GEMs
GOOD EVIDENCE MATTERS

GEMs of the Week

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What's in this week's issue?

Week of October 24 - 28, 2022

SPOTLIGHT: Help Your Diabetic Patients Improve Quality of Their Oral Health with Simple Interventions

- Kids Hit in the Head May Lead to Dread: Concussion and Mental Health in the Pediatric Population
- Can Semaglutide Match the Efficacy of Bariatric Surgery for Sustained Weight Loss?
- Interactive Digital Health-Based Self-Management Program to Reduce Hospitalizations

Help Your Diabetic Patients Improve Quality of Their Oral Health with Simple Interventions

Implementation of an Oral Care Protocol for Primary Diabetes Care: A Pilot Cluster-Randomized Controlled Trial

Verhulst MJL, Teeuw WJ, Gerdes VEA, Loos BG. Implementation of an Oral Care Protocol for Primary Diabetes Care: A Pilot Cluster-Randomized Controlled Trial. *Ann Fam Med*. 2021;19(3):197-206. doi:10.1370/afm.2645

KEY TAKEAWAY: Incorporating simple oral health interventions into their routine primary care visits significantly improves oral health related quality of life among patients with type 2 diabetes.

STUDY DESIGN: Cluster-randomized controlled trial

LEVEL OF EVIDENCE: STEP 3 (downgraded due to lack of randomized recruitment)

BRIEF BACKGROUND INFORMATION: Diabetes can lead to chronic complications including oral diseases and complaints. Given that medical and dental care providers often work separately, diabetic patients do not receive the comprehensive oral care that they need. The implementation of an oral health care protocol at the level of the General Practitioner (GP) office has been recommended to fill this gap.

PATIENTS: Dutch adults with type 2 diabetes receiving primary care

INTERVENTION: Oral health education, encouragement to visit dentists, dentist visit referral, and oral hygiene products

CONTROL: Standard primary care management of diabetes care

PRIMARY OUTCOME: Oral health-related Quality of Life (QoL)

Secondary Outcomes: Oral health complaints, general health related QoL

METHODS (BRIEF DESCRIPTION):

- 24 GP offices in the Amsterdam city and surrounding area were randomly assigned to either intervention group or control group.
- Intervention group received oral health education at each visit, encouragement to visit dentists, dentist visit referral, and oral hygiene products, whereas control group did not receive these interventions.
- The primary outcome of oral health related QoL was measured using Dutch version of the short-form Oral Health Impact Profile (OHIP-NL14). Total scores ranged from 0 to 56, with lower scores representing better oral health.
- Secondary outcomes were assessed by the patients' reported oral health complaints (i.e., mouth pain, dry mouth, and bad breath), and by their general health QoL using validated Dutch 36-item Short Form Health Survey (SF-36). Scores ranged from 0 to 100, with higher scores representing better general health.
- χ^2 was used to analyze differences in improvement of oral health related QoL between the intervention and control groups.
- Intra-cluster correlation coefficient ICCs was computed to adjust the effect of clustering within GP offices.

INTERVENTION (# IN THE GROUP): 352

COMPARISON (# IN THE GROUP): 412

FOLLOW UP PERIOD: One year

RESULTS:

Primary Outcome –

- The intervention including oral health education and encouragement to visit dentists significantly improved oral health related QoL when compared with the control group (35% vs 26%, χ^2=4.0; *P*=.046).

Secondary Outcomes –

- No significant differences in both resolution of oral health complaints and general health related QoL between the two groups were found.

LIMITATIONS:

- GP offices did not recruit patients randomly, possibly avoiding recruitment of complex patients who required more visits.
- Hawthorne effect may have played a role at both provider and patient levels.
- Patients were recruited from GP clinics in the Amsterdam metropolitan area where there already may be a high baseline quality of oral health due to a high density of dental clinics in the area.
- Only patients from GP offices with follow-up of ≥60% were included in the analysis as 221 (29%) patients were lost to follow-up.

