Non-Pharmacological Intervention Society

NPIS GUIDELINES

NPI

NON-
PHARMACOLOGICAL
INTERVENTIONS

ABSTRACT

The NPIS Guidelines are a didactic document that summarizes the non-pharmacological interventions' (NPI) ecosystem. This handbook presents the international scientific society NPIS and answers the questions most frequently asked about NPI in the field of evidence-based health solutions applied in prevention, care, work assistance, social protection, and end-of-life support.

SUGGESTED CITATION

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1 NPI in context

The following organisations describe non-pharmacological interventions (NPI) as personalized services (or protocols or practices) provided by professionals which target a health problem: the World Health Organization (2003), the French National Authority for Health (2011), the French National Solidarity Fund for Independent Living (2014), the French Ministry of Health (2018), the French High Council for Public Health (2019), the European Centre for Disease Prevention and Control (2020), WHO/ Europe (2021), the European Commission (2022), the French Economic, Social and Environmental Council (2023), the French Court of Auditors (2024), and the French National Health Insurance Fund (2024).

In the past, the notion of what an NPI was varied according to the healthcare setting, discipline and profession. Terms associated with the notion included 'supportive care', 'psychosocial intervention', 'interventions for rehabilitation', 'evidence-based approach in prevention and health promotion', 'early healthcare intervention', 'population health intervention', 'disease management programme', 'individual action for the most vulnerable retirees', 'complex intervention', 'salutogenic practice', 'occupational treatment', 'health device', 'non-physician intervention, 'primary/first-line care' (namely, psychotherapeutic, educational and social aid'), 'non-drug-based care', 'complementary therapy', 'traditional medicine', 'integrative medicine', 'natural remedy', 'naturopathic technique', 'unconventional care practice', and 'holistic approach'.

Was an NPI an approach, an organization, a rule, a strategy, a type of care, a method, a technique, a component or a measure? Was it a product or a service? Was it an intervention contributing to a diagnosis or a preventive or therapeutic solution? Indeed, the very concept of an intervention in the field of health is vast. *The National Institute for Health and Care Excellence* glossary (NICE, 2024) describes a health intervention as follows: "In medical terms this could be a drug treatment, surgical procedure, diagnostic test or psychological therapy. Examples of public health interventions could include action to help someone to be physically active or to eat a more healthy diet. Examples of social care interventions could include safeguarding or support for carers".

Faced with this difficulty in defining what an NPI is or is not, after 10 years of preliminary work by a collaborative university platform in Montpellier, France, **the international scientific society the 'Non-Pharmacological Intervention Society (NPIS)' was created in 2021 in Paris, its mission being to clarify and operationalize the concept of NPI in collaboration with all the stakeholders involved**.

2 The international scientific society NPIS

BACKGROUND

The NPIS is a non-profit, non-governmental, scientific organization of general interest with the official status of an association (1901 French law). It continues the epistemological work on NPI which was started in 2011 by the CEPS collaborative university platform in Montpellier, France and which was financially supported by the European Union, the French Ministry of Education and Research, the Occitanie Region, the Montpellier Metropolis and the French National Cancer Institute.

VISION

The NPIS defines NPI as evidence-based, effective, personalized, non-invasive disease prevention or care protocols, registered and supervised by a qualified professional, which aim to prevent, treat or provide support for a health problem known to evidence-based medicine (also known as Western medicine). These protocols represent a major area of innovation that complements biomedical products and devices, as well as surgery and public health measures. They can help reduce unplanned healthcare expenses and promote the creation of local jobs in healthcare, a sector which now incorporates prevention, assistance with independent living, social support and end-of-life support.

MISSION

The NPIS works for the international development of research and innovation in the sector of NPI. It contributes to rigorous, transparent, transdisciplinary and intersectoral research for active, equitable and sustainable human health. In concrete terms, the NPIS issues expert appraisals and recommendations for good scientific and multi-professional practices regarding NPI. It shares this knowledge internationally through global open access tools. More specifically, it is currently developing an NPIS Registry, an NPIS Glossary and multi-professional training courses leading to open badge certification for research and practice in NPI. It organizes annual multi-stakeholder congresses each October, called NPIS Summits, as well as thematic conferences, called NPIS Satellites, and economic meetings, called NPI Forums. The NPIS is eligible to receive tax-deductible financial support and donations. It has transparent partnerships with public and private organizations. A day reserved in May or June for NPIS members, partners and contacts is devoted to presentations of the society's activities, projects, and the annual general meeting.

VALUES

The NPIS is driven by six cardinal values: integrity, scientific rigor, transdisciplinarity, pragmatism, universalism and humanism.

MEMBERS

The NPIS welcomes members and organizations from all backgrounds.

EXECUTIVE BOARD MEMBERS

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3 Definition of NPI

An NPI is an **"evidence-based, effective, personalized, non-invasive health prevention or care protocol, registered and supervised by a qualified professional"** (NPIS White Paper, 2024).

An NPI aims to prevent, treat or provide support for a health problem known to evidence-based medicine, also known as Western medicine. The problem may be an acute illness (e.g., sprain, benign paroxysmal vertigo), a rare disease (e.g., Duchenne muscular dystrophy), a chronic disease (e.g., osteoarthritis, cancer, depression, multiple sclerosis, rheumatoid arthritis, Alzheimer's disease), a symptom explained by a medical diagnosis (e.g., pain, fatigue), a risk factor (e.g., sign of fragility in an elderly person, smoking, sedentary lifestyle, night work, musculoskeletal disorders of people working in construction and public works), a disability (e.g., paraplegia), or the end-of-life period.

An NPI is a standardized protocol clearly described in a manual which can be personalized according to the user or the user group. It corresponds to a set of specifications implemented by a professional; the latter takes into account the user's preferences and state of health as well as current statutory rules and regulations. Despite being offered for a limited period, it can have a lasting effect on a health behaviour (e.g., quitting smoking), or a lifestyle (e.g., using a bicycle for daily travel). An NPI complements other health solutions **(Figure 1)**.

NPI can be **codified, supervised, traced and financed**. They improve on the existing prevention and care offer; accordingly, State health insurance systems, social protection and social action organizations, pension schemes, mutual insurance companies, local authorities, foundations, associations, etc. are all encouraged to finance them fully or partially.

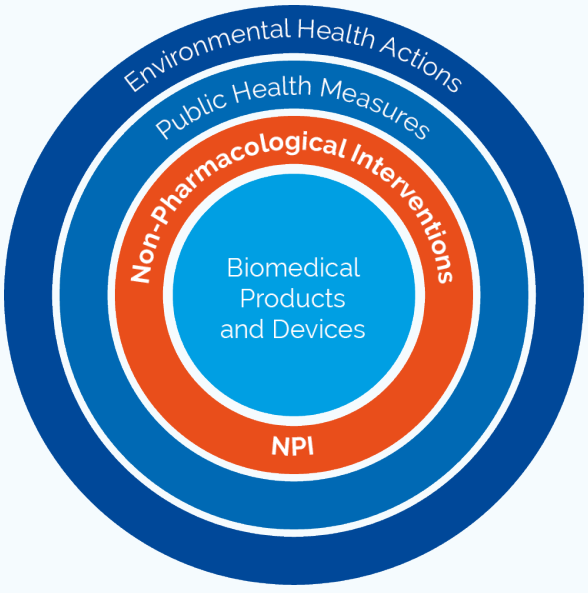

Figure 1: NPI complement other health solutions

An NPI is a prevention or care protocol that has a **physical, nutritional or psychosocial** focus **(Figure 2)**. Examples of physical-focused NPI are physiotherapy protocols, manual therapies, adapted physical activity programmes, occupational therapy methods, psychomotor programmes, midwifery protocols, nursing protocols, speech therapy methods, horticultural therapies and animal-assisted therapy programmes. Psychosocial-focused NPI include psychotherapies, disease prevention

programmes, disease-management programmes, art therapy protocols, music therapy programmes, psychosomatic practices and animal-assisted therapies. Examples of nutritional-focused NPI are specific diets and intermittent fasting.

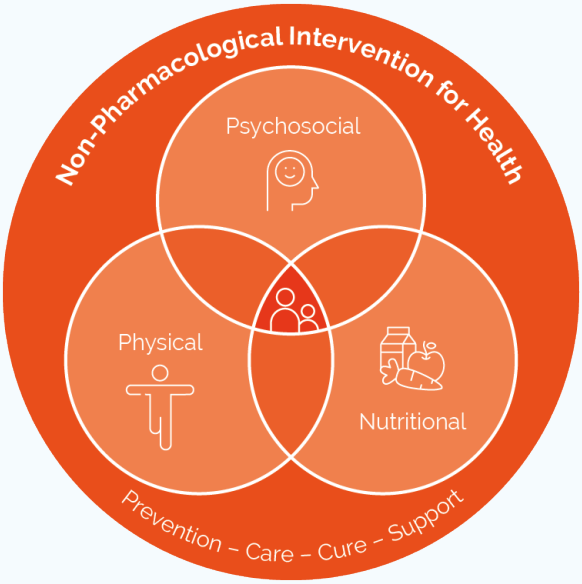

Figure 2: Scope of NPI

The NPIS (see above) has formalized the description of NPI from a conceptual and practical perspective. Once validated by a standardized, transparent, and rigorous expert appraisal process, a scientifically-supported descriptive file of the NPI (called an 'NPI card') is created which provides information under four standardized headings:

– An **information notice** accessible to all users (simplified instructions),
– A **professional, implementable protocol** accessible to all healthcare practitioners and health operators (specifications described in **Figure 3 and Table 1**),
– **Standardised indices** (financial support, etc.),
– A **module for suggestions for improvement by users and professionals**.

Figure 3: NPI protocol description for professionals

		TYPE OF STUDY
Designation	Name (abbreviation if applicable)	3, 4
Main health benefit	Health problem prevented, treated or cured	4
Secondary benefits	Benefits on other health markers (biological and/or psychosocial)	4, 5
Risks	Side effect(s), risky interaction(s)	1, 2, 4, 5
Mechanisms	Biological mechanism(s) of action and/or active psychosocial process(es) explaining the benefits on the health markers of interest	2
Target population	Responding public(s), contraindication(s)	1, 3, 4, 5
Protocol	Components (ingredients, techniques, procedures), procedure (duration, number and frequency of sessions, dose), material (physical, digital) required to guarantee the reproducibility of the effects of the NPI on health	3, 4
Professional	Required qualifications for a professional to implement the NPI	3, 4, 5
Context of use	Places of practice, conditions of use, good implementation practices, precautions, good sustainability practices, regulatory characteristics, initiators	3, 4, 5

1. observational study (box 1) published in a peer-reviewed scientific journal.
2. mechanistic study (box 1) published in a peer-reviewed scientific journal.
3. prototype study (box 1) published in a peer-reviewed scientific journal.
4. intervention study (box 1) published in a peer-reviewed scientific journal.
5. implementation study (box 1) published in a peer-reviewed scientific journal.

Table 1: Characteristics of an NPI

Box 1: Definition

Observational study

Researchers do not intervene in the course of events, and only observe on health markers a non-pharmacological practice, be it an approach, method, technique or ingredient. This is done either prospectively or retrospectively.

Mechanistic study

Researchers highlight the active biological mechanisms and psychosocial processes which explain the benefits of the NPI for health, autonomy, quality of life and/or survival, and the interactions with the environment or other treatment.

Prototype study

Researchers identify all the practical characteristics of an NPI by using methods for collecting information on practitioner and on user experience.

Intervention study

Researchers highlight the effectiveness of an NPI on a target population, that is to say the benefits and risks on this population's health. The controlled trial focuses on establishing whether there is a direct causal relationship between the NPI and its health effects. This method provides the best evidence that under similar conditions, the NPI will provide the same health benefits and expose to the same side effects.

Implementation study

Researchers determine the conditions for successful deployment of an NPI in a specific territory and modalities for adjusting it depending on the context. An implementation study provides specifications for transferability and usage precautions that field-based teams can adjust without losing the effectiveness on health markers demonstrated in previous intervention study, the traceability procedures, or the elements of quality improvement.

4 NPIS Registry

Evidence in published scientific studies enables scientific societies, agencies and health authorities to identify explainable, effective, safe and reproducible human health practices that may be considered NPI. After an independent and transparent appraisal process coordinated by the NPIS - which can be checked and verified by any health authority - these practices may or may not become **NPIS©-labelled protocols**.

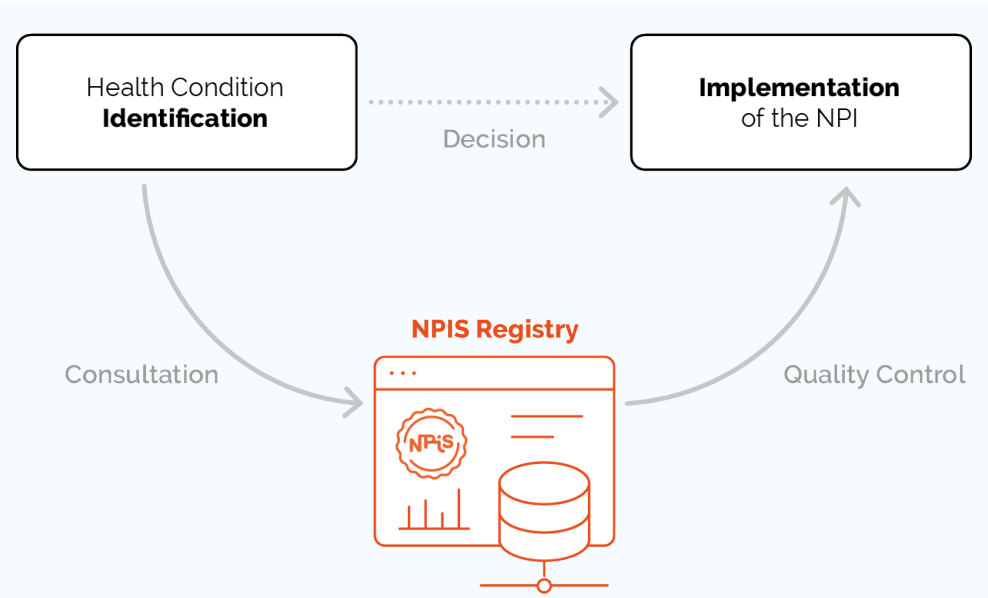

Figure 4: Implementation of an NPI in an area of health; from assessment of the need for an NPI to its use

The above-mentioned standardization process provides standardized specifications as to how the relevant NPI must be employed, as well as recommendations for its implementation and tailoring. These specifications can be thought of as a user manual or guide to good practice. NPIS©-labelled protocols are included in a universal, centralized, multilingual, shared catalogue of codified, applicable, traceable and fundable NPI **(Figure 4)**. The NPIS calls this catalogue the NPIS Registry. It constitutes a resource for targeted, personalized, essential, non-material-based, universal services for health prevention and care. This development process makes upstream research more efficient and downstream user feedback more exploitable **(Figure 5)**.

