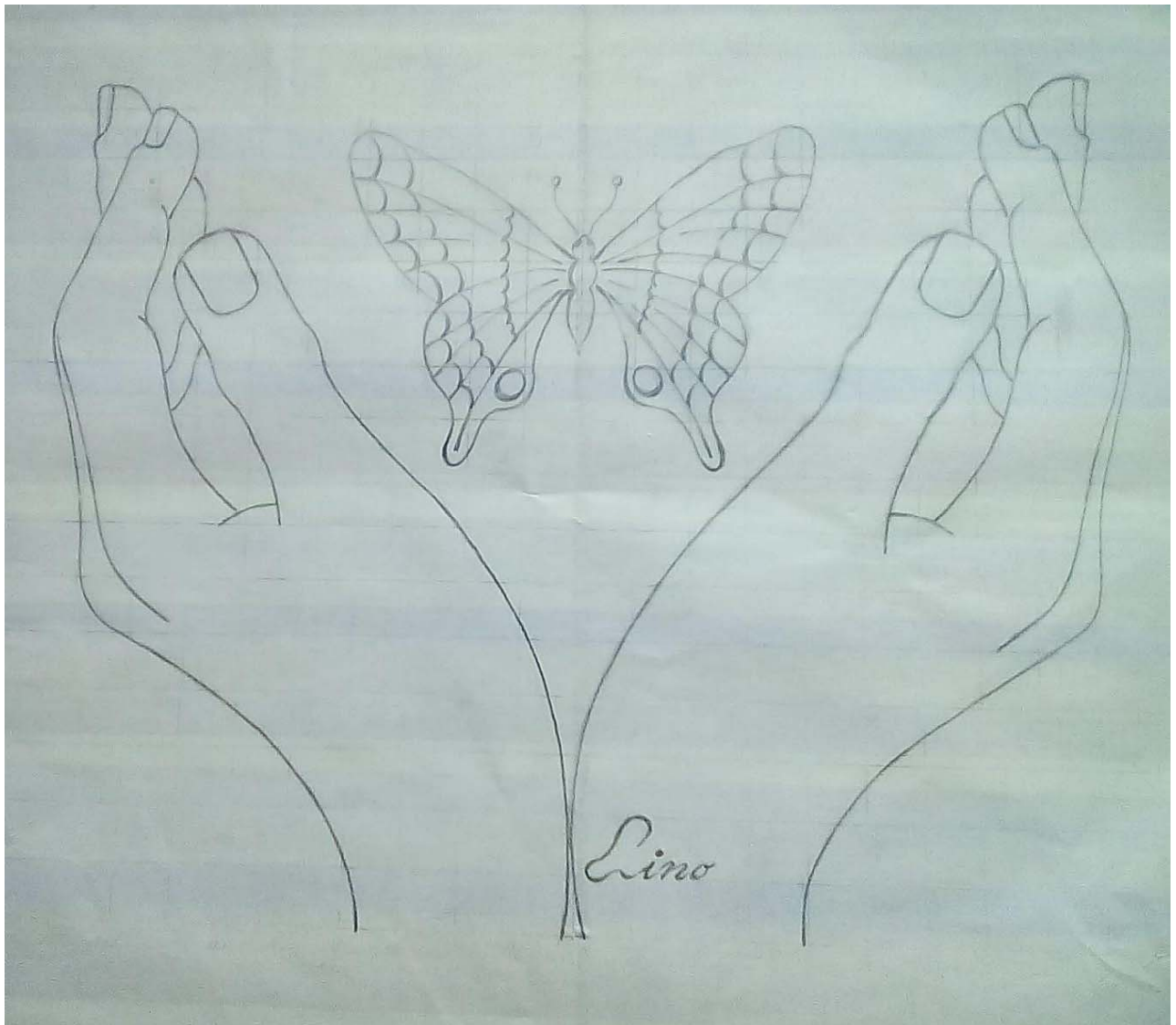


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Evaluation of antioxidant effect and safety of PSYCOTON in elderly: medical and nursing approach.

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KEY-WORDS: psycoton, MMSE GDS, nursing approach.

