The paradigm of real-word evidence in lifestyle medicine: Insights, considerations, and opportunities for medical writers

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Abstract

Non-communicable diseases are rising at an alarming rate across the globe, with many attributed to our sedentary habits, unhealthy diets, chronic stress, poor sleep, and social, and environmental factors. Lifestyle medicine is an evidence-based discipline that has the potential to prevent, treat, and sometimes reverse chronic illnesses by addressing modifiable lifestyle factors through behavioural interventions. This article highlights the importance of real-world data to objectively evaluate outcomes and advance research in lifestyle medicine. We explore the current literature and the characteristics of the body of evidence on lifestyle interventions and provide tips for medical writers when working with this type of data.

Lifestyle medicine and its potential

With the growing prevalence of non-communicable diseases (NCDs), such as obesity, type 2 diabetes, cardiovascular disease, and cancers, researchers and policymakers are recognising the significant role our lifestyle habits and environmental factors play in this global health burden.[1,2] According to the WHO, 80% of deaths related to NCDs are linked to key modifiable lifestyle-related risk factors: tobacco use, physical inactivity, unhealthy diet, and the harmful use of alcohol.[3,4]

Lifestyle medicine (LM) is emerging as a practical and efficacious medical approach to manage/address/contain the NCD epidemic.[5] It is an evidence-based medical discipline that targets daily habits to address the root causes of health conditions, thereby preventing, treating, and sometimes reversing many chronic diseases that affect people worldwide. Some of the official definitions of LM from established national and international organisations are provided in Table 1.

> Lifestyle medicine addresses the risk factors of chronic diseases, rather than simply alleviating symptoms and signs. It emphasises behavioural interventions to achieve sustainable health improvements.

As we can see, LM comprises specific pillars:[6]

- Nutrition
- Physical activity
- Stress management
- Restorative sleep
- Social connection
- Avoidance of risky substances (drugs, tobacco, alcohol)

Two extra pillars have been recognised by the European Lifestyle Medicine Organisation (ELMO):

- Sexual health and fertility
- Environmental exposure

In line with recent and fast-growing initiatives in the patient engagement space, which in general invite patients to be more involved in their health journey, LM actively engages the patient as a partner in care and decision-making. LM coaching consists of a collaborative process based on motivational interviewing to recognise issues and habits and to empower patients to improve their health through behavioural interventions.[7] LM should not be confused with integrative or alternative therapies, or therapies such as acupuncture or nutraceuticals.[8] Equally, pharmacological treatments are not necessarily excluded from LM interventions; in fact, they may be necessary in many cases for different reasons. Thus, lifestyle and conventional medicine complement each other in clinical practice and in research studies.

Unfortunately, many of us lead sedentary lives and eat westernised diets. There is (still) no pill to replace healthy lifestyles. Despite recent obesity drugs making dramatic improvements for some people, they are not an option for everyone and they are not free of side effects.[9]

Randomised clinical trials (RCT), as the gold standard for clinical research, make drug development possible and safe. But our daily habits have long-term and multifactorial effects on our health – influenced also by social, physical, and mental health factors – which require different methods.[10] In addition, as LM is an evidence-based discipline, real-world data (RWD) and real-world evidence (RWE) are essential to drive LM forward.[11,12] RWD provide substantial data to measure outcomes and RWE provides insights into the effectiveness of lifestyle interventions in diverse populations over

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extended periods. There is a general belief that all evidence in LM stems from RWD; however, clinical trials like the PREDIMED trial can also explore the outcomes of lifestyle interventions.[13,14]

To evaluate how much of LM evidence relies on RWD, we conducted a simple literature search to identify the RWE on lifestyle interventions and the characteristics of the body of evidence in this discipline. We present our findings below. We also provide information on data sources and useful tips that medical writers (MWs) could apply when working in LM research.