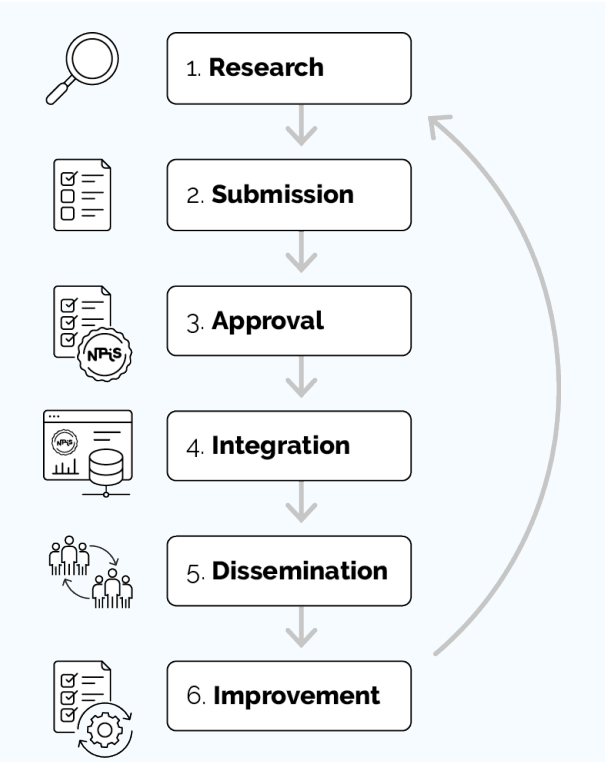

Figure 5: NPI© Development Process

5 NPI Research Framework

Unlike the different phases of drug development model, where scientific consensus on the process for evaluating pharmacological products was reached in the 1960s, and where specific regulations are recognized throughout the world, before 2023, the sphere of NPI was characterized by a large number of heterogeneous research frameworks. Indeed, a review of the scientific literature in April 2019 identified 46 different models (Carbonnel and Ninot, 2019). With so many research frameworks, evaluating service-based solutions was more difficult than evaluating drugs. The NPIS spent two years co-designing a transdisciplinary, intersectoral and transpartisan scientific framework specific to NPI with all the relevant stakeholders, employing a patient-centred approach. This work was inspired by existing recommendations and rigorously adhered to international health research standards. The NPI research framework is called the NPIS Model **(Figure 6)**.

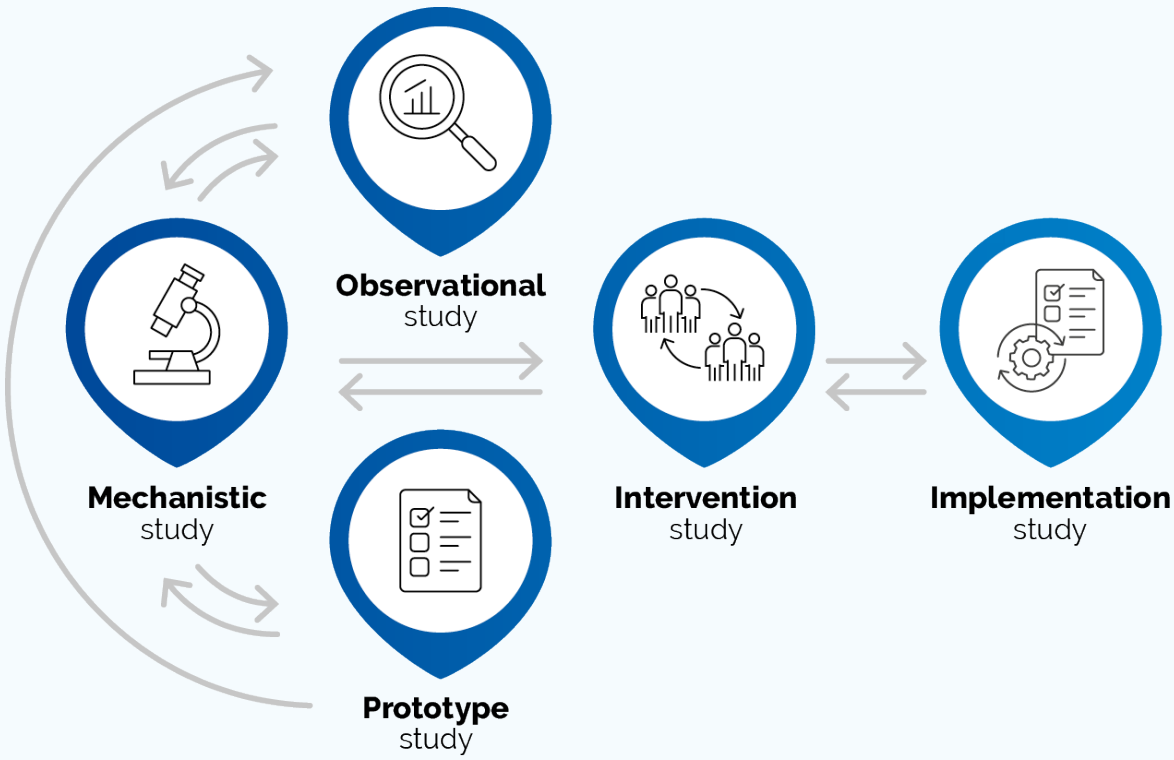

Figure 6: NPIS Model: the NPI research framework which comprises 77 methodological and ethical recommendations

The NPIS Model proposes 77 recommendations (i.e., invariants): 14 ethical and 63 methodological. The latter depend on five types of study design **(box 1)**: those focusing on explanatory mechanisms and processes (mechanistic), those explaining the content of practices (prototype), studies explaining the evolution of practices (observational), those explaining the benefits and risks of the relevant NPI (interventional), and finally, studies explaining the strategies of application and personalization (implementation). Of course, the 14 ethical invariants hold for all model types. Through these invariants, the research framework facilitates the justification, design, promotion, comparison and valorisation of studies on NPI. Moreover, it improves the relevance, quality and reliability of studies on NPI. In consequence, it facilitates the implementation, transferability and market accessibility of NPI.

The NPIS Model is currently (2024) supported by 31 French medical and scientific societies and 3 French health authorities. It has been presented to all French health authorities (the Senate, the Ministry of Health, the French Authority for Health, the French Public Health Agency, the French Academy of Medicine, the General Inspectorate for Social Affairs, the Health Innovation Agency, the French Health Insurance System, the French National Solidarity Fund for Independent Living, and the French Pension Fund).

Initially developed for the French context in order to test its feasibility and relevance, the NPIS Model has been enhanced and expanded at the European level since 2024, especially through collaboration with the European Public Health Association (EUPHA).

6 Impacts of NPI

NPI, the NPIS Model and the NPIS Registry have multiple impacts on health, society, the economy, and environment **(Figure 7)**.

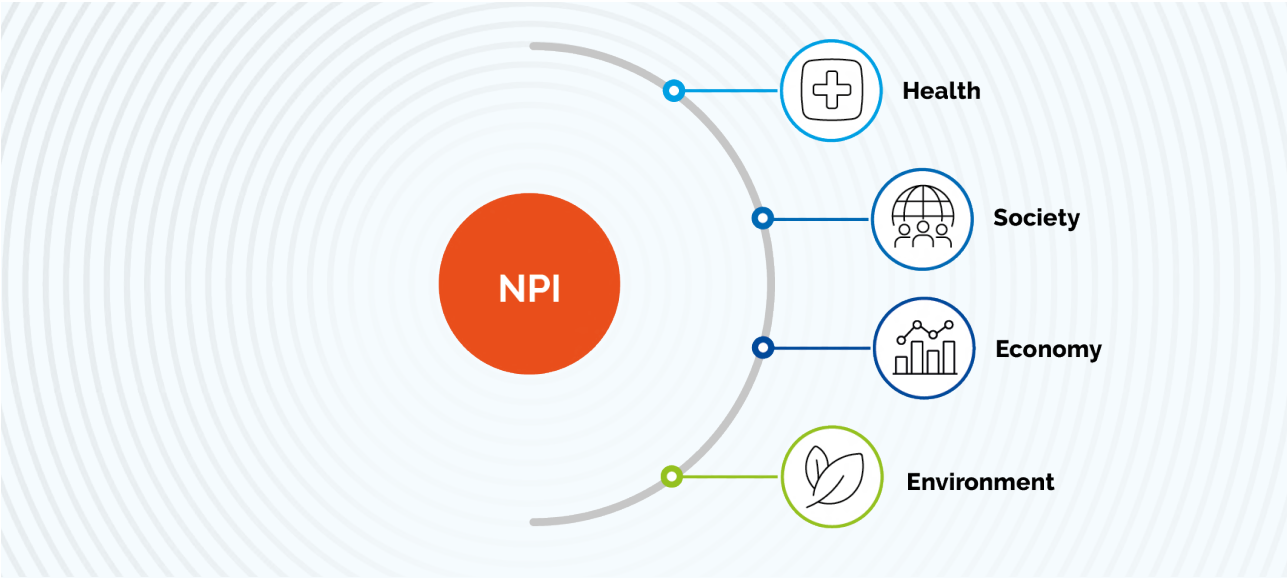

Figure 7: Impacts of NPI, the NPIS Model and the NPIS Registry

Impacts on health

– Improved life expectancy with better health
– Improved independent living
– Improved health-related quality of life
– Improved quality of life at work for health professionals
– Better quality studies and comparability between their results
– Better consolidation of knowledge and adressing the knowledge gaps
– Better transferability of research to practice
– Better prescription (e.g., human decision and articifical intelligence system)
– Intradisciplinary and crossdisciplinary harmonisation of NPI and health research concepts
– Facilitation of expert appraisals by ethics committees and organizations responsible for calls for tenders
– Bringing together siloed care, prevention, social work and education professions
– Improvement of the quality and safety of practices by analysing user feedback
– Standardized coding from a shared register of NPI (nomenclature, classification, etc.)

Impacts on society

– Better precision of the prescription and implementation of NPI
– Better transferability of research to practice
– Improved relevancy of public policy concerning NPI
– Creation of local assets and local jobs
– Improved citizen information (limiting the spread of rumours, disinformation, misinformation, etc.)
– Better collection of users' and professionals' experience
– Greater credibility of researchers, health practitioners and other stakeholders in the NPI sector
– Reduction of social inequalities (currently, only the most economically comfortable persons benefit from NPI)
– Improvement in the work performed by the press in disseminating evidence-based information

Impacts on the economy

– Better targeting of research/innovation calls for tenders from public and private funders
– Improved public and private healthcare and social insurance reimbursement of NPI
– Improved professional training on the content and implementation of NPI
– Traceability of practices by interoperable systems (software publishers, etc.)
– Development local healthcare responses and regional organizations
– Reduction in avoidable - and often very costly - healthcare expenses (hospitalization, emergency care)
– Reduction in the frequency and duration of sick leave and in related social assistance benefits
– Reduction in the number of biased, useless (e.g., predatory journals) and unethical studies (e.g., conflict of interest, burden for patients)
– Consolidation of intellectual property and research investments
– Better use of human, material and financial resources in research care and health system

Environmental impacts

– More sustainable commitment to behaviours that promote health and protect the environment
– Increased awareness of environmental issues related to health and sobriety
– Reduced use of products with a high environmental impact and fewer journeys to receive care by providing local services
– Reduced carbon footprint of healthcare professionals and healthcare by using secure digital communication systems
– Increased awareness among healthcare professionals of the environmental determinants of health problems
– Increased awareness of healthy environment, and salutogenic architecture and design

7 Frequently Asked Questions about NPI (FAQ)

WHY CREATE AN INTERNATIONAL SCIENTIFIC SOCIETY FOR NPI?

NPI constitute a sector characterized by a great deal of confusion between scientific knowledge and opinion. This is because of their objective – to improve human health – and because of the way they operate: non-material based protocols. However, it is important to learn to distinguish between science and research given the proliferation of information tools and vectors (Klein, 2020); this is particularly true concerning NPI, where the same communication channels are used to convey scientific knowledge as well as beliefs, opinions, comments, etc. One type of information contaminates another type of information (i.e., information pollution). Knowledge can become the belief of a particular community, and vice versa.

Science corresponds to a body of knowledge established on well-defined and precise questions. Until proven otherwise, this knowledge should not be called into question. A researcher does not ask himself/herself what the shape of the Earth is; it is a given: the Earth is round. The question is settled. Science is about moving towards the truth. Scientific societies play a major role in establishing scientific consensus about what is known (i.e., what is true) and remains to be known.

Research corresponds to well-defined questions for which we do not have the answers. A researcher works on a subject matter using different methods and strategies. Research cultivates doubt. Scientific societies work to develop research on a specific area and on a specific theme.

Given that NPI is a universal health protocol which is focused on improving the health of humans and which are administered by humans, an international multidisciplinary scientific society needed to be created. This happened in 2021 with the creation of the NPIS (see above).

ARE ALL WELLNESS PRACTICES NPI?

Moving, eating, drinking, sleeping, talking, reading, writing, painting, listening to music, watching a movie, dancing, laughing, walking, singing, meditating, gardening, and spending time with friends, are all examples of daily life activities, some of which generate joy, pleasure, a sense of fulfilment, well-being, etc. Everyone in a democratic country is free to interpret and live these activities as they please. Associated terms which come to mind are a philosophy of life, a lifestyle, the art of living, and personal development **(Figure 8)**.

In other words, a daily life activity in itself is not an NPI, despite the fact that it may contribute randomly and occasionally to better health in certain people. Daily life activities or treatment solutions of a medically diagnosed health problem are different.

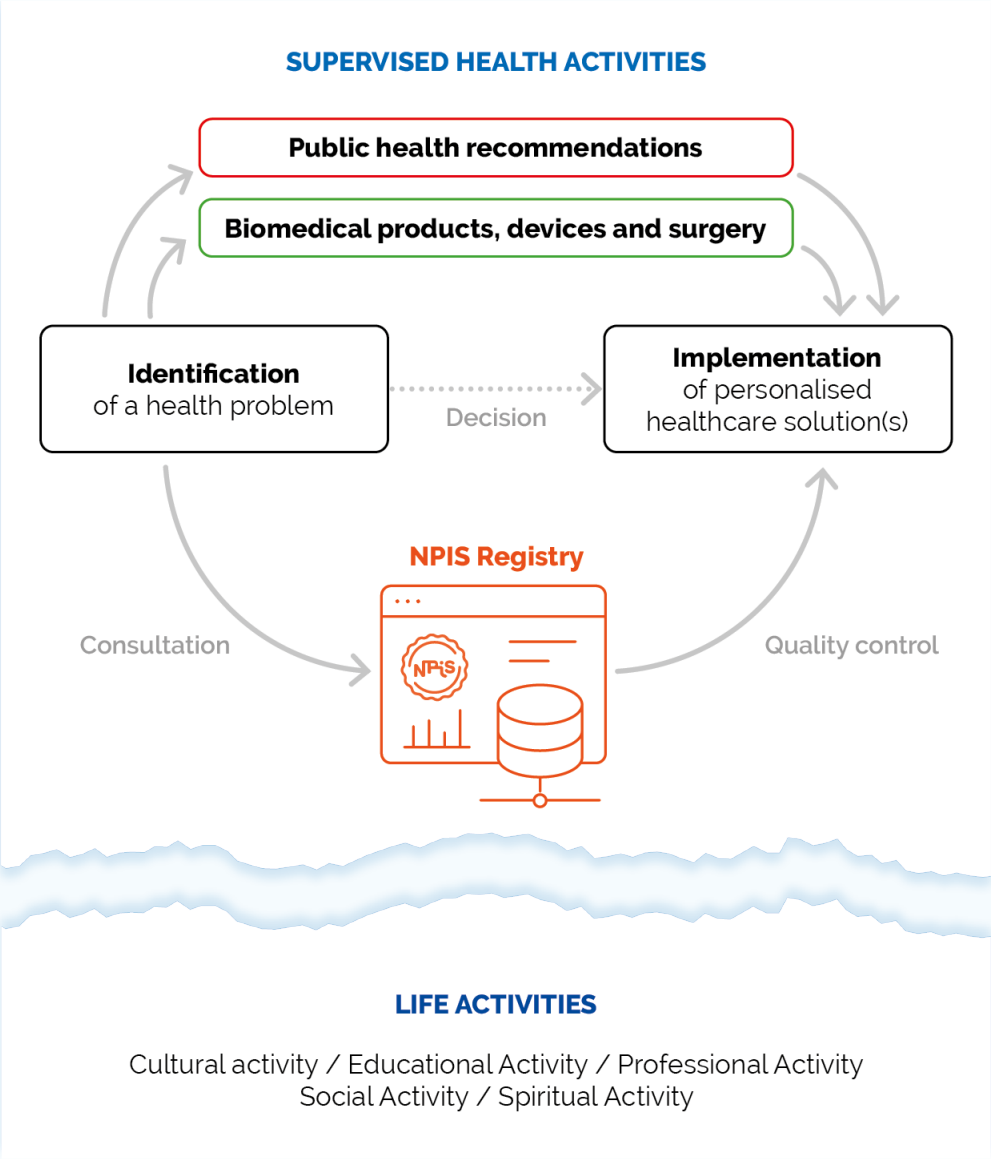

Figure 8: Differences between health-based and occupational-based practices

The following products are not NPI:
– Health products (medication, biomaterial implants, food supplements, etc.),
– Medical devices (artificial organs, prostheses, orthoses, digital applications, monitoring systems, etc.).
– Natural products (plants, foodstuffs, mushrooms, essential oils, etc.),
– Hygiene and beauty products (shampoo, toothpaste, hairbrush, body cream, etc.),

The following goods and services are not NPI:
– Cultural products or services (video games, books, podcasts, artistic practices, museum visits, theatrical performances, writing, etc.),
– Consumer products or services (hairdressing, eating in a restaurant, etc.).

