SAFE HEALTH REPORT

Scientific Data … Informed Choice … Actionable

April 2024 *Official Newsletter for MrGineaPig* *Issue 21*

Please repeat once before proceeding: He Can Do It, She Can Do It, I Can Do It!

Inside …

Food As Medicine Trial

Your Ticket to Exuberant Health for the Next 5 Years

Effect of an Intensive Food-as-Medicine Program on A1C and Healthcare Use. This summary examines the findings of a randomized controlled trial (RCT) by Doyle et al. investigating the effectiveness of an intensive food-as-medicine program for individuals with type 2 diabetes. The program aimed to improve glycemic control and healthcare utilization compared to usual care.

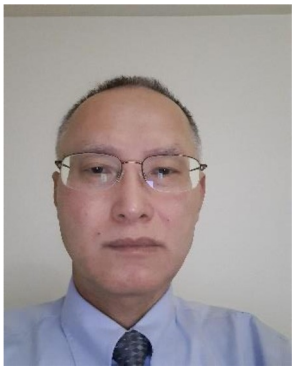
Recruitment:

Researchers conducted a large-scale screening process, evaluating over 3,700 patients for eligibility in the study.

From this pool, 1,000 patients were approached to participate in the program.

Participation:

Out of the 1,000 patients invited, 500 consented to participate in the study. Of those who consented, 349 patients ultimately completed the entire one-year program.



Ike Kim
Editor

Baseline Data:

The average participant age was 54.6 years old.

Glycemic control, measured by HbA1c, was relatively poor at baseline, with an average of 10.3%.

The participant demographics were somewhat diverse, with slightly more than half being female, 9% Hispanic, and 7% Black.

Study Design

The researchers conducted a stratified RCT with a waitlist control design. Participants with a diagnosis of type 2 diabetes (A1c ≥ 8%) and self-reported food insecurity were recruited from two communities (one urban, one rural). After stratification by baseline A1c, participants were randomly assigned to either:

Intervention Group: Received the intensive food-as-medicine program immediately.

Control Group: Placed on a waitlist for the program, receiving usual care for six months before receiving the intervention.

Both groups were followed for a total of one year.

Program Engagement:

The food-as-medicine intervention group had significantly more interaction with the healthcare system compared to the control group.

This was evident in the number of clinic visits (13 visits for the intervention group vs. 1 visit for the control group) over the 6-month program period.

Similarly, the intervention group had more consultations with dietitians (2.7 visits on average) compared to the control group (0.6 visits on average).

Additionally, patients in the intervention group reported feeling they were adopting healthier eating habits throughout the program.

Intervention Details

The intensive food-as-medicine program consisted of several components:

Meal Delivery: Participants received weekly delivery of ingredients for 10 healthy meals designed to meet individual dietary needs determined by a dietitian. These meals focused on whole grains, fruits, vegetables, lean proteins, and low-fat dairy products.

Nutritional Education: Participants received ongoing education and support from registered dietitians to guide healthy food choices and meal preparation.

Medical Management: The program included regular consultations with nurses and access to diabetes education.

Primary Outcome

The primary outcome measure was the change in glycemic control as assessed by HbA1c levels at 12 months.

Secondary Outcomes

Secondary outcomes included:

Changes in blood pressure, cholesterol, triglycerides, and fasting glucose levels.

Weight changes at 6 and 12 months.

Healthcare utilization (hospital admissions, clinic visits, medication use)

Results

Primary Outcome:

The study did not find a statistically significant difference in HbA1c levels between the intervention and control groups at 12 months. The mean A1c reduction was 1.5 percentage points in the intervention group and 1.3 percentage points in the control group (between-group adjusted mean difference -0.10, P=0.57).

Secondary Outcomes:

Blood Pressure and Lipids: No significant differences between the groups were observed in blood pressure, cholesterol, or triglycerides at 6 or 12 months.

Weight: Surprisingly, the intervention group gained an average of 1.95 kg (4.3 lbs) more weight compared to the control group at 6 months (adjusted mean difference 1.95 kg, P=0.04).

