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# Is the use of alternative therapy in children just another form of medicalization? A prospective study.

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# Abstract

**Aim:** The use of complementary and alternative medicines (CAM) seems widespread in adults and children, despite the conflicting evidence regarding its effectiveness and safety. This study aims to investigate the prevalence of the use of CAM in a population of Italian children.

**Methods:** This is a prospective observational study conducted in 4 family pediatric clinics, in Friuli Venezia Giulia, Italy, from February to June 2019. Children were enrolled after being visited. The use of CAM and essential therapies (ET) in the previous year was investigated with an anonymous questionnaire. The demographic characteristics of children and families were also collected.

**Results:** Six hundred children were enrolled, mean age 5.8yrs, 50% females. In the previous year, 358 (60%) children used both essential therapies and CAM, 209 children (35%) only essential therapies, 25 (4%) only CAM, and 8 (1%) no therapy. CAM was more frequently used in children whose parents have a higher educational level and come from high-income countries (p<0.0001). Non-vaccinated children received more CAM than vaccinated ones (p < 0.003).

**Conclusion:** In our population, more than 60% of children receive CAM. The use of this medical approach seems strictly related to the social and cultural status of families.

# Key Notes

- The use of Complementary and Alternative Medicine (CAM) among children is increasing, despite conflicting evidence of effectiveness.

- Among a cohort of 600 children who presented to four pediatric clinics in Italy, 383 (64%) used CAM.

- Pediatricians should investigate the use of CAM in their patients, in order to advise them on possible side-effects, drug interactions, and the risk of excess-medicalization CAM may represent.

## INTRODUCTION

Every two years, the World Health Organization (WHO) draws up the list of essential therapies (ETs) for children based on the latest scientific evidence on safety, efficacy and costs of drugs. ET are those medicines that satisfy the priority health care needs of the population [1].

On the other hand, all the classes of drugs, products and body-mind therapies which do not fall within the WHO classification, including homeopathy, naturopathy, phytotherapy, antitussives and mucolytics may be considered as complementary and alternative medicines (CAM) [2].

In western countries, the use of CAM seems widespread in young and older people [3–6] despite conflicting evidence regarding its efficacy and safety [7]. Parents used to CAM intake are likely to administer CAM to their children [8]. People find them affordable because they perceive them as natural, harmless, non-industrial, organic, and they are convinced of their efficacy [9,10]. CAM use includes both treatment and support therapy of acute and chronic disease, as well as preventive therapy in healthy children[4–6].

This study aims to investigate the use of CAM in children in four clinics of family pediatricians in Friuli Venezia Giulia, Italy, and to assess whether there is any correlation between the use of CAM and maternal education, country of origin and vaccination status of the children.

## METHODS

We conducted a prospective observational study in four pediatric clinics in Friuli Venezia Giulia (FVG), a northeastern region of Italy, from February to June 2019.

FVG has 1.217.000 inhabitants and 148.300 children from 0 to 14 years of age. There are approximately 148 pediatric clinics, each of which follows between 800 and 1200 patients.

The four clinics were selected because they participated in the educational training program for pediatric residents of the University of Trieste. One was located in the suburban area of Monfalcone (28,000 inhabitants), another in Muggia (13,000 inhabitants), and two in the urban area of Trieste (205,000 inhabitants). The Italian National Health System establishes that all

children can be registered at their local clinic with a so-called "family pediatrician" who is in charge of providing them with free pediatric assessments.

Eligible patients were children from 1 to 14 years old presenting at the family pediatric clinic with their parents for a scheduled or unscheduled visit. Exclusion criteria were: children with parents unable to understand and fulfill an anonymous questionnaire written in the Italian language, and children already enrolled in the study.

Patients' enrolment was conducted when pediatric residents were present in the clinics, in the morning or afternoon, according to the clinic's schedule, approaching children and parents in the waiting room after they were visited. A specially trained pediatric resident explained the purpose of the study and provided a questionnaire to the parents of the enrolled children once informed consent was obtained.

The enrollment took place only after the medical evaluation by the family pediatrician, who was not informed of the questionnaire results. All data were collected anonymously, assigning an identification code to each child.

The questionnaire developed explicitly for the study, included items about demographical features, vaccination status of children, maternal educational level, country of origin, the presence of chronic diseases in the child, the number and type of ET and CAM used in the previous year, the number and length of treatment cycles.

The resident helped the parents fill out the questionnaire in case of difficulty in understanding the questions.