Exploring published and current clinical studies in LM

To explore the current state of research and publications on LM and its pillars, we conducted searches in clinicaltrials.gov and PubMed. We acknowledge, as a limitation of this preliminary search, that some of the studies found in clinicaltrials.gov may be published and thus duplicated in the search in PubMed. Although these searches do not constitute a formal review, the aim was to explore the evidence objectively and provide MWs with concrete information to help them understand this field and be better prepared when they encounter these topics in their work. Please see the Appendix for a detailed description of the methods we used.

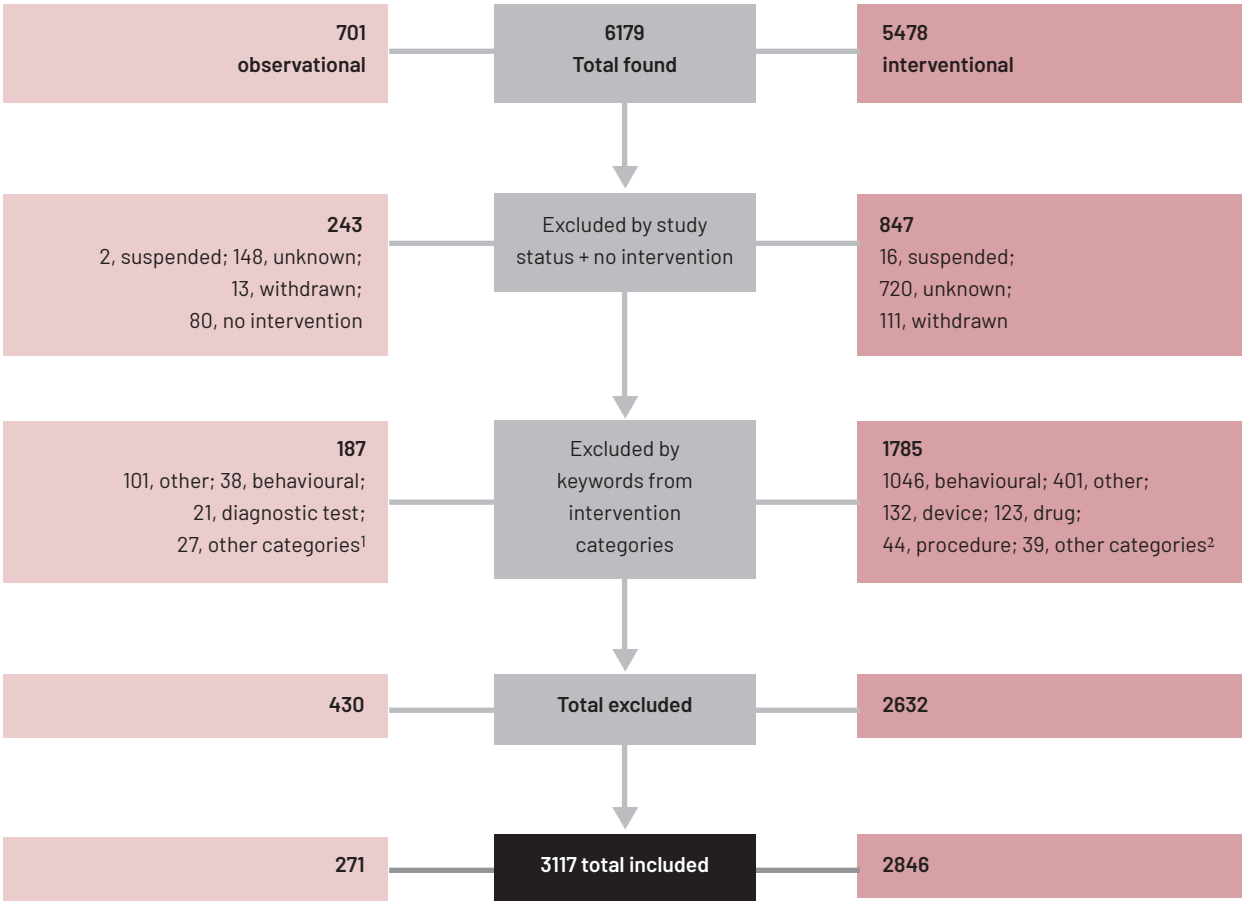
Our clinicaltrials.gov search yielded 6179 studies: 701 observational and 5478 interventional.