The following actions are not NPI:
– Public health promotion supports (communication campaigns, videos, posters, booklets, websites, posts, etc.),
– Architectural modifications (creation of an access ramp for people with reduced mobility, etc.),
– Environmental modifications (reforestation of a park, creation of a sports area, etc.).

The following approaches are not NPI:
– Professional disciplines (physiotherapy, psychology, dietetics, public health, etc.),
– Educational approaches (personal development, etc.),
– Esoteric practices (spiritual practices, religious worship, divination, witchcraft, etc.).

The following organizations are not NPI:
– Health organizations (networks, health hospitals, heath systems, digital platforms, etc.),
– Professional organisations,
– Patient associations.

The following measures are not NPI:
– Health policies (strategy, plan, programme, etc.),
– Regulations (decrees, laws, etc.),
– Court decisions (warnings, convictions, etc.).

WHY WAS THE TERM NPI CHOSEN, A SEEMINGLY NEGATIVE TERM THAT APPEARS TO OPPOSE THE USE OF DRUGS?

The term non-pharmacological intervention (NPI) was not coined by the NPIS. It has been used by scientists since 1975 (NPIS White Paper, 2024) and is firmly established. Several health authorities and agencies use it, including the WHO (2003), the French National Authority for Health (2011), the European Centre for Disease Prevention and Control (2020), and the European Commission (2022).

Moreover, many national and supranational medical and scientific societies use the term NPI in their recommendations. Despite the efforts of professionals to increase awareness and recognition of NPI, these underestimated non-material-based healthcare solutions are often 'stuck' in a void between being considered health products (e.g., medicines, medical devices) and being considered public health recommendations (e.g., dietary rules, hygiene measures, environmental actions) **(Figure 1)**.

They may be buried in compilations of healthcare solutions that mix health promotion actions with targeted programmes, or that mix methods for identifying a health problem with methods for solving a health problem **(Box 2)**. Given this context, the challenge for health organisations is to guarantee better traceability of NPI to ensure continuous improvement of their quality, safety, implementation and related training. These health prevention and care solutions can easily be shared between countries. The term NPI does not mean 'anti-medicine' or 'alternative medicine'. It was inspired by the rigorous global standardized process of drug validation for establishing good scientific and clinical practices. In the long term, we believe that the acronym NPI will take precedence over its full name, just like the WHO, IBM, and so many other abbreviations.

Box 2: Registries of non-pharmacological approaches with imprecise criteria and definitions

NPI seem to be buried in databases and platforms that compile all sorts of health practices. Some of these practices are aimed at the general population, while others are targeted at specific groups. Healthcare objectives differ, categories of practices vary, the contents of programmes are imprecise, and implementation strategies diverge. Three examples – although there are many others – are the EBCCP database and the Mindtools platform, both in the USA, and the Capitalisation Santé portal in France.

WHY IS THE TERM NPI SO MISUNDERSTOOD?

The term NPI has been used by scientists working in the health field since 1975. However, other similar terms are used as synonyms. More specifically, 10 different terms exist in Pubmed **(Table 2, column 1)**. In addition, 28 different assimilated terms exist in Pubmed **(Table 2, column 2)**. Creating an exhaustive NPI inventory on a search engine for scientific articles is currently impossible, as researchers use so many different terms with different meanings.

non-pharmacological OR	**non-pharmacological intervention OR**
non-drug	non-pharmacological **actions**
non-medication	non-pharmacological **activities**
non-pharmaceutical	non-pharmacological **advice**
non-pharmacologic	non-pharmacological **alternative**
nondrug	non-pharmacological **approach**
nonmedication	non-pharmacological **care**
nonpharmaceutical	non-pharmacological **complementary**
nonpharmacologic	non-pharmacological **management**
nonpharmacological	non-pharmacological **measure**
	non-pharmacological **method**
	non-pharmacological **modality**
	non-pharmacological **modus operandi**
	non-pharmacological **option**
	non-pharmacological **prevention**
	non-pharmacological **preventive measures**
	non-pharmacological **procedure**
	non-pharmacological **programmes**
	non-pharmacological **protocol**
	non-pharmacological **rehabilitation**
	non-pharmacological **remedies**
	non-pharmacological **solution**
	non-pharmacological **strategy**
	non-pharmacological **support**
	non-pharmacological **technique**
	non-pharmacological **therapeutics**
	non-pharmacological **therapy**
	non-pharmacological **treatment**

Table 2: Synonyms of 'non-pharmacological intervention' found on Pubmed

A search on Pubmed on 15 August 2024 highlighted 55,689 articles citing the term 'non-pharmacological' or an equivalent term up to and including 2023 **(Figure 9)**. Nevertheless, this number is an underestimation because the Pubmed database focuses more on i) health products than on health services, ii) biological treatments than psychosocial treatments, iii) studies on North American

populations and journals published by North American organizations. This is of course perfectly understandable given that Pubmed is an official US government site developed and maintained by the National Center for Biotechnology Information (NCBI).

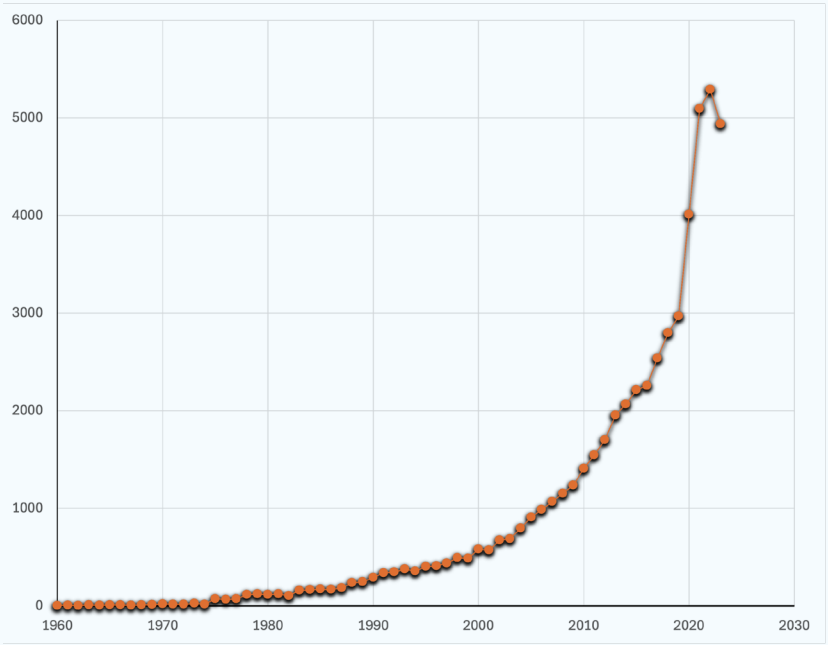

Figure 9: Articles published up to December 2023 listed on Pubmed citing the term 'non-pharmacological' or an equivalent term (search on 15 August 2024)

Moreover, another Pubmed search on the same date highlighted 11,642 articles citing the term 'non-pharmacological intervention' or an equivalent term up to and including 2023 **(Figure 10)**. Both curves in **Figures 9 and 10**, show an increase in use since 2000, and a clear acceleration since 2010.

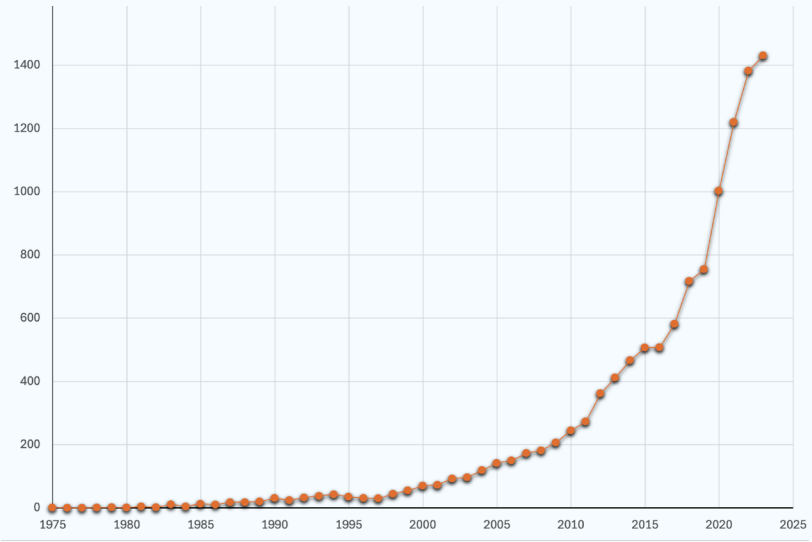

Figure 10: Articles on Pubmed citing the term "non-pharmacological intervention" or an equivalent term up to and including 2023 (search 15 August 2024)

The French National Authority for Health has been encouraging the use of the term NPI in health since a report it published on these healthcare solutions in 2011.

WHY CREATE A STANDARDISED UNIVERSAL MODEL FOR EVALUATING NPI?

A standardized universal process for the scientific development of drug has existed since the 1960s, with specific regulations recognised worldwide by health authorities in different countries and regions, for example the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the French National Agency for the Safety of Medicines and Health Products (ANSM). A similar model has been in place for medical devices in the European Union since 2021. In contrast, prior to 2023, no such methodological and ethical consensus-based model existed for NPI; this was primarily because of confusion between the different approaches, protocols and techniques/ingredients used. In order to overcome this scientific shortcoming, and based on 10 years of preliminary work by a collaborative university platform in Montpellier, France, the international scientific society NPIS spent two years developing a standardized universal framework for the scientific validation of NPI in collaboration with all the stakeholders involved, through a participatory, pragmatic and multidisciplinary consensus-building process which rigorously adhered to international scientific health recommendations for NPI (Ninot *et al.*, 2023). Finalised in 2023, this research framework (called the NPIS Model, see above) takes into account the specific characteristics of NPI, associated health risks, the balance between internal and external validity, the justification of explanatory mechanisms and of health ethics, and respect for contexts of use. The NPIS Model accelerates research by harmonizing stakeholders' methodological and ethical expectations of NPI.

The NPIS Model also accelerates the identification, referencing, transferability and implementation of NPI for the benefit of user health and safety. Furthermore, it improves the quality of training. Ultimately, the NPIS Model makes it possible to distinguish individualized services based on science which aim to treat a health problem known to Western medicine from occupational practices (lifestyle, the art of living, work, socio-cultural activities, personal development, the pursuit of happiness, spiritual practices, etc.). In this sense, the model does not restrict people's freedom to choose a particular lifestyle. It aims to act on a health problem of an individual or a group of people in a specific moment within a limited timeframe and according to a framework regulated by the health sector. The NPIS Model encourages innovations in all sectors of health, and in particular in the field of health organizations and actions focussing on early detection of health problems.

WHY DEVELOP A TRANSDISCIPLINARY RESEARCH FRAMEWORK TO EVALUATE NPI?

As of April 2019, there were a total of 46 different research frameworks for NPI in the scientific literature (Carbonnel and Ninot, 2019). They were built by researchers for researchers, most often using a mono-disciplinary approach, and few were patient-centred. The result was considerable heterogeneity in study protocols and in how to design NPIs (approach, method, technique or material). The results were disparate, debatable, not very transferable, and rarely reproducible. Consequently, there was little recognition of each NPI outside the context of the individual study (establishment and/or dependent practitioner). This failing led to doubts about their efficacy (e.g., effectiveness, safety, relevance, utility, cost-effectiveness), their content (e.g., doses, procedures, ingredients, techniques, contexts, and target populations), their approval (e.g., ethics committees, expert commissions), their dissemination (e.g., contradictory opinions of scientific journal reviewers), their teaching (e.g., protocols, good practices) and their official recognition (e.g., authorization, integration into official nomenclature, and reimbursement by health insurance). In turn, these doubts generated obstacles i) to investment in research and innovation, ii) to the contribution of consolidated knowledge, iii) to the transferability of practices, and iv) to the recognition of professionals who wished to implement NPI.

The absence of a universal framework for evaluating NPI led to the belief that each professional had to reinvent the NPI he/she had developed for each new patient, given the very large number of recommendations from authorities, agencies and scientific societies that were either too broad in scope or sometimes contradictory. It also led to the belief that in the sector of NPI, the only real

impact on patients' health was a positive patient-provider relationship (Ninot, 2020). In addition, it left the way open to pseudoscientific practices, and more generally, to non-evidence-based medicines (Ernst and Smith, 2018).

These beliefs gained ground in the USA in the field of oncology, where some authors hoped to juxtapose two medical offers, one based on experimental science almost exclusively focused on surgery, medication, radiotherapy and medical devices, and another based on 'complementary, integrative and traditional' medicine based on individual experience, opinions and traditions (Mao *et al.*, 2022). This second offer seems to be the unique way for prevention and care.

The NPIS Model was co-constructed with the idea that experimental science could prove the existence of effective, safe and reproducible prevention and care protocols. The development of the research framework brought together more than 1,000 people in France under the direction of a committee of 22 multidisciplinary experts, including two NPI-user representatives. As of 2024, the NPIS Model has the backing of 31 French medical and scientific societies, the French National Centre for Palliative and End-of-Life Care, the French National Cancer Institute, and the French Platform of Clinical Research Networks.

HOW IS EVIDENCE FOR THE VALIDITY OF AN NPI COLLECTED AND ASSESSED?

