*Modulo richiesta assegno*

| TUTOR | Katia Mattarozzi | | |
|---|---|---|---|
| PRODUZIONE SCIENTIFICA TUTOR NELL'ULTIMO QUADRIENNIO | | | |
| | ARTICOLO (autori, titolo, rivista, anno) | INDICE UNICO | *Punti* |
| 3 lavori in extenso su riviste indicizzate con valutazione indice unico da VRA2022 | Colonnello, V., Mattarozzi, K., & Russo, P. M. Emotion recognition in medical students: effects of facial appearance and care schema activation. *Medical Education*, 2019, *53*(2), 195-205. | 0,93 | |
| | Mattarozzi, K., Colonnello, V., De Gioia, F., & Todorov, A. (2017). I care, even after the first impression: Facial appearance-based evaluations in healthcare context. *Social Science & Medicine*, *182*, 68-72. | 0,87 | |
| | Mattarozzi, K., Sfrisi, F., Caniglia, F., De Palma, A., & Martoni, M. (2017). What patients' complaints and praise tell the health practitioner: implications for health care quality. A qualitative research study. *International Journal for Quality in Health Care*, *29*(1), 83-89. | 0,88 | |
| Totale | | | |

| DISSEMINAZIONE SCIENTIFICA E ATTIVITÀ DI TERZA MISSIONE TUTOR NELL'ULTIMO QUADRIENNIO | | |
|---|---|---|
| **Tipologia** (seminario, congresso nazionale, congresso internazionale, attività di terza missione inserita su catalogo IRIS) | **Titolo** | Punti |
| 12th Congress of the European Pain Federation EFIC – Pain in Europe XII (EFIC, 2022) 27-30 th April 2022, Dublin, Ireland | Familiar-looking faces induce analgesia.<br><br>AUTHORS: Bagnis A., Altizio, I., Colonnello, V., Fanti, S., Russo, P., Todorov, A., Mattarozzi, K.<br><br>Poster | |
| 4th International Conference of the Society for Interdisciplinary Placebo Studies, 10-13 May 2023 Duisburg | "The contagion of nocebo: fear, believe and negative expectations coming from COVID-19 pandemic worsens flu-like symptoms"<br><br>AUTHORS: Bagnis A., Capucci F., Cremonini V., De Palma A., Mazzoni R., Pandolfi P., Russo P., Mattarozzi K.<br><br>Talk – Selected by the Scientific Board for Special Spotlight Session "Nocebo and Covid" | |
| 4th International Conference of the Society for Interdisciplinary Placebo Studies (SIPS)<br><br>10-13nd May 2023, Duisburg, Germany | "Special Needs by Placebo": Programme to Advise, Normalize And Control its European Administration (PANACEA).<br><br>AUTHORS: Mattarozzi K., Babel P., Bajcar E. A., Evers A. W. M, Haas J.W., … Vlaeyen J., Bagnis A.<br><br>Poster | |
| 4th International Conference of the Society | Sharing pain: nocebo and placebo effects in a group context | |

| | | |
|---|---|---|
| for Interdisciplinary Placebo Studies (SIPS)<br><br>10-13nd May 2023, Duisburg, Germany | AUTHORS: Ceccarelli I., Babel P., Bagnis A., Casadio L., Klosowska J., Ottaviani, C., Mattarozzi, K.<br><br>Talk – Selected by the Scientific Board for Datablitz Session "Social Aspects of Placebo Effects" | |
| RIMS - Rehabilitation in Multiple Sclerosis. Translating Knowledge into Practice: Embracing the Complexity of MS Rehabilitation. Genova, 4-6 maggio 2023. | Development and validation of a Subjective self-Assessed on-line Version quEstionnaire on Quality of Life (SAVE-QoL)<br><br>AUTHORS: Bagnis, A., Giordano, A., Solari, A., Mattarozzi, K<br><br>Poster | |
| **Totale** | | |

| | |
|---|---|
| **Commissione proposta**<br>3 commissari +<br>1 supplente | Mattarozzi Katia (Presidente) |
| | Martoni Monica (Segretario) |
| | Mazzetti Michela (Commissario) |
| | Paolo Maria Russo (Supplente) |

