BIBLIOGRAPHIC INFORMATION SYSTEM

JOURNAL FULL TITLE: Journal of Biomedical Research & Environmental Sciences
ABBREVIATION (NLM): J Biomed Res Environ Sci **ISSN:** 2766-2276 **WEBSITE:** https://www.jelsciences.com

SCOPE & COVERAGE

- **Sections Covered:** 34 specialized sections spanning 143 topics across Medicine, Biology, Environmental Sciences, and General Science
- Ensures broad interdisciplinary visibility for high-impact research.

PUBLICATION FEATURES

- **Review Process:** Double-blind peer review ensuring transparency and quality
- **Time to Publication:** Rapid 21-day review-to-publication cycle
- **Frequency:** Published monthly
- **Plagiarism Screening:** All submissions checked with iThenticate

INDEXING & RECOGNITION

- **Indexed in:** Google Scholar, IndexCopernicus (**ICV 2022: 88.03**)
- **DOI:** Registered with CrossRef (**10.37871**) for long-term discoverability
- **Visibility:** Articles accessible worldwide across universities, research institutions, and libraries

OPEN ACCESS POLICY

- Fully Open Access journal under Creative Commons Attribution 4.0 License (CC BY 4.0)
- Free, unrestricted access to all articles globally

GLOBAL ENGAGEMENT

- **Research Reach:** Welcomes contributions worldwide
- **Managing Entity:** SciRes Literature LLC, USA
- **Language of Publication:** English

SUBMISSION DETAILS

- Manuscripts in Word (.doc/.docx) format accepted

SUBMISSION OPTIONS

- **Online:** https://www.jelsciences.com/submit-your-paper.php
- **Email:** support@jelsciences.com, support@jbresonline.com

HOME ABOUT ARCHIVE SUBMIT MANUSCRIPT APC

Vision: The Journal of Biomedical Research & Environmental Sciences (JBRES) is dedicated to advancing science and technology by providing a global platform for innovation, knowledge exchange, and collaboration. Our vision is to empower researchers and scientists worldwide, offering equal opportunities to share ideas, expand careers, and contribute to discoveries that shape a healthier, sustainable future for humanity.

JOURNAL OF BIOMEDICAL RESEARCH & ENVIRONMENTAL SCIENCES
ISSN: 2766-2276
SUBJECT AREA(S): NUTRITION
DOI: 10.37871

PERSPECTIVE

Double-Blind RCTs for Plant-Based Diets- When Science Misses the Point

Dasaad Mulijono[1-3*]

[1]Department of Cardiology, Bethsaida Hospital, Tangerang, Indonesia
[2]Indonesian College of Lifestyle Medicine, Indonesia
[3]Department of Cardiology, Faculty of Medicine, Prima University, Medan, Indonesia

Abstract

Randomised Controlled Trials (RCTs), particularly those utilising a Double-Blind (DBRCT) design, are the gold standard in medical research. However, applying this model to dietary interventions-especially Plant-Based Diets (PBDs)-poses considerable methodological and ethical challenges. The inability to blind participants, adherence variability, and the prolonged time horizon required to observe dietary effects render DBRCTs impractical for PBD research. Despite a growing body of evidence from observational studies, case series, and non-blinded interventional trials demonstrating the efficacy of PBDs in managing Coronary Heart Disease (CHD), widespread scepticism persists within the medical community. Criticisms often cite small sample sizes, observational designs, and perceived researcher bias, compounded by peer reviewers' resistance, industry influence, and systemic biases in scientific publishing.

Against this backdrop, the Cardiology Centre at Bethsaida Hospital, Tangerang, Indonesia, has pioneered the integration of PBDs into standard cardiovascular care since 2018, under the leadership of Prof. Dasaad Mulijono (DM). This initiative represents the first formal adoption of PBD in Indonesia's hospital setting. Over nearly six years, our clinical data show significant outcomes including hypertension reversal, Type 2 Diabetes (T2D) remission, LDL-C reduction without advanced lipid-lowering agents, sustainable weight loss, renal function improvement, enhanced heart failure parameters, regression of atherosclerosis, and a markedly low restenosis rate following Drug-Coated Balloon (DCB) angioplasty. These real-world results support the feasibility, scalability, and transformative potential of PBDs in reversing or stabilising chronic diseases, particularly in low- and middle-income country contexts where cost-effective, preventive strategies are urgently needed.