Evidence is theoretical or practical knowledge acquired through rigorous and honest scientific reasoning and methodology. The NPIS Model follows this logic in the field of health **(Figure 6)**. It provides methodological and ethical recommendations for five different health study designs in the context of evaluating NPI: those focusing on explanatory mechanisms and processes (mechanistic), those explaining the content of practices (prototype), studies explaining the evolution of practices (observational), those explaining the benefits and risks of the NPI (interventional), and finally, studies explaining the strategies of application and personalization (implementation). The results from these different types of studies provide evidence for the describability, explainability, effectiveness, safety, and implementability (≥ 1 implementation study in the country) of a **NPIS©-labelled** NPI. For NPIS© accreditation, the following minimum number of studies must have been published for the NPI under consideration: ≥ 1 prototype study; ≥ 1 mechanistic study; ≥ 2 intervention studies; ≥ 1 implementation study.

WHY IS THERE SUCH A DIRECT LINK BETWEEN MECHANISTIC, CLINICAL AND IMPLEMENTATION STUDIES EVALUATING NPI IN THE NPIS MODEL?

The interlinking between mechanistic, interventional and implementation studies forms the backbone of the NPIS Model's epistemological positioning in terms of the evaluation of NPI. This does not mean that an interventional study, for example, cannot also investigate biological mechanisms or psychosocial processes. This backbone gives coherence to the studies, and structures the validation process of NPI for integration into the NPIS Registry (see above).

WHY DID THIS MISSION TO CREATE A UNIVERSAL CONSENSUS-BASED MODEL FOR NPI BEGIN IN FRANCE?

The NPIS Model is part of the national French 2023-2027 strategy for research and innovation in global health. This strategy aims to meet the imperatives of equity and solidarity, to make a greater commitment to disease prevention and health promotion, and to take better account of the interdependencies between climate change, ecosystem protection, and health (French Government, 2023). In 2021, France also set up a Health Innovation Agency with an investment plan worth €7.5 billion until 2030 (Health Innovation Agency, 2021). This agency aims to anticipate the impacts of

innovations on the prevention and care system, to create cooperation between public and private actors, and to identify research priorities. This development is based on the central institution in France for research and health issues, called INSERM (INSERM, 2024). The development of the NPIS Model was financially supported by a participatory research seed fund from INSERM. The NPIS Model facilitates the effective and rapid delivery of NPI innovations from basic research to practice. The French government's ten-year strategy on supportive care, published in 2024, also stressed the need for a standardized NPI evaluation framework (France Government, 2024).

WHY HAVE TRIPLE-BLIND RANDOMIZED TRIALS NOT BEEN INCLUDED AS A CRITERION FOR NPI VALIDATION IN THE NPIS MODEL?

Triple-blind randomized trials are a criterion for the scientific validation of drugs. Including a similar criterion for NPI evaluation was not feasible as, for example, the idea of psychologist-led psychotherapy or a dietician-led diet being concealed from a study participant is impossible. During the development of the NPIS Model, everything was done to ensure the best causal link between a proposed practice (i.e., NPI) and its effects on health, taking into account the specific nature of the NPI being evaluated, without ever deviating from the rigour and ethics required in health research. While our recommendations minimise bias and promote validity and reproducibility, this will never prevent certain individuals or promoters from committing fraud. Given the lower health risks of NPI compared to fast-acting disease products (e.g., surgery, fast-acting medication, implantable medical devices) and their potential value in health prevention, effectiveness trials are the best way of taking risks into account. Having said that, one cannot extrapolate effectiveness trial results from one country to another, because of differences between healthcare systems. Accordingly, as well as effectiveness trials, an implementation study is necessary in the new country.

WHY WAS THE TERM 'PROFESSIONAL' AND NOT 'PRACTITIONER' USED IN THE DEFINITION OF NPI?

French law limits the term 'healthcare professional' to 24 types of professions (French Public Health Code, 2024). A clinical psychologist and a kinesiologist are two examples of professionals who work to improve the health of people by implementing NPI for preventive or therapeutic purposes. However, these two professions are not on the Public Health Code's list of 'healthcare professionals'. Moreover, some healthcare professions fall under France's Social Action and Families Code (e.g., specialised educator). At the European level, and more generally, worldwide, the ambiguity surrounding the terms 'professional' and 'practitioner' becomes even more complex, because not all health-related professions are given the same name. For example, the term 'kinésithérapeute' is used in France (not 'physiothérapeute') while most countries around the world use 'physiotherapist'. NPI validated by the NPIS Model can become common denominators between countries, because they will have a unique code and unique specifications indicated on their associated NPI Card (see above).

WHY ARE IMPLEMENTATION STUDIES REQUIRED TO EVALUATE NPI?

If a clinical trial demonstrates the effectiveness of an NPI in one country, this does not mean that this disease prevention or care protocol is equally relevant, feasible and/or acceptable in another country. Accordingly, an implementation study in the country where the NPI is to be used is necessary. Furthermore, the NPIS Model recommends conducting an implementation study to identify the conditions for implementing the specific NPI in a given health region or country (good practices that respect culture, habits, customs and individual preferences).

WHAT IS A PROTOTYPE STUDY?

Before evaluating an NPI, it must be described. Sometimes, health practices can be a combination of diagnostic methods and treatments, for example in osteopathy. An NPI does not aim to identify a health problem or to diagnose it; it is a preventive or therapeutic solution to resolve a health problem, sometimes in association with other treatments. Another issue that often leads to confusion is the distinction between an NPI and the terms 'approach' and 'technique'. Approach is too vague a term, as it does not precisely describe the content of an NPI. The term technique is too singular; a technique is only one element of an NPI. A prototype study makes it possible to describe all the characteristics of an NPI, its objective in terms of health improvement, its target population, its mechanisms of action, its content, its implementation context and the professional requirements needed to implement it.

WHY ASSIGN A UNIQUE CODE TO EACH NPI LISTED IN THE NPIS REGISTRY?

Interoperability between the information systems of health operators and funders is the cardinal condition for the efficacy of NPI. Assigning a unique code to an NPI improves information transfer, decision-making, the quality of its implementation, traceability, monetisation, and impact analyses. Accordingly, an NPI becomes a procedure identified in an institutional nomenclature and a AI system.. The characteristics of an NPI are described and justified by studies published in peer-reviewed scientific journals that meet the expectations of international health research. These characteristics must comply with the NPIS Model. NPI validated by this model become NPIS©-labelled NPI through a process of standardization and independent expert assessment. They can be integrated into personalized health pathways by a professional, a multidisciplinary team, a health centre, a healthcare facility, a medico-social structure, a health network, a digital platform or any other organization authorized to deliver health solutions. By assigning a unique code to each NPIS©-labelled NPI which is interoperable with insurance/profession nomenclatures, national authorities and insurance systems can implement control and feedback procedures for the use of NPI according to their level of risk management. Data from the uses and experiences of users, of professionals, of health operators and of institutions fuel new research questions. Research fosters innovation, for example, by isolating more specific, more effective, more implementable and more efficient NPI.

HOW CAN I USE THE NPIS REGISTRY IN PRACTICE?

Independent healthcare professionals or multidisciplinary teams from, for example, healthcare networks, hospitals, medico-social structures, medico-educational structures, nursing homes, prevention centres, occupational health services, school/university establishments, palliative care services, can all choose to integrate one or more NPI in the individualized health pathway of a person. This person may be losing the capacity for independent living (e.g., a fragile person aged over 90), may be exposed to increased risk of illness (e.g., an employee who smokes), may be disabled (e.g., loss of independent living due to paraplegia) or may be sick (e.g., neuro-progressive disease). Since today's health problems are multifactorial and complex, multiple solutions can be found to improve the health of the individual; these solutions depend on local contexts (e.g., can a physiotherapist provide a service close the patient's home?). A doctor, any other authorized health professional (e.g., pharmacist, nurse, midwife, physiotherapist) or a medical team can propose several NPI for prevention, care and support for the same patient. These NPI are catalogued in the centralized digital platform called the NPIS Registry (see above). They complement other health solutions offered at a specific moment in a person's life (e.g., medication, medical device, hospitalization, social assistance). They evolve over time depending on the recipient's state of health, fragility and preferences **(Figure 8)**.

WHAT ARE THE CHARACTERISTICS OF AN NPI?

Every NPI card in the NPIS Registry is first submitted by a professional or researcher on the NPIS's dedicated platform. Each record is assessed by an independent and transparent scientific committee. Any competent medical society, and scientific society or health authority can verify the decisions taken regarding the NPI's validation at any time **(Figure 11)**.

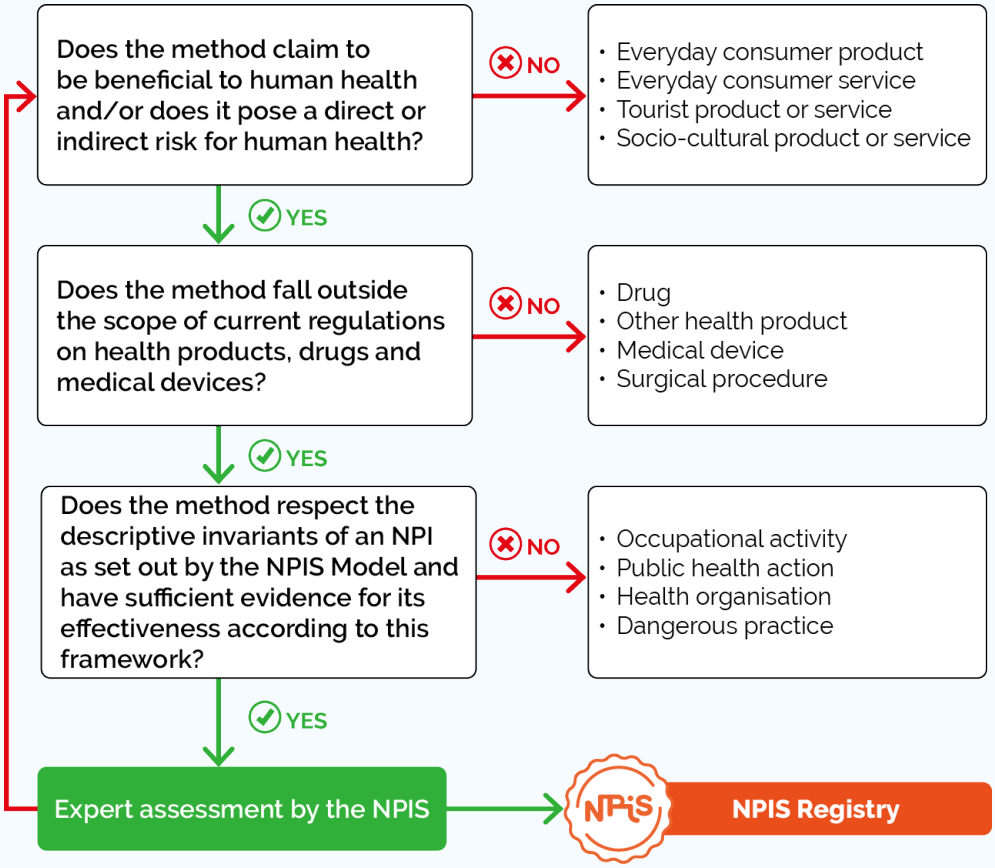

Figure 11: Procedure for adding an NPI to the NPIS Registry

Each validated NPI card is reviewed by a committee of users and professionals. Once the submitted card has been validated and labelled NPIS©, the card is translated into English and French (translation into other languages is also possible, but English and French are mandatory) and integrated into the NPIS Registry. The card has standardized content supported by scientific studies in accordance with: i) the definition of NPIs by the international scientific society NPIS, ii) the expected characteristics of an NPI **(Table 1)**, and iii) the consensus-based framework for evaluating NPIs, called the NPIS Model. The card contains i) instructions for the use and implementation of the specific NPI for professionals, ii) an information notice for users, iii) a space for indices, particularly financial support, and iv) an area for anonymized feedback. The card can therefore evolve. It is part of a virtuous circle of continuous improvement of the relevant NPI.

In terms of evaluation studies, a minimum of 1 prototype study, 1 mechanistic study, 2 interventional studies and 1 implementation study published in peer-reviewed journals that comply with the NPIS Model, are necessary for a proposed NPI to be admissible for assessment by the NPIS's independent and unbiased expert committee. Specifically, the experts on this committee must have sufficient evidence to vote anonymously on each of the following criteria:
– **Described** (≥ 1 prototype study),
– **Explainable** (≥ 1 mechanistic study),
– **Effective** (≥ 2 interventional studies),
– **Safe** (≥ 2 interventional studies),
– **Implementable** (≥ 1 implementation study in the country).

The NPI card is validated and labelled NPIS© if at least 80% consensus from the experts committee is obtained for each of all the above-mentioned criteria. Once published on the NPIS Registry, every healthcare professional worldwide will have access to specific features of the NPI in question, its context for use, its conditions of implementation, as well as the equipment and the training required to implement it. Every person using the NPI receives a notice simply explaining the why, the how and who to contact regarding the NPI.

CAN YOU GIVE SOME EXAMPLES OF NPI?

A PSYCHOSOCIAL FOCUS

Psychotherapies
– Cognitive stimulation therapy for memory strategies in persons living with Alzheimer's disease: 14 sessions by a psychologist in a healthcare facility, a nursing home or a private practice.
– *Mindfulness Based Stress Reduction* programme for anxiety during cancer treatment: 8 group sessions led by a clinical psychologist, a psychiatrist or a doctor in an oncology department, a patient association, a private practice, a nursing home, or a healthcare facility.
– *Acceptance and Commitment Therapy* for chronic pain: 9 group sessions by a clinical psychologist or a psychiatrist in a healthcare facility, a nursing home or a private practice
– Cognitive-Behavioural Therapy for insomnia (CBT-I): 8 individual remote or face-to-face sessions led by a neuropsychologist, a clinical psychologist, a psychiatrist or a neurologist in a healthcare facility, a nursing home, or a private practice.

Disease management and health behaviour change programmes
– *Living well with COPD* management programme against the symptoms and exacerbations of Chronic Obstructive Pulmonary Disease (COPD): two-month programme with 4 face-to-face or remote sessions by a nurse, doctor or pharmacist in a healthcare facility, health centre or private practice
– CHESS *(Chronic Headache Education and Self-management)* method for self-managing migraines, led by a nurse or doctor in a healthcare facility, health centre or private practice.
– *MyFriend Youth* programme for the prevention of anxiety and depression disorders in students aged 12 to 15: 10 sessions led by school psychologist or school nurse in a school premises.
– Spiegel hypnotherapy method specializing in smoking cessation: 3 sessions led by a psychologist, nurse, doctor or hypnotherapist in a private practice, healthcare facility, health centre or office.
– Cognitive behavioural therapy for depression (CBT-D) led by a clinical psychologist or psychiatrist in a health facility, nursing home or private practice.

A PHYSICAL FOCUS

Physiotherapy protocols

– McKenzie Method for back Pain led by a physiotherapist in a healthcare facility, nursing home or private practice.
– Pelvic floor muscle training (PFMT) programme led by a midwife or physiotherapist in a healthcare facility or private practice.
– Hip replacement rehabilitation programme: 8 sessions led by a physiotherapist in a healthcare facility, nursing home or private practice.

