0.81).
  - Patients with DM: RR 0.77 (95% CI, 0.73–0.81)
  - Patients without DM: RR 0.79 (95% CI, 0.72–0.87)

LIMITATIONS:

- Data such as the rate of change of eGFR was not available from all trials.
- Heterogeneity was not stated in the article.
- The number of participants taking SGLT2i's versus placebo was not clearly stated.

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private views of the authors and are not to be construed as official or as reflecting the views of the US Army Medical Department, the US Army at large, or the Department of Defense.

Can You Fall Back on Aspirin?

Daily Low-Dose Aspirin and Risk of Serious Falls and Fractures in Healthy Older People: A Substudy of the ASPREE Randomized Clinical Trial

Barker AL, Morello R, Thao LTP, Seeman E et al. Daily Low-Dose Aspirin and Risk of Serious Falls and Fractures in Healthy Older People: A Substudy of the ASPREE Randomized Clinical Trial. *JAMA Intern Med*. 2022 Dec 1;182(12):1289-1297. doi: 10.1001/jamainternmed.2022.5028.

KEY TAKEAWAY: Aspirin does not decrease the occurrence of fractures in older adults, and it may increase the risk of serious falls for patients who are underweight or with poor health status.

STUDY DESIGN: Multi-site, double-blind, secondary analysis of randomized trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Observational studies of aspirin support a theoretical association with lower odds of fracture. However, the effect of bone architecture has not been investigated. There are no randomized controlled trials that investigate the association between aspirin and the risk of fracture in human subjects.

PATIENTS: Older adults

INTERVENTION: Aspirin

CONTROL: Placebo

PRIMARY OUTCOME: Incidence of fracture

Secondary Outcome: Incidence of falls

METHODS (BRIEF DESCRIPTION):

- Analysis of participants ≥70 years old from Australia in a sub-study of the Aspirin in Reducing Events in the Elderly (ASPREE) trial who did not have preexisting cardio- or cerebrovascular disease.
- Exclusion criteria included dementia or cognitive impairment, substantial physical disability, or known high risk of bleeding.
- Participants had a median age of 74 years, and an average baseline BMI of 27, 55% were women, 3.4% were smokers, and 75% had hypertension.
- For 4 weeks, the treatment group received run-in aspirin 100 mg oral daily followed by daily use during the trial.
    - Comparison group received a placebo run-in for four weeks then continued daily placebo.
- Incidence of fractures and falls measured via annual visits and six-month telephone follow-ups.
    - Incidence of fractures was also measured from a review of emergency and hospital visits.
    - Fractures included hip, vertebral, and other traumatic and pathologic fractures confirmed by imaging.
    - Falls were defined as an "event which results in a person coming to rest inadvertently on the ground or floor or other lower level".

INTERVENTION (# IN THE GROUP): 8,322

COMPARISON (# IN THE GROUP): 8,381

FOLLOW-UP PERIOD: Median 4.6 years

RESULTS:

Primary Outcome –

- The incidence of first and recurrent fractures were similar between the two groups.

Secondary Outcome –

- The incidence of falls was higher in the aspirin group as compared to the control group (incidence rate ratio 1.2; 95% CI, 1.03–1.3).
- The incidence of serious falls in underweight patients was higher in the aspirin group as compared to placebo (hazard ratio [HR] 1.8; 95% CI, 1.03–3.2), a difference that may not be clinically meaningful.
- The incidence of serious falls in patients with fair to poor health was higher in the aspirin group as compared to placebo. (HR 1.52; 95% CI, 1.02–2.3), a difference that may not be clinically meaningful.

LIMITATIONS:

- The study population was older and relatively healthy which may not be applicable to practice populations.
- Typical dose of aspirin in the United States would be 81mg but 100mg was included in this study.
- The study duration may not have been long enough to detect meaningful changes.
- The study did not measure bone density or quality.

