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Review of Issues and Challenges in the Growing Use of Herbal-Based Products

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ABSTRACT

Since the beginning of human life, herbs have been an integral part of society, with both dietary and therapeutic values recognised. Natural ingredients are increasingly used as key ingredients in food product preparation. The food system and its effects have encouraged people to use natural resources to provide a wide range of nutritional products and good quality healthy foods. A recent consumption pattern among Malaysians on herbal-based food products shows an upward trend indicating that they are looking for healthy, safe, and natural products. The herbal-based products continue to be accepted and supported by the locals for their health and illness treatment. This has led to a rise in the popularity of herbal-based products in Malaysia. However, because safety remains the primary concern with using herbal-based products, relevant regulatory authorities must implement appropriate measures to protect public health by ensuring that all herbal-based products are safe to consume and of the right quality. This review highlights herbal-based product issues, major safety concerns associated with consuming herbal products, and significant challenges associated with effective safety and quality monitoring.

Keywords: *Herbal products, food safety, food quality, food regulations*

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Herbal industry in Malaysia

The value of herbs in Malaysia extends beyond their medicinal advantages to local and traditional knowledge of herbs. More than 2,000 plant species in Malaysia have healing qualities and a high potential for commercialisation [1]. The rich tropical biodiversity of Malaysia provides a good source of natural health products. According to Ahmad and Othman [2], the herbal industry generated more than RM5.4 billion in gross profits from herbal products. The Malaysian Government recognised and established the role of herbal products in making a significant contribution to the national economy for further development. Accordingly, Malaysia introduced New Key Economic Areas (NKEA) EPP1 for high-value herbal products under the Economic Transformation Plan (ETP) (National Agricultural Policy 2011-2020) to recognise the promising future of the herbal industry. This initiative emphasises improving product quality and marketing activities in the upstream and downstream segments to address global demand for herbal-based products like dietary supplements and botanical drugs.

The growing use of herbal products

In Malaysia, multi-ethnic communities, including Malay, Chinese, and Indian, have a long history of consuming herbal products such as *Jamu*, traditional Chinese medicine, and Ayurvedic [3, 4]. The locals usually use these herbal products as an alternative to conventional medical care. According to Salleh [5], Malaysia imports approximately RM1.2 billion in herbal products annually. Rezai et al. [6] observed the upward trend as a shift in Malaysian consumption patterns to healthy, safe, and natural, leading to a rise in the popularity of herbal products. The increased use of herbal products for medicinal and general health purposes is seen in Malaysia and is also popular worldwide [7].

According to a survey conducted by the Council for Responsible Nutrition (CRN) in 2012, about 314 million Americans are concerned about their health, with 23% leaning towards herbal products. Some European countries, such as the United Kingdom, which has a long tradition of using herbal medicines, make extensive use of herbal medicines. The Asian market has seen China pour USD 11 billion into the dietary supplement business to stimulate expansion. In India, the Ayurvedic market value had reached up to USD 2 billion [8]. The World Health Organization (WHO) estimates that 80% of the world's population relies on traditional herbal medicine as basic health care. According to the Statistical Portal in 2017, the largest global market share for herbal products is Western Herbs at 45.9%, followed by Chinese Herbs (36.6%), homoeopathy (9.7%), and Ayurveda (7.8%). In Asia, China dominates herbal production through conventional Chinese medicinal products worth around USD 48 billion and an export value of around USD 3.6 billion in 2010. Meanwhile, Malaysian herbal-based products showed an 8% rise in value sales to RM1.3 billion in 2017. Table 1 presents the upward trend in sales from 2012 to 2017.

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Table 1: Sales (in millions) of herbal/traditional products by category (2012-2017)

Category/Year	2012	2013	2014	2015	2016	2017
Herbal/Traditional Topical Analgesics	68.5	72.7	77.4	82.6	88.2	94.4
Herbal/Traditional Cough, Cold and Allergy (Hay Fever) Remedies	217.8	228.1	241.8	257.5	275.5	295.9
Herbal/Traditional Digestive Remedies	11.4	11.6	11.9	12.2	12.7	13.1
Herbal/Traditional Dietary Supplements	456.0	473.7	499.1	533.3	567.3	602.8
Herbal/Traditional Tonics	189.0	213.6	243.5	267.8	292.7	327.6

Source: Report on Malaysia's and Singapore's Nutritional Supplement Industry Market [9]

Herbal-based products are projected to record a 3% constant growth rate annually to hit revenue of RM1.5 billion in 2022. Table 2 recorded forecast sales of herbal/traditional products by category (value) from 2017 to 2022.