We argue for a more inclusive and context-sensitive approach to evaluating

***Corresponding author(s)**

Mulijono D, Department of Cardiology, Bethsaida Hospital, Tangerang, Indonesia
Email: mulijonodasaad@yahoo.com
DOI: 10.37871/jbres2290

Submitted: 26 December 2025

Accepted: 13 April 2026

Published: 14 April 2026

Keywords

Plant-based diet; Randomised controlled trials-double-blind study; Bethsaida hospital; Prof. Dasaad Mulijono; Reversal of coronary heart disease; Restenosis; Medical scepticism; Publishing bias; Compliance challenges

Scan Me

How to cite this article: Mulijono D. Double-Blind RCTs for Plant-Based Diets- When Science Misses the Point. J Biomed Res Environ Sci. 2026 Apr 14; 7(4): 7. Doi: 10.37872/jbres2290

nutritional interventions-one that recognises the limitations of traditional RCT models and values the cumulative weight of diverse forms of clinical evidence. Bridging the gap between empirical success and academic acceptance is critical to expanding the role of plant-based nutrition in modern medicine.

Introduction

PBDs have been extensively investigated for their potential role in preventing and even reversing CHD [1-5]. Numerous studies highlight their positive impact on cardiovascular health, metabolic disorders, and longevity [6-8]. Nevertheless, the widespread adoption of PBDs in clinical practice is hindered by concerns over the lack of high-quality RCTs, particularly those employing a double-blind design. This article examines the methodological barriers to conducting such trials, the prevailing scepticism among medical professionals, and the challenges researchers face in publishing findings related to plant-based dietary interventions.

The impossibility of double-blind RCTs for PBDs

Although RCTs, particularly double-blinded ones, are considered the most rigorous form of clinical evidence [9], their application to dietary interventions, especially PBDs, presents insurmountable challenges:

Blinding is practically impossible

- In pharmacological studies, double blinding is feasible because interventions can be encapsulated and indistinguishable from placebos.
- In dietary interventions, participants inherently know whether they are consuming a plant-based or omnivorous diet, making blinding impractical. Even single-blind designs are challenging due to the necessity of personal food choices and lifestyle adjustments.

Dietary compliance and long-term feasibility

- Unlike pharmaceutical interventions involving standardised drug dosages, dietary interventions require significant behavioural modifications.
- Adherence is influenced by individual food preferences, cultural factors, and personal habits, making strict compliance challenging over extended periods.

Ethical constraints

- Forcing individuals to adopt specific dietary patterns without regard for personal preference raises ethical concerns.
- Restricting omnivorous participants from consuming certain animal products could lead to dissatisfaction and potential nutritional deficiencies, further complicating ethical feasibility.

Longitudinal nature of dietary impact

- Chronic diseases such as CHD develop over decades, necessitating long-term dietary adherence, which is difficult to enforce under controlled conditions.

- Most pharmaceutical RCTs are designed for short durations, whereas dietary interventions often require years to yield clinically significant outcomes.

Existing evidence and medical scepticism

Despite the challenges associated with double-blind RCTs, substantial evidence supports the health benefits of PBDs:

- **Observational studies** consistently demonstrate an association between PBDs and lower incidences of CHD, hypertension, and T2D [1-8].
- **Case-control studies** have demonstrated beneficial outcomes in patients who adopt a plant-based dietary pattern [10,11].
- **Non-blinded RCTs,** such as those conducted by Dr. Dean Ornish and Dr. Caldwell Esselstyn [1,2], have demonstrated CHD regression through plant-based dietary modifications.

Please refer to the **figure** to define the types of studies and their relative strength in establishing causality.

Nevertheless, scepticism persists, with criticisms including:

- "The study had a small sample size." While some studies are limited in scale, findings remain consistent across diverse populations.

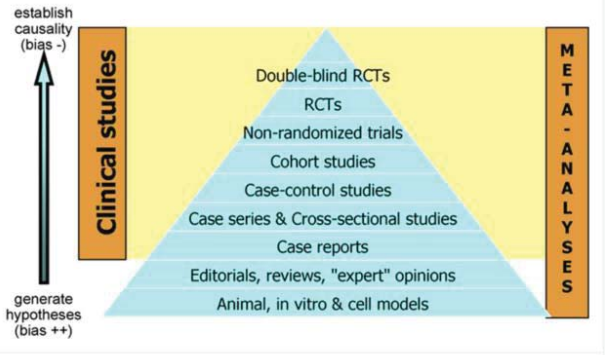

Figure. Levels of evidence for various research designs, based on their internal validity. RCTs indicates randomized controlled trials.