Table 1. Official definitions of lifestyle medicine

Belgian and European LM Organisation (BELMO or ELMO)	LM is a branch of medicine that has the goal to maintain optimal health and to **prevent, treat, and reverse chronic illness** across all life stages. The health interventions used in LM include evidence-based behavioural strategies, while considering equity, and sustainability, to enhance self-management skills for optimising nutrition, sleep hygiene, stress management, social connection, sexual health, fertility, and physical activity, and minimising substance use and environmental exposures.
British Society of LM (BSLM)	LM is evidence-based, clinical care that supports behaviour change through person-centred techniques to improve mental wellbeing, social connection, healthy eating, physical activity, sleep, and minimisation of harmful substances and behaviours. It acknowledges the need for action on socioeconomic determinants of health, provides education around the six key pillars as well-proven techniques to sustain lifestyle changes. To be an effective antidote to the chronic disease problem, LM requires a multidisciplinary multi-system approach — which embraces and works alongside other approaches such as self-care, self-management, social prescribing, and group consultations. It requires clinicians, public health professionals, researchers, scientists, and educators working together to affect change. The principles of LM must be applied not only at the clinical practice level, but must also encompass public health policy and prevention. Healthcare professionals, individuals, and governments, and policy makers must play their part.
American College of LM (ACLM)	LM is a medical specialty that uses therapeutic lifestyle interventions as a primary modality to treat chronic conditions including, but not limited to, cardiovascular diseases, type 2 diabetes, and obesity. LM certified clinicians are trained to apply evidence-based, whole-person, prescriptive lifestyle change to treat and, when used intensively, often reverse such conditions. Applying the six pillars of LM – a whole-food, plant-predominant eating pattern, physical activity, restorative sleep, stress management, avoidance of risky substances, and positive social connections – also provides effective prevention for these conditions.

Abbreviation: LM, lifestyle medicine

Figure 1. Flowchart showing the study filtering process after preliminary search in clinicaltrials.gov using "lifestyle" as the intervention



After the exclusion process shown in Figure 1, we selected 3117 studies: 271 observational and 2846 interventional. In both categories, the studies aimed to treat predominantly NCDs (obesity, 660; diabetes, 426; cardiovascular, 323; cancer, 230) but many other conditions as well (neurologic, 183; mental /stress, 100; female, 71; sleep, 62). Among the 2846 interventional studies, 2342 were randomised, and 1308 of these 2342 studies had some type of masking (mostly single, but also double, triple, etc.). Notably, fewer than one in ten of the study postings (268/3117) included study results.

Over a third of the studies took place in the US followed by the sum of countries located in Europe (Table 2). Two-thirds of them consisted of behavioural interventions followed by "other" which were mostly lifestyle-focused, dietary supplements, drugs, and devices. Among the interventional studies, close to half of them had a single lifestyle/pillar-focused intervention and over half of them consisted of ≥2 interventions, where one was always a lifestyle/pillar-focused intervention and the others a different lifestyle/pillar-focused intervention or varying combinations of drugs, combination products, devices, diagnostic tests, procedures, etc.

Close to two-thirds of all the studies were focused on lifestyle; studies focused on the other pillars were less common (nutrition, physical activity, stress, and sleep). But considering that we searched using a unique keyword (lifestyle, under intervention), we obtained fewer studies on individual pillars. We did not include pillar-specific keywords in our search.