Adapted physical activity programmes

– *Dance therapy for Parkinson's Disease* programme to reduce the psychological symptoms of the disease, led by an exercise professional in a health facility, a health centre or a private practice.
– Ventilatory threshold exercise rehabilitation programme for COPD-induced dyspnoea, led by an exercise professional or a physiotherapist in a health facility, a health centre or a private practice.
– Anti-fatigue exercise programme for persons on treatment for breast, prostate or colon cancer, led by an exercise professional in a health facility, a health centre or a private practice.

A NUTRITIONAL FOCUS

– Gluten-free diet for persons with celiac disease led by a dietitian in a health facility, nursing home or private practice.
– FODMAP diet for gastrointestinal disorders led by a dietitian in a health facility, nursing home or private practice.

ARE NPI SIMPLY 'RECIPES' TO APPLY?

NPI are protocols to be implemented with a target population, but they are only general specifications. They must be contextualized and personalized. The NPIS Registry provides recommendations on good practices and advice on how best to implement an NPI. In addition, the scientific society NPIS recommends multi-professional training in health ethics for professionals who wish to implement them. In this perspective, the society is currently working with its partners to develop an ad hoc core training programme, and to have it officially recognised; the training itself could be carried out, for example, in higher education establishments in collaboration with the Ministry of Health. This ethics training programme will provide all the knowledge, know-how and interpersonal skills necessary for efficient interprofessional practice in health. Health professions experienced in this field, for example doctors, will have equivalent qualifications.

WHAT IS THE ADDED VALUE OF THE NPIS REGISTRY FOR A HEALTHCARE PROFESSIONAL?

NPI that are freely accessible for consultation

– Strengthening the quality and safety of existing practices (formalization, harmonization, security, etc.)
– Integration of codified NPI into health professional, administration and insurance software
– Computerized documentation available for a computer, tablet or smartphone
– Extension of validation of NPI to all professionals working for the State
– Quick and easy accessibility to NPI when a decision on prevention and care needs to be made
– Simple monitoring, and an evolving 'good implementation practice' process (identification of obstacles professional leadership, provision of training and assistance for NPI protocol implementation, etc.)

Means of controlling quality and deviations from validated NPI

– Traceability through the use of NPI with unique codes
– Strengthening the link between the human therapeutic alliance and care protocol implementation
– Monitoring of relevant indicators
– Tool for continuing training
– Brand that can be identified for all decision-making support systems (health data, artificial intelligence)
– Regular updating through feedback

Means of valorisation

– Response to a multi-professional problem identified by a team from a local healthcare structure
– Extension of the role of certain professionals, most often non-physicians
– Abandonment of ineffective, dangerous and/or costly protocols
– Reduction of the number of single or multi-professional meetings required when developing an intervention
– Support for innovation and confidence-building of professionals experimenting with new practices
– Financial valorisation and optimization of resources in use **(Box 3)**

Box 3: Examples of messages of support for the NPIS Registry initiative from October 2024

Marguerite Cazeneuve
Director of Care Management and Organisation, French National Health Insurance Fund
"We wish to express our support for and our commitment to this initiative, which will provide a registry of validated NPI. We will continue to support this initiative, which will help to guarantee that the NPI offer stays relevant."

Maëlig Le Bayon
Director of the French National Solidarity Fund for Independent Living
"This digital platform 'NPIS Registry' fully aligns with the work of the CNSA and its evidence resource centre. Irrespective of the tools used, our aim is to help funders and those who implement actions to prevent a deterioration in independent living, to identify and implement prevention programmes that have been proven to be effective. This platform will help them do just that."

Philippe Bergerot
President of the French National League Against Cancer
"Supportive care helps to improve patients' quality of life, reduce after-effects and increase life expectancy. One example is adapted physical activity. It has been shown to reduce fatigue and improves survival, provided it is prescribed as part of a rigorous and secure framework. The NPIS Registry will make it possible to define these conditions and to provide the level of evidence required by healthcare funding bodies. For the League, this is a key issue of equal access for all patients to this type of supportive care."

Hervé Naerhuysen
Chairman of the Health Observatory PRO BTP and Managing Director of PRO BTP
"The recognition of the first non-pharmacological intervention protocols and the emergence of a recognised registry are a major step forward for health in France. As a social protection group, we are proud to support this preventive health solution, which will significantly improve patient care, offering efficiency, safety and well-being. This is an integral part of our social innovation approach, which we have been pursuing for several years, and which aims to provide the best possible support for individuals throughout their lives, particularly when they are vulnerable."

Jérôme Salomon
Assistant Director-General for Universal Health Coverage, Infectious Diseases, Chronic Diseases, and Mental Health at the World Health Organisation
"I look forward to future collaborations."

DOES THE NPIS REGISTRY DICTATE THE CHOICE AND IMPLEMENTATION OF AN NPI?

The NPIS Registry in no way dictates the choice of which NPI to use or when to implement it in a person's health prevention and care pathway; moreover, influencing these choices is in no way part of the NPIS's mission. These decisions depend on individual health situations, preferences, availability of professionals, professionals' qualifications, accessibility in a given area, and socio-cultural contexts. The art of combining NPI with each other and with other health solutions, at the right time, is the responsibility of professionals, expert systems, multi-professional organizations and the health system of the relevant country. The NPIS Registry highlights essential practices that have proven themselves and are continually evolving through research and analysis of feedback. The NPIS has no prerogative to impose the choice of NPI on anyone. Professionals are free to implement whatever NPI they wish, or to create their own. The same goes for health organisations.

IS THE NPIS REGISTRY A TOOL TO COMBAT DISINFORMATION IN THE HEALTH FIELD?

The NPIS Registry contributes to the development of effective and active solutions for precision medicine. Let us take a counter-example. How can we hope to advance NPI in the treatment of pain and not confuse patients when a medical school as renowned as Stanford publishes a vague, incomplete and non-hierarchical list on its website **(Box 4)**?

Box 4: List of NPI proposed by Stanford University School of Medicine in the treatment of pain

"Physical activity, acupressure, acupuncture, application of heat or cold, aquatherapy, art therapy, biofeedback, family coaching, individual coaching, psychological conditioning, desensitization, therapeutic education, occupational therapy, horticultural therapy, hypnosis, physical therapy, massage lotions, meditation, music therapy, posturology, presence of a companion, psychosocial support, transcutaneous electrical nerve stimulation, comfort therapy, drama therapy, psychosocial therapy, toning and strengthening, yoga."

By using alternative medicines and non-validated NPI, how many patients' hopes have been dashed? How much time have they lost? How much effort have they wasted? How much money have they squandered? How much unnecessary carbon-based transport have they used? The NPIS and its partners are proposing a solution to interrupt this destructive pattern, primarily for the benefit of people with health problems, by providing reliable information on the most relevant NPI and by no longer pitting drug-based therapy against NPI, but rather combining them in the right way and at the right time.

WHAT IS THE NPIS ROADMAP TO 2030?

The NPIS developed a 2021-2030 roadmap aligned with the strategies of European and international institutions responsible for health **(Figure 12)**. To this end, it has already started discussions with the European Public Health Association (EUPHA), which is involved in innovation in health services, the European Centre for Disease Prevention and Control which managed a repository of NPI until 30 September 2022 to cope with the COVID-19 pandemic (ECDC, 2023), the European Commission, which wants to promote "health, nutrition, mental health and psychosocial supports to communities" (European Commission, 2022), and WHO Europe, which says it wants to identify the "most effective health interventions" by 2030 (WHO Europe, 2021). The NPIS has already submitted several European projects. It is also in contact with the WHO, which has been advocating i) self-care interventions since 2022 (WHO, 2022), ii) NPIs in its Global Mental Health Action Plan published in 2022 (WHO, 2022), iii) "the most effective and feasible interventions in a national context" in a report published in 2021 (WHO,

2021), iv) "evidence-based interventions for rehabilitation" (WHO, 2023), and v) health actions to reduce environmental risks through a compendium of interventions on environmental health (WHO, 2024).

Finally, the NPIS is in contact with other international bodies such as UNESCO, which has been advocating specific health and well-being education interventions since 2016 (UNESCO, 2016), UNICEF, which has been advocating the sharing of effective interventions in health since 2016 and the development of primary health care since 2018, the UN, which has been advocating the acceleration of essential health services since 2023 (UN, 2023), and the Coalition of Partnerships for Universal Health Coverage and Global Health, which has been advocating population-centred, comprehensive and integrated services since 2021. In other words, an NPI ecosystem, which ranges from research to practice, and which includes training and delivery, is being built. The NPIS is participating in this process by scaling up its NPIS Registry **(Box 5)** and its two Open Science Badge and Open Practice Badge training courses **(Figure 13)**.

Box 5: International deployment objectives presented at each NPIS Summit

October 16, 2024: Launch of the NPIS Registry and 2 multi-professional science and practice open badge training courses
October 15, 2025: 300 NPI cards added to the NPIS Registry and 100 open badges issued
October 13, 2026: 1,000 NPI cards added to the NPIS Registry and 500 open badges issued
October 12, 2027: 2,000 NPI cards added to the NPIS Registry and 1,000 open badges issued
October 17, 2028: 3,000 NPI cards added to the NPIS Registry and 3,000 open badges issued
October 16, 2029: 5,000 NPI cards added to the NPIS Registry and 5,000 open badges issued
October 15, 2030: 10,000 NPI cards added to the NPIS Registry and 10,000 open badges issued

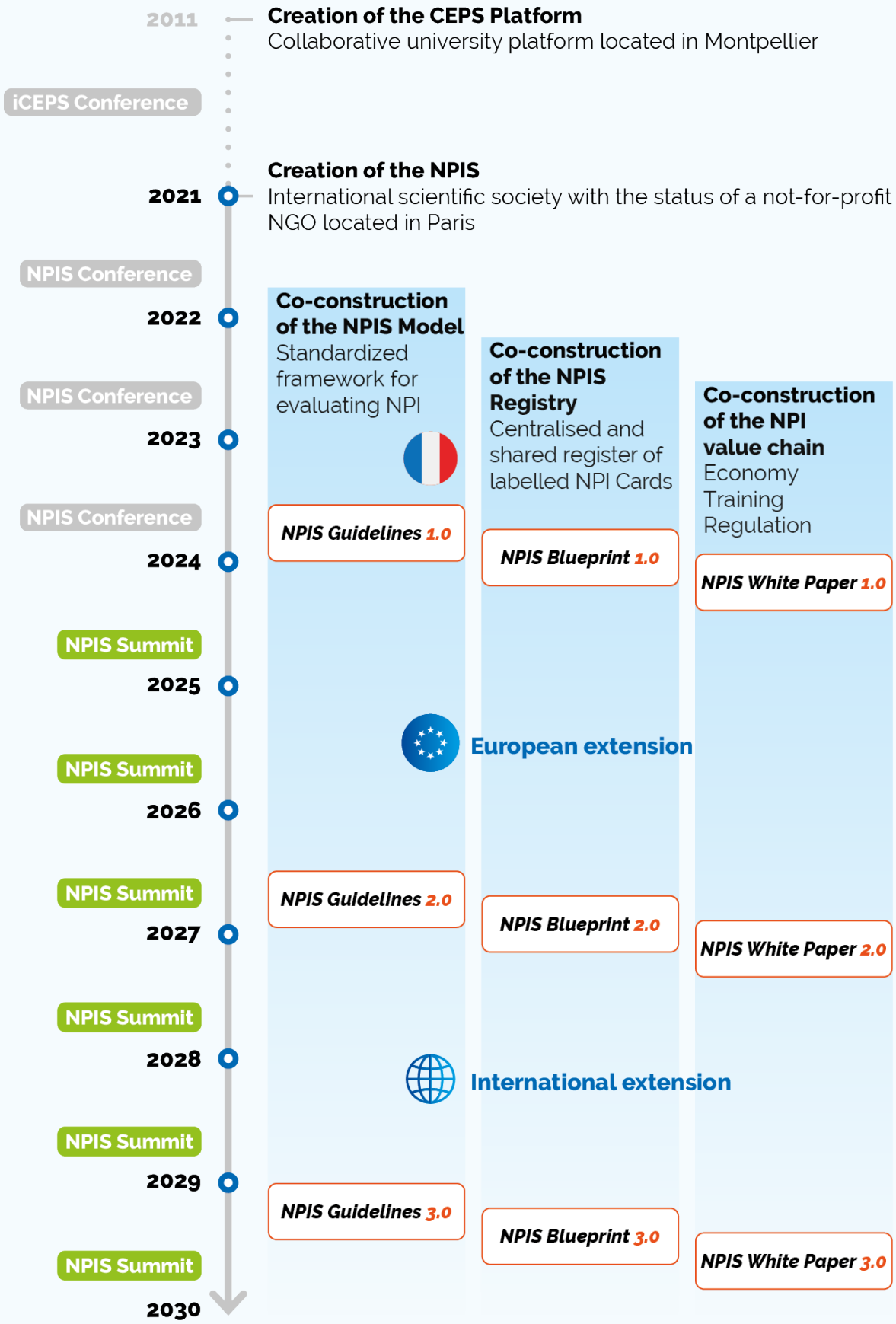

Figure 12: The NPIS Roadmap to 2030

Figure 13: Open Science Badge and Open Practice Badge training courses

The NPIS involves academic and non-academic stakeholders in health to create a genuine value chain for the benefit of science-based personalised and precision medicine, sustainable health and equitable. With an estimated global population of over 2.1 billion people aged over 60 in 2050, multi-stakeholder collaborations will be the foundations of an economy based on sustainable and equitable longevity (World Economic Forum, 2024). The NPIS organises multistakeholder meetings on NPI since 2024, called NPI Forums.

The scientific society also organises international 2-day events, called NPIS Summits, every year in October. This event brings together all NPI stakeholders over two days in October in a hybrid (i.e., on-site and remote) format in two official languages, French and English. A scientific committee selects oral and poster communications and awards prizes. In parallel, participants are invited to attend a trade show for professionals, a Business-to-Business 'speed-dating' event, forums, workshops and multi-stakeholder round tables. A day reserved for NPIS members is devoted to presentations of the scientific society's activities, projects and the annual general meeting.

Regional events called NPIS Satellites bring NPI professionals and users together on a specific health theme. For example, in March 2024, an NPIS Satellite was held on the prevention and treatment of obesity in Lille, France.

DOES THE NPIS ADVOCATE THE PRESCRIPTION OR REIMBURSEMENT OF ONE NPI OVER ANOTHER?

Absolutely not! The NPIS is working towards something that is bigger than itself and that brings people with different backgrounds and beliefs together for a just cause: the development of a scientific approach promoting best practices in prevention, care and targeted and personalized assistance with independent living; these practices are called NPI by health authorities. The NPIS also defends the humanism and science inherited from the Age of Enlightenment. Moreover, it does not favour one NPI over another. It provides factual knowledge at a given time t based on a rigorous collective independent assessment process that can be examined at any time by any health authority. It facilitates the traceability of NPI in health systems, and leaves prescribers and medico-social teams free to choose which NPI they wish to use, sometimes in combination with other health solutions. It is up to national prevention, care and independent living support organisations as well as political decision-makers to decide on the nature, modalities and level of their support for NPI with representatives of professionals and users.

IS THE NPIS CREATING A NEW VALUE CHAIN?