Healthcare Utilization: The intervention group had significantly more interactions with the clinic (13 vs. 1) and dietitians (2.7 vs. 0.6) compared to the control group over the 6-month study period. Additionally, the

intervention group reported higher self-rated scores for healthy eating. There were no significant differences in hospitalization rates, but the intervention group showed a numerical increase in prescriptions for metformin and glucagon-like peptide 1 medications.

Discussion

This RCT yielded surprising results. Despite the intensive nature of the food-as-medicine program, it did not lead to significant improvements in glycemic control compared to usual care. The intervention group even experienced a modest weight gain. However, the program did increase engagement with healthcare professionals and self-reported improvements in healthy eating habits.

Several factors may explain the lack of improvement in glycemic control. The short duration of the study might not have been sufficient to observe significant

changes, particularly for individuals with long-standing diabetes. Additionally, addressing the complex interplay of genetics, lifestyle factors, and medication adherence alongside dietary changes might be necessary for optimal glycemic control.

Limitations

The generalizability of the findings might be limited as the recruited population had a specific profile (type 2 diabetes, food insecurity). Additionally, the self-reported measure of food insecurity might not be as reliable as objective assessments.

Conclusion

This RCT challenges the notion that food-as-medicine programs universally improve glycemic control in individuals with type 2 diabetes. While the program did not achieve its primary objective, it highlights the importance of patient education and engagement in healthy eating practices. Further research is needed to explore the long-term effects of such programs and identify optimal strategies for managing diabetes through dietary interventions.

References:

Doyle, JD, Guthrie, JF, Etzioni, DA, et al. Effect of an Intensive Food-as-Medicine Program on Health and Health Care Use: A Randomized Clinical Trial. JAMA Intern Med. 2023;153(12):1233-1242. doi:10.1001/jamainternalmed.2023.4032107

Take Home Lesson:

- ✓ **The first major food-as-medicine study failed to show any benefit over the control arm as expected.**
- ✓ **Once the disease has taken hold of a specific tissue, food as medicine probably does not have a major role to play in reversing the disease state due to epigenetic changes that have taken place.**
- ✓ **Food As Medicine may still hold a place in reversing pre-disease states such as**
- ✓ **hypertension, hyperlipidemia, overweight, and certain inflammatory conditions.**
- ✓ **Once a given tissue has lost its function in a disease state, it is often irreversible and too late to use food as medicine despite well-publicized demagoguery by so-called medical experts.**

Plastic Particles Found in Arteries Linked to Potential Increased Heart Disease Risk

A new study published in the medical journal New England Journal of Medicine (https://www.nejm.org/) suggests a potential link between tiny plastic particles and an increased risk of heart disease.

Measurable Plastic Particles in Plaque Buildup

Researchers led by Dr. Marfella investigated the presence of microplastics

and nanoplastics in plaque, the fatty deposits that build up within arteries. The study involved 304 patients undergoing a procedure to remove plaque from their carotid arteries.

Microplastics Detected: The analysis revealed measurable amounts of microplastics, particularly polyethylene, in the plaque of nearly 60% of participants. Additionally, 12% had traces of PVC.

Potential Health Impact: While the study doesn't definitively prove causation, Dr. Marfella expressed concerns about the potential negative effects of these plastic particles on cardiovascular health.

Higher Risk of Heart Events Observed

The researchers followed up with 257 participants for up to 34 months after their surgeries. They observed a concerning trend:

Increased Risk: Individuals with microplastics in their plaque were 4.5 times more likely to experience a heart attack, stroke, or death within the follow-up period compared to those without plastic particles.

Call for Further Research and Awareness

The study findings highlight the need for further investigation into the potential link between plastic exposure and cardiovascular disease.

Lifestyle Changes: Dr. Marfella emphasizes the importance of reducing plastic use and exploring alternative materials in daily life.

Environmental Awareness: He underscores the crucial role of raising public and governmental awareness about the potential health risks associated with environmental pollution by plastics.