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Non-Suicidal Self Injury Among LGBTQ+ Minorities

Prevalence and Correlates of Non-Suicidal Self-Injury Among Lesbian, Gay, Bisexual, and Transgender Individuals: A Systematic Review and Meta-Analysis

Liu RT, Sheehan AE, Walsh RFL, Sanzari CM, Cheek SM, Hernandez EM. Prevalence and correlates of non-suicidal self-injury among lesbian, gay, bisexual, and transgender individuals: A systematic review and meta-analysis. *Clin Psychol Rev*. 2019;74:101783. doi:10.1016/j.cpr.2019.101783

KEY TAKEAWAY: Non-suicidal self-harm is prevalent and disparate amongst LGBTQ communities and gender minorities.

STUDY DESIGN: Meta-analysis of 51 mostly cohort studies (N=344,607)

LEVEL OF EVIDENCE: STEP 3 (downgraded due to bias and study heterogeneity)

BRIEF BACKGROUND INFORMATION: The prevalence and importance of non-suicidal self-injury (NSSI), defined as deliberate harm to one's own body tissue without suicidal intent, has been increasingly recognized. There is a growing body of evidence to suggest that NSSI more strongly predicts suicide attempts than a prior history of suicide attempts. Although sexual and gender minority (SGM) populations are known to have elevated risk for NSSI, reliable estimates on NSSI prevalence within the SGM community are lacking, as is data on why this population is at greater risk of NSSI.

PATIENTS: Community-dwelling and at-risk adults and adolescents

INTERVENTION: Sexual and/or gender minority status

CONTROL: Cisgender and/or heterosexual status

PRIMARY OUTCOME: Lifetime and previous year prevalence of NSSI

METHODS (BRIEF DESCRIPTION):

- A systematic literature search was completed in PsycINFO, MEDLINE, and Embase from inception to July 2019.
- Inclusion criteria included sexual and gender minorities and evidence of NSSI evaluation.
- Non-quantitative studies and studies that did not examine NSSI in the context of SGM status were excluded.
- Most included studies were community-based, with a mean participant age ranging from 15–52 years old.
- Utilizing random effects models, NSSI prevalence rates (lifetime and past year) were evaluated in conjunction with sexual or gender minority status.
- Weighted lifetime and post-year prevalence rates for NSSI were calculated for all SGM groups as well as heterosexual and/or cisgender individuals.

INTERVENTION (# IN THE GROUP): Not available

COMPARISON (# IN THE GROUP): Not available

FOLLOW-UP PERIOD: Not available

RESULTS:

Primary Outcome –

- SGM had a higher prevalence of NSSI than their heterosexual and/or cisgender counterparts.
  - SGM individuals: 30% (95% CI, 24–36; I^2=94%)
  - Gender minorities: 47% (95% CI, 39–54; I^2=95%)
  - Heterosexual and/or cisgender peers: 15% (95% CI, 11–19; I^2=98%)
- SGM had a higher prevalence of NSSI than their heterosexual and/or cisgender counterparts in the past year.
  - SGM individuals: 25% (95% CI, 19–32; I^2=99%)
  - Gender minority individual: 47% (95% CI, 36–58; I^2=97%)
  - Heterosexual and/or cisgender peers: 11% (95% CI, 9.1–12; I^2=99%)
- Bisexual and transgender individuals were at the greatest risk for NSSI compared to heterosexual and cisgender peers.
  - Bisexual individuals: Cohen's d (d) 0.92 (95% CI, 0.75–11)
  - Transgender individuals: d=0.91 (95% CI, 0.72–1.1)
- Age and White race were negatively associated with the lifetime prevalence of NSSI (d –0.52; 95% CI, –0.08 to –0.24 and d –0.15; 95% CI, –0.24 to –0.07, respectively).
- NSSI prevalence increased with female gender (d 0.41; 95% CI, 0.33–0.49) and low socioeconomic status (d 0.37; 95% CI, 0.04–0.7).

LIMITATIONS:

- High heterogeneity of studies limited data interpretation.
- Publication bias was likely as authors did not search unpublished literature.
- Only two studies included in the systematic review employed a longitudinal design, making assessments of lifetime NSSI risk less reliable and limiting assessment of NSSI risk evolution over time in this population.
- Causation cannot be demonstrated from by this population-based study.