- "The study was observational" – Observational studies, despite lacking randomisation, provide valuable insights into the long-term effects of dietary habits.
- "The study was case-controlled but small." Smaller trials contribute to the cumulative body of evidence.
- "The study was a case report." Although case reports lack rigorous controls, they provide compelling clinical narratives supporting dietary interventions.

Challenges in publishing PBD studies

Researchers investigating PBDs frequently encounter obstacles in securing funding and publication [12,13]:

Funding limitations

- Funding for PBD research is scarce, particularly in developing nations.
- Unlike pharmaceutical research, which attracts industry sponsorship, PBD studies offer minimal financial incentives to corporate stakeholders.
- Government and institutional grants for dietary research remain limited, prioritising pharmaceutical or technology-driven interventions.

Acceptance in reputable journals

- Studies from less-renowned institutions or researchers outside elite medical circles face difficulties gaining acceptance in high-impact journals.
- Prestige bias often favours established researchers with extensive funding and institutional backing.

High Article Processing Charges (APC)

- Publication fees in high-impact journals often reach thousands of dollars,

restricting accessibility for researchers from low- and middle-income countries.

Bias in peer review

- Reviewers may harbour scepticism toward PBD [14-16], which can influence editorial decisions.
- Since many medical professionals remain unconvinced about plant-based approaches [17], implicit bias may lead to more severe critiques and rejections.

Prolonged review processes

- The peer review process can span months or even years, delaying the dissemination of critical findings.
- Lengthy and discouraging review procedures dissuade busy clinicians and researchers from pursuing publication.

Preference for highly technical articles over practical research

- Medical journals often favour highly sophisticated, niche research that benefits a small subset of researchers over practical dietary intervention studies that could aid a broader medical audience.
- Research papers demonstrating real-world applications, such as plant-based dietary interventions, may struggle to compete with more technically intricate studies, even if they offer valuable insights for medical practice in general.

Economic incentives and potential systemic bias

- There may be an unspoken incentive structure within healthcare and academia that favours procedural and pharmaceutical interventions over dietary approaches. Industries centred on stents, drug-coated balloons, and chronic medication regimens generate substantial revenue and are deeply integrated into modern healthcare systems.
- In contrast, a widespread shift toward PBDs—a cost-effective, preventative, and often restorative approach—offers limited commercial profitability.
- This economic imbalance may inadvertently discourage investment in PBD research, and in some cases, active resistance may emerge when dietary solutions are perceived as threatening to entrenched business interests.
- While not always overt, such systemic dynamics raise essential questions about whether scientific inquiry is being subtly steered toward treatments that sustain, rather than reduce, long-term medical dependency.

Solutions to enhance research and acceptance of PBDs

Redefining research standards

- Recognising well-designed observational studies, case-control trials, and non-blinded RCTs as valid evidence.
- Encouraging meta-analyses and systematic reviews to synthesise existing research on PBDs.

Promoting Open-Access and affordable publishing

- Advocating for reduced APCs for researchers from developing regions.
- Supporting open-access journals dedicated to the field of nutritional science.

Strengthening Institutional support

- Encouraging universities, hospitals, and research centres to fund and promote research on PBDs.
- Establishing dedicated grants for dietary intervention studies.

Educating medical professionals

- Integrating PBD into medical curricula.
- Offering Continuing Medical Education (CME) programs on evidence-based dietary interventions.

Enhancing public awareness and policy support

- Engaging policymakers to support nutrition-based preventive healthcare initiatives.
- Securing governmental funding for large-scale dietary research.

Encouraging collaborative research networks

- Forming international research alliances to conduct large-scale dietary studies.
- Supporting multi-centre trials to enhance the credibility of research on PBDs.

Clinical outcomes at the Bethsaida Cardiac Centre

The Cardiology Centre at Bethsaida Hospital in Tangerang, Indonesia, has implemented a PBD as part of its standard cardiac care protocol for nearly six years. This initiative, started seven years ago under the leadership of Prof. DM, now recognised as a national authority on plant-based nutrition, marks the first formal integration of evidence-based nutritional therapy into cardiovascular practice in Indonesia.

While the clinical outcomes have been compelling, broader dissemination and implementation remain constrained by several factors. Internationally, Indonesian research contributions are often marginalised, partly due to systemic limitations in funding, infrastructure, and perceived research quality. Locally, rigid adherence to conventional guidelines and considerable scepticism from medical peers have further limited the uptake of this approach—issues to be discussed in a separate forthcoming analysis.