It is important to note that this is a preliminary search. Nevertheless, we found that lifestyle-related interventions are being included in research for multiple conditions as lone interventions or as valid comparators. In addition, we obtained more interventional than observational studies; we speculate that this could be because interventional studies should be registered in a clinical trials registry to be considered for publication (per many journal editorial policies) and thus, would bias the results we have obtained.

A potential weakness of our review is that clinicaltrials.gov study postings rarely include results. This is a well-reported problem regardless of the topic under investigation.[15,16] Although it would be logical to hypothesise that the results of the two searches may overlap, it is worth noting that not all published studies are posted in clinical trial registries and that clinicaltrials.gov is not the only registry of this kind. Future reviews should include manual verification of the

Table 2. Characteristics of interventional and observational studies found in clinicatrials.gov preliminary review

	Interventional	Observational
Intervention		
Behavioural	1917	82
Other (mostly lifestyle-focused)	481	75
Dietary supplement	150	4
Drug	140	8
Device	94	8
Procedure	42	6
Other categories	22	9
TOTAL	**2846**	**271**
Pillar		
Lifestyle, coaching, habits, behaviour, counselling, motivational	1756	204
Nutrition, diet	436	40
Exercise, physical activity	487	17
Sleep	67	6
Stress, mindfulness, meditation	100	4

	Interventional	Observational
Country		
United States	1132	56
Canada	123	12
UK	80	14
Spain	136	11
Italy	80	19
Netherlands	66	7
Germany	64	5
Sweden	63	1
Norway	58	4
France	44	17
Start Year		
2020–2025	1187	124
2015–2019	688	72
2010–2014	539	37
2005–2009	299	20
2000–2004	102	9
<1999	21	9

Abbreviations: CT, clinical trial; RCT, randomised clinical trial

Table 3. Types of articles and their publication years found in PubMed that had in their titles keywords representative of LM and four of its pillars

	Lifestyle	Nutrition	Physical activity	Stress	Sleep
CT or RCT	2520	17,423	24,997	11,745	7394
Observational	316	2103	1750	1163	1598
Case report	125	3635	2275	3258	3029
Review	3053	45,627	22,812	31,460	15,031
Systematic reviews and meta-analyses	862	7021	9541	4073	3807
Editorial	586	6359	3256	3232	3116
Letter	487	63,640	4041	3646	3739
Practice guideline and guidelines	27	750	242	82	167
TOTAL	**7949**	**145,808**	**68,672**	**58,577**	**37,714**
Year of publication					
<1999	632	20,076	9548	14,366	5811
2000–2004	1214	25,562	12,697	22,201	8070
2005–2009	2351	36,054	20,537	37,841	12,474
2010–2014	4494	57,434	33,428	60,563	20,394
2015–2019	6469	83,225	47,445	83,548	29,959
2020–2025	11,712	136,164	68,910	129,566	49,958

Abbreviations: CT, clinical trial; LM, Lifestyle Medicine; RCT, randomised clinical trial

overlap between published studies and results posted in clinicaltrials.gov, to better understand its magnitude.

Our PubMed search results showed similar number of studies for lifestyle and four of its pillars (7949): nutrition, physical activity, sleep, and stress (Table 3). Unlike in the clinicaltrials.gov search, the PubMed search enabled us to look individually at lifestyle and each of the selected pillars. We found that the overall pattern was the same: observational studies were only a small percentage compared to clinical trials (7.0% to

21.6%). This is remarkable because the usual paradigm is that RWE predominates in LM.

A large proportion (38.4%) of the other article types was reviews (Table 3), followed by systematic reviews and meta-analyses (10.8%). Notably, practice guidelines and guidelines constituted a very small proportion (0.034%). Yet, considering that we sought only articles with the specific lifestyle-related keyword in the title of the article, the existence of guidelines denotes significant and focused efforts to incorporate LM and its pillars into clinical practice.

Our two searches showed that the number of studies on LM and some of its pillars have increasing trends across each 5-year period studied. For example, in 2015–2019, 760 studies were started, and 6469 articles were published; while in 2020–2025, these increased to 1311 and 11712, respectively. Even if we subtracted those from the first quarter of 2025, the increase is important (Tables 2 and 3).