Overall Significance:

This study offers a significant new lead in understanding potential risk factors for heart disease. While more research is required to solidify the link, it underscores the growing concern about the impact of environmental pollutants on human health. The findings call for both individual efforts to reduce plastic use and broader societal action to address plastic pollution.

Reference:

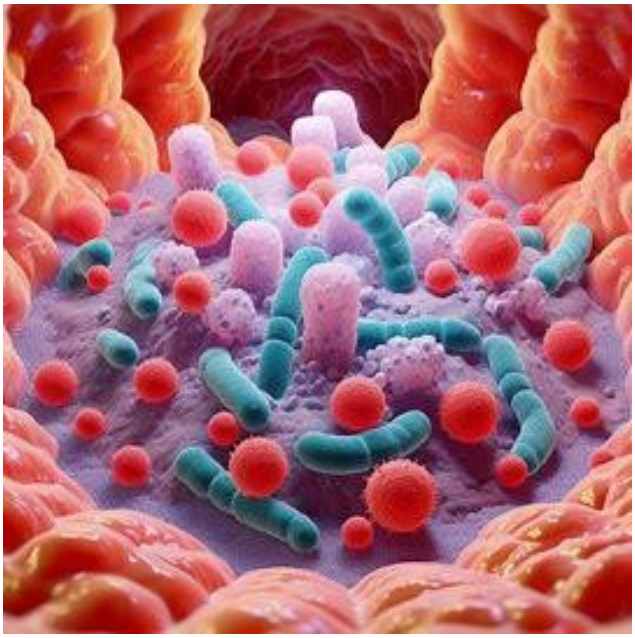
Marfella R, Prattichizzo F, Sardu C, et al. Microplastics and Nanoplastics in Atheromas and Cardiovascular Events. N Engl J Med. 2024 Mar

7;390(10):900-910. doi: 10.1056/NEJMoa2309822. PMID: 38446676.

Fusobacterium and Colon Cancer

Mouth Bacterium Subtype Linked to Colorectal Cancer Growth

A new study by researchers at Fred Hutchinson Cancer Center sheds light on a specific subtype of bacteria potentially driving colorectal cancer growth. The findings, published in Nature, could pave the way for improved treatments and earlier detection methods for this prevalent cancer.



Key Points:

Researchers identified a specific subtype of Fusobacterium nucleatum (Fn) bacteria linked to colorectal cancer growth.

This Fn subtype, found in about 50% of analyzed tumors, was significantly higher compared to healthy tissue.

The bacteria appears to travel from the mouth to the gut, potentially contributing to cancer progression.

Higher levels of this Fn subtype were also detected in stool samples from colorectal cancer patients.

Implications:

Targeting this specific Fn subtype could lead to the development of new therapies and screening methods.

The study suggests potential for microbial cellular therapies using modified bacteria to combat colorectal cancer.

Early detection of this Fn subtype in stool samples could offer a less invasive screening approach.

Future Directions:

Researchers plan to explore the mechanisms by which this Fn subtype promotes cancer growth.

Development of targeted therapies and screening methods based on this specific bacterial subtype are potential next steps.

Overall Significance:

This study identifies a specific bacterial culprit potentially driving colorectal cancer and opens doors for novel therapeutic and early detection strategies. By focusing on this distinct Fn subtype, researchers hope to improve the outlook for colorectal cancer patients.

Reference:

Zepeda-Rivera, M., Minot, S.S., Bouzek, H. et al. A distinct Fusobacterium nucleatum clade dominates the colorectal cancer niche. Nature (2024). https://doi.org/10.1038/s41586-024-07182-w