Table 2: Forecast Sales (in millions) of herbal/traditional products by category (2017-2022)

Category/Year	2017	2018	2019	2020	2021	2022
Herbal/Traditional Topical Analgesics	94.4	95.8	98.7	101.5	104.1	106.5
Herbal/Traditional Cough, Cold and Allergy (Hay Fever) Remedies	295.9	305.8	317.7	328.8	338.7	345.4
Herbal/Traditional Digestive Remedies	13.1	13.6	13.9	14.2	14.4	14.5
Herbal/Traditional Dietary Supplements	602.8	609.2	622.5	533.3	567.3	602.8
Herbal/Traditional Tonics	327.6	337.0	350.8	363.8	376.2	388.2

Source: Report on Malaysia's and Singapore's Nutritional Supplement Industry Market [9]

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The demand for natural and safe food products has driven both suppliers and producers in the herbal industries to engage in their efforts to expand the medicinal and nutritious plant industry at various stages before entering the natural health goods manufacturing industry. It also requires the total commitment of herbal industry players to fulfil various roles in handling and manufacturing herbal products. Thus, there is a great need for natural ingredients to manufacture herbal products [10]. The most popular herbs used by the Malaysian herbal industry for the development of herbal products are *Belalai Gajah*, *Dukung Anak*, *Gelenggang*, *Halia*, *Hempedu Bumi*, *Kacip Fatimah*, *Karas*, *Makhota Dewa*, *Mas Cotek*, *Mengkudu*, *Merunggai*, *Misai Kucing*, *Pegaga*, *Peria Katak*, *Rozel*, *Sambung Nyawa*, *Senduduk Putih*, *Serai Wangi*, *Sirih*, and *Tongkat Ali*. Table 3 shows the most common local herbs used in the formulation of herbal products.

Table 3: Most common local herbs used in formulating herbal products

No	Traditional Herbal Products	Part used
1	*Eurycoma longifolia (Tongkat Ali)*	Roots
2	*Labisia pumilla (Kacip Fatimah)*	Leaves
3	*Orthosiphon stamineus (Misai Kuching)*	Leaves
4	*Centella asiatica (Pagaga)*	Leaves
5	*Hibiscus sabdariffa* calyx (roselle)	Calyx
6	*Andrographis paniculata (Hempedu Bumi)*	Plant
7	*Garcinia atroviridus (Asam Gelugor)*	Fruit
8	*Cosmos caudatus (Ulam Raja)*	Leaves
9	*Serenoa repens* (saw palmetto, palm tree)	Fruit/Leaves
10	*Ficus deltoidea (Mas Cotek)*	Leaves
11	*Curcuma longa (Kunyit)*	Roots
12	*Ginkgo biloba* (gingko)	Plant
13	*Camellia sinensis* (green tea)	Leaves
14	*Ocimum basilicum (Selasih)*	Leaves
15	*Zingiber offcinale* (ginger)	Root
16	*Triticum aestivum* (wheat grass)	Leaves
17	*Phyllanthus niruri (Dukong Anak)*	Plant
18	*Piper betle (Sirih)*	Fruit
19	*Croton caudatus* (*Pokok Angguk-Angguk*)	Leaves
20	*Cymbopogon citratus* (*Serai*)	Leaves

Source: [11]

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Factors influencing consumption of herbal products