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A Chance to Touch is a Chance to Heal: Using OMM in Athletes with Acute Concussion Symptoms

Effectiveness of Osteopathic Manipulative Medicine vs Concussion Education in Treating Student Athletes with Acute Concussion Symptoms

Yao SC, Zwibel H, Angelo N, Leder A, Mancini J. Effectiveness of Osteopathic Manipulative Medicine vs Concussion Education in Treating Student Athletes with Acute Concussion Symptoms [published online ahead of print, 2020 Aug 7]. *J Am Osteopath Assoc*. 2020;10.7556/jaoa.2020.099. doi:10.7556/jaoa.2020.099

KEY TAKEAWAY: Osteopathic manipulative medicine (OMM) techniques may decrease the number and severity of concussion symptoms in some young adults shortly after a concussion incident.

STUDY DESIGN: Randomized, un-blinded, controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to small sample size and limited generalizability)

BRIEF BACKGROUND INFORMATION: Concussions are a relatively common injury among student athletes. Aside from removal from the game, rest, and medications for symptom control, there are few therapies available for concussion treatment.

PATIENTS: Student athletes seeking concussion treatment/evaluation

INTERVENTION: OMM treatment

CONTROL: Educational intervention

PRIMARY OUTCOME: Number and severity of concussion symptoms

METHODS (BRIEF DESCRIPTION):

- Student athletes 18–27 years old within 12 days of concussion onset without life-threatening or emergent conditions were included.
- Patients were randomly placed into one of two groups and were not blinded.
  - OMM treatment group:
    - Structural exam and assessment of somatic dysfunctions including cranial, spine, thoracic cage, pelvis, and extremities.
    - OMM techniques aimed at improving circulation including thoracic inlet release, rib raising, occipitoatlantal decompression, V spread, balance membranous tension for cranial strain patterns, cranial lifts, compression of fourth ventricle, balanced ligamentous tension, muscle energy, facilitated positional release, articulatory techniques, high-velocity low-amplitude, and counterstrain.
  - Education group:
    - CDC's topics including "Facts About Concussions and Brain Injury: Where to Get Help" and "Heads Up Concussion: A Fact Sheet for Teachers, Counselors, and School Professionals"
    - Concussion discussion points including definition, recognition/diagnosis, risk factors, predictors, recovery/management, and expectations.
- Interventions were performed by board-certified neuromusculoskeletal medicine/OMM physicians and were not blinded.
- Concussion symptom number and severity were self-reported by participants using the symptom evaluation portion of the SCAT5.
  - 22 symptoms (0=no symptoms; 22=all symptoms)
  - Six degrees of severity for each possible symptom (1=mild; 6=severe; max total score of 132)

INTERVENTION (# IN THE GROUP): 16

COMPARISON (# IN THE GROUP): 14

FOLLOW-UP PERIOD: 48 to 72 hours after intervention

RESULTS:

Primary Outcome –

- OMM treatment reduced total symptoms more than concussion education at 48 to 72 hours post-intervention compared to pre-intervention (–3.9 vs –0.67, respectively; *P*=.002).
- OMM treatment reduced symptom severity more than concussion education at 48 to 72 hours post-intervention compared to pre-intervention (–17 to –3.6, respectively; *P*=.001).

LIMITATIONS:

- Given the small sample size, the results may not be adequately representing the identified population.
- The narrow study population limits the generalizability of the results.

- Due to the large variety of OMM techniques used, the effectiveness of individual techniques on concussion symptoms remains unknown.
- As this study did not look at each symptom individually but rather only the sum number and severity of all symptoms, more research is needed to identify the specific symptoms most affected by OMM.

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Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-Induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study

Gazit S, Shlezinger R, Perez G, et al. Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Naturally Acquired Immunity versus Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: A Retrospective Cohort Study. *Clin Infect Dis*. 2022;75(1):e545-e551. doi:10.1093/cid/ciac262

KEY TAKEAWAY: Natural immunity confers longer-lasting and stronger protection against infection from the COVID-19 Delta variant when compared to the BioNTech Pfizer BNT162b2 vaccine.

STUDY DESIGN: Retrospective observational cohort study

LEVEL OF EVIDENCE: STEP 3

BRIEF BACKGROUND INFORMATION: The paucity of data on the novel SARS-CoV-2 virus and rapid reaction to vaccinate large numbers of people is leading to confusion, conflicting evidence, suppression of evidence, and distrust in institutions. Therefore, there is high interest in comparing natural and vaccine-induced immunity.

