



UNIVERSITÀ  
DEGLI STUDI  
FIRENZE

FLORE

## Repository istituzionale dell'Università degli Studi di Firenze

### **The use of complementary and alternative medicines during breastfeeding: results from the Herbal supplements in Breastfeeding**

Questa è la Versione finale referata (Post print/Accepted manuscript) della seguente pubblicazione:

*Original Citation:*

The use of complementary and alternative medicines during breastfeeding: results from the Herbal supplements in Breastfeeding InvesTigation (HaBIT) study / Bettiol, Alessandra; Lombardi, Niccolò; Marconi, Ettore; Crescioli, Giada; Bonaiuti, Roberto; Maggini, Valentina; Gallo, Eugenia; Mugelli, Alessandro; Firenzuoli, Fabio; Ravaldi, Claudia; Vannacci, Alfredo. - In: BRITISH JOURNAL OF CLINICAL

*Availability:*

The webpage <https://hdl.handle.net/2158/1136035> of the repository was last updated on 2022-05-04T12:35:57Z

*Published version:*

DOI: 10.1111/bcp.13639

*Terms of use:*

Open Access

La pubblicazione è resa disponibile sotto le norme e i termini della licenza di deposito, secondo quanto stabilito dalla Policy per l'accesso aperto dell'Università degli Studi di Firenze (<https://www.sba.unifi.it/upload/policy-oa-2016-1.pdf>)

*Publisher copyright claim:*

La data sopra indicata si riferisce all'ultimo aggiornamento della scheda del Repository FloRe - The above-mentioned date refers to the last update of the record in the Institutional Repository FloRe

(Article begins on next page)

## ORIGINAL ARTICLE

# The use of complementary and alternative medicines during breastfeeding: results from the Herbal supplements in Breastfeeding Investigation (HaBIT) study

**Correspondence** Professor Alfredo Vannacci MD, PhD, Department of Neurosciences, Psychology, Drug Research and Child Health, Viale G. Pieraccini, 6-50139, Florence, Italy. Tel.: +39 055 42 71 270; E-mail: alfredo.vannacci@unifi.it

**Received** 28 February 2018; **Revised** 2 May 2018; **Accepted** 5 May 2018

Alessandra Bettiol<sup>1,†</sup>, Niccolò Lombardi<sup>1,†</sup>, Ettore Marconi<sup>1</sup>, Giada Crescioli<sup>1</sup>, Roberto Bonaiuti<sup>1</sup>, Valentina Maggini<sup>2,3</sup>, Eugenia Gallo<sup>2,3</sup>, Alessandro Mugelli<sup>1</sup>, Fabio Firenzuoli<sup>3</sup>, Claudia Ravaldi<sup>4,‡</sup> and Alfredo Vannacci<sup>1,4,\*</sup> 

<sup>1</sup>Department of Neurosciences, Psychology, Drug Research and Child Health Section of Pharmacology and Toxicology, University of Florence; Tuscan Regional Centre of Pharmacovigilance and Phytovigilance, Florence, Italy, <sup>2</sup>Department of Experimental and Clinical Medicine, University of Florence, Florence, Italy, <sup>3</sup>Center for Integrative Medicine, Careggi University Hospital, University of Florence, Florence, Italy, and <sup>4</sup>CiaoLapo Onlus, Charity for Healthy Pregnancy, Stillbirth and Perinatal Grief Support, Prato, Italy

\*Principal Investigator.

†Co-first authors.

‡Co-last authors.

**Keywords** adverse drug reactions, breastfeeding, complementary medicine, herbal medicine, pregnancy

## AIMS

The use of complementary and alternative medicines (CAMs) during breastfeeding is increasing, mainly because of their presumed greater safety compared with conventional medications. However, CAMs can cause serious adverse effects, and there is limited high-quality evidence supporting their use during lactation. In Italy, specific investigations on the attitude of lactating women towards CAMs are lacking. The Herbal supplements in Breastfeeding Investigation (HaBIT) study aimed to explore attitudes to and knowledge on CAMs among lactating women.