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Kids Hit in the Head May Lead to Dread: Concussion and Mental Health in the Pediatric Population

Mental Health After Paediatric Concussion: A Systematic Review and Meta-Analysis

Gornall A, Takagi M, Morawakage T, Liu X, Anderson V. Mental health after paediatric concussion: a systematic review and meta-analysis. *Br J Sports Med*. 2021;55(18):1048-1058. doi:10.1136/bjsports-2020-103548

KEY TAKEAWAY: Pediatric concussions are associated with an increased risk of short-term and long-term internalizing and externalizing mental health difficulties.

STUDY DESIGN: Meta-analysis of 40 articles, including prospective longitudinal studies, cohort studies, cross-sectional studies, case-control studies, inception cohort studies and qualitative studies (N=89,114)

LEVEL OF EVIDENCE: STEP 1

BRIEF BACKGROUND INFORMATION: Concussions are a common injury suffered in the pediatric population. Studies have shown that children have a delayed recovery from concussion symptoms compared to adults. Thus, the pediatric population may be more susceptible to post-concussive mental health difficulties including internalizing symptoms (e.g., anxiety, depression, withdrawal) and externalizing symptoms (e.g., conduct disorder, attention deficit/hyperactivity [ADHD]). Although the evidence has been inconclusive and conflicting thus far, this review aims to clarify those uncertainties.

PATIENTS: Children

INTERVENTION: Concussions

CONTROL: Orthopedic injury or TDC (Typically developing controls)

PRIMARY OUTCOME: Internalizing and external mental health difficulties

METHODS (BRIEF DESCRIPTION):

- A comprehensive review of seven databases (Medline, Embase, PsycINFO, CINAHL, SportDiscus, Scopus, PubMed) was conducted to select studies published from 1980 to June 2020.
- Individuals' mental health outcomes following concussion at 0–18 years old with a weighted mean age of 12 years old were observed.
- Children with concussions were compared with controls such as children with orthopedic injury or TDC.
- Concussion was defined according to the Berlin concussion in sports group (CISG) criteria and required diagnosis by a health professional or by a clinically validated measure.
- Outcomes were measured as externalizing (conduct problems, aggression, ADHD), internalizing (anxiety, depression, PTSD, withdrawal), and total mental health difficulties.
- Outcomes were further analyzed to the time mental health difficulties occurred post-concussion:
    - Acute: <3 months
    - Persisting: 3–13 months
    - Chronic: >12 months
- The effect size was measured using *Hedges g* which was adjusted for sample size to provide the standard mean difference [SMD] between the concussion group and control group. Effect sizes were interpreted as:
    - Small (<0.32)
    - Moderate (0.33–0.55)
    - Large (>0.59)
- Heterogeneity for meta-analysis was quantified using I^2 statistic, which describes the percentage of variation in outcomes between the studies. Heterogeneity was interpreted as:
    - Low/unimportant (0-30%)
    - Moderate (30-50%)
    - Substantial (50-80%)
    - Considerable (80-100%)

INTERVENTION (# IN THE GROUP): 6,819

COMPARISON (# IN THE GROUP): 56,271

FOLLOW UP PERIOD: Ranged from admission to 20 years post-injury

RESULTS:

- Children with concussions had a significant risk for acute, persisting, and chronic internalizing mental health difficulties, compared with controls.
    - Acute (4 studies, n=326; SMD 0.45; 95% CI, 0.2–0.7; I^2=0%; moderate effect size)
    - Persisting (12 studies, n=1,407; SMD 0.42; 95% CI, 0.20–0.63; I^2=51%; moderate effect size)
    - Chronic (14 studies, n=1,172; SMD 0.41; 95% CI, 0.10–0.72; I^2=49%; moderate effect size)
- Similarly, children with concussions had a significant risk for acute, persisting, and chronic externalizing

mental health difficulties, compared with controls.