Non-material-based prevention and care solutions have existed since the dawn of time. It is simply that the combination of a diversification of practices, the multiplication of professions at the crossroads of prevention, care and social assistance, as well as the globalisation of information systems, has downgraded and equated these services in the sense that an NPI of better quality is equated with one of lesser quality. Moreover, this combination has obscured NPI at a time when medicine has made considerable progress in the early detection and diagnosis of health problems. Studies and institutional reports attesting to the socioeconomic benefits of NPI have multiplied since the beginning of the century (NPIS White Paper, 2024). **Figure 14** summarizes this virtuous circle.

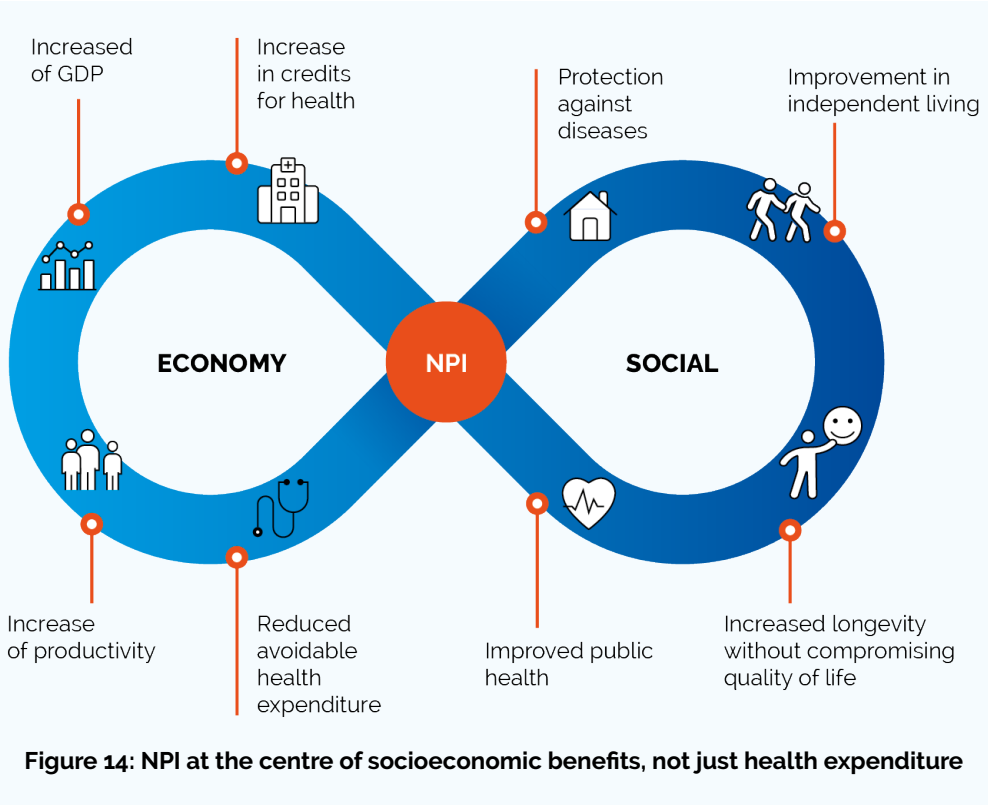

Figure 14: NPI at the centre of socioeconomic benefits, not just health expenditure

The interdisciplinary and multi-sectoral approach the NPIS employs generates a real value chain **(Figure 15)**, from the design of NPI to their implementation, regulation and financing. Particularly innovative business model initiatives are being launched all over the world: fee-for-service, flat-rate payment, social and solidarity economy services, social assistance, services promoting sustainable development, the e-health economy, human innovation packages, crowdfunding, charity-business, the long-term economy (World Economic Forum, 2024). Moreover, NPI Forums, NPIS Summits, or specific thematic events such as the NPIS Satellites invite all those who have experience in NPI innovation to come and share their experiences.

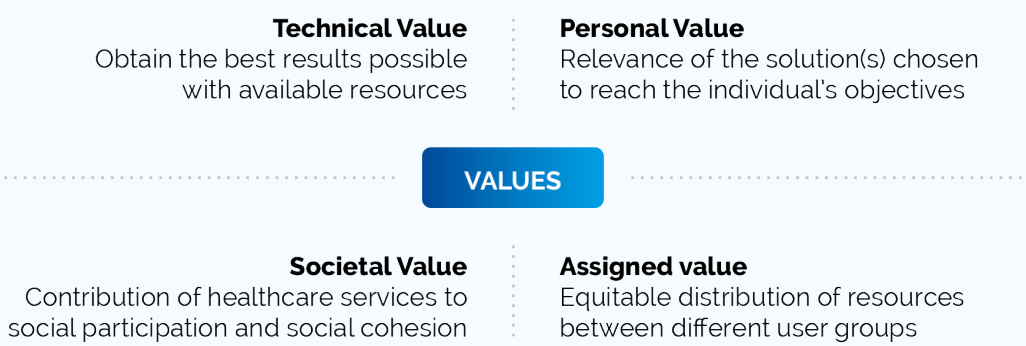

Figure 15: NPI at the centre of economic benefits, not just health expenditure

DOES THE CREATION OF AN INTERNATIONAL COMMUNITY ON NPI MAKE SENSE?

An alliance on NPI is essential today in the face of siloed proposals from different disciplines (biology, psychology, public health, etc.), professions (medical, paramedical, educational, social, etc.), sectors (evidence-based medicine, patient-centered medicine, 4P medicine, anti-age medicine, traditional medicine, One Health, etc.), trends (traditional medicine, scientific medicine, etc.) at both national and supranational levels. The NPIS brings these scattered and sometimes divided actors together to develop better understanding, better implementation, and better recognition of NPI. It contributes to the development of an NPI ecosystem, something that was previously often overlooked. It brings together hundreds of professionals and users around the world to reduce the burden of 21st century public health problems. It highlights essential NPI and related best practices to be proposed to the right people at the right time in their personalised care pathways without criticizing other health solutions **(Figure 16)**.

In concrete terms, the NPIS enables:
- research stakeholders to develop, evaluate and promote NPI,
- healthcare, prevention and social support professionals to enhance their skills and have access to best practice recommendations and tools for implementing NPI,
- health operators to choose, organize, track, consolidate, secure and sustain investments in NPI,
- national and supranational health agencies to improve their knowledge in order to design efficient NPI strategies,
- governments, non-governmental organizations, user associations and federations of health stakeholders to have a common language within a defined scope in order to develop fair, equitable and sustainable policies.

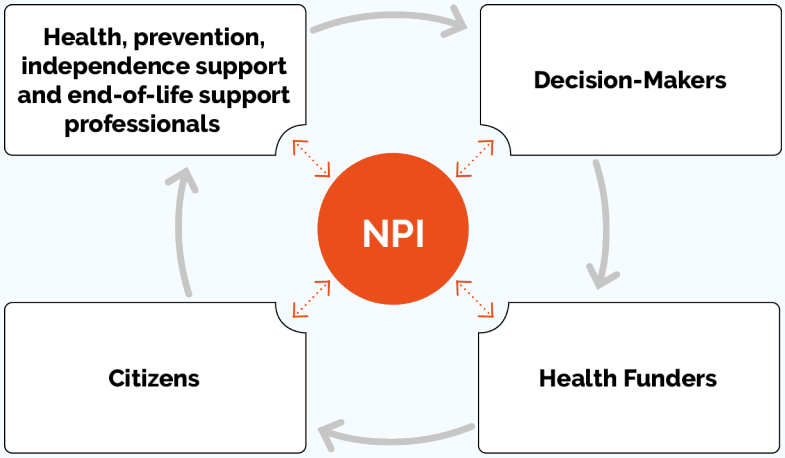

Figure 16: The NPI Value Chain currently being co-constructed by the NPIS and all relevant stakeholders

Now that the NPIS has developed a standardized model for evaluating NPI (i.e., the NPIS Model), it is continuing its efforts to encourage the creation of an interprofessional, intersectoral and trans-partisan NPI alliance. More specifically, through international summits held annually in the third week of October (called NPIS Summit), it brings together all the stakeholders in the nascent NPI ecosystem. This major event discusses the regulatory, economic, technological, educational and informational structuring of this ecosystem. Each edition is organized in a highly symbolic location. The 2024, 2025 and 2026 editions have been organized at the *Cité Universitaire Internationale de Paris*, a humanist environment par excellence, open to the world, to science and to peace, created between the two world wars in the last century. Everyone can participate and contribute to this international dynamic, which was founded with the sole aim of legitimizing NPI in health system offerings without denigrating other health solutions. This informal coalition is called the NPI Alliance **(Figure 17)**.

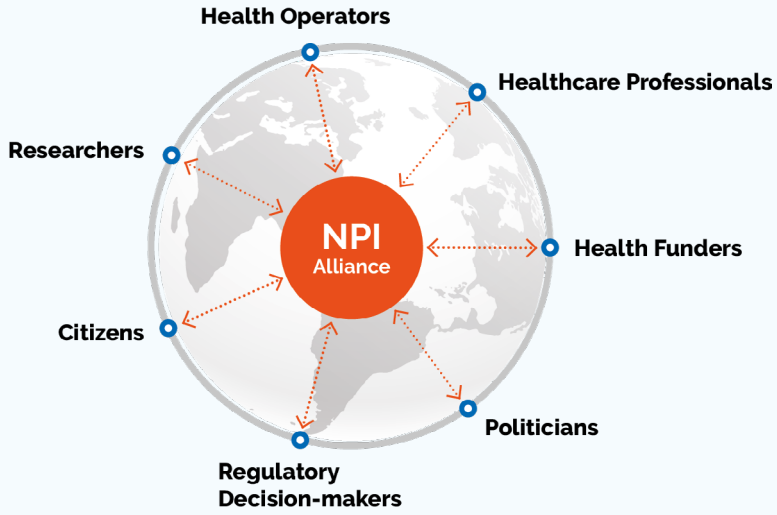

Figure 17: An Alliance for the development of NPI

The NPIS is working towards something that is bigger than itself and that brings people together for a useful cause: the development of a scientific approach promoting best practices in prevention, care and targeted and personalized assistance with independent living; these practices are called NPI. The NPIS also defends the humanism and science inherited from the Age of Enlightenment.

8 Tools

GLOSSARY

Given the diversity of people interested in NPI, the NPIS has decided to create an online glossary of relevant terms that draws on definitions in particular from the WHO and other scientific bodies dedicated to health.

NPIS BLUEPRINT

The NPIS Blueprint is the technical specification for the tools proposed by the NPIS for research and multi-professional practice in the context of NPI.

NPIS GUIDELINES

The NPIS Guidelines are a didactic document that summarizes the non-pharmacological interventions (NPI) ecosystem. This handbook also presents the international scientific society NPIS and answers the questions most frequently asked about NPI in the field of evidence-based health solutions applied in prevention, care, work assistance, social protection, and end-of-life support.

NPIS MODEL

From 2021 to 2023, the NPIS co-constructed a standardized scientific framework for evaluating NPI with all relevant stakeholders. This framework meets the scientific expectations of international health research. The framework uses a transdisciplinary, intersectoral, transparent, patient-centred approach.

NPIS OPEN BADGE

Together with its partners, the NPIS has designed two international open badge training programmes, Practice and Science. Each course is divided into three pluriprofessional modules: knowledge, skills and health-related ethics. Equivalences can be granted on request, depending on diplomas, qualifications and professional experience. Both programmes are aimed at all professionals in the fields of prevention, care and independent living. They are delivered by trainers with full open badge certification. They can be implemented by academic or private training organisations from any country that has signed an agreement with the NPIS. For trainees who successfully complete this training, these badges attest to their having the minimum knowledge, know-how and interpersonal skills required for multidisciplinary practice and research in the sphere of NPI. Trainees who successfully complete the training are given access to the NPIS's shared resources for one year (publications, videos, case studies, glossary, NPIS Registry with premium access, etc.). They can also access the contact details of the NPIS's international community of professionals, user representatives and investors.

NPIS WHITE PAPER

The first version of the NPIS White Paper was published in October 2024 in French. It was written after an awareness that advances in the early detection of disease and signs of frailty, coupled with the demand for more effective and personalized healthcare services, called for clarification as to what an NPI is and is not. Unlike medicines, which are continuously perfected following an internationally standardized evaluation framework, prior to 2023, the heterogeneity of ways to evaluate NPI was holding back their scientific development, legal recognition, deployment, economic valuation and professional appreciation. This heterogeneity led to NPI becoming downgraded and equated (i.e., better quality NPI were considered equivalent to lower quality NPI). Furthermore, NPI risked being used in pseudoscientific practices. Professionals developing and implementing them could be discredited. In 2023, the international scientific society NPIS finalised a multi-stakeholder consensus-based evaluation model for NPI. This framework, which was co-constructed over 12 years, defines the scope of these non-material-based practices (or protocols), protects them through scientific validation, legitimizes an international benchmark for them, facilitates the sharing of best implementation practices, accelerates stakeholder training, encourages investment and federates a global ecosystem. The 2024 white paper outlines the challenges facing NPI, and explains the NPIS roadmap up to 2030, in line with European and international health authorities' plans for sustanaible and equitable development. It is the fruit of collective intelligence and multiple and diverse encounters. All royalties from the sale of this white paper shall be donated to the NPIS to advance research and innovation in NPI for the benefit of personalized and precision medicine and for active, sustainable human health.

NPIS REGISTRY

The NPIS Registry is a digital platform of standardized, non-material-based best practices for NPI. This universal register of codified, applicable, traceable and fundable NPI records, called NPI Cards, can be accessed free of charge by the general public and by healthcare professionals. Data from the experiences of users and professionals are collected to improve practices.

9 Events

NPI FORUMS

The NPIS involves academic and non-academic stakeholders in health to create a genuine value chain for the benefit of science-based personalised and precision medicine, as well as sustainable and equitable health.. With an estimated global population of over 2.1 billion people aged over 60 in 2050, multi-stakeholder collaborations will be the foundations of an economy based on sustainable and equitable longevity (World Economic Forum, 2024). The NPIS organises multistakeholder meetings on NPI since 2024, called NPI Forums **(Box 6)**.

Box 6: NPI Forum schedule

October 17, 2024: Cité Universitaire Internationale de Paris
December 5, 2024: Maison Irène et Frédéric Joliot-Curie in Brussels
October 16, 2025: Cité Universitaire Internationale de Paris
October 14, 2026: Cité Universitaire Internationale de Paris
July 1, 2027: WHO-Europe in Copenhagen (under discussion)

NPIS SATELLITES

Regional events called NPIS Satellites bring NPI professionals and users together on a specific health theme **(Box 7)**. For example, in March 2024, an NPIS Satellite was held on the prevention and treatment of obesity in Lille, France.

Box 7: NPIS Satellite schedule

December 1, 2021: NPI and cancer at the Ministry of Health in Paris
March 22, 2024: NPI and obesity at the Lille Pasteur Institute

NPIS SUMMITS

The scientific society also organises international two-day events, called NPIS Summits, every year in October. These events bring together all NPI stakeholders in the third week of October in a hybrid (i.e., on-site and remote) format in two official languages, French and English. A scientific committee selects oral and poster-based communications and awards prizes **(Box 8)**. In parallel, participants are invited to attend a trade show for professionals, a Business-to-Business 'speed-dating' event, forums, workshops and multi-stakeholder round tables.