PATIENTS: COVID-19 naïve patients

INTERVENTION: COVID vaccine

CONTROL: Naturally acquired immunity from SARS-CoV-2 viral infection

PRIMARY OUTCOME: SARS-CoV-2 infection, symptomatic disease, SARS-CoV-2 infection-related hospitalization, SARS-CoV-2 infection-related death

METHODS (BRIEF DESCRIPTION):

- This retrospective observational cohort study compared SARS-CoV-2 infection rates following a nationwide vaccination campaign/mandate in Israel almost exclusively using the BioNTech Pfizer BNT162b2 vaccine.
- The outcomes were compared following cohort models where patients were matched for age and sex.
    - Model 1: Previous infection vs. vaccinated individuals with matching for the time of the first event
    - Model 2: Previous infection vs. vaccinated individuals without matching for the time of the first event
- The first event (preliminary exposure) was either the time of administration of the second dose of vaccine or the time of documented infection with SARS-CoV-2 (positive PCR test).
- The first group was SARS-CoV-2-naïve individuals who received a two-dose regimen of the BioNTech/Pfizer mRNA BNT162b2 vaccine.
- The second group was people with previous infection from SARS-CoV-2 who have not been vaccinated with the Pfizer mRNA BNT162b2 vaccine.
- Three multivariate logistic regression models were applied and the four outcomes were evaluated.

INTERVENTION (# IN THE GROUP):

- Model 1: 16,215
- Model 2: 46,035

COMPARISON (# IN THE GROUP):

- Model 1: 16,215
- Model 2: 46,035

FOLLOW-UP PERIOD: 2.5 months

RESULTS:

Model 1 –

- Increased risk for breakthrough infection (infection after vaccination), as opposed to reinfection (infection after prior infection), remained significant with OR 14 (95% CI, 8.5–23).

Model 2 –

- Increased risk for breakthrough infection (infection after vaccination) as opposed to reinfection (infection after prior infection) remained significant with an OR of 6.3 (95% CI, 5.1–7.8).

LIMITATIONS:

- This study only evaluated one specific variant with a homogenous patient demographic.
- Findings may not be generalizable to other SARS-CoV-2 variants.

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Can Osteopathic Interventions Be Delivered Through a Telehealth Format?

Osteopathic Interventions via Telehealth in a Pediatric Population: A Retrospective Case Series

Kramer JL, De Asis K. Osteopathic interventions via telehealth in a pediatric population: a retrospective case series. *J Osteopath Med*. 2021;121(11):857-861. Published 2021 Aug 19. doi:10.1515/jom-2021-0124

KEY TAKEAWAY: Osteopathic interventions given via telehealth may decrease pain in pediatric populations while providing safe distancing measures during the COVID-19 pandemic.

STUDY DESIGN: Retrospective case series

LEVEL OF EVIDENCE: STEP 4

BRIEF BACKGROUND INFORMATION: The Coronavirus (COVID-19) pandemic dramatically changed how osteopathic manipulative treatment could be delivered to patients. It is generally provided by a trained osteopathic physician in an in-person setting, often with prolonged contact between the physician and the patient. However, due to limitations on in-person visits and the rise of telehealth visits, the idea of delivering this therapy at home by family members/caretakers may prove to be beneficial.

PATIENTS: Patients six months to 19 years old

INTERVENTION: Osteopathic techniques

CONTROL: Baseline and pain from patient's most recent in-person visit

PRIMARY OUTCOME: Pain

METHODS (BRIEF DESCRIPTION):

- Patients six months to 19 years old from an osteopathic pediatrician's practice were followed for 54 visits (n=18).
- The patient's parent or caretaker received instructions on set-up and positioning before their telehealth visit.
- Parents/caretakers were given a voluntary survey to complete after.
- Sessions were 30 minutes in length where an osteopathic pediatrician gave verbal directions and when possible, would employ students to demonstrate techniques.
    - Osteopathic interventions included inhibition, soft tissue, and counterstrain.
- Patients three years old and older used the Wong-Baker FACES to rate their pain prior to the intervention and after the intervention.
- Demographics, anatomical locations treated, techniques used, and pain scales were recorded.
- Paired sample t-tests and p-value were used to determine significance.
- Telehealth pain scores were also compared with the last in-person pain scores for the same subset of patients.

