

Development of a neuropsychophysiological protocol to evaluate oral films for the delivery of neuroactive substances

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1 Introduction / Resume

Oral films (OF) are a relevant delivery system of drugs for oral administration with several advantages, such as, the convenience of the administration when compared to conventional oral formulations. Many pharmaceutical and nutraceutical companies have invested in the knowledge of these innovative products and technologies, but the regulatory guidelines for development and evaluation of these OF are still limited. Currently, several characterizations and *in vitro* studies have been published; however, little is presently known about the release profile and performance in the body of the neuroactive substances (NS) administered by these OF. To address this issue, we developed a neuropsychophysiological (NPSY) protocol, with many advantages, including more direct, affordable, and noninvasive assessment; not sharing method variance with self-report or other collateral informants, and producing accurate real-time results.

Inclusion Criteria

Report clinical and psychophysiological assays in human.

Exclusion Criteria

No human assays, reviews, oral films development and characterization, films for radiology in dental medicine.

ORAL FILMS ADVANTAGES:

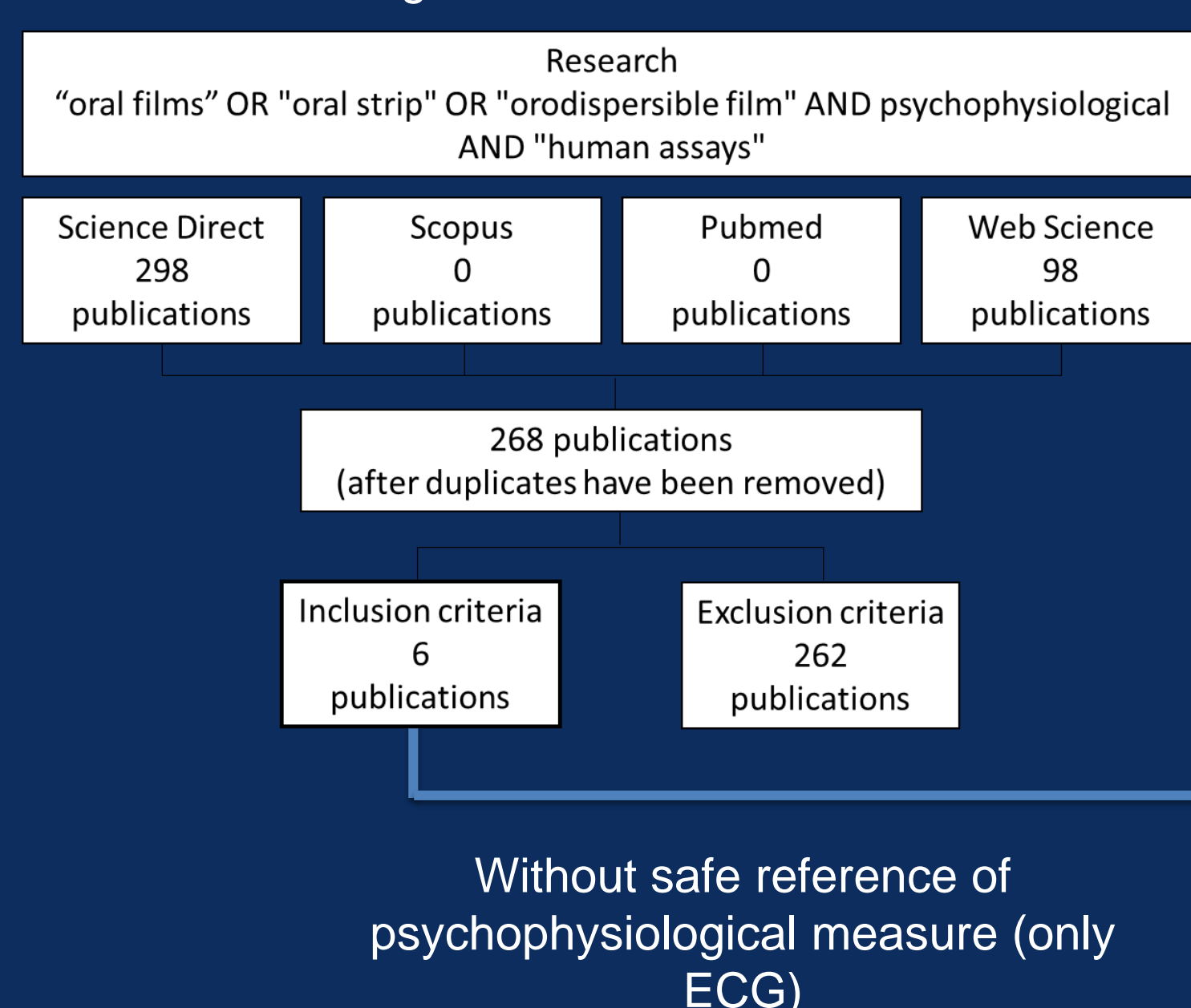
- > Convenience of the administration;
- > Flexible, ultra-thickness, and less obtrusive structure (comfortable and better adaptation to the mucosal surface);
- > Ease of handling or transportation;
- > Do not need water for administration.
- > Higher acceptable rate by younger, older and other individuals with swallowing impairments.
- > Precise dose administration.