Factors influencing people worldwide to use herbal products may differ from one population to another. Jantan [12] claimed that consumers believe there are no side effects from natural products, and their displeasure with conventional medicines has led to the rising popularity of herbal products. Deshpande [13] attributed consumers' green attitudes, particularly in purchasing cosmetics and prioritising natural or herbal ingredients. Ahmad et al. [3] further claimed that natural products and plant-based skin care are trending among consumers because it is not harmful and has no side effects. On another note, Aagard et al. [1] highlight the widespread use of herbal-based medicines to treat pregnancy-related diseases and support safe pregnancies and general wellness. In Malaysia, leaves from *pokok angguk-angguk,* scientifically known as *Croton caudatus*, coconut oil, and lemongrass (*Cymbopogon citratus)* are among the few commonly used by Malay women during pregnancy and in postnatal treatment [14, 15]. According to a study by Mohamad et al. [16], *Kacip Fatimah* is the most common raw herb used by Malay women in Malaysia for postnatal care. On treating illnesses, Ekor [17] reported that individuals suffering from chronic diseases often use herbal products to cure their diseases. It supports Aziz and Tey's [18] earlier argument that adults who appear to be more likely to have chronic illnesses consume both herbal supplements and medicines alongside conventional medications. Mohamad et al. [16] also highlighted that herbal products are used mainly by people for health purposes.

Apart from all these factors, Chintamunnee and Mahomoodally [19] and Sooi and Keng [20] implied that the preferences for herbs in some developing countries are due to the accessibility and availability of the products. Siregar et al. [21] ascribed the product's availability to emerging herbal products as a primary healthcare tool for low-income populations. Besides, herbal products are usually inexpensive treatment sources relative to conventional medicines. A study by Ramli et al. [22] found that lower-income families comprised the most regular users of herbal products in the local population. According to Arumugam [23], the primary source of information and knowledge about herbal products is mainly from the older generations, family, and friends. A recent trend of herbal usage shows that herbal products are common in most cultures and are accepted by both rural and urban communities for good reasons [1, 24]. Aziz and Tey's [18] early research found that the use of herbal products was often influenced by culture and ethnicity.

Mitha et al. [25] also supported that culture and ethnicity significantly influence the usage of herbal products. Specifically, Malaysians' interest in herbal products is influenced by practical experiences, observations, and practices derived from socio-religious beliefs passed down from generation to generation [26]. Moreover, Islahudin et al. [27] revealed that individuals with a positive mindset and strong belief in herbal use are more likely to use herbal products for healthcare. The study by Kautsar et al. [28] addressed herbal product purchasing trends in Malaysia based on the regular use of herbal products, consumer loyalty, and purchasing behaviour. Table 4 shows Malaysian herbs' classification by product groups used mainly by Malaysians.

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Table 4: Malaysian herbs classification by product groups

Classification	Product groups
Flavours and Fragrance	a. Cosmetics
	b. Perfumes
	c. Essential oil
	d. Beverages
Pharmaceuticals/Herbal	a. Remedies/Drugs
	b. Vitamins/Supplements
Health/Functional Food	a. Health food
	b. Herbal teas
	c. Herbal supplements
Bio-Pesticides	a. Insect repellent
	b. Crop pesticides
	c. Household pesticides

Source: Islahudin et al. [27]

Issues and challenges

a. Self-medication

Consumption of herbal products is increasingly growing worldwide as an effective cure to relieve various health issues, including heart disease, diabetes, high blood pressure, and even certain cancers [17]. Herbal products are readily available and can be purchased without a prescription. In addition, companies misguide people by claiming their product is free of adverse effects. Advertising and marketing in the media about herbal products as miracle products are used as a driving factor for attracting consumers [29]. Such television commercials deliberately appeal to the various age ranges that exist in society. For children, the gimmick promotes natural or safe growth and development, whilst young adults are advised to take advantage of the nutritional qualities of the herbs for their euphoric effects. It claims to provide vital ingredients to help young adults to cope with daily stress and avoid or delay the progression of ageing.

Meanwhile, older people need herbal products as anti-ageing agents or rejuvenating effects. Many people are drawn towards herbal products and start self-treatment because they believe that natural products are always safe and suitable for them. However, it is only valid some of the time. Despite the health benefits claimed by herbal products, they can also endanger and harm users.