Despite these barriers, the clinical impact of PBD has been unequivocal. The following summarises key outcomes observed in our patient population:

Hypertension reversal without Pharmacological Intervention: A substantial proportion of hypertensive patients achieved normotensive blood pressure levels without the use of antihypertensive medications. Dietary adoption of potassium-, magnesium-, and Nitric Oxide (NO)-rich leafy greens, combined with avoidance of sodium-laden animal products, resulted in measurable blood pressure normalization within several weeks to months.

T2D Management without Insulin: Numerous patients with T2D successfully discontinued insulin therapy while maintaining glycaemic control with minimal or no oral antidiabetic agents. Significant reductions in HbA1c were recorded, accompanied by reports of enhanced energy levels and improved quality of life.

Reduction of LDL Cholesterol without PCSK9 Inhibitors: Patients receiving high-intensity statins and ezetimibe, in conjunction with PBD, demonstrated profound reductions in Low-Density Lipoprotein Cholesterol (LDL-C), effectively eliminating the need for Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9) inhibitors. These effects are attributable to the diet's high fibre content and the absence of saturated fats and dietary cholesterol.

Sustainable weight Loss: Individuals classified as overweight or obese achieved sustainable weight loss, reaching Body Mass Index (BMI) targets of 20–22 without needing caloric restriction. Plant foods' high satiety index and nutrient density facilitated natural caloric regulation and portion control.

Renal function restoration: Patients with stage 2-3 Chronic Kidney Disease (CKD)

exhibited improvements in serum creatinine levels and Glomerular Filtration Rate (GFR). In some cases, stabilisation or partial reversal of renal dysfunction was observed, reducing the need for dialysis or further pharmacological intervention.

Improved outcomes in heart failure: In patients diagnosed with Heart Failure with Reduced Ejection Fraction (HFrEF), significant symptomatic improvement and increased Left Ventricular Ejection Fraction (LVEF) were observed following the incorporation of PBD into standard heart failure management protocols.

Coronary artery disease regression and superior restenosis rates: Among patients with CHD, angiographic and Computed Tomography Coronary Angiography (CTCA) regression of atherosclerotic plaques was frequently noted, facilitated by comprehensive lifestyle modification and pharmacotherapy. Notably, our DCB restenosis rate remains at 2%, markedly lower than the 10–20% rates reported at comparable centres.

Amelioration of chronic inflammatory conditions: Patients with autoimmune disorders (e.g., rheumatoid arthritis, psoriasis) and other chronic inflammatory conditions demonstrated clinical improvement and modulation of disease activity under a plant-based dietary regimen. Additionally, select patients with early-stage malignancies reported disease stabilisation or partial regression.

Conclusion

Despite growing evidence supporting the efficacy of PBDs in cardiovascular health and the prevention of chronic diseases, their integration into mainstream medical practice remains limited. Methodological constraints—particularly the impracticality of conducting DBRCTs—combined with entrenched scepticism and systemic publication biases, have contributed to the under-recognition of nutritional therapy in evidence-based medicine.

Implementing a PBD at Bethsaida Hospital's Cardiology Centre offers a compelling counterpoint. As the first centre in Indonesia to adopt PBDs as part of standard cardiac care, our nearly seven-year experience has demonstrated significant and reproducible clinical outcomes, including atherosclerosis reversal, hypertension reversal, diabetes remission, improved lipid profiles, renal recovery, enhanced heart failure metrics, and markedly reduced restenosis rates following DCB angioplasty. These results challenge conventional treatment paradigms and highlight the untapped potential of lifestyle-based interventions, particularly in low- and middle-income settings where scalable, cost-effective solutions are urgently needed.

To advance the role of PBD in modern medicine, a more inclusive and holistic research paradigm is essential—one that values diverse forms of clinical evidence, supports systematic reviews and real-world data, addresses structural barriers in scientific publishing, and prioritises nutrition education in medical training. Integrating PBD into healthcare delivery will ultimately require scientific validation, visionary leadership, institutional support, and a shift in medical culture toward truly preventive, patient-centred care.

Author Contributions

D.M.; Conceptualization, writing, review and editing.

Funding

This research received no external funding.

Institutional Review Board Statement

Not applicable.

Informed Consent Statement

Not applicable.

Data Availability Statement

Data are contained within the article.

Conflict of Interest

The authors declare no conflict of interest.