Recent FDA Medication/Supplement December Recall

Recall Date	Brand Name	Product Description	Recall Reason Description	Company Name
3/6/2024	Colonna	Marcum Ground Cinnamon & Supreme Tradition Ground Cinnamon	Elevated Lead Levels	Colonna Brothers, Inc.
3/6/2024	AJI MORI	CHILLIMAMI SAUCE	Potential Foodborne Illness - Clostridium botulinum	AJI MORI Sauce Corp. DBA Susi Koo
3/7/2024	El Chilar, La Fiesta	Ground Cinnamon "Canela Molida"	Potential Metal Contaminant – Lead.	E Raja Foods LLC La Fiesta Food Products
3/12/2024	Par Pharmaceutical	C Treprostinil 20mg/20mL Injection	Potential Presence of Silicone Particulate Matter	Endo International, Par Pharmaceutical
3/18/2024	Trader Joe's	50% Less Salt Roasted & Salted Whole Cashews	Potential to be contaminated with Salmonella	Wenders LLC
3/18/2024	Mojo, Mojo 2, iQ 2, Phantom 2	CPAP and BIPAP Masks with Magnets	Potential interference with certain medical implants	Sleepnet Corporation
3/20/2024	Various	Dietary supplements for sexual enhancement	Undeclared Sildenafil and/or Tadalafil	Pyramid Wholesale
3/30/2024	Helados Mexico	mango bars in the variety pack	Potential to be contaminated with Salmonella	Tropicale Foods

Case 16: 71-year-old female with 10 year-history of heart failure

What's the probability of 5-year survival for this 71-year-old female with heart failure?

The following real-life case examples are hypothetical stories in the palliative or hospice care settings, imagined by the author with the help of artificial intelligence. Frailty scores are commonly used not only to decide if a patient should be placed in palliative or hospice care but also to assess whether the patient is a suitable candidate for major surgery in the case of surgical intervention. Unfortunately, patients with low frailty scores often do not survive five years after a major health crisis. No one is no exception since everybody eventually succumbs to the law of gravity.

Yasmin Jones, a 71-year-old Caucasian woman, grapples with left-sided heart failure—a condition that significantly impacts her quality of life. Her ejection fraction, a crucial measure of heart function, stands at a modest 35%.

Prescribed medications:

Losartan 15 mg daily

Metoprolol succinate 25 mg daily

Atorvastatin (not taking)

Vitamin D 2000 units daily

Calcium 1000 mg daily

Seeking answers, Yasmin turns to the digital realm, where famous physician-turned YouTubers—Jefferey Gundry, Dean Fong, and Dr. Buzz—sing praises of berberine. But beneath the surface lies a complex decision—one that involves not just berberine but also the prescribed atorvastatin. Let's explore Yasmin's journey.

The Berberine Buzz

The YouTube Influence

Yasmin's curiosity about berberine stems from the virtual corridors of YouTube. These influential content creators, once physicians themselves, now wield their authority in the digital domain. Their endorsement of berberine—a natural compound derived from various plants—has captured Yasmin's attention. Could this unassuming supplement hold the key to better health?

Yasmin Jones

*All patient data is fictional and imagined by the author with AI assistance. Safe Health Report complies fully with US HIPPA regulations.

Age: 71
Sex: .....female
Weight: .....165 pounds
Height: .....5 feet 2 inches

Activities of Daily Living (ADL) components: transfer, bed mobility, toileting, and eating

- **0 – Independent: If the resident completed the activity with no help or oversight every time during the 7-day prior period.**
- **1 – Supervision: If oversight, encouragement, or cueing was provided three or more times during prior 7 days.**
- **2 – Limited Assistance: If resident was highly involved in the activity and received physical help in guided maneuvering of limb(s) or other non-weight-nearing assistance three or more times during the last seven days.**
- **3 – Extensive Assistance: If resident performed part of the activity over the prior 7 days, help of the following type(s) was provided three or more times: ▪ Weight-bearing support provided three or more times. ▪ Full staff performance of activity during part, but not all, of the prior 7 days.**
- **4 – Total Dependence: If there was full staff performance of an activity with no participation by the resident for any aspect of the ADL activity. The resident must be unwilling or unable to perform any part of the activity over the entire prior 7-day period. ▪ 7 – Activity occurred only once or twice: If the activity occurred but not 3 times or more. ▪**
- **8 – Activity did not occur: If, over the prior 7-day period, the ADL (or any part of the ADL) was not performed by the resident or staff at all. ADL support measures the most support provided by staff over the prior 7 days.**

*Adapted from Minnesota Department of Health Guideline

Yasmin's ADL Score 2

The Atorvastatin Conundrum

However, Yasmin's quest for alternatives isn't solely about berberine. She grapples with a prescription—atorvastatin—an established lipid-lowering medication. Her

cardiologist, well-versed in managing heart conditions, recommended it. Yet, Yasmin hesitates. Why? The answer lies in her complaint of "side effects." But here's the twist: Upon closer examination, these side effects remain elusive. Yasmin's discomfort isn't neatly categorized; it manifests as a gradual weariness and breathlessness—a silent erosion of vitality.