It should be noted that both searches, despite their preliminary nature, yielded consistent results. The increasing number of studies and publications over time on these topics matches prior findings that highlighted how work in and around LM and its pillars is steadily and rapidly increasing, even compared with the number of studies published in oncology (see Rojido MC, *Medical Writing*, 2019).[8]

What type of LM RWD can we gather and from where?

We can see that there is a growing trend of studies and publications around lifestyle interventions; but, where does this data come from? How do researchers gather RWD to analyse the lifestyle interventions in interventional and real-world settings?

RWD provide a rich source of insights for researchers to analyse health outcomes in non-controlled, everyday settings, and can be transformative in LM. Even more so, we are in an era where digital health is literally at our fingertips, on our smart phones, watches and rings, and these sources are now advancing with the development of sophisticated AI and machine learning programmes. Thus, there are various methods to gather LM-related health data. Here are just a few:

- **Wearable biometric devices:** A vast amount of data is being generated and shared by fitness and health trackers, such as smartwatches, bracelets, or rings. These are often AI-enabled wearable biometric devices and sensors that continuously monitor health metrics like heart rate, blood pressure, and sleep patterns, and can alert the wearer to abnormalities detected. They have a two-way facet: firstly, they assist users in pursuing a healthier lifestyle and in being in control of their health, and secondly, they can provide a constant stream of data for health and safety monitoring, chronic disease management, disease diagnosis, and treatment and rehabilitation.[17] Data is usually saved on the device or the smartphone app and uploaded to servers so users can access their health data across devices. If a user selects third-party services, then the data will be shared (usually anonymously) with health research platforms, the user's healthcare provider, or other providers.
- **Mobile health (mHealth) technologies:** Similar to the wearable devices, users can input their data into mHealth apps on smartphones, web-based technologies, and telecommunications or telemedicine services and log physical activity (steps, exercise minutes, GPS-traced walks or runs, etc.), nutrition (food logs, photo-based meals, calorie counts, etc.), sleep (duration, quality, bedtime, wake time, self-reported restfulness, etc.), mental wellbeing (mood check-ins, stress levels, meditation logs, etc.), as well as monitor goal tracking and habit forming patterns – all extremely relevant in LM interventions. Evidence suggests that mHealth apps, web-based technologies, and telehealth technologies can improve chronic disease management, alleviate disease-related symptoms and patient adherence to interventions or medications.[18] Again, if the users give permission, their data can be anonymously shared with research platforms, healthcare professionals or coaches, or other institutes, to study the efficacy and impact of lifestyle interventions.
- **Electronic health records (EHRs):** Nowadays, health data from physicians, or other healthcare providers store data, such as medical history, symptoms, and diagnoses, clinical notes, prescriptions, treatment plans, and progress notes using EHRs. EHRs have also been widely adopted and evaluated on their accuracy to extract information.[19] Data is usually inputted manually either with free-text or voice dictation or through structured forms or checklists that the physicians will use to document vital signs, risk assessments, or screening questionnaires. EHRs can also be linked to laboratory systems (e.g., blood tests or imaging); medical devices (e.g., electrocardiogram monitors); wearable devices or mHealth technologies; as well as hospital systems that provide admissions, treatment, and discharge summaries. In relation to LM, EHRs allow clinicians and patients to set up specific goals or interventions and track progress at regular check-ins with the patient using blood biomarkers, imaging, or patient characteristics, such as weight and body mass index (BMI). With the development of AI and natural language processing to analyse free-text inputs,[20,21] EHRs are becoming more useable and connected and a reliable source of RWD on disease management.
- **Patient-reported outcomes (PROs):** PROs are a type of data collected often by clinicians and healthcare providers and are increasingly important in relation to LM as they help track interventions that are targeting a specific behaviour, quality of life, or the functional health of an individual. These are things only a patient can really report on. There are different methods to collect information – digitally, paper versions or verbally – depending on the outcome a physician or healthcare provider is assessing (Table 4).[22–37] PROs can be also be integrated into EHR systems for tracking, e.g., REDCap for clinical research, MyChart (a patient portal by Epic Systems), Apple Health, or Google Fit, as well as custom LM apps. Linking PROs with wearable devices is also possible by combining data collected with specific questions, such as "how did you sleep last night?".
- **Community health programmes:** Collecting meaningful, ethical, and actionable data using community health programmes can be a practical way to see how real-world settings paint a picture of health behaviour in a diverse population. Specific models, such as RE-AIM Framework exist, which help healthcare providers apply and assess community interventions and engagement (see Table 4 for links). Community health workers can conduct interviews or surveys (similar to the PROs mentioned above) and guide patients in using tools or devices to help gather quality data within a community. They can also provide health screening and pop-up clinics to regularly track blood pressure, waist