Systematic Review

NPSY measures importance
(Low attention)

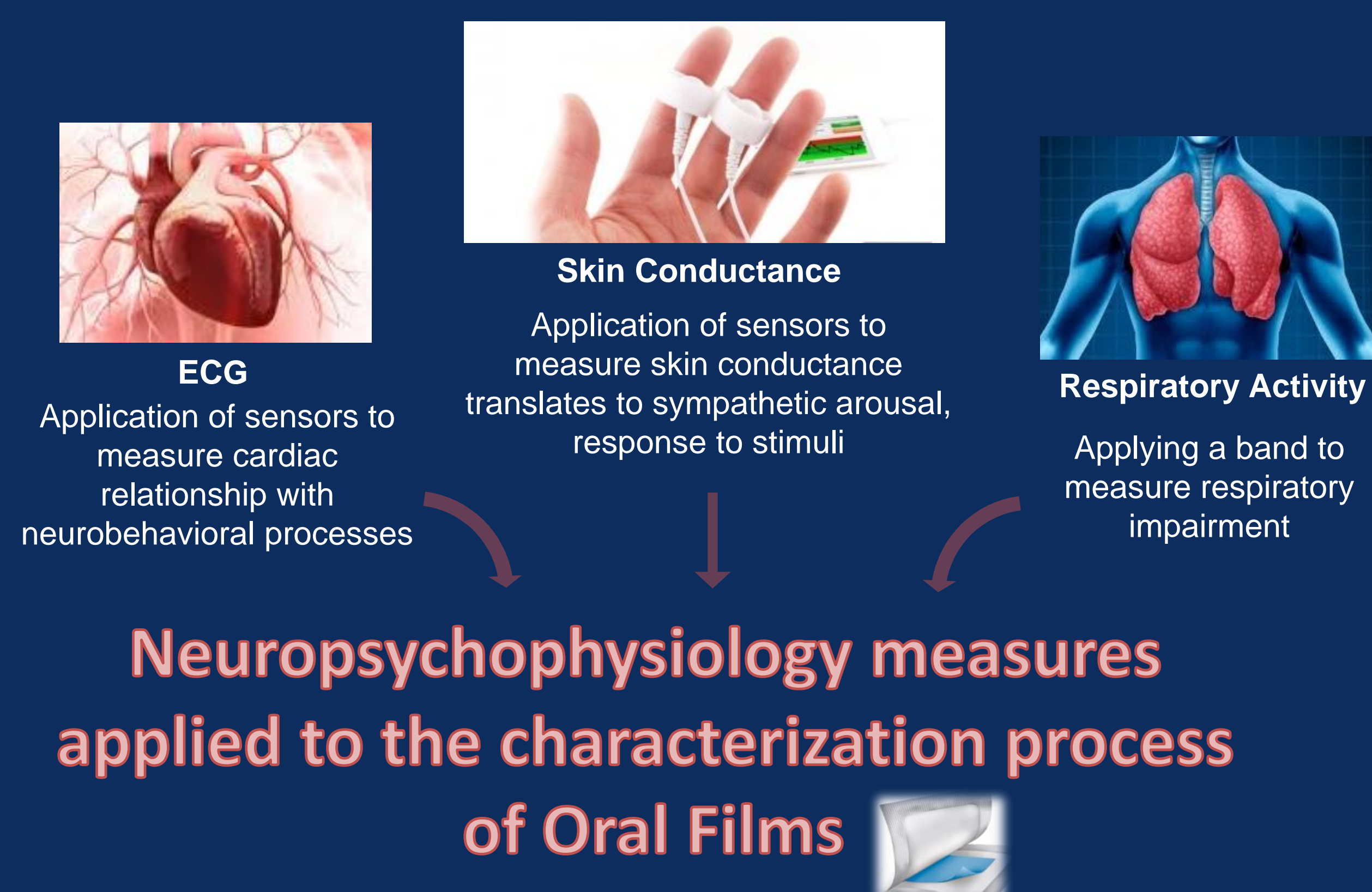
Pharmacokinetic Characterization
(More frequently used)

Scheme 1. Search and evaluation strategy of literature sources according to PRISMA.