Navigating the Crossroads

The Heart Failure Reality

Yasmin's heart, weakened and struggling, demands attention. Left-sided heart failure—a condition where the heart's left ventricle falters—poses serious risks. Her ejection fraction of 35% signifies compromised pumping efficiency. The stakes are high; fatigue and breathlessness may herald further deterioration. Yasmin's first order of business? A consultation with her cardiologist—an urgent dialogue to decipher her symptoms.

Berberine vs. Atorvastatin: A Consideration for Yasmin

Yasmin, a diligent patient, recently initiated a conversation with her pharmacist, seeking guidance on a critical decision: Could she safely replace her current medication, atorvastatin, with berberine? Her inquiry was fueled by apprehension—specifically, the fear of potential side effects associated with atorvastatin. Interestingly, as we delve deeper into Yasmin's concerns, it becomes evident that her motivation to explore berberine extends beyond mere caution; it is rooted in her growing fatigue over the past few months.

Addressing the Patient's Concerns

The Complex Landscape of Chronic Conditions

In an ideal world, chronic diseases would be reversible. We would witness the miraculous transformation of heart failure, diabetes, and other ailments into pristine health. However, reality paints a different picture—one that is often less optimistic. Chronic conditions, by their very nature, tend to progress over time. The best we can hope for is to slow down this inexorable march, rather than achieving complete reversal. Dietary supplements, while valuable, rarely hold the power to cure these complex states. Instead, they serve as adjuncts to conventional treatments.

Lifestyle Modifications: A Crucial Role

Enter lifestyle modifications—the unsung heroes in the battle against chronic diseases. These changes, seemingly small, wield immense influence. They act as both preventive measures and management strategies for pre-disease states. Consider hypertension, hyperlipidemia, and insulin resistance: Lifestyle adjustments—such as dietary choices, exercise routines, and stress management—can significantly impact disease progression. While they won't

magically erase the condition, they can tip the scales in favor of stability.

The Role of Social Media

YouTube: A Double-Edged Sword

YouTube, the digital juggernaut, has democratized information dissemination. Content creators—YouTubers—occupy a unique position. On one hand, they wield immense influence, shaping public opinion and driving conversations. Their commitment to promoting healthier lifestyles is commendable. After all, they, too, need to sustain their online presence. However, here lies the caveat: Some YouTubers venture into treacherous territory by making bold claims about disease reversibility. Cancer, kidney failure, liver dysfunction, Alzheimer's—the list goes on. They promise hope, but often at the expense of scientific rigor.

The Reality Check

Let's be clear: Lifestyle changes are not a panacea. They cannot cure terminal illnesses. While they complement medical interventions, they cannot replace them. The YouTuber's promise of a miraculous turnaround may resonate with viewers, but it's essential to temper enthusiasm with evidence. Cancer cells don't retreat solely because of kale smoothies, nor does a failing liver rejuvenate through meditation alone. We must tread carefully, separating inspiration from misinformation.

Recommendations for Yasmin

Priority One: Consult the Cardiologist

Yasmin's fatigue is a red flag—an urgent signal. She must prioritize a consultation with her cardiologist. Heart failure, a formidable adversary, demands attention. Is her heart function deteriorating? Is her fatigue a harbinger of worsening symptoms? These questions require expert evaluation. Yasmin's well-being hinges on timely intervention.