| **TITOLO DEL PROGETTO** | | | |
|---|---|---|---|
| "Special Needs by Placebo": Programme to Advise, Normalize And Control its European Administration (PANACEA). | | | |
| ASSEGNO FINANZIATO DA PROGETTO COMPETITIVO<br>*(barrare la casella corrispondente)* | X☐ SI | ☐ NO | *Punti* |
| SE IL FINANZIAMENTO È COMPETITIVO L'ENTE FINANZIATORE | Erasmus+ Programme of the European Union IT02–KA220–HED–000088065–Cooperation partnerships in Higher Education | | |

| | | |
|---|---|---|
| PROGETTO/ATTIVITÀ A SCOPO COMMERCIALE *(es. sperimentazione profit)* | ☐ SI | X☐ NO |
| CARATTERISTICHE DEL PROGETTO (*biomedico/osservazionale/clinico-interventistico/multidisciplinare*) | multidisciplinare | |
| STATO DI APPROVAZIONE DEL PROGETTO DA PARTE DEL COMITATO ETICO (*se necessario per il tipo di studio barrare o evidenziare la casella corrispondente*) | Non Necessario☐ Ottenuto | ☐ Da ottenere |

| **DESCRIZIONE DEL PROGETTO** *(max 800 parole)* | *Punti* |
|---|---|

(1)obiettivi, (2)materiali e metodi, (3) risultati/impatto attesi, (4) attività formativa e (5) di ricerca dell'assegnista

PANACEA aims to contribute to an educational need and to reduce a skills mismatching on a topic of clinical relevance, i.e., placebo and nocebo effects on clinical outcomes. Several laboratory and clinical evidence consistently indicate that placebo/nocebo mechanisms and effects are actives any time a patient is taken care by a healthcare practitioner and receive a treatment (Finniss et al., 2010). Although substantial progress has been made in understanding psychosocial factors and mechanisms at work during placebo/nocebo effects, the scientific community agrees that there is a gap between evidence-based evidence and their implementation in clinical practice (Evers et al., 2018). As stated by general practitioners themselves, placebo, as agent or mechanism, is frequently used by doctors (e.g., more than 88 % declare to use placebo), however it is deliberately administered without in-depth knowledge of the phenomenon or in accordance with evidence-based recommendations (Louhiala, 2012). Likewise, practitioner routinely communicate with patients about therapy's advantages and potential side effects, but little attention is giving to minimize nocebo responses. Any efforts to promote placebo and to reduce nocebo effects first requires knowledge as to clinical relevance, and evidence-based recommendations to assist practitioner decisions about appropriate health care (Kaptchuk & Miller, 2015). PANACEA aims to contribute to reducing the gap between placebo/nocebo scientific evidence and clinical practice stimulating HE and VET with teaching practice and innovative learning. Specifically, PANACEA address the first and the second selected priorities thanks to a development of an educational programme in which the participating organization operate jointly at transnational level to achieve 4 main closely interconnected concrete results: 1) placebo/nocebo learning materials rigorously selected from the scientific literature and best practice guidelines to be implement in HE, VET and clinical practice; 2) a course syllabus that better meet the learning needs of students to be included in medical and nurses school curricula and extended to current healthcare professionals; 3) a webApp able to improve a student-centered learning experience (second priority), and to engage students in clinical decision making task, critical thinking, debate and discussion among peers and with experts; 4) a broad dissemination of these results through HE medical schools of European universities, medical-scientific societies and VET institutes. The PANACEA partnership is realized on the basis of strong synergies between academic and research institutions (i.e., 5 Universities of different European countries, the European Pain Federation) and a partner expert (RE2N) in the development of new technologies applied to education and learning.

The project will have an important impact on medical and nursing students. During their learning, students will improve their skills and competencies by benefiting from standardized learning materials and a syllabus with specific learning outcomes on placebo and nocebo effects and from the use of the digital webApp where to find evidence-based and up-to-date literature about placebo/nocebo effects and where to receive immediate and interactive feedback about their expertise progress. Also, PANACEA will have an impact on academic professors that will benefit from the possibility to update their knowledge constantly, to follow a syllabus, and to use the webApp to support, expand and complement their teaching programme.

PANACEA may be an important stakeholder to propose to WHO and define guidelines on the placebo/nocebo management with specific rules to guide healthcare professional daily clinical practice.

Finally, PANACEA will have an impact on patients. Of course, they will not use the project results directly, but they will benefit from better treatments provided by healthcare professionals trained during their medical HE and VET and led by best-practice guidelines.