## METHODS

A web-based survey was conducted over a 6-year period among lactating women resident in Tuscany, Italy. Data on lactating behaviour, CAMs use during pregnancy or breastfeeding, and women's knowledge about the efficacy and safety of CAMs were collected.

## RESULTS

A total of 388 lactating women answered the questionnaire. The majority of them were primiparae, with a high educational level. Of these, 204 women declared themselves to have used CAMs during breastfeeding. Moreover, 61% and 48% of subjects reported also using CAMs before and during pregnancy, respectively. A significant proportion of subjects were unable to identify correctly the types of CAMs they were using. Seventy-three per cent of women were convinced that CAMs were equally safe or safer than conventional medications; nevertheless, 65% of women admitted to have no scientific information about the potential risks of CAMs, and 14 CAMs users reported that they had experienced side effects.

## CONCLUSIONS

These results demonstrate the need for healthcare providers to increase the awareness of breastfeeding women about CAMs. Further research is needed to support the evidence base for nonpharmaceutical approaches for symptom control during breastfeeding.

## WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT

- The use of complementary and alternative medicines (CAMs) during breastfeeding is generally increasing, mainly because of their presumed higher safety compared with conventional medications. Indeed, CAMs can cause serious adverse effects, and high-quality evidence supporting their use during lactation is limited.

## WHAT THIS STUDY ADDS

- In Italy, specific investigations on the attitude of lactating women towards CAMs are lacking. The Herbal supplements in Breastfeeding InvesTigation (HaBIT) aimed to explore the attitudes to and knowledge on CAMs among lactating women in Italy.

## Introduction

The use of drugs during breastfeeding has been widely studied worldwide, raising major concerns for lactating women about the safety and potential effects of medications on the quantity and quality of the milk produced [1]. However, most available studies have focused only on the secretion of conventional medicines into human milk, whereas the evidence on herbal compounds is still lacking [2]. Moreover, the use of complementary and alternative medicines (CAMs) during pregnancy and breastfeeding is increasing worldwide [1, 3]. It is estimated that 15% of breastfeeding women in the United States (43% internationally) use herbal products [4]. This frequent use, often on a self-treatment basis [5], may be either breastfeeding related – for example, to increase milk production or for engorgement or mastitis – or related to specific health conditions, such as constipation, common colds or depression [6, 7]. Herbal products, being natural, are perceived by women and some healthcare providers as being ‘softer’, cheaper and safer than conventional drugs [8]. However, as with conventional medications, plant extracts also have the potential to cause serious adverse effects [9].

In Italy, specific investigations on the attitude of pregnant and lactating women towards CAMs are still scarce. In a survey performed by Zaffani *et al.* [10], 35.2% of women declared the use of herbal drugs during pregnancy. In another survey by Lapi *et al.* [11], 48% of pregnant women were reported to have taken at least one CAMs previous to and/or during pregnancy. To our knowledge, there is no evidence on the use of, and attitudes to, herbal medicines among Italian breastfeeding women. As the concerns on the use of herbal drugs during breastfeeding are widely debated, we developed the Herbal supplements in Breastfeeding InvesTigation (HaBIT) in order to explore the attitudes to, beliefs in and knowledge of CAMs in a sample of Italian breastfeeding women.

## Methods

### Study population

A web-based survey was conducted over a 6-year period (from 1 February 2012 to 31 October 2017). The sample consisted of currently breastfeeding women or women who interrupted breastfeeding in the 6 months before the survey, resident in Tuscany (Italy) and attending the facilities of the CiaoLapo Onlus Association (an Italian charity for pregnancy and perinatal health). Moreover, the midwife associations of seven Italian cities were involved in distributing the survey. All potential participants, recruited consecutively, received information about the study and an invitation to participate

via an online form. Written electronic informed consent was obtained.