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b. Standard of herbal products

Some herbs may cause adverse effects due to adulteration, improper formulations, interactions between plants and drugs, and often life-threatening or lethal effects. Herbal products often contain non-herbal materials, minerals, heavy metals, and even different pharmaceutical products not listed on the product label. Even though certain herbal products can heal or cure and are widely used to treat diseases, most herbal products remain untested [19]. This has been pointed out by Raynor et al. [30] that even though the intake of some herbal medicines, supplements, or healthcare foods and drinks is common, many still need to be tested, and their use is also not monitored. Similarly, Ahmad and Othman [2] noted the lack of authorised regulation on the purity and potency of herbal products. Because of these, Lee et al. [31] warned of the possibility of severe injuries and life-threatening conditions arising from using such herbal products. Therefore, the safety of herbal products has become a major concern to consumers [32].

c. Improper consumption

Suleiman [33] described that herbal products have often been used by people who lack knowledge of their correct use. According to a study by Lee et al. [31], herbal products may produce a wide range of undesirable effects on the user if used too frequently. For instance, some herbal medicinal products are called dietary supplements, yet no proper dose is specified [29]. Early research by Ekor [16] also revealed the side effects of herbal products if consumed irregularly, in large doses, or combined with other medications. Most herbal products do not specify the duration of intake, so some people continue for months or years, which could be detrimental to human health in the long run.

d. Natural products

Consumers have become more conscious of the processed food consumed over the last few years. Synthetic preservatives, which have been used for decades in foods, may have adverse health implications. Besides, synthetic compounds have significant drawbacks, such as increased costs, hazard handling, questions regarding food residues, and risks to the human environment [3]. Therefore, there is a renewed interest in replacing synthetic preservatives with safe, effective, and non-toxic compounds. The concept of herbal use for health is “any plant-derived products used to maintain or recover health” [34]. Any products made of botanicals used for maintaining or improving health can be called herbal products, botanicals, or phytomedicines [17]. These products are sold as tablets, capsules, powders, teas, extracts, and fresh or dried plants.

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Reported harmful plants and the side effects

Generally, herbal products consist of parts of plants or unpurified plant extracts containing several constituents that are often thought to work synergistically. However, European Commission [35] findings have shown that long-traditional use does not support the 'well-established use' requirements for efficacy and safety. Past research studies have reported that many plants are highly toxic [11, 29]. The variation in chemical compounds in plant parts and the quality and stability of raw materials has resulted in poor regulation, making quality control exceptionally tough.

According to Kumar and Ashaq [36], the quality and safety of herbal products depend on the plant parts used (fruits, roots, leaves, stem), harvesting time, soil condition, and plant species. Several factors contribute to herbal toxicity, including hepatotoxicity of main constituents, contamination during preparations by microorganisms, heavy metals (e.g., mercury, lead, arsenic), pollens, allergens, insect parts and drugs, pesticide residues, and adulterants [37]. Hence, to ensure the safety and quality of herbal products, Ismail [11] and the Drug Registration Guidance Document [38] have listed poisonous plants to be avoided. Those plants that are not allowed and their side effects are described in Table 5.

Table 5: Plants not allowed and its side effects

No	Plants	Side Effects
1.	*Dryabalanops aromatica* and *Borneolum syntheticum*	Contains camphor and borneol, not allowed in oral preparations
2.	*Larrea tridentata* (Chaparral)	Reported to cause liver damage
3.	*Hydrastis canadensis* (Goldenseal)	Reported to cause nerve system disruptions
4.	*Magnolia Officinalis*	Reported to cause kidney damage
5.	*Stephania tetrandra*	Reported to cause kidney damage
6.	*Piper methysticum* (Kava-kava)	Reported to cause liver damage
7.	*Packera aurea* (Life root)	Reported to cause liver toxicity
8.	*Borneolum* (Bingpian)	Contains borneol not allowed in oral preparations
9.	*Dioscorea hispida* (*Ubi gadong, ubi bekoi*)	Reported to cause a burning sensation in the throat, giddiness

Source: Ismail [11] and Drug Registration Guidance Document [38]

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Reported cases of toxicity in herbal products

Herbal products are marketed in most countries without compulsory safety or toxicological assessment. Thus, herbal products are likely to present a greater risk of adverse effects and reactions than complementary products. For instance, a previous study by Fatima and Nayeem [29] indicated the relationship between the consumption of traditional herbal products and their effect on liver fibrosis growth in Uganda. Many Chinese herbal medicines and other herbal medicines from various parts of the world were also implicated in poisoning cases [17]. The increasing incidences of poisoning associated with the use of herbal products in many parts of the world necessitate a detailed investigation of toxicity. This is to ensure the product's safety and protect public health [3]. Focusing on the context of Malaysia, although many herbal products have not been reported in adulteration cases, many products have been detected to contain unlawful substances and cause side effects. Some such cases reported under the National Pharmaceutical Regulatory Agency (NPRA) are listed in Table 6.

