NPI MODEL

A Standardized Scientific and Ethical Evaluation Framework of Non-Pharmacological Interventions (NPIs) in the Domain 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, 2023)

Non-Pharmacological Intervention Society

The NPI 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.

NPI MODEL

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.

Ethical recommendations

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)
https://pro.inserm.fr/rubriques/recherche-responsable/integrite-scientifique/integrite-scientifique-2

[2] French law (Jardé) governing research on humans (2012)
https://www.legifrance.gouv.fr/codes/section_lc/LEGITEXT000006072665/LEGISCTA000006154978/

[3] European regulations relating to medical products (2014) and medical devices (2022)
https://sante.gouv.fr/systeme-de-sante/innovation-et-recherche/article/evolutions-europeennes-en-matiere-d-evaluations-de-certains-projets-de

[4] European Regulation on Food Supplements (2015)
https://www.economie.gouv.fr/dgccrf/complements-alimentaires-plantes

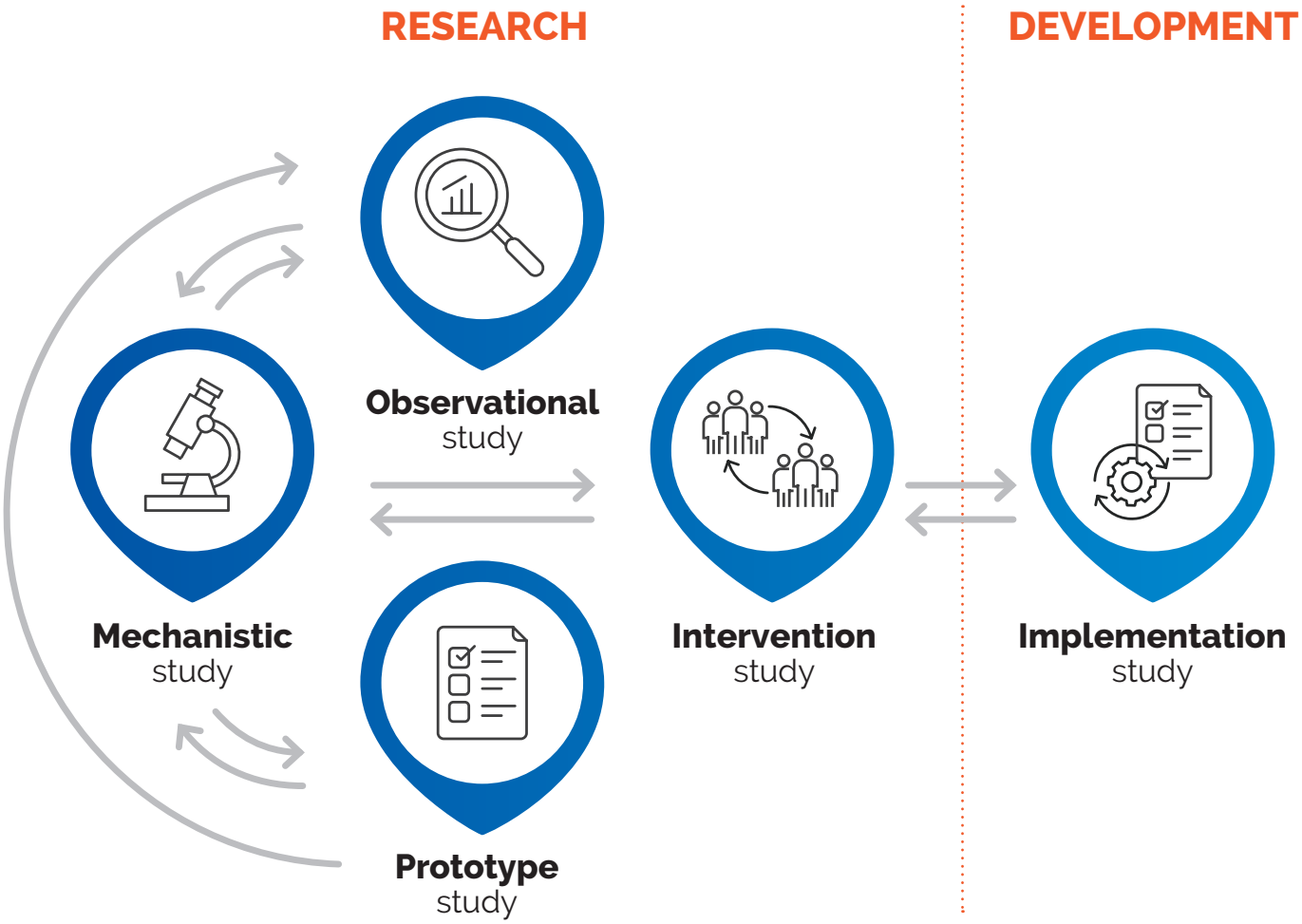
[5] Singapore Declaration on Research Integrity (2010)
https://www.ouvrirlascience.fr/declaration-de-singapour-sur-lintegrite-en-recherche/