### Data collection

Data were collected by means of a semi-structured web-based questionnaire (Appendix S1) which took about 10 min to fill in, administered using the SurveyMonkey® web platform (<https://www.surveymonkey.com>). This online tool provided a reliable and user-friendly method of real-time data collection. Women used a simple web browser on a computer or mobile device (smartphone or tablet) to answer questions quickly and intuitively, and, at the same time, the study operator could check the overall status of the answers remotely with intuitive schemes, summaries and graphs. Data were stored on SurveyMonkey's servers in the cloud, providing state-of-the-art reliability, privacy and safety. Before each interview, women received a definition of CAMs, generally defined as any type of product manufactured from plants or with natural origin. The questionnaire was composed of 36 items, closed ( $n = 23$ ) and open-ended ( $n = 13$ ) questions, divided into four main sections. The first section comprised patients' sociodemographic data, information on breastfeeding behaviour and use of CAMs before, during or after pregnancy. The second section investigated the use of CAMs during the current breastfeeding period. Women in the study were also asked to classify products or practices in the following categories: acupuncture, chiropractic/osteopathy/manual medicine, dietary supplements, domestic and traditional preparations, herbal preparations, homeopathy, natural preparations and phytotherapy. Afterwards, each product was classified by a team of trained specialists (A.B., N.L., E.M. and G.C.) by means of the European Pharmacopoeia [12]. The third section investigated information sources on CAMs: through close-ended questions, women were asked about their usual source of information about CAMs (the choices were: general practitioner, gynaecologist, midwife, pharmacist, herbalist, integrative medicine expert, naturopath, friends/family, internet or magazines); two close-ended questions then investigated women's beliefs about the safety and efficacy of these types of products. Finally, the fourth section was focused on phytopharmacovigilance and investigated the pre-existing knowledge and the occurrence of adverse events during CAMs use. The questionnaire was designed and planned according to specific methodological literature [13–15]. It was validated by an *ad hoc* panel of experts (pharmacologists, epidemiologists, toxicologists, pharmacists and clinicians) from the Tuscan Regional Centre of Pharmacovigilance and Phytovigilance and from the Center for Integrative Medicine (V.M., E.G., F.F., C.R. and A.V.).

## Data analysis

Categorical variables were expressed as a percentage and analysed using the chi-square test. Continuous variables were reported as the mean  $\pm$  standard error of the mean (SEM) or as the median and interquartile range, according to data distribution, and analysed using the *t*-test or the Mann–Whitney test, respectively. To assess the women's knowledge about CAMs, their classification of the CAMs they used during breastfeeding was compared with the European Pharmacopoeia classification. Cohen's kappa was calculated to evaluate concordance. The kappa value, in accordance with Landis and Koch, was categorized as fair (0.2–0.4), moderate (0.4–0.6), good (0.6–0.8) and very good (0.8–1) [16].

A *P*-value  $<0.05$  was considered statistically significant. All analyses were performed using the software STATA version 14 (StataCorp, Texas, USA).

## Results

A total of 476 women participated in the web-based interview. At the time of completing the questionnaire, 32 women (6.72%) were not breastfeeding, and were therefore excluded from the analysis; other 56 participants (11.76%) were excluded because they failed to complete any items on the questionnaire ( $n = 16$ ) or because of missing information on the use of CAMs during breastfeeding ( $n = 40$ ). Among the other 388 women, 204 (52.58%) declared themselves to be users of CAMs during breastfeeding, whereas 184 (47.42%) declared no use of these products (Table 1). Regarding their

sociodemographic characteristics, their mean age was  $35.05 \pm 0.88$  years; 227 (58.51%) had a university degree; and 233 (60.05%) had one child, 117 (30.15%) had two children and 38 (9.79%) had three or more children. With regard to the type of birth they underwent, 225 (57.99%) women had vaginal delivery without anaesthesia, whereas 100 (25.77%) women had a caesarean section. The mean age of their children at the time of interview was  $14.30 \pm 0.59$  months. Sociodemographic characteristics were comparable between CAMs users and non-users, except for the number of children they had, which was significantly lower among CAMs users (66.67% vs 52.72% of CAMs users and non-users had one child, respectively;  $P = 0.014$ ).