Table 4. Validated questionnaires to gather health data in lifestyle medicine

Lifestyle medicine pillar	Tool
Physical activity	IPAQ - International Physical Activity Questionnaire[22]
Nutrition	Rate Your Plate[23] DHQ – Diet History Questionnaire[24] MEDAS - Mediterranean Diet Adherence Screener[25]
Sleep	Pittsburgh Sleep Quality Index (PSQI)[26]
Stress / emotional health / mental health	Perceived Stress Scale (PSS)[27] Patient-reported outcomes measurement Information system (PROMIS)[28] Depression, Anxiety, and Stress Scale – 21 Items (DASS-21)[29] Patient Health Questionnaire-9 (PHQ-9) and PHQ-2[30]
Quality of life	RAND 36-item short form[31] Patient Activation Measure (PAM)[32]
Specific LM assessments	Lifestyle Medicine Assessment (LMA)[33] Hierarchies of Evidence Applied to LM (HEALM) assessment tool for studies[34]
Community models	RE-AIM (reach, effectiveness, adoption, implementation, maintenance)[35] PRECEDE-PROCEED Model[36] WHO STEPwise approach[37]

circumference, BMI, etc. and engage with patients and assist them to ensure they adhere to the intervention. Importantly, these programmes, such as nutrition classes, walking groups, etc. can gather data at baseline, during, or end of an intervention, at post-intervention, and at follow-up, e.g., 6–12 months after. These programmes can offer benefits with a more structured study design but are resource heavy.

What should we consider when using this data?

We need to be careful with any data, especially those that are not obtained from RCTs, i.e., obtained from studies not conducted in a controlled manner. Some key considerations for MWs when assisting researchers using RWD and publishing their findings would be:

- **Ethical consideration:** Ensure that informed consent was given for data collection either by the user accepting third-party sharing or sharing with care teams. Be transparent about the data and sources; providing storage links if necessary. Ensure the study is compliant with specific guidelines, such as GDPR or compliant with local health authorities and research ethics guidelines. Data should be protected, de-identified, and encrypted if digital, to ensure patient privacy.
- **Patient diversity and data variability:** RWD capture outcomes for diverse patient populations, including those with complications or vulnerabilities that are often excluded from RCTs.[34] However, they can also be restricted to a specific population and lack diversity, thus, findings would not be applicable to other populations. For example, many of the wearable devices and mHealth technologies are available in more middle- and high-income countries and therefore, lack data coming from low-income countries or regions with fewer resources. Consider the data source (EHR, app, registry, etc.), cultural context, socioeconomic status, and access to systems before generalising the findings and drawing a firm conclusion.
- **Long-term effects:** Lifestyle interventions typically require long study periods to show significant health impacts, which can be captured through RWD, but the data are often unreliable on the long-term effects of interventions due to data input, adherence, and patient participation. Consider the timeframes, the population group, and the inclusion and exclusion criteria, specifically examine the number of excluded individuals due to missing data points or drop-outs. Ideally, include a workflow to show data selection.
- **Comprehensive and quality of data:** RWD potentially provide large data sets that can reveal trends in various demographics and a more holistic view of patient health, including factors such as adherence, quality of life, and economic impacts. However, data quality and consistency is affected by the high variability in how people log their health activities and how accurately they do it, by study design (which is often poor and not adhered to across multiple sites), and by the bias that arises from self-reporting. Taken together, this means that it can be hard to draw meaningful conclusions. Check the study design and methodology, e.g., data source, unmeasured confounding factors, and consider the guidelines that were followed, as well as the statistical analyses that were done, e.g., propensity score matching and sensitivity analyses.