INTERVENTION (# IN THE GROUP): 18

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW-UP PERIOD: Not applicable

RESULTS:

Primary Outcome –

- Telehealth osteopathic treatment decreased pain compared to pre-treatment (2.6 vs 6.8, respectively; $P<.01$).
- There was no difference between post-treatment pain with telehealth compared to post-treatment pain from their last in-person session (4.2 vs 3.3, respectively; $P=.17$).
- Four patients (9%) had pain after treatment which resolved later the same day.
- Four out of the five parents/caretakers reported being uncomfortable performing these techniques prior to the telehealth visit. After the telehealth visit, all five responded to feeling comfortable.

LIMITATIONS:

- Parents/caregivers did not receive feedback regarding position and force as they likely would have in an in-person setting.
- The study had a small sample size. Data obtained was further limited as only those three years old and older were able to use the Wong-Baker FACES to rate their pain before and after treatment.
- This was also a retrospective study, limiting how much data could be analyzed.

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Universal Stressors: Familiar Correlates of Anxiety in Saudi Arabia

A Cross-Sectional Study on Generalized Anxiety Disorder and Its Socio-Demographic Correlates Among the General Population in Saudi Arabia

Aljurbua FI, Selaihem A, Alomari NA, Alrashoud AM. A cross-sectional study on generalized anxiety disorder and its socio-demographic correlates among the general population in Saudi Arabia. *J Family Med Prim Care*. 2021;10(10):3644-3649. doi:10.4103/jfmpc.jfmpc_847_21

KEY TAKEAWAY: The prevalence of anxiety in Saudi Arabia was highest among people 18–24 years old, inhabitants of western Saudi Arabia, students, and patients with chronic medical conditions (colon conditions, heart conditions, thyroid disorders, SLE, and depression).

STUDY DESIGN: Cross-sectional observational study

LEVEL OF EVIDENCE: STEP 4

BRIEF BACKGROUND INFORMATION: Little attention has been given to mental health disorders in Saudi Arabia, despite prior studies noting increased prevalence in pharmacy students and younger populations. This study sampled a larger population to estimate the prevalence of Generalized Anxiety Disorder and co-morbidities.

PATIENTS: Adults not currently undergoing treatment for an anxiety disorder in Saudi Arabia

INTERVENTION: Sociodemographic variables

CONTROL: Not applicable

PRIMARY OUTCOME: Anxiety

METHODS (BRIEF DESCRIPTION):

- 338 adults in Saudi Arabia were screened with an Arabic GAD-7 and a demographic questionnaire, delivered electronically via email and social media platforms.
- Scores on the GAD-7 were categorized into mild, moderate, and severe anxiety.
- Individuals under the age of 18 or already undergoing treatment for generalized anxiety disorder were excluded from the study.

INTERVENTION (# IN THE GROUP): 338

COMPARISON (# IN THE GROUP): Not applicable

FOLLOW-UP PERIOD: Not applicable

RESULTS:

Primary Outcome –

- Anxiety was highest in the age group 18–24 and lowest in the age group 45–54 (comparison numerical values not available; p=0.005).
- Anxiety was highest in Western regions and lowest in Eastern regions (comparison numerical values not available; p=0.015).
- Anxiety was highest in students and lowest among the employed (comparison numerical values not available; p=0.001).
- Comorbid medical conditions with the greatest anxiety were colon conditions, Lupus erythematosus, heart conditions, and thyroid conditions (comparison numerical values not available; p=0.001).
- Among correlated psychiatric conditions, extreme anxiety was the most prevalent in respondents with depression and bipolar disorder (comparison numerical values not available; p=0.00).
- No significant differences in anxiety were correlated to gender, BMI, or smoking status.

LIMITATIONS:

- Screening over the internet skewed to younger respondents.
- The GAD-7 is a screening tool rather than a diagnostic tool, so the correlates may be overestimated.

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