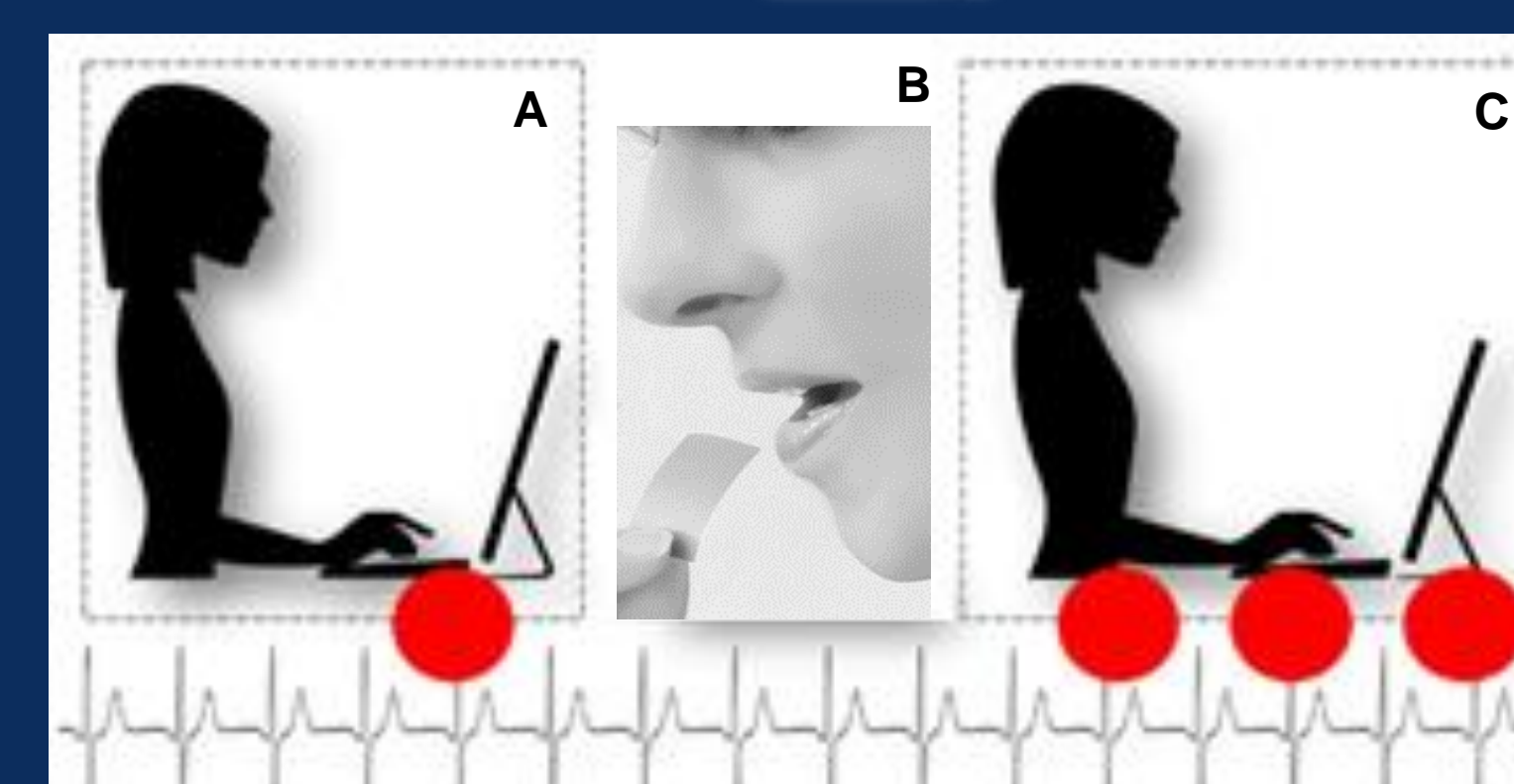
2 Objectives

The aim of this study was to develop a neuropsychophysiological protocol, an easily implementable approach which provides sensitive and objective measures of the effects of NS incorporated into oral films.



New Protocol

NPSY measures



Scheme 2.

Neuropsychophysiological protocol: three evaluation moments:
(A) Baseline;
(B) Caffeine oral film intake;
(C) Physiological, cognitive and behavioral performance evaluation;

- We developed an easily implementable NPSY protocol, which provides sensitive and objective measures of the effects of NS incorporated into oral films (caffeine used as a model).
- NPSY measures have been receiving increasing attention in different research areas (offer a variety of potential advantages):
 - more direct, affordable and noninvasive assessment,
 - not sharing method variance with self report or other collateral informants,
 - have accurate real-time result
 - easily implementable and
 - can improve the current understanding of the effects of bioactive molecules (incorporated into oral films) in the human body.

3 Conclusions

- > Despite the growing interest in **Oral Films (OF)**, their impact (physical and mental effects) into the human body is largely neglected.
- > We wish to draw attention to the lack in the literature of studies on the characterization of OF on the release profile and performance of the neuroactive substances and the importance of adding **Neuropsychophysiological measures (NPSY)** as a key part of the evaluation protocols.
- > There are several advantages of using NPSY measures and this neuroscience approach can complement the *in vitro/in vivo* tests or clinical studies.
- > To get a full picture of the potentiality underlying the OF, the contribution of a NPSY approach needs to be considered in future studies to ensure the feasibility of their commercialization.

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