Reporting guidelines and checklists can help with this, e.g., STROBE, Hierarchies of Evidence Applied to LM (HEALM) (Table 4).[38]

Conclusion

The characteristics and trends around LM-related research and publications show that LM and its pillars are increasingly prominent. They are not isolated but rather permeate efforts to make progress in the management of multiple conditions. Additionally, the toolbox of methods to gather RWD has evolved enormously thanks to recent technological advances. Combining wearable data, mHealth technologies, EHRs, and PROs can create objectively measurable RWD of patient behaviour, disease progression, and treatment effectiveness. As these technologies and systems advance, so will RWD standards. This will drive LM's principles and interventions forward to combat the vast burden of NCDs. Thus, LM is definitely a medical field MWs of all specialisations should be aware of, as they could encounter opportunities within these areas or in studies and publications where LM constitutes part of the research. They should understand the characteristics of the body of evidence and the importance of RWD and RWE in driving the scientific evidence supporting this field.

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The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Disclosures and conflicts of interest

The authors declare no conflicts of interest.

Data availability statement

The methods for the literature search appear in the Appendix following this article. For inquiries about data and other supplemental information, please contact the corresponding author.

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Appendix: Methodology of clinical trials and publications searches on lifestyle medicine

To find out the types of studies in LM, we searched in clinicaltrial.gov and PubMed. First, we performed a search on clinical trials.gov for observational and interventional studies where the intervention was lifestyle (this was the exact term used); no other filters were applied. We excluded those with suspended, unknown, or withdrawn study status. From the resulting list, we used the "sort" function in Excel and searched on the study titles and interventions columns using text filters for words representative of LM and its key methodology: lifestyle, coaching, health coaching, counselling, motivational, habits, and behaviour. We also searched terms related to the eight pillars of LM in the study title and intervention columns. We focused on four pillars: diet, physical activity, stress, and sleep because they contained much more entries than the other pillars. Thus, the rows with the following representative words were included: nutrition and diet; exercise and physical activity; sleep; stress, mindfulness, and meditation. We also searched the location column with text filters for rows containing country names and counted those with >10 studies. We ordered the study design column and obtained the numbers and subtypes of randomised studies. Lastly, we ordered the start year column and counted the number of studies that fell into 5-year subcategories. We also counted and classified the number of studies with more than one intervention. Lastly, we colour-coded, and made an initial count of the most common conditions treated.

Secondly, to find out the types of publications in our areas of interest, we performed targeted searches in PubMed with the following search strings: lifestyle[Title]) AND (1995:2025 [pdat]), ((nutrition[Title]) OR (diet[Title]) OR (dietary[Title]) OR (food[Title])) AND (1995: 2025[pdat]), ((stress[Title]) OR (meditation [Title]) OR (mindfulness[Title])) AND (1995: 2025[pdat]), ((exercise[Title]) OR (physical activity[Title])) AND (1995:2025 [pdat]), ((sleep[Title])) AND (1995:2025 [pdat]). We then used the filters for the following article types: observational and case reports; clinical trial and randomised clinical trial; systematic reviews and meta-analyses; reviews; practice guidelines and guidelines; editorials; and letters.