- Acute (3 studies, n=290; SMD=0.37; 95% CI, 0.09–0.65; I^2=0%; moderate effect size)
- Persisting (10 studies, n=1,296; SMD=0.46; 95% CI, 0.25–0.66; I^2=67%; moderate effect size)
- Chronic (12 studies, n=5,151; SMD=0.25; 95% CI, 0.09–0.41; I^2=91%; small effect size)

LIMITATIONS:

- This review excluded non-English language articles and unpublished articles lending to publication and language bias.
- Most studies did not separate data by sex and age groups.
- Pre-concussion mental health in patients was reported in less than half of the studies included.

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Can Semaglutide Match the Efficacy of Bariatric Surgery for Sustained Weight Loss?

Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults with Overweight or Obesity: The STEP 4 Randomized Clinical Trial

Rubino D, Abrahamsson N, Davies M, et al. Effect of Continued Weekly Subcutaneous Semaglutide vs Placebo on Weight Loss Maintenance in Adults with Overweight or Obesity: The STEP 4 Randomized Clinical Trial. *JAMA*. 2021;325(14):1414-1425. doi:10.1001/jama.2021.3224

KEY TAKEAWAY: Semaglutide helps overweight and obese patients to continue to lose weight for one year, and nearly matches the efficacy of bariatric surgery.

STUDY DESIGN: Multisite, double-blind, randomized trial with withdrawal design

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: Obesity is a chronic disease with frequent relapsing for patients, and sustained weight loss is necessary for improved health. Currently, approved weight loss drugs have only moderate efficacy, so there is a need for weight loss medications that can provide patients with significant weight loss that can be maintained long-term.

PATIENTS: Adults with BMI >30, or >27 with one weight-related comorbidity

INTERVENTION: Semaglutide

CONTROL: Placebo

PRIMARY OUTCOME: Percent change in body weight

Secondary Outcomes: Waist circumference, BMI, systolic blood pressure, physical functioning

METHODS (BRIEF DESCRIPTION):

- Participants were adults without diabetes who have attempted weight loss unsuccessfully in the past, with a BMI of at least 30, or at least 27 with at least one weight-related comorbidity.
- After participants completed 20 weeks of semaglutide (starting at 0.25 mg, increased every 4 weeks to maintenance dose 2.4 mg), they were randomized in a 2:1 ratio to either continue semaglutide 2.4 mg or to receive placebo injection weekly from week 20 to 68.
- All participants received lifestyle intervention from week 0 to week 68, including monthly counseling, reduced-calorie diet, and increased physical activity.
- The primary outcome was percent change in body weight from week 20 to 68.
- Secondary outcomes were changes in waist circumference, systolic blood pressure, and physical functioning from week 20 to 68.
- Physical functioning was measured using SF-36, a generic patient-reported outcome questionnaire. The range of lowest to highest scores for the physical functioning domain is 19.03 to 57.60. An increase in score represents an improvement in health status.

INTERVENTION (# IN THE GROUP): 535

COMPARISON (# IN THE GROUP): 268

FOLLOW UP PERIOD: 68 weeks

RESULTS:

Primary Outcomes –

- Semaglutide reduced body weight more than placebo (mean difference –15%; 95% CI, –16 to –14%).
- Semaglutide reduced body weight by 17% over 68 weeks total; those who switched to placebo at week 20 regained weight.
- 40% of participants who took semaglutide for 68 weeks lost 20% or more of their initial body weight.

Secondary Outcomes –

- Semaglutide reduced waist circumference from week 20 to week 68 of treatment (mean difference –10 cm; 95% CI, –11 to –8.5 cm).
- Semaglutide decreased body mass index from week 20 to week 68 of treatment (mean difference –5 kg/m^2; 95% CI, –5 to –4 kg/m^2).
- Semaglutide decreased systolic blood pressure, while placebo significantly increased it (mean difference in decrease by semaglutide –4 mmHg; 95% CI, –6 to –2.0 mmHg).
- Semaglutide significantly improved physical functioning scores compared to placebo (mean difference 2.5; 95% CI, 1.6 to 3.3).