## DESCRIZIONE DELLE ATTIVITÀ DELL'ASSEGNISTA

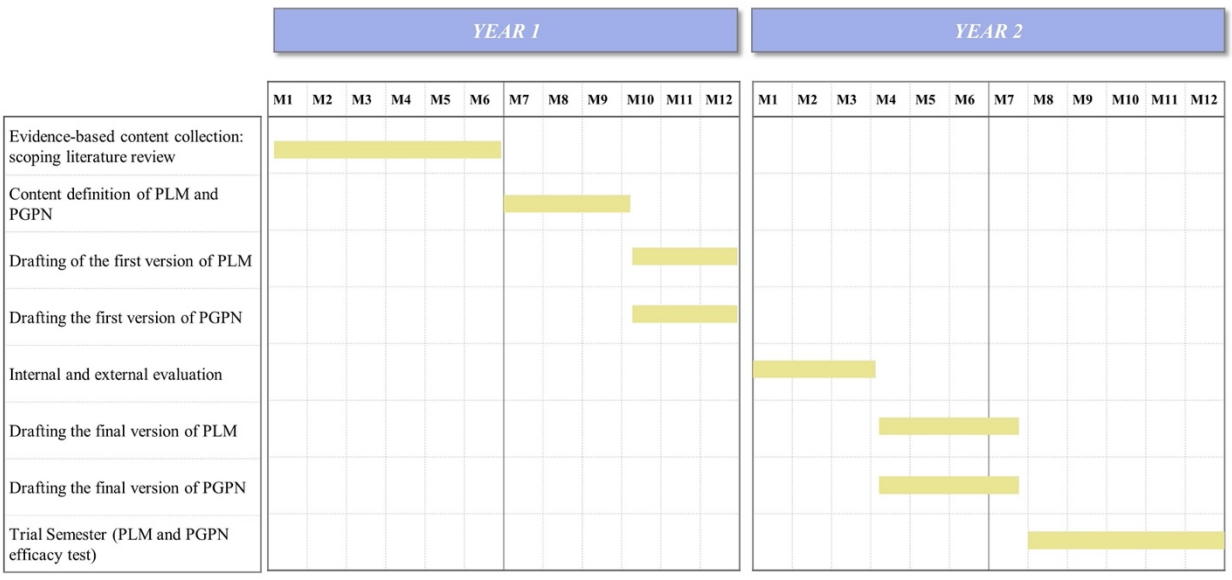
The activity will involve:

- performing a scoping review on placebo and nocebo effect (protocol attached)
- organizing and defining content based on the scoping review results
- drafting learning materials and best practice guidelines
- verifying the efficacy of learning materials and best practice guidelines during a trial semester within the school of medicine and surgery, and the school of nurses.

Good knowledge and skills in literature search and meta-analysis are required

*Punti*

Gantt for the activity plan of the first and second year




PLM = PANACEA Learning Material
PGPN = PANACEA Guidelines on Placebo and Nocebo

*Scheda attività assistenziale (se prevista)*

| ATTIVITÀ ASSISTENZIALI DELL'ASSEGNISTA/ N. ORE SETTIMANA |
|---|
| Nessuna |
| |
| |
| AZIENDA SANITARIA PRESSO CUI SI SVOLGERÀ L'ATTIVITÀ |
| // |

Si ricorda che, come previsto dagli Accordi sull'impiego nell'attività assistenziale dei Titolari di assegni di ricerca, sottoscritti tra l'Università di Bologna e le Aziende Ospedaliere di riferimento, una volta stipulato il contratto con il vincitore della selezione, il tutor deve consegnare alla Direzione Medica Ospedaliera la relativa modulistica, nella quale andranno riportate le attività qui segnalate.

Co-funded by the Erasmus+ Programme of the European Union

**PANACEA**

**IT02-KA220-HED-000088065**

**"Special Needs by Placebo": Programme to Advise, Normalize And Control its European Administration**

# SCOPING REVIEW ON PLACEBO AND NOCEBO EFFECTS

DATE OF ISSUE: 13/03/2023
DOCUMENT TYPE: Internal (Reseach Protocol)
VERSION: V4
AUTHORS: Arianna Bagnis, Elżbieta Anita Bajcar, Julia Haas, Stefanie Meeuwis, Mary O'Keeffe on behalf of PANACEA group