Eye of the Tiger Test for Yasmin Jones

***All patient data is fictional. Safe Health Report complies fully with US HIPPA regulations.**

Clinical Frailty Score

- **1 – Very Fit: Very fit for their age with no disease symptoms, very active, and exercise regularly- 5 days a week**
- **2 – Fit: Still no active disease as in 1 but exercise only occasionally – three times a week or only seasonally**
- **3 – Managing Ok: Disease symptoms are well managed. Not able to exercise at all other than walking.**
- **4 – Very Mild Frailty: Symptomatic disease. Not dependent on others for daily activities but disease symptoms slow down their activities. May need a cane for walking occasionally for example**
- **5 – Mild Frailty: Symptomatic disease limits daily activities. Needs walkers. Needs help with walking and shopping.**
- **6 – Moderate Frailty: Needs help with walking, shopping, climbing stairs, and bathing with disease progression.**
- **7 – Severe Frailty: Completely dependent for personal care and daily activities but seem stable and at risk of death within the next 6 months.**
- **8 – Very Severe Frailty: Same as 7 but unstable and even mild illness is likely to cause death.**
- **9 – Terminally Ill: As in 8 but not likely to live next 3-6 month.**

*Adapted from Rockwood & Theou 2020

Yasmin's Frailty Score 3

Berberine: Proceed with Caution

Berberine, the alternative Yasmin contemplates, warrants careful consideration. Its interaction with bilirubin—a crucial component in our blood—raises concerns. Berberine can displace bilirubin from its binding site on albumin. Coincidentally, Yasmin also takes losartan, another medication bound to albumin (approximately 99%). The risk lies in potential overexposure to losartan and its active metabolite. Yasmin must engage her cardiologist in this dialogue. Together, they can weigh the risks and benefits, ensuring her safety.

Conclusion

In the grand theater of health, Yasmin's role is pivotal. She stands at the crossroads, balancing fear, fatigue, and hope. As healthcare professionals, we guide her journey—one step at a time. Let us honor science, respect social media's influence, and empower Yasmin to make informed decisions. The path ahead is uncertain, but with knowledge as our compass, we navigate toward better health.

MrGineaPig's Core Long-Term Trial

LONG-TERM TRIAL	SUPPLEMENT	START DATE	
Muscle Weakness	Hyaloronic Acid	07/01/2019	50 mg-1 capsule daily
Back Pain	Pantothenic acid Pantethine	09/1/202 09/01/2022	500 mg 1 capsule daily 450 mg 1 capsule daily
Mealtimes	Breakfast 09:00 -Lunner (13:00)	01/07/2023	+Salad with Balsamic Vinegar Lunner = Lunch + Dinner
BPH Prevention	Lycopene	01/31/2024	20 mg daily

Risk Factors for Premature or Unexpected Death

Immediate Risks	Internal Threat	External Threat	Other Topics
1. COVID-19 2. RSV 3. Flu 4. Fentanyl death 5. Drug shortages 6. Gun violence	1. Poor diet 2. Smoking 3. High blood pressure 4. Obesity 5. Sedentary Lifestyle 6. Suicide	1. War 2. Microplastics 3. FDA recalls 4. Meat preservatives 5. Trans fatty acid 6. Pesticides 7. Heavy metals	1. Shortness of breath 2. Back pain 3. Hemorrhoids 4. Incontinence 5. Joint swelling 6. Fibromyalgia 7. Health Insurance

Topics Chosen: Covid-19 update, Clostridium difficile, Search of Best Diet Series

Format of Safe Health Report

Section 1: Conditions or internal environment that increases the risk of premature death or

pose an immediate danger to your health (both mental and physical) as in an avalanche.

Section 2: External environment that increases premature death, FDA recalls.

Section 3: Case examples of premature death. If you are in a similar situation, remove yourself out of harm's way! Can we extend **our expiration dates** when in the eye of the storm before disease strikes at a tissue level. Remember epigenome is what activates a specific set of genes.

Purpose of Safe Health Report

If you feel you are being used by someone or somebody or institution or institutionalized philosophy or even by your parents or siblings or your coworkers or even your boss, you are a GineaPig. This newsletter is designed to empower GineaPigs in the area of human health and possibly decrease the risk of **premature death**.

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