We classified the drugs according to the WHO classification of essential therapies (ET) [1] and considered CAM all those who did not fall within it. We classified the use of ET and CAM according to the kind of drug, frequency of therapeutic cycles, duration of cycles and the number of products employed in one year.

Maternal education, country of origin, and the child's vaccination status of the were self-reported by parents in the questionnaire. We intentionally classified the children whose vaccination status did not fully comply with the national vaccination program as "unvaccinated."

According to the criteria of the World Bank list 2017[11], which classifies the wealth of countries according to their gross domestic product (GDP) per capita, the whole population was divided into three groups based on the mother's country of origin. Low and Low-middle income group (L)

(<3955 $/year), Upper-middle income group (M) (3956-12235 $/year) and High income group (H) (>12235 $/year) were identified.

The independent bioethics committee of the FVG approved the study protocol (RC 35/17).

The primary outcome of the study was to evaluate the number of children who received CAM in the previous year, as reported by parents.

Secondary outcomes were: the times each child used CAM in the previous year, the concomitant or exclusive use of CAM and ET, and the correlation between the use of CAM and maternal education, country of origin, and vaccination status of the child.

## Statistical analyses

Continuous variables were reported as means and standard deviations (SD) when normally distributed and with medians and interquartile ranges (IQR, 25th-75th centiles) when non-normally distributed. Categorical variables were presented as numbers and percentages.

We evaluated the correlations between CAM and ET users, the adhesion or not to the vaccination calendar, maternal level of education, and mother's country of origin using exact Fisher's or Chi-square tests. Statistical significance was accepted for $p<0.05$. Statistical analyses were performed using a statistical website (Graphpad) [12].

### RESULTS

During the study period, 643 families were considered eligible and received the questionnaire. Of these, 38 did not agree to participate in the study, and 5 were not able to understand the Italian language.

Six hundred children (302 females, 50%), mean age 5.8 years (3.5 SD), with mothers coming from 42 different countries, were enrolled. The main characteristics of the study population are reported in Table 1.

Fifty children (8%) were affected by chronic diseases: 11 children had autism spectrum disorder, 10 celiac disease, 8 syndromic diseases, 6 epilepsy, 6 chronic asthma, 2 hypothyroidism, 1

congenital heart disease, 1 adreno-genital syndrome, 1 congenital glaucoma, 1 diabetes mellitus type I, 1 Hashimoto thyroiditis, 1 psoriasis, 1 congenital myasthenia.

Threehundredsixtyone children (61,2%) had an ongoing acute disease. Among these, 179 had a respiratory infection (uri, influenza, viral wheezing, cough, pneumonia, sinusitis), 39 otitis media, 27 dermatitis , 17 gastroenteritis , 13 conjunctivitis, 11 allergic symptoms (oculorinitis, asthma), 7 urinary tract infection, 9 came in for trauma and 59 had other problems.

In the previous year, 209 children (35%) used ET exclusively , 358 (60%) used both ET and CAM, 25 (4%) used CAM exclusively , 8 (1%) did not use any therapy (Fig 1).

Among the children who used ET, 559 (99%) utilized NSAIDs, 222 (39%) antibiotics, 38 (7%) steroids, 28 (5%) bronchodilators, and 19 (3%) other drugs.

Among the children treated with CAM, 175 (46%) took antitussives or mucolytics, 133 (35%), phytotherapy, 131 (34%) probiotics, and 116 (30%) homeopathy.

CAM was used in 378 cases (99%) for acute illness and 140 cases (35%) as a preventive therapy, 119 with the intention to reinforce the immune system and 21 to prevent infections. CAM for children was suggested by pharmacists in 46% of cases and it was self-prescribed in 43%. The family pediatricians prescribed it in 5% of the cases, homeopaths in 3% and herbalists in 3%.

Table 2 shows the number of different drugs administered in a year, the frequency of use, the number of children who underwent a cycle of therapy for longer than 30 consecutive days. Among the 383 children who used CAM, 109 (29%) used 3 or more different products, compared to 38 (7%) of the 567 children who used ET. 164 (43%) CAM users underwent ten or more cycles of therapies, versus 37 (7%) ET users. Remarkably, as much as 112 (29%) children took CAM products for 30 or more consecutive days, compared to 11 (2%) who took ET products for such long periods.     There was a statistically significant difference between children who resort to ET and CAM, in the number of drugs, cycles of therapies, and frequency of continuous therapies.