# Table of contents

## Introduction

PANACEA aims to collect and organize learning materials according to the best available scientific evidence, to describe effectively what placebo and nocebo are, in terms of effects (reductions or worsening in symptoms), procedures/interventions (contextual factors or what the clinician/experiment does in order to reach the effect), and the psychological and biological mechanisms involved in these effects and their clinical implications. For the goal of increasing knowledge among healthcare (e.g., medical, nurses, physiotherapist) students and providing best practice guidance, this is a first step to introduce and better understand how to implement placebo procedure/interventions in clinical practice and reduce nocebo effects to enhance treatment effects. Indeed, besides organizing theoretical evidence-based learning materials, PANACEA wants to contribute to the development of best practice guidelines, shared among the partnership at European level, to 1) regulate an ethical and optimal use of placebo procedures/interventions, and 2) to detect and reduce nocebo effects in clinical practice. Best Practice Guidelines on placebo and nocebo will contribute to support a harmonized clinical behaviour exploiting placebo and nocebo advantages and disadvantages and to make clear practical and ethical restrictions.

Collecting information from the scientific literature (evidence-based knowledge) on placebo and nocebo effects is one of the main activities of the WP1, aimed at developing learning materials and guidelines on these topics.

The goal is to contribute to reducing the gap between placebo/nocebo empirical findings and clinical practice, improving placebo/nocebo knowledge and competencies, raising awareness of their importance amongst current and future clinicians, and guiding them in clinical practice.

First, key publications from a selection of experts on placebo and nocebo (see Annex 1) will be searched to clarify placebo and nocebo key concepts and definitions. Then, a scoping review of systematic reviews and meta-analyses to examine basic and clinical evidence on placebo and nocebo will be performed.

Following the guidelines for conducting a scoping review (Peters et al., 2015; Peters et al., 2022; Tricco et al., 2018), the present protocol predefines the objectives and methods of the scoping review. Specifically, it defines the following aspects:

- review objective
- concept
- context
- study design and registration
- eligibility criteria
- search strategy
- search activity and decision process
- data extraction
- analysis

## Review Protocol

### Review objective

The objective of the present scoping review is to examine basic and clinical evidence on placebo and nocebo effects, considering factors related to:

- Healthy individuals'/Patients' beliefs and characteristics (e.g., past experience and learning, expectations and beliefs, personality traits, cognitive profile, etc.)
- Experimenters'/Practitioners' belief and characteristics (e.g., expectations and beliefs)
- Context (e.g., social context, lab setting, healthcare setting)
- Experimental condition vs Treatment characteristics (e.g., disease specific treatment, impure placebo, pure placebo)
- Relationship (e.g., communication, patient-practitioner interaction, instructions)
- Biological correlates of placebo and nocebo effects
- Clinical conditions
- Clinical implications

- Bioethical issues (e.g., bioethical implications of placebo and nocebo procedures/interventions)

### Concept

Several concepts (i.e., main topics) will be mapped, including psychological, contextual, clinical, and biological determinants of placebo and nocebo effects, clinical implications, and bioethical issues.

### Context

The context of the present scoping review encompasses different disciplines, including psychology, neuroscience, general medicine, specialities (e.g., gastroenterology, rheumatology, immunology, oncology, psychiatry), pharmacology, bioethics.

### Study design and registration

We will report this scoping review according to the PRISMA extension for Scoping Reviews (PRISMA-ScR). For publication, we will create and pre-register a specific protocol on Open Science Framework.

### Eligibility criteria

Only systematic reviews and meta-analyses will be included in the scoping review. The reason is feasibility. A large number of studies on placebo and nocebo effects have been published over the years and reviewing all of them individually is beyond the scope of the present review.

Specifically, we will include:

- systematic reviews or meta-analyses that mentioned “placebo/nocebo ” in the title, matching the review's objectives
- publications on humans
- publications available in English
- peer-reviewed publications.

We will exclude non-peer reviewed publications (e.g., conference proceedings, preprints), primary research articles, narrative reviews, and publications on animals.

## Search strategy

We will search relevant databases from their inception to April 11th, 2023.

The approach to searching for studies follows four steps:

1. Selection of relevant databases
    a. PubMed
    b. Scopus
    c. Cochrane Library
    d. PsychINFO
    e. Embase
    f. Web of Science

The search strategy, including all identified keywords and index terms, will be adapted for each included database.