References

1. Ornish D, Scherwitz LW, Billings JH, Brown SE, Gould KL, et al. Intensive lifestyle changes for reversal of coronary heart disease. JAMA. 1998 Dec 16;280(23):2001-2007. doi:10.1001/jama.280.23.2001. Erratum in: JAMA. 1999 Apr 21;281(15):1380. PMID:9863851.
2. Esselstyn CB Jr, Gendy G, Doyle J, Golubic M, Roizen MF. A way to reverse CAD? J Fam Pract. 2014 Jul;63(7):356-364. PMID:25198208.
3. Katz DL. Plant-based diets for reversing disease and saving the planet: past, present, and future. Adv Nutr. 2019 Nov 1;10(Suppl 4):S304-S307. doi:10.1093/advances/nmy124. PMID:31728489; PMCID:PMC6855967.
4. Massera D, Zaman T, Farren GE, Ostfeld RJ. A whole-food plant-based diet reversed angina without medications or procedures. Case Rep Cardiol. 2015;2015:978906. doi:10.1155/2015/978906. PMID:25755896; PMCID:PMC4338379.
5. Kerley CP. A review of plant-based diets to prevent and treat heart failure. Card Fail Rev. 2018 May;4(1):54-61. doi:10.15420/cfr.2018:1:1. PMID:29892479; PMCID:PMC5971679.
6. Tuso P, Stoll SR, Li WW. A plant-based diet, atherogenesis, and coronary artery disease prevention. Perm J. 2015 Winter;19(1):62-67. doi:10.7812/TPP/14-036. PMID:25431999; PMCID:PMC4315380.
7. Mehta P, Tawfeeq S, Padte S, Sunasra R, Desai H, et al. Plant-based diet and its effect on coronary artery disease: a narrative review. World J Clin Cases. 2023 Jul 16;11(20):4752-4762. doi:10.12998/wjcc.v11.i20.4752. PMID:37583985; PMCID:PMC10424050.
8. Peña-Jorquera H, Cid-Jofré V, Landaeta-Díaz L, Petermann-Rocha F, Martorell M, et al. Plant-based nutrition: exploring health benefits for atherosclerosis, chronic diseases, and metabolic syndrome—a comprehensive review. Nutrients. 2023 Jul 21;15(14):3244. doi:10.3390/nu15143244. PMID:37513660; PMCID:PMC10386413.
9. David S, Khandhar PB. Double-blind study. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan.
10. Gholizadeh E, Ayremlou P, Nouri Saeidlou S. The association between dietary pattern and coronary artery disease: a case-control study. J Cardiovasc Thorac Res. 2020;12(4):294-302. doi:10.34172/jcvtr.2020.48. PMID:33510878; PMCID:PMC7828759.
11. Salehin S, Rasmussen P, Mai S, Mushtaq M, Agarwal M, et al. Plant-based diet and its effect on cardiovascular disease. Int J Environ Res Public Health. 2023 Feb 14;20(4):3337. doi:10.3390/ijerph20043337. PMID:36834032; PMCID:PMC9963093.
12. Fabbri A, Lai A, Grundy Q, Bero LA. The influence of industry sponsorship on the research agenda: a scoping review. Am J Public Health. 2018 Nov;108(11):e9-e16. doi:10.2105/AJPH.2018.304677. PMID:30252531; PMCID:PMC6187765.
13. Storz MA. Is there a lack of support for whole-food, plant-based diets in the medical community? Perm J. 2019;23:18-068. doi:10.7812/TPP/18-068. PMID:30589405; PMCID:PMC6307547.
14. Alcorta A, Porta A, Tárrega A, Alvarez MD, Vaquero MP. Foods for plant-based diets: challenges and innovations. Foods. 2021 Feb 1;10(2):293. doi:10.3390/foods10020293. PMID:33535684; PMCID:PMC7912826.
15. Viroli G, Kalmpourtzidou A, Cena H. Exploring benefits and barriers of plant-based diets: health, environmental impact, food accessibility and acceptability. Nutrients. 2023 Nov 8;15(22):4723. doi:10.3390/nu15224723. PMID:38004117; PMCID:PMC10675717.
16. Clark BE, Pope L, Belarmino EH. Personal bias in nutrition advice: a survey of health professionals' recommendations regarding dairy and plant-based dairy alternatives. PEC Innov. 2022;1:100005. doi:10.1016/j.pecinn.2021.100005.
17. Espinosa R, Arpinon T, Maginot P, Demange S, Peureux F. Removing barriers to plant-based diets: assisting doctors with vegan patients. J Behav Exp Econ. 2024;109:102175. doi:10.1016/j.socec.2024.102175.