Table 3 shows the correlations between CAM, maternal education, country of origin, vaccination status of children, and the presence of a chronic disease.

Parents with higher education and coming from high-income countries used CAM much more significantly than others (p <0.0001). 100% (19/19) of non-vaccinated patients used CAM, versus 63% (366) of vaccinated patients, (p=0,003). Among children affected by chronic diseases, 74% used CAM.

**DISCUSSION**

This study shows that the use of CAM is widespread in our population, with over 60% of interviewed parents using it for their children, either for acute illnesses or as preventive therapies. These data are consistent with the prevalence of the use of CAM in European children [13,14], while they detect a higher prevalence of its use if compared to previously reported data on Italian children [15–17]. An Italian study in 1999 showed a prevalence of the use of CAM in children of 39% [18]. This variance is probably related to the growing trend of this habit in Italy. Our prevalence is also higher when compared to the data collected by the National Health and Nutrition Examination Survey (NHANES) from 2003 to 2014, which reported that over a third of American children and adolescents used dietary supplements [17].

The reasons for such widespread use of therapies not supported by proof of efficacy could be a matter of speculation. A previous Italian study demonstrated that patients tend not to disclose CAM use to the attending pediatrician in at least half of cases [18,19].   Data from our study reveal that children using CAM take more per os or inhaled products, with 29% of them receiving more than three different products in a year, compared to children who use only essential therapies. Moreover, they take therapies more often, during the year, and for more extended periods: 43% take more than ten cycles of drugs per year and 29% for more than 30 consecutive days in a year. A reason for this could be the absence of standardized protocols and guidelines for CAM therapies, besides the misleading perception of CAM being "not harmful". We found that the use of CAM was significantly more frequent in children whose mothers have a higher education level and come from high-income countries. This difference is even more evident if we compare children from the most represented high-income country (Italy) and the most represented low-income country (Bangladesh) considering that the use of CAM in the previous year was 73% and 26%, respectively (Table 3).  Remarkably, in our population, most of the times, CAM was not prescribed by the family pediatrician, but self-prescribed or suggested by other professionals (mainly pharmacists). These data could be explained by the "paradox of pseudo-culture," which states that those who have the means to invest in science prefer to obtain information on the variety of electronic platforms without being able to effectively distinguish

the credibility of sources. In the emerging social media communities, participants may trust each other more than they trust experts [20], they perceive CAM as non-industrial, not harmful, natural [7], and probably this is the reason for its widespread use. Above all, the fear of adverse reactions still seems to be the main reason that influences parents' decision to use CAM [18,19]. However, it seems a substantial contradiction that this search for "natural" leads to the more frequent use of "chemicals" and "medical" products. Similarly, in our series, it seems that the choice of non vaccinating correlates with the choice of CAM. All unvaccinated children in our population use CAM. This issue could be related to a possible "reification of natural" in these families, who frequently refuse industrial chemicals by BigPharma [9], but are prone to trust other forms of alleged "natural" industrial products. Other Authors found a symbiotic relationship between CAM and vaccine rejection which they explained as an attempt to adapt to the ideology of the society in which they live or as a consequence of a personal experience in which essential medicine has not been decisive, and they have found comfort in CAM [21]. In the end, our data suggest that CAM is strictly related to a family and social status where many resources are available, and a great selection of products is sold and often promoted by different professionals.

This study has some limitations. It was performed in four family pediatric clinics in a single geographical region; therefore, we cannot generalize our findings. Nevertheless, we involved several urban areas and included a large variety of children whose families come from 42 countries and represent different socioeconomic statuses. We are also aware that some patients probably go to homeopaths only and do not usually come to the conventional clinics where the study was performed, so that we may possibly underestimate the percentage of CAM prescribed by a doctor-homeopath. We collected data through the administration of a questionnaire, excluding people who did not understand the Italian language; therefore, we cannot rule out that this may have influenced the study results. We requested the compilation of the questionnaire only in the hours when residents were present in the clinics; hence we were not able to collect data about all the children who arrived in the clinics during the study period. A questionnaire can limit the quality of responses through the lack of embodied visual cues compared to face-to-face interviews, and some questions could perhaps be perceived as difficult to understand. In order to limit this pitfall, the residents helped parents to understand the

questions when needed. We did not analyze of the costs related to the use of CAM and ET, which could have helped to quantify the burden of these therapies on the families. Finally, having included antitussigen and mucolytic products in CAM might represent a confounding factor since they are commonly prescribed even by pediatricians, despite the lack of evidence. We used the WHO list of products included in ET, that excluded antitussigen and mucolytic products.