2. Identification of keywords and index terms
    a. Placebo [Title] OR nocebo [Title]
    b. Placebo [Title] OR nocebo [Title] AND (clinic*[Title/Abstract] OR clinical practice [Title/Abstract] OR implementation [Title/Abstract])
3. Identification of search filter
    a. Publication type: Systematic review, Meta-analysis
    b. Species: Human
    c. Language: English
4. Searching the reference list of all identified articles for other relevant systematic reviews and meta-analyses.

## Search activity and selection process

Following the search, the output of each database will be uploaded on Rayyan to start the screening against the inclusion criteria. All identified studies will be collated, and duplicates will be removed. Pair of two independent researchers will screen studies first by reading title and abstract and then their full text. We will conduct backward and forward citation tracking by examining the reference list of included studies and citations (using Google Scholar) to the included studies. Disagreements will be resolved by discussion and consensus. If no consensus is reached a third researcher will arbitrate. Each study found during the search activity must be reported in the Annex 3, specifying whether is included and, if not, the reasons for exclusion (both after title/abstract screening and full-text screening). During and after the screening, each researcher needs to report the number of results found and selected in the Annex 4. At the end of the literature search, a search decision flowchart (See Annex 5) indicating the results from the search, removal of duplicate citations, reasons for exclusions, and additions from reference list searching and final number of studies included (Moher et al., 2009).

### Data extraction

Two independent researchers will use an Excel spreadsheet to extract data from eligible studies. This spreadsheet will first be piloted on 25 studies to ensure reliability and accuracy (See Annex 6). Refinement of these fields may be required during the conduct of the review.

Extraction fields:

- Author(s)
- Journal
- Year of publication
- Publication type (Systematic review, Meta-analysis)
- Research (Basic, Clinical, Both)
- Concept (e.g., psychological, contextual, clinical, biological, bioethical, etc)
- Context (e.g., medicine, psychology, neuroscience)

- Aim
- Placebo definition
- Nocebo definition
- Healthy individuals'/Patients' beliefs and characteristics
- Experimenters'/Practitioners' belief and characteristics
- Context (e.g., lab setting, healthcare setting)
- Experimental condition/ Treatment characteristics
- Relationship (e.g., communication, patient-practitioner interaction, instructions)
- Biological correlates
- Clinical implications
- Bioethical issues
- Study population (if applicable)
- Procedure/Intervention type and control group (if applicable)
- Investigated clinical condition (if applicable; e.g., chronic pain, dermatological conditions, psychiatric conditions)
- Outcomes (e.g., pain, itch, anxiety, adherence)
- Outcome measurement (subjective, objective)
- Key findings (related to the review objective)
- Methodological quality (using R-AMSTAR)

### Analysis

The range of evidence that was identified to meet the objectives of the scoping review will be presented in a narrative format. When necessary, basic descriptive analysis (i.e., frequency counts of concepts, populations, conditions) may be provided. Narrative and descriptive results can then be mapped in various visual presentations, such as tables or graphs.

## References

Haddaway, N. R., Collins, A. M., Coughlin, D., & Kirk, S. (2015). The role of Google Scholar in evidence reviews and its applicability to grey literature searching. *PloS one, 10*(9), e0138237.

Peters, M. D., Godfrey, C. M., Khalil, H., McInerney, P., Parker, D., & Soares, C. B. (2015). Guidance for conducting systematic scoping reviews. *JBI Evidence Implementation, 13*(3), 141-146.

Peters, M. D., Godfrey, C., McInerney, P., Khalil, H., Larsen, P., Marnie, C., ... & Munn, Z. (2022). Best practice guidance and reporting items for the development of scoping review protocols. *JBI evidence synthesis, 20*(4), 953-968.

Shea, B. J., Bouter, L. M., Peterson, J., Boers, M., Andersson, N., Ortiz, Z., ... & Grimshaw, J. M. (2007). External validation of a measurement tool to assess systematic reviews (AMSTAR). *PloS one, 2*(12), e1350.

Tricco, A. C., Lillie, E., Zarin, W., O'Brien, K. K., Colquhoun, H., Levac, D., ... & Straus, S. E. (2018). PRISMA extension for scoping reviews (PRISMA-ScR): checklist and explanation. *Annals of internal medicine, 169*(7), 467-473.

## Annexes

1. List of experts
2. Experts Reviews
3. List of citations extracted
4. Search activity table
5. Search decision flowchart
6. Extraction fields table