Table 6: Products contain unlawful substances

No	Herbal Products	Reported Toxicity
1.	Jamu Tok	Sibutramine
2.	Kama-Max Booster with Extract Ginseng	Sildenafil
3.	ABC Acai Berry Herba Pelangsing	Sibutramine
4.	Extra Herba-Kapsul Resdung Gali	Chlorpheniramine, Dexamethasone
5.	Herba Qaseh Serata Herbs	Dexamethasone
6.	Herbal Body Slim	Sibutramine
7.	Kopi Jantan +++	Sildenafil
8.	Maca Tongkat Ali Extra	Tadalafil
9.	Pati Herba Sakti-X	Phenylbutazone
10.	SBC Miracle Herbs	Dexamethasone Chlorpheniramine Ibuprofen Chloramphenicol Tetracycline HCL Lovastatin

Source: National Pharmaceutical Regulatory Agency [39]

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Regulations on herbal products

Ya'akob et al. [40] identified the four main elements required to standardise herbal product manufacturing: raw materials, planting, processing, and product creation. Some uncertainties and complexities pose a risk of fraud involving raw materials, which could affect the quality of the finished product and potentially harm public health [41]. Masand et al. [42] warned of the danger of selling inappropriate raw materials and deliberately mislabeling materials. The authors further highlighted the importance of storage conditions in establishing and enhancing raw materials' quality, safety, and efficacy. Accordingly, proper arrangements and segregation in the store are necessary for different types of materials where temperature and humidity in the storehouse should be controlled, and proper ventilation should be regulated [42]. The production of fresh produce, i.e., herbal plants, should meet guidelines on good agricultural practices (GAP). Fundamentally, the physiological growth stage determines the quality of herbal plants [40]. Good agricultural practices (GAP) are essential as technical guidance on producing good quality herbal plant materials and for the sustainable development of herbal plants. Generally, good agricultural practices (GAP) require the identification of cultivated herbal plants, seed selection, cultivation problems, harvesting methods, and personnel performance, which could significantly impact plant quality, safety, and efficacy.

To ensure quality of herbal products, good manufacturing practices (GMP) are implemented as part of quality control to guarantee the quality of herbal products. This ensures that goods are continuously manufactured and regulated according to the quality standards relevant to their intended use [40]. All manufacturing processes should be based on GMP guidelines developed by WHO, which clearly state that qualified operators should carry out all procedures, records regarding manufacture and distribution are made, products should be stored in proper condition, and a high level of sanitation and hygiene during manufacture to prevent and reduce contamination [43]. Overall, GMP is a good indicator of quality improvement as required by marketing and national authorisation. One of the practical advantages of GMP is that it can reduce the risk inherent in herbal product manufacturing.

In addition to the mandatory systems that ensure quality and safety, standards for herbal products also cover the entire supply chain, including transportation, storage condition, retail and service outlets and equipment, packaging and labelling, cleaning agents, additives, and ingredients. Carriers transporting raw materials, semi-finished products, or finished products should be cleaned between loads during the transportation. One of the critical elements in maintaining the quality and safety of herbal products is storage conditions. Raw materials should be kept at moderately low temperatures between 2-8°C, whereas frozen herbal products should be placed at less than -20°C, and segregation is needed for poisonous herbs [44]. It should also be emphasised that processed herbal products require immediate packaging to mitigate deterioration and pest infestations.