In conclusion, this study shows that CAM is widespread among children attending family pediatrician clinics. It may be inferred that parents who rely on CAM end up giving their children more per os or inhaled "therapies" than needed. Clinicians should probably acquire more information about CAM in order to advice their patients on possible side effects and interactions[14]. Moreover, knowing about patients' use of CAM could also help the clinician try to understand and better address the patients' or parents' needs. Having underlined the lack of adequate and correct information that often brings patients to use CAM, besides ideological factors, we find that as medical doctors we need to propose a model of better information and we may need to consider that many patients do not disclose CAM use due to physicians' manifest hostility about it[14]. Further studies are indeed required to better understand and measure the use of CAM in children.

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**TABLES**

**Table 1. Main population characteristics.**

| Population characteristics | Total (n= 600) |
|---|---|
| **Sex** | |
| Male | 298 (50%) |
| Female | 302 (50%) |
| **Age** (years: mean and SD) | 5.8±3.5 |
| **Affected by a chronic disease** | 50 (8%) |
| **Vaccination status** | |
| Vaccinated children | 581 (97%) |
| Non-vaccinated children | 19 (3%) |
| **Maternal education level** | |
| Elementary-middle school diploma | 138 (23%) |
| High school-University diploma | 462 (77%) |
| **Maternal country origin** | |
| Low-middle income country: | 102 (17%) |
| - Bangladesh | 72 (12%) |
| - Ukraine | 7 (1%) |
| - Moldova | 5 (1%) |
| - 9 other countries | 18 (3%) |
| Upper-middle income country: | 101 (17%) |
| - Romania | 20 (3%) |
| - Albania | 12 (2%) |
| - Serbia | 9 (2%) |
| - 18 other countries | 60 (10%) |

| | |
|---|---|
| High income country: | 397 (66%) |
| - Italy | 377 (63%) |
| - Croatia | 5 (1%) |
| - Poland | 5 (1%) |
| - 6 other countries | 10 (2%) |

**Table 2. Use of ET and CAM in the study population**

|  | Essential therapies (ET) | Complementary and alternative medicines (CAM) | p value |
|---|---|---|---|
| Type of therapy | 567 (95%) | 383 (64%) |  |
| Use of < 3 different drugs | 529 (93%) | 274 (72%) | <0.0001 |
| Use of ≥ 3 different drugs | 38 (7%) | 109 (29%) | <0.0001 |
| Use of < 10 cycles | 530 (94%) | 219 (57%) | <0.0001 |
| Use of ≥ 10 cycles | 37 (7%) | 164 (43%) | <0.0001 |
| Use of therapies for 30 consecutive days or more | 11 (2%) | 112 (29%) | <0.0001 |

**Table 3.** Correlation between CAM use and material education and country of origin and children's vaccination status.

| | Essential therapies (ET) | p value | Complementary and alternative medicines (CAM) | p value |
|---|---|---|---|---|
| Maternal education level: | | | | |
| - Elementary-middle school diploma (n 138) | 132 (96%) | | 58 (42%) | 0.79 |
| - High school-University diploma (n 462) | 434 (94%) | | 323 (70%) | <0.0001 |
| Maternal country origin: | | | | |
| - Low-middle income country (n 102) | 97 (95%) | | 35 (34%) | <0.0001* |
| - Upper-middle income country (n 101) | 97 (96%) | | 56 (57%) | 0.0016** |
| - High income country (n 397) | 373 (94%) | | 290 (73%) | 0.0003*** |
| Maternal country origin: | | | | |
| - Bangladesh (n 72) | 68 (94%) | | 19 (26%) | <0.0001 |
| - Italy (n 377) | 352 (93%) | | 275 (73%) | |
| Children vaccination status: | | | | |
| - Vaccinated (n 581) | | 0.0025 | | 0.003 |

| | | | | | |
|---|---|---|---|---|---|
| -    Non-vaccinated (n 19) | 552 (95%) 14 (73%) | | 366 (63%) 19 (100%) | | |
| Children affected by chronic diseases (n 50) | 50 (100%) | | 37 (74%) | | |

* correlation between LM and UM group; ** correlation between UM and H group *** correlation between LM and H group.