Box 8: Calendar of NPIS Summit (or equivalent)

March 25, 2011: Corum in Montpellier
April 5, 2013: Corum in Montpellier
March 19-21, 2015: Corum in Montpellier
May 19-21, 2016: University of Quebec in Montreal (UQAM)
May 18-20, 2017: Corum in Montpellier
March 23, 2018: Montpellier Metropolis
March 28-30, 2019: Faculty of Medicine in Montpellier
November 24-25, 2020: Remote because of COVID-19
April 3, 2021: Remote because of COVID-19
June 23-24, 2022: Vivacity in Paris
March 22-24, 2023: Palais des Sports René Bougnol in Montpellier
October 16-18, 2024: Cité Internationale Universitaire de Paris
October 15-16, 2025: Cité Internationale Universitaire de Paris
October 13-14, 2026: Cité Internationale Universitaire de Paris
October 12-13, 2027: European Commission in Brussels (under discussion)
October 17-18, 2028: European Commission in Brussels (under discussion)
October 16-17, 2029: European Commission in Brussels (under discussion)
October 15-16, 2030: WHO in Geneva (under discussion)

10 Acknowledgements

NPIS partners (providing financial and other material support to the NPIS)
Caisse nationale de l'Assurance Maladie (CNAM)
Caisse Nationale de Solidarité pour l'Autonomie (CNSA)
PRO BTP – Observatoire Santé PRO BTP
Harmonie Mutuelle – groupe VYV
Fondation Méderic Alzheimer
LNA Santé
Clariane
Ligue Nationale française contre le Cancer
AG2R La Mondiale
Silver Occ

Other supporters of the NPIS (i.e., non-funding)
Alzheimer Europe
Association Parkinson
Belgian Brain Council
Cancer Patients Europe
Comité Novateur d'Étude sur la Fragilité des seniors
Ensemble pour le cerveau
European Brain Council
European Public Health Association (EUPHA)
Fibromyalgie France
France Alzheimer
France Parkinson
INSERM
Institut Desbrest d'Épidémiologie et de Santé Publique
Parkinson Europe
Université de Montpellier

Scientific societies which endorse the NPIS Model
Association des Chercheurs en Activités Physiques et Sportives (ACAPS)
Association Française d'Urologie (AFU)
Association Française de Psychiatrie Biologique et Neuropsychopharmacologie (AFPBN)
Association Francophone des Soins Oncologiques de Support (AFSOS)
Collège de la Médecine Générale (CMG)
Collège National des Généralistes Enseignants (CNGE)
Collège National des Sages-femmes de France (CNSF)
European Public Health Association (EUPHA)
Société d'Éducation Thérapeutique Européenne (SETE)
Société de Pneumologie de Langue Française (SPLF)
Société Française d'Accompagnement et de Soins Palliatifs (SFAP)
Société Française d'Alcoologie (SFA)
Société Française d'Allergologie (SFA)
Société Française d'Anesthésie Réanimation (SFAR)
Société Française d'Endocrinologie (SFE)
Société Française d'Étude et Traitement de la Douleur (SFETD)
Société Française de Cardiologie (SFC)

Société Française de Neurologie (SFN)
Société Française de Nutrition (SFN)
Société Française de Pédiatrie (SFP)
Société Française de Physiothérapie (SFP)
Société Française de Psychiatrie de l'Enfant et de l'Adolescent et Disciplines Associées (SFPEADA)
Société Française de Psychologie (SFP)
Société Française de Rhumatologie (SFR)
Société Française de Santé Publique (SFSP)
Société Française de Tabacologie (SFT)
Société Française et Francophone d'Éthique Médicale (SFFEM)
Société Francophone d'Étude et de Recherche en Orthoptie (SFERO)
Société Francophone de Néphrologie, Dialyse et Transplantation (SFNDT)
Société Francophone de Santé et Environnement (SFSE)
Société Francophone Nutrition Clinique et Métabolisme (SFNCM)
Société Nationale Française de Gastro-Entérologie (SNFGE)

Health authorities which endorse the NPIS Model
Centre National des Soins Palliatifs et de la Fin de Vie (CNSPFV)
Institut National du Cancer (INCa)
Plateforme Française des Réseaux de Recherche Clinique (F-CRIN)

NPIS MODEL

Standardized Research Framework for Evaluating NPI in the Field of Health

The Non-Pharmacological Intervention Society defines an NPI as an evidence-based, effective, personalized, non-invasive health prevention or care protocol, registered and supervised by a qualified professional. "
(NPIS White Paper, 2024)

The NPIS Model is the result of a transdisciplinary, intersectoral, transpartisan, participatory, independent, pragmatic, and rigorous research project which involved over 1000 researchers, practitioners, healthcare users, health operators, members of scientific societies, and members of health authorities. The work was initiated in 2011 by a collaborative university platform in Montpellier, and has been continued by the international scientific society the Non-Pharmacological Intervention Society (NPIS) since 2021. The project has always followed the principles of honesty, scientific integrity and responsibility, three cornerstones on which the public bases its trust in research. The project's goal is to promote patient-proactive and sustainable human health.

Ethical recommendations

CODE	ETHICAL INVARIANTS	EXPLANATION
E1	**Respect the laws, regulations and ethics charters of the research professions in the territory where the NPI evaluation study is conducted**	In France, anyone involved in an NPI evaluation study is required to respect the national charter of ethics for research professions[1]. All NPI evaluation studies must comply with the law on research involving humans[2]. An NPI evaluation study must not fall under European Regulation 536/2014 relating to clinical trials of medicinal products for human use[3], European Regulation 2017/745 relating to medical devices[3], or European Regulation 2283/2015 relating to food supplements[4]. This legal framework applies to principal investigators, persons associated with the study, persons participating in the study, the study sponsor, and the investigative centre.
E2	**Specify the promoter, manager and person responsible for the NPI evaluation study**	Specify the organization and person responsible for the study, particularly for insurance and legal issues.
E3	**Declare the competing interests of the NPI evaluation study**	Indicate the competing interests of the study for all oral or written communication for a period of 5 years. Furthermore, specify all the kinds of support received.
E4	**Obtain agreement from an ethics committee before conducting the NPI evaluation study**	Submit the study protocol to a research ethics committee. Agreement from an ethics committee is required both to commence the study and for all its stages until its publication. The protocol can be subject to a posteriori control.
E5	**Protect the confidentiality of the data collected on individuals**	Comply with the data protection principles of the French Data Protection Agency and the European Union's General Data Protection Regulation.
E6	**Use international scientific literature to justify the NPI study**	Consult general health databases (e.g., Pubmed, Cochrane, Science Direct, Google Scholar, HAL, CORE), and databases specializing in NPIs (e.g., PEDro, APA PsycInfo).
E7	**Register as a researcher on the international ORCID registry**	Register on the *Open Researcher and Contributor ID* (ORCID) registry. Scientific journals require this individual code to publish a study and facilitate traceability of the researcher.
E8	**Respect international rules of scientific integrity**	Irrespective of the protocol for the NPI evaluation study, follow the principles and obligations of the Singapore Declaration on Research Integrity[5].
E9	**Systematically publish the results of the NPI evaluation study in a peer-reviewed scientific journal and/or in an open scientific archive**	Publish the results of the study, whether positive or negative. Consult the list of peer-reviewed scientific health journals in SCImago. In France, the relevant open archive is called HAL.

CODE	ETHICAL INVARIANTS	EXPLANATION
E10	**Archive raw data while respecting the confidentiality of personal data**	Making raw data accessible enables their reuse for new analyses, ancillary studies and meta-analyses. Guarantee the sustainability of these data.
E11	**Archive analysed data and make them accessible for publication while protecting the confidentiality of personal data**	Ensuring the accessibility of analysed data enables their reuse for new analyses, ancillary studies, and meta-analyses. Guarantee the sustainability of these data. Specify if, where, and how the data are accessible.
E12	**Archive the study analysis report**	Ensuring access to the complete data analysis report encourages interdisciplinary views, which are particularly relevant in the study of NPIs.
E13	**Involve healthcare users concerned by the subject of the study (or their representatives) in the design of the study protocol, the implementation of the study, and the promotion of the results**	In all stages of the study, involve participants who directly benefit from it (e.g., patients, associations) in its design and implementation[6].
E14	**Present the results to each study participant in an intelligible and systematic manner**	Adapt the format of the presentation of the results according to the levels of education, culture and knowledge of the study participants.

[1] French charter of ethics for health research (2015)

[2] French law (Jardé) governing research on humans (2012)

[3] European regulations relating to medical products (2014) and medical devices (2022)

[4] European Regulation on Food Supplements (2015)

[5] Singapore Declaration on Research Integrity (2010)

[6] National Institute of Health and Medical Research (INSERM), best practices in participatory research (2022)

Methodological recommendations

Evidence-based data is theoretical or practical acquired using scientific methodology and reasoning rooted in scientific integrity. The NPIS Model uses this approach in the field of health **(Figure 6)**. In addition to ethical recommendations which are applicable to all studies, the NPIS Model offers methodological recommendations according to five types of NPI evaluation studies which focus on explanatory mechanisms and processes (mechanistic), the content of practices (prototype), the evolution of practices (observational), the benefits and risks of the NPI (intervention), and finally, the strategies of application and personalization (implementation).

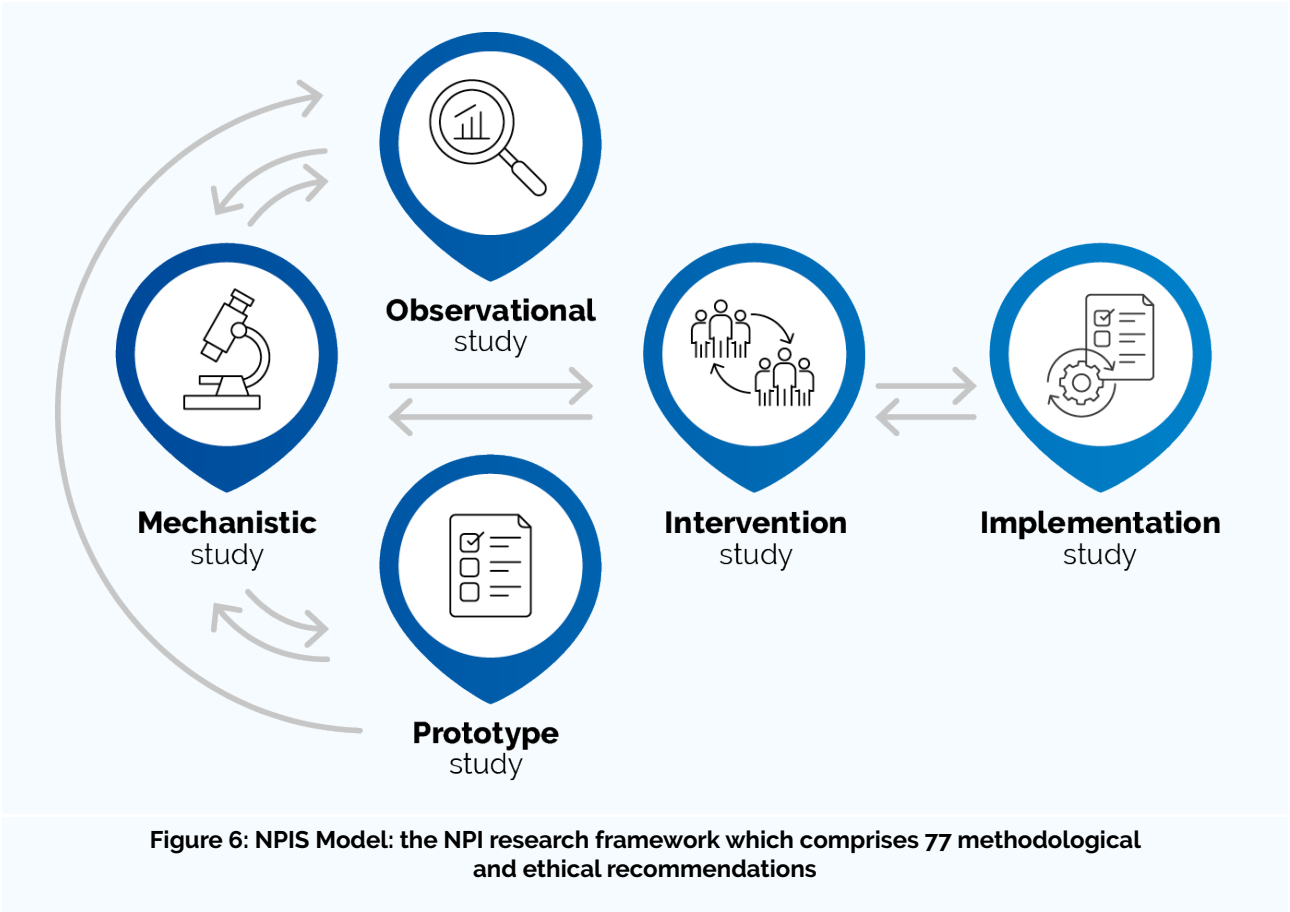

Figure 6: NPIS Model: the NPI research framework which comprises 77 methodological and ethical recommendations

Observational study

In an observational study on humans, researchers do not intervene in the course of events, and only observe a non-pharmacological practice, be it an approach, method, technique or ingredient. This is done either prospectively (e.g., cohort) or retrospectively (e.g., datamining, big data analysis). In 2007, the Enhancing the QUAlity and Transparency Of health Research network established an international recommendation for reporting observational studies in epidemiology, named STROBE (Von Elm et al., 2007). STROBE details how the results of a study should be presented in a scientific article (title, abstract, introduction, method, results, discussion, and other necessary information).

Mechanistic study

In a mechanistic study, researchers highlight the active biological mechanisms and psychosocial processes which explain the benefits of the NPI for health, autonomy, quality of life and/or survival, and the interactions with the environment or other treatment.

Prototype study

In a prototype study, researchers identify all the practical characteristics of an NPI by using methods for collecting information on practitioner and on user experience. The empirical study details the NPI protocol through feedback from practitioners and target users. The NPI prototype is then described along the grounds of the NPIS Model **(Table 1)** and is recorded in a sort of user manual intended for professionals in the health field. It details the contents of the NPI, the target population, the professional prerequisites to implement it, and the different contexts where the NPI can be used, in order to guarantee the reproducibility of its effects on health markers.

Intervention study

In a clinical trial with patients or an intervention study with people without a declared disease, researchers highlight the effectiveness of an NPI on a target population, that is to say the benefits and risks on this population's health. The controlled trial focuses on establishing whether there is a direct causal relationship between the NPI and its health effects. This method provides the best evidence that under similar conditions, the NPI will provide the same health benefits and cause the same side effects and health risks. Researchers must use the SPIRIT guide (2022) to communicate the results of a clinical trial (Chan et al., 2013; Butcher et al., 2022). Furthermore, researchers must use the TIDieR guide (2014) to describe the intervention, so that it can be better replicated in health practice or research (Hoffmann et al., 2013). Moreover, researchers must use the CONSORT Nonpharmacologic Treatments guide (2017) for randomized trials (Boutron et al., 2017).