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Current environmental consciousness necessitates that packaging is environmentally friendly (pollution-free), safe, dry, and in good condition [45]. All information about the herbal products, such as the botanical name of the herbs, the parts of the plant, source of origin, time of cultivation and selection, quantitative details, and the name of the grower, should be clearly stated on the product labelling. The tools and utensils used for producing, handling, storing, and transporting herbs and herbal products must be devoid of poisonous substances, odour and taste and be cleanable and disinfectable. Also, additives and ingredients in herbal products should comply with national legislation, and permission should be obtained from accredited and approved suppliers.

Policy implications

Despite consumers' positive perception of the use of herbal products in terms of efficacy and safety, the issue of the safety of herbal products remains a significant concern. In reality, safe and natural are not meant to be the same. More research should be encouraged on the adverse reactions of locally available herbal products, and mass education should emphasise herbals' good and harmful effects. Therefore, it is necessary to standardise and extensively strengthen relevant policies on herbal products worldwide. Authorising regulators must be vigilant and continue to enforce effective measures to protect public health and ensure that all herbal products licensed for sale are safe and meet the quality requirements.

It is also critical that all plant suppliers, manufacturers, producers, and retailers of herbal products are sufficiently empowered to monitor the safety and quality of herbal products. This should be done in collaboration with the Ministry of Health Malaysia (MoH) with a new set of policies should be developed to cover certain aspects of clinical testing that are specific to herbal products [36, 46]. Additionally, Rajendran and Kamarulzaman [4] highlighted that collaboration with the Department of Islamic Development Malaysia (*JAKIM*) to develop standards with *halalan toyibban* features may create new opportunities. The *halalan toyyiban* reference standards are crucial for the global recognition and commercialisation of the products. These will improve cooperation in the field of good manufacturing practices (GMP) between regulatory authorities and the food and pharmaceutical industry and eventually result in more regulatory-approved products [46].

Aside from that, evidence-based research should be encouraged to document the data regarding the positive and/or adverse effects of using herbs and drugs in combination. Research and development (R&D) should be expanded to include the safety, efficacy, quality, and stability of formulation in preclinical studies, halal product development, food safety, and other related fields. With these, a highly regulated global herbal industry with highly acclaimed herbal products can be enhanced.

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CONCLUSION

The real value of herbal products as medical agents depends on how much they comply with efficacy, safety, and quality standards. Herbal-based products can be the best healers, but the substances can be poisonous and harmful to humans if they fail to fulfil the requirements related to safety and quality. All herbal products should not be considered safe unless prescribed by registered authorities. Otherwise, manufacturers selling these herbal products mislead consumers with such claims. In terms of social and practical considerations, poisonous or dangerous products pose the most severe threat to public trust, regulatory governance, and the general well-being of a particular society. Thus, scientific studies must be carried out for reliable and trustworthy evidence to improve consumer confidence. The promotion and sale of herbal products as an alternative product through testimonials, talk shows, and publicity in popular media, radio, television, and the internet can always be checked if there is a combined effort by the legal authorities and health professionals. This is followed by information on the label of the herbal product that must be verified with the seal of regulatory authority and expiry date. Consumers must be aware of and avoid using herbal products containing heavy metals such as arsenic, lead, and mercury. Besides, overuse of herbal product intake should be avoided, and dosing instructions must be followed. Consumers should be made aware of the importance and risks of herbal products. The point is, what would it look like to make trust in food that directs people on how to react to scientific controversies or mitigate risks in modern Malaysian society? How would the change in existing food policies and laws for herbal-based products be enhanced towards strengthening healthy social networks? These questions are open for debate and future studies. Further, it begs for the expansion of the context of the study to investigate the risk in society and how we can balance between the need to be healthy and the fear of being poisoned in everyday life. Overall, this review article provides insights into the growing use of herbal products for health and their effects. Recognising the potential of herbal products to optimise proper health management is critical. Promoting a better understanding of the possible risks associated with herbal products is also essential.

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AUTHOR'S CONTRIBUTION

Salini Devi Rajendran carried out the research, wrote, and revised the article, while Nitty Hirawaty Kamarulzaman supervised the research study, anchored the review and revisions, and approved the article submission.

CONFLICT OF INTEREST STATEMENT

The authors agree that this research was conducted without any self-benefits or commercial or financial conflicts and declare the absence of conflicting interests with the funders.

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