ABSTRACT

BACKGROUND: Senile dementia is undoubtedly one of the most serious conditions affecting the elderly population today. It is, as is known, a disorder characterized by a progressive cognitive decline, which manifests itself in various forms and can be traced back to multiple causes. A battery of cognitive tests is used for the follow-up of patients with dementia and many electrocardiographic indices have been proposed for the evaluation of cardiovascular and arrhythmic risk. These different ECG indices can be based on repolarization, conduction, or both. Repolarization indices include QT and QTc and Tpeak to Tend index are indices that have been proposed for arrhythmic risk stratification. Conduction indices include QRS duration and QRS dispersion. Regarding the repolarization marker, the Tpeak-Tend index and Tpeak-tend/QT ratio represent the repolarization dispersion. **AIM:** The purpose of this study is to evaluate the antioxidant effect and the safety of nutraceutical (Psycoton) explored by Qt, Qtc and Tpeak to Tend index.. **MATERIALS and METHODS:** Our pilot study started in September 2021 and was conducted by collecting and processing patient data from the Geriatric Clinic of the San Giovanni di Dio hospital, Fondi (Latina). The data of our study relate to a total of 18 patients (6 men and 11 women) affected by dementia and with an average age of 86 + 8 years (minimum age of 80 years and maximum age of 94 years) who completed the of follow up. All patients enrolled in the study gave their informed consent to the observational study. All patients continued home pharmacological treatments in compliance with ethical guidelines. As regards the use of rating scales, they have been standardized to the

international reference system for laboratory tests and instrumental tests. Screening eligibility requirements included being at least 18 years of age. All patients gave informed consent. Exclusion criteria included treatment with antiarrhythmic drugs for assessment of heart rate variability in patients with heart disease to avoid bias in heart rate variability. At enrollment, a run-in period occurred for all enrolled subjects who underwent geriatric multi-dimensional evaluation (MMSE and GDS) and 12-lead non-invasive digital electrocardiographic recording in order to evaluate the effect of the nutraceutical. on cardiovascular risk explored by the analysis of QT, Qtc and Tpeak by End T Index (Tp/Te). The three different cardiovascular risk indices were evaluated by electrocardiographic tracing at baseline status and after about 30 days of treatment with Psycoton at outpatient control. The treatment is performed using sachets of 3 g once daily for 1 month. Data were measured using Xai-medica cardiolab software and analyzed with SigmaStat 3.5 software for Windows XP. We used the Paired T test to analyze numerical data from pre- and post-treatment recordings in the same subjects enrolled in the study. The Paired T test allows you to perform comparative statistical analyzes on small groups. (Table 1). Statistical significance was set at $P < 0.05$. The treatment was well tolerated in routine clinical practice even though 3 patients reported nausea after taking Psycoton in 250 cc of water. The therapy is better tolerated in elderly subjects by diluting the Psycotn stick in 500 cc of water to be taken in the morning. All patients started the study drug and no subject was excluded after the patient's run-in period due to the absence of adverse events. **RESULTS:** Our study was designed to provide evidence supporting the efficacy of nutraceutical treatment (Psycoton) with great antioxidant potential in the management of dementia in elderly patients. The study data underline that there are no significant reductions in MMSE after just one month of therapy. The depressive picture remains substantially superimposable. The nutraceutical Psycoton, administered with a 250 cc dilution in the study group (except in the 3 patients who reported nausea but tolerated the dilution in 500 cc of water) has the property of significantly change the RR interval without changing the QT values. index TpTe resulting therefore irrelevant from the point of view of the global arrhythmic risk. **DISCUSSION and CONCLUSION:** Although the data from our pilot study demonstrate the absence of a statistically significant variation in the values of MMSE and GDS at a dosage of 1 sachet per day in patients with an average age of $86 + 8$ years. Furthermore, the arrhythmic

risk evaluated by exploring the Qt index, and Tpeak to Ten end index confirms the safety of the treatment from the point of view of the cardiovascular arrhythmic risk in patients belonging to the extreme geriatric age range.

Reference:

1) Bahare Salehi et coll. Insights on the Use of α -Lipoic Acid for Therapeutic Purposes. *Biomolecules*. 2019 Aug 9;9(8):356.

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