LIMITATIONS:

- Patients were mostly white (84%) and female (79%).
- The study population may have been more tolerant of semaglutide and more likely to be medically compliant compared to the general population as the run-in period was strict in the dose titration schedule.
- There was no assessment of adherence to lifestyle interventions.
- The withdrawal design can result in selection bias, resulting in overestimation of weight loss.
- The study was industry-funded.

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Interactive Digital Health-Based Self-Management Program to Reduce Hospitalizations

Assessment of an Interactive Digital Health-Based Self-Management Program to Reduce Hospitalizations Among Patients with Multiple Chronic Diseases

Lear SA, Norena M, Banner D, et al. Assessment of an Interactive Digital Health-Based Self-management Program to Reduce Hospitalizations Among Patients with Multiple Chronic Diseases: A Randomized Clinical Trial. *JAMA Netw Open*. 2021;4(12):e2140591. Published 2021 Dec 1. doi:10.1001/jamanetworkopen.2021.40591

KEY TAKEAWAY: A chronic disease management (CDM) program involving self-management of symptoms in patients with multiple chronic diseases does not reduce all cause hospitalizations when compared to the traditional ambulatory care model.

STUDY DESIGN: Single blind randomized controlled trial

LEVEL OF EVIDENCE: STEP 2

BRIEF BACKGROUND INFORMATION: For patients with multiple chronic diseases, self-management of symptoms and therapeutics is key in preventing unnecessary hospitalizations and avoidable disease complications, especially when patients live in under resourced rural or urban areas. For many patients, it is easy to fall through the cracks in the current ambulatory health care model and be lost to follow up. Digital health-based self-assessments are a potentially effective tool to reduce these knowledge disparities and give patients more information and autonomy in the management of their own health care.

PATIENTS: Adults with at least two chronic conditions

INTERVENTION: Interactive digital chronic disease management (CDM) tool.

CONTROL: Usual ambulatory care

PRIMARY OUTCOME: All-cause hospitalizations

Secondary Outcomes: One hospitalization, time to first hospitalization, length of stay

METHODS (BRIEF DESCRIPTION):

- Patients were at least 19 years old, living in rural or small urban areas in British Columbia, Canada, with at least two chronic conditions (CKD, COPD, DM, CHF, Ischemic heart disease).
- Patients were randomly assigned to the intervention arm, an interactive CDM tool, or traditional ambulatory care follow up.
- Research coordinators were blinded to group assignments; however, the patients and their clinical care team were aware of their designation.
- The internet CDM program was designed by an advisory committee of various health care professionals. Patients were in weekly contact with their clinical care team, whereas quantitative data from the control arm of the experiment was obtained at the end of the first and second years through a telephone interview and then later confirmed by hospital records.
- The primary outcome measured was all cause hospitalizations.
- Secondary outcomes were hospital length of stay, risk of time to first hospitalization, and at least one hospitalization event during the length of the study.

INTERVENTION (# IN THE GROUP): 113

COMPARISON (# IN THE GROUP): 117

FOLLOW UP PERIOD: Two years

RESULTS:

Primary Outcome –

- CDM did not reduce all-cause hospitalizations compared to the control group (RR 0.68; 95% CI, 0.43–1.1).

Secondary Outcomes –

- Fewer participants in the CDM group experienced at least one hospitalization compared to the control group (odds ratio [OR]0.55; 95% CI, 0.31–0.96).
- CDM lowered the risk of time to first hospitalization compared to the control group (HR0.62; 95% CI, 0.39–0.97).
- CDM did not reduce average hospital length of stay compared to the control group (RR0.52; 95% CI, 0.24–1.1).

LIMITATIONS:

- This study only involved small urban and rural geographic locations.
- Over 70% of PCP's contacted to enroll their patients did not have an EMR system; therefore, they were less inclined to enroll patients manually.

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