[6] National Institute of Health and Medical Research (INSERM), best practices in participatory research (2022)
https://pro.inserm.fr/rubriques/recherche-responsable/recherche-participative/vers-de-bonnes-pratiques-de-recherche-participative

NPI MODEL

Methodological recommendations

Evidence-based data is theoretical or practical knowledge acquired using scientific methodology and reasoning rooted in scientific integrity. The *Non-Pharmacological Intervention Model* (NPI Model) uses this approach in the field of health (Figure 1). In addition to ethical recommendations which are applicable to all research studies, the NPI Model offers methodological recommendations according to five types of NPI evaluation studies which focus on explanatory mechanisms and processes (mechanistic), the content of practices (prototypical), the evolution of practices (observational), the benefits and risks of the NPI (intervention), and finally, the strategies of application and personalization (intervention).



RESEARCH

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).

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.

RESEARCH

Mechanistic study

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

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.

RESEARCH

Prototypical study

In a prototypical study, researchers identify all the practical characteristics of an NPI by using methods for collecting information on practitioners 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 NPI Model (a. designation; b. main health benefit; c. secondary benefits; d. risks; e. mechanisms; e. target population; g. protocol; h. professional; i. context of use) 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.

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.

RESEARCH

Intervention study

In a clinical trial with patients or an intervention study with people without a declared disease, researchers highlight the level of effectiveness of an NPI on a target population, that is to say the benefits and risks on this population's health. The study 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).

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 study

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.

Intervention 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.

Intervention 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.

DEVELOPMENT

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/clinical trial, 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.

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.

Implementation study

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).

Descriptive characteristics of an NPI

a	**Designation**	Name (abbreviation if applicable)	[3, 4]
b	**Main health benefit**	Health problem prevented, cared or cured	[4]
c	**Secondary benefits**	Benefits for other health markers (biological and/or psychosocial)	[4, 5]
d	**Risks**	Side effect(s), risky interaction(s)	[1, 2, 4, 5]
e	**Mechanisms**	Biological mechanism(s) of action, and/or active psychosocial process(es) explaining the benefits for the health markers of interest	[2]
f	**Target population**	Public responder, contraindication(s)	[1, 3, 4, 5]
g	**Protocol**	Components (e.g., ingredients, techniques, gestures), procedure (e.g., duration, number and frequency of sessions, dose), equipment (e.g., physical, digital) required to guarantee the reproducibility of the effects on health	[3, 4]
h	**Professional**	Required qualifications	[3, 4, 5]
i	**Context of use**	Places of practice, good implementation practices, precautionary measures, regulatory characteristics, initiators	[3, 4, 5]

[1] observational study reference published in a peer-reviewed scientific journal
[2] mechanistic study reference published in a peer-reviewed scientific journal
[3] prototypical study reference published in a peer-reviewed scientific journal
[4] intervention/clinical study reference published in a peer-reviewed scientific journal
[5] implementation study reference published in a peer-reviewed scientific journal

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GLOSSARY

Given the diversity of professionals involved in NPIs and the diversity of their users, the expert committee of the NPI Model has created a glossary of relevant terms which is freely accessible online at npisociety.org/glossaire.

FAQ

Frequently asked questions during the development of the NPI Model led to the creation of an FAQ page which is freely accessible online in French and English on the NPI Model page npimodel.org.

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CITE

NPIS. A Standardized Scientific and Ethical Evaluation Framework of Non-Pharmacological Interventions in the Domain of Health. Paris, 2023.

NPIS: THE NON-PHARMACOLOGICAL INTERVENTION SOCIETY

The international scientific society NPIS was created in 2021, with the legal French status of a non-profit general interest association. It works to develop research and innovation in NPIs. The work of this non-governmental organization builds on the epistemological work in the same area of research conducted by the CEPS collaborative university platform in Montpellier between 2011 and 2020. The epistemological work was financially supported by the European Union, the French State, the French region of Occitanie, and the Montpellier Metropole. The NPIS is located in Paris. It contributes to transdisciplinary and intersectoral knowledge in the field of human health. Accordingly, this scientific society is not a professional organization, and as such, it does not defend one profession over another. It encourages international research to identify good NPI practices and their implementation with a view to ensuring more patient-proactive and sustainable human health. The NPIS proposes recommendations for good research practices (epistemology, methodology, metrology, and ethics) and good inter-professional practices (ethics, implementation, alliance, communication) specific to NPIs using a transdisciplinary, intersectoral and transpartisan approach. In particular, the NPIS organizes an annual international scientific congress, publishes a scientific journal, and produces an NPI register.

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