Implementation study

In implementation studies, researchers determine the conditions for successful deployment of an NPI in a specific territory and modalities for adjusting it depending on the context (e.g., territorial, social, cultural, economic). An implementation study provides specifications for transferability and usage precautions that field-based teams can adjust without losing the effectiveness on health markers demonstrated in previous intervention study, the traceability procedures, or the elements of quality improvement. An international recommendation for reporting implementation studies, named STaRI, was established in 2017 (Pinnock et al., 2017). Depending on what is already known about the context of the implementation of interventions and potential deployment strategies, implementation studies may focus on identifying barriers and facilitators to implementation of the NPI, on the development and/or selection of implementation strategies, and even on comparing the value of different implementation strategies, particularly in relation to the adoption, effective implementation and/or sustainability of the NPI in its context.

Observational study

Population

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
OP1	**Specify the demographic, medical and socio-cultural characteristics of the study population**	Collecting data (at the very least) on study participants' age, gender, profession and place of residence, helps researchers to identify NPI responders and limit population biases.
OP2	**Identify the relevant experience of traditional or complementary practices in study participants**	Data collection on traditional or complementary practices habits provides relevant information on patients' expectations about the possible effects of the NPI.
OP3	**Specify the relevant past and current medical treatments that may have significant effects in study participants**	Data collection on biomedical treatments is necessary to take into account the influence of these treatments on the effects observed.

Intervention

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
OI4	**Identify the characteristics of non-pharmacological practices**	The characterization of a hypothetical NPI requires the description of its content (e.g., number, duration and frequency of sessions, mode of use of the equipment used, place of practice, practitioner, NPI access conditions (i.e., face-to-face or telemedicine), and the description of its components (e.g., equipment, technique, skill, ingredient). Two or more NPIs may be combined.

Comparison

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
OC5	**Use a sufficiently long monitoring time and data collection frequency to assess the effects of the NPI being evaluated on the criteria considered.**	NPIs rarely have immediate effects on health. A sufficiently long monitoring time with sufficient data collection frequency is required to observe the kinetics of the different markers evaluated.

Outcome

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
OO6	**Systematically record health markers (state of health, autonomy, quality of life, survival), and where possible, social, economic and environmental indicators**	An analysis of health data (e.g., benefits, adverse effects), autonomy (e.g., behaviours), quality of life (e.g., patient-reported outcomes) and life expectancy (e.g., life expectancy without loss of quality of life), as well as social (e.g., social participation), medico-economic (e.g., hospitalization, work stoppage) and environmental (e.g., energy expenditure) analyses, enable the identification of possible systemic effects of an NPI on a cohort.

Mechanistic study

Population

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
MP1	**Accurately describe the study population and recruitment procedures**	This type of study makes it possible to isolate the mechanisms at play (e.g., active principle in biology, processes in human science) which explain the effect of an NPI on health. Furthermore, the study population must be described accurately. Depending on the question asked, the data obtained can be compared to control situations.
MP2	**Describe the reasons justifying participant withdrawal from the NPI evaluation study**	Study participants may withdraw their consent, be excluded because of protocol violation, be lost to follow-up, experience a side effect of the NPI, or declare a contraindication.

Intervention

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
MI3	**Describe the content and context of the hypothetical NPI being evaluated as accurately as possible**	This description makes it possible to take into account the effect of the context on the mechanism(s) studied.
MI4	**Describe the experience and qualification of the person implementing the hypothetical NPI if necessary**	This description makes it possible to take into account the effect of the practitioner's experience on the mechanism(s) studied.

Comparison

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
MC5	**Describe, as accurately as possible, the experimental condition whose aim is to isolate the mechanism(s) of action studied.**	The study design highlights the mechanism(s) of action and the process(es). A mechanism can impact several markers. Whether a study targets the microscopic or macroscopic level, the researcher must be aware that an NPI mobilizes several mechanisms simultaneously. The method of measuring the observed phenomenon must be reproducible.

Outcome

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
MO6	**Analyse the phenomenon observed using scientifically validated tools**	An NPI mobilizes mechanisms and processes that can be observed on biological, physiological, behavioural, psychological, and social markers.

Prototype study

Population

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
PP1	**Target a population which may potentially respond to (i.e., be affected by) the NPI prototype**	An NPI cannot benefit everyone in the same way. The NPI evaluation study must target a homogeneous population with the objective of improving this population's state of health.
PP2	**Justify the number of people needed to answer the research question**	Having a minimum number of people participating in the study makes it possible to consolidate the reproducibility of the NPI.
PP3	**Take into account the past experience of the people participating in the NPI prototype evaluation study**	The effect of an NPI may differ depending on a person's past experiences.

Intervention

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
PI4	**Describe as accurately as possible the content and context of the NPI prototype**	The NPI evaluation study makes it possible to design the NPI protoype with an original name which describes its content and its implementation conditions. Doing this differentiates the NPI from an approach or a component. The NPI is therefore characterized, described and deployed in order to become reproducible in a similar context.

Comparison

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
PC5	**Define and justify the temporality of the data collected.**	The evaluation of the NPI prototype can be made before and/or during and/or after its implementation. Furthermore, the evaluation can be repeated.
PC6	**Promote the use of a mixed-methods approach**	A methodology which collects qualitative and quantitative data is advantageous to collect the multiple impacts of an NPI.

Outcome

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
PO7	**Collect data on user experience**	The study should make it possible to clarify the satisfaction, acceptability, and level of support for the NPI (disincentives and motivations).
PO8	**Collect data on the experience of the practitioner implementing the NPI prototype**	The study should make it possible to specify the conditions for the routine implementation of the NPI and the resources required.
PO9	**Define in advance the main health outcome which the NPI prototype is supposed to improve**	The study must specify the main health criterion targeted by the NPI, and, if possible, its secondary criteria. These criteria may be unique or composite.

Intervention study

Population

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
CP1	**Specify the demographic, socioeconomic and cultural characteristics of the population studied**	Providing at least the following population characteristics - age, gender, and at least one socioeconomic indicator - makes it possible to specify which populations may potentially respond to (i.e., be affected by) the NPI being evaluated, and to promote the comparability and reproducibility of the study. The characteristics of people not included in the study should also be specified.
CP2	**Specify the medical characteristics of the study participants**	The nature and severity of participants' pathologies, risk factors and medical history may modify the observed effects of the NPI. Collecting information on biomedical treatments is necessary to take into account their influence in the effects observed.
CP3	**Specify the recruitment strategies used.**	The recruitment context plays a role in the effects observed. Specify whether the people participating in the study received financial compensation.
CP4	**Justify the quality of the sampling method**	Describe how the sampling method used is representative of the target population, how sampling was conducted, and possible biases.

Intervention

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
CI5	**Name the NPI**	The study must explicitly cite the name of the NPI, and where applicable, its acronym and the persons who designed it.
CI6	**Define the main health objective and the primary outcome**	The study must confirm a hypothesis for the effect of the NPI on a main health marker (e.g., risk behaviour, symptom, sequelae, disease, functional capacity, survival, quality of life) – also called the primary outcome – with a defined action *(prevent, care or cure)*. The study must determine the specific effect, the overall effect, and/or the contextual effect of the NPI evaluated.
CI7	**Describe the content of the NPI**	The study must describe the NPI, its components (e.g., ingredients, techniques, skills), its procedure (e.g., sessions, dose/intensity, duration, frequency) and the equipment required in order to make it reproducible. The conditions of access to the intervention and possible interactions with biomedical treatments must also be specified (e.g., medical prescription).
CI8	**Describe the psychosocial processes and/or biological mechanisms likely to explain the effect on the main health marker**	Develop a rationale describing the principles of actions that may explain the expected benefits of the NPI.
CI9	**Specify the characteristics of the professional(s) implementing the NPI**	Name the job of the professional implementing the NPI and describe his/her skills and qualifications.
CI10	**Conduct NPI implementation training for all the stakeholders who will implement the NPI during the study**	This involves guaranteeing homogeneity and ensuring the standardization of practice between groups, or between establishments collaborating in the study.

Comparison

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
CC11	**Conduct a pragmatic controlled intervention study**	The study evaluates the real-world *effectiveness* of the NPI. The study is intended to isolate the specific effect of the NPI on the main health outcome. The choice of comparison groups and the method of assigning people to groups must be justified.
CC12	**Declare the intervention study protocol before its completion on an official platform**	Several reporting platforms exist upstream of the intervention study protocol. The most used general platform is *Clinical Trials*. An example of a platform specialized in physiotherapy is *PEDro*.
CC13	**Describe the inclusion and non-inclusion criteria of people participating in the study as well as the exclusion criteria**	Justify the criteria and the number of persons needed to treat.
CC14	**Specify secondary objectives**	Detail all the health criteria likely to be modified by the NPI being evaluated.
CC15	**Justify the choice of the control group**	The control group must make it possible to evaluate the specific effect of the NPI being tested.
CC16	**Guarantee a pragmatic and blind trial**	The possibility of blinding must take precedence over the difficulty in implementing the NPI. The hypothesis to which each group is blinded, including the evaluator, must be defined. The professional who implements the NPI cannot always be blinded. The people participating in the trial should be blinded as much as possible. Evaluators should be blinded as much as possible. In all cases, specify the measures taken to ensure blinding.
CC17	**Always report effectiveness using a statistical test of significance, and a confidence interval to report the magnitude of the effect**	Always combine the confidence interval, p-value and effect size of all the outcomes assessed.
CC18	**Prefer intention-to-treat analyses**	Intention-to-treat analyses are closer to real life and are applied in the field of health. Include an analysis with imputation of missing data either in the main analysis or in a sensitivity analysis.
CC19	**Use *resampling* techniques as much as possible in statistical evaluation**	*Resampling* techniques (permutation test, bootstrap) are more robust than parametric statistical tests in most cases. As they are also simpler to implement and easier to interpret, they should always be preferred.
CC20	**When *resampling* cannot be used, always indicate that the characteristics of the study population align with the assumptions of the parametric model being used**	*Resampling* is not suitable for small samples or samples not randomly chosen from the target population. In this case, a parametric model can give valuable results if - and only if - the characteristics of the study population align with the model assumptions. One must always check for this and report that it is indeed the case.
CC21	**Check the hypotheses of the *a posteriori* study power calculation, and interpret the significance of the results based on this new calculation**	The calculation of the study power is useful to provide information on the reason for the non-significance of a result (e.g., number of people participating in the study is too low a posteriori). It can help refine hypotheses for calculating the study power, and the minimum number of people needed to participate in a future study.

Outcome

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
CO22	**Choose relevant outcomes measured by validated and sensitive tools**	Use objective and subjective criteria (e.g., *patient-reported outcomes*) using a SMART approach (Specific, Measurable, Achievable, Realistic, and Timely), measured with validated instruments in the local language and, if possible, with a minimal clinically important difference (MCID).
CO23	**Specify study withdrawals**	Indicate the withdrawal rates and reasons, as well as the rates of loss to follow-up. Limit the exit of people participating in the study irrespective of the group (i.e., intervention group, control group), even in the event of withdrawal.
CO24	**Specify patient compliance to the NPI**	Measure the patient compliance rate (percentage of completion of scheduled sessions).
CO25	**Record concomitant treatments**	Other NPIs, medicine, surgery, medical devices, hospital admission, etc.
CO26	**Identify adverse events**	Healthcare practices involve risks. Ensure the research team has the means to search for adverse events as part of a vigilance system and report them in the presentation of results.
CO27	**Identify unexpected events**	An intervention study/clinical trial may reveal unexpected health benefits. Record observations of the professionals implementing the NPI and of participants (or their care givers).
CO28	**Measure economic indicators as much as possible**	NPIs can impact direct expenses (e.g., the NPI itself, biomedical treatment, care, hospitalization) and indirect (e.g., sick leave, caregiver contributions) expenses.

Implementation study

Population

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
IP1	**Identify and describe the healthcare service, establishment or territory studied**	Describe the meso- and macro-environmental characteristics of the healthcare service, establishment or territory targeted for the implementation of the NPI (social, economic, political, organizational, cultural and structural specificities). This makes it possible to estimate the external validity of the study. In addition, the modification of these characteristics can influence the implementation of the NPI over time, and produce unpredictable effects which will require adaptation.
IP2	**Describe the characteristics of study participants**	Describe the eligibility criteria for study participants. The description provides information on the possibility of implementing the NPI in similar populations.

Intervention

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
II3	**Build on the NPI specifications established during the original intervention study. Detail each NPI used and describe its "invariants" and its "modular components"**	The "invariants" are the essential and indispensable elements of the NPI. In contrast, "modular components" are elements, structures and systems that can be adapted depending on the location of the study and the users, without compromising the integrity of the NPI. Insufficient adherence to the invariants can dilute the effect of the NPI while insufficient adaptation of the "modular components" can inhibit its effect.
II4	**Limit the participation of the researcher/evaluator on the study site**	This provision consolidates the validity of the study. The researcher must limit personal involvement, from data collection to the training of the professionals who will implement the NPI. If the researcher cannot limit his/her involvement, justification is required.
II5	**Describe the professionals implementing the NPI**	Describe the qualifications, roles and training of the professionals implementing each NPI and the number of professionals implementing it.

Comparison

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
IC6	**Specify the objectives of the study**	Describe the objectives of the implementation of the NPI (e.g., acceptability, adoption, commitment, safety, scope, sustainability, transferability, integration into the care/health pathway, cost).
IC7	**Justify the sample size**	Justify the sample size according to the constraints of the study (budgetary, practical, data analysis). Depending on the design and objectives of the study, a sample size calculation is possible.
IC8	**Describe the implementation strategy used**	Describe how the NPI is implemented to enable its adoption, transferability and sustainability.
IC9	**Describe the data collection process**	The data collection process concerns the extraction of routine clinical data and risk assessment data (side effects, interactions). It is recommended to create a standardized recording procedure to avoid inconsistencies in entries (e.g., missing data, under- or over-estimation).
IC10	**Involve operational partners in the field and involve healthcare users**	Involve operational partners in the field and users of the NPI from the conception of the protocol all the way to the analysis of results. Develop a formal implementation strategy together that overcomes obstacles and empowers facilitators to increase adoption of the intervention.
IC11	**Describe adaptation approach to the NPI implementation strategy for optimal use in real-world situations**	The adaptation of the NPI implementation strategy must be described. The complexity of the implementation context - inherent to the heterogeneity and the needs of the study population - will necessarily require the implementation strategy to be adapted (e.g., refresher training courses for persons implementing the NPI to maintain their commitment to it). Social aid strategies to compensate for social inequalities must be clarified (e.g., compensation for travel costs for health consultations).

Outcome

CODE	METHODOLOGICAL INVARIANTS	EXPLANATION
IO12	**Describe the measured variables**	Describe the health and social contexts, and, if possible, the political context in which data collection will occur.
IO13	**Identify the acceptability, commitment and feasibility of the NPI in different contexts and over time**	Commitment is the most important element for the successful implementation on an NPI. Evaluate acceptability, commitment and feasibility iteratively in order to increase the chances of transferability and sustainability of the NPI in a real-world context (through adaptations), and in order to evaluate the impact of the implementation. It is preferable to consider these "implementability" factors when developing the study.
IO14	**Identify the obstacles and drivers to fostering the routine adoption of the NPI**	This evaluation must be conducted with all the stakeholders involved (e.g., people participating in the study, establishment, organization, promoter, decision-makers).

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The NPIS Guidelines are a didactic document that summarizes the non-pharmacological interventions' (NPI) ecosystem. This handbook presents the international scientific society NPIS and answers the questions most frequently asked about NPI in the field of evidence-based health solutions applied in prevention, care, work assistance, social protection, and end-of-life support.

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