Information on breastfeeding is described in Table 2. Out of 388 women, 305 (78.61%) said that they had received information on the importance of breastfeeding. As expected, the primary source of information for the majority of women were midwives and paediatricians. A total of 241 women (62.11%) reported some difficulties in breastfeeding; in particular, the most frequent complications were breast fissures ( $n = 130$ ; 33.51%), engorgement ( $n = 121$ ; 31.19%), poor milk production ( $n = 40$ ; 10.31%) and mastitis ( $n = 39$ ; 10.05%). The occurrence of engorgement and inverted nipple was significantly more frequent in the group of CAMs users compared with non-users [35.78% of CAMs users experienced engorgement vs. 26.09% of non-users ( $P = 0.039$ ); 10.78% of CAMs users had inverted nipples vs. 4.89% of non-users ( $P = 0.033$ )]. A significant proportion of women ( $n = 137$ ; 35.31%) reported two or more breastfeeding-related difficulties; this proportion was significantly higher

**Table 1**

Sociodemographic characteristics of the breastfeeding women interviewed

	Breastfeeding women, overall ( $n = 388$ )	CAMs non-users ( $n = 184$ )	CAMs users ( $n = 204$ )	<i>P</i> -value
<b>Mean age <math>\pm</math> SEM (years)</b>	35.05 $\pm$ 0.88	36.23 $\pm$ 1.80	34.29 $\pm$ 0.39	0.270
<b>Educational level</b>				
<b>Middle-school certificate</b>	21 (5.41)	8 (4.35)	13 (6.37)	0.627
<b>High-school certificate</b>	140 (36.08)	69 (37.50)	71 (34.80)	
<b>University degree</b>	227 (58.51)	107 (58.15)	120 (58.82)	
<b>Number of children</b>				
<b>1</b>	233 (60.05)	97 (52.72)	136 (66.67)	0.014 <sup>a</sup>
<b>2</b>	117 (30.15)	68 (36.96)	49 (24.02)	
<b>3+</b>	38 (9.79)	19 (10.33)	19 (9.31)	
<b>Mean age of newborn <math>\pm</math> SEM (months)</b>	14.30 $\pm$ 0.59	14.95 $\pm$ 0.89	13.73 $\pm$ 0.77	0.299
<b>Type of birth</b>				
<b>Vaginal without anaesthesia</b>	225 (57.99)	117 (63.59)	108 (52.94)	0.168
<b>Vaginal with anaesthesia</b>	48 (12.37)	19 (10.33)	29 (14.22)	
<b>Vacuum-assisted vaginal delivery</b>	15 (3.87)	5 (2.72)	10 (4.90)	
<b>Caesarian</b>	100 (25.77)	43 (23.37)	57 (27.94)	

CAMs, complementary and alternative medicines; SEM, standard error of the mean

<sup>a</sup>*P*-value statistically significant ( $P < 0.05$ ).

Table 2

Provision of information on breastfeeding

	Breastfeeding women, overall (n = 388)	CAMs non-users (n = 184)	CAMs users (n = 204)	P-value
<b>Declared to have received information on breastfeeding importance</b>	305 (78.61)	146 (79.35)	159 (77.94)	0.736
<b>Breastfeeding-related difficulties – problems:</b>				
<b>Mastitis</b>	241 (62.11)	114 (61.96)	127 (62.25)	0.418
<b>Breast fissures</b>	39 (10.05)	20 (10.87)	19 (9.31)	0.611
<b>Breast fissures</b>	130 (33.51)	61 (33.15)	69 (33.82)	0.889
<b>Engorgement</b>	121 (31.19)	48 (26.09)	73 (35.78)	0.039 <sup>a</sup>
<b>Inverted nipple</b>	31 (7.99)	9 (4.89)	22 (10.78)	0.033 <sup>a</sup>
<b>Poor milk production</b>	40 (10.31)	14 (7.61)	26 (12.75)	0.097
<b>Incompatibility with work</b>	15 (3.87)	9 (4.89)	6 (2.94)	0.320
<b>Practical difficulties in breastfeeding management</b>	31 (7.99)	15 (8.15)	16 (7.84)	0.911
<b>Intolerance, discomfort</b>	20 (5.15)	6 (3.26)	14 (6.86)	0.109
<b>Practical difficulties in management of other children</b>	22 (5.67)	9 (4.89)	13 (6.37)	0.529
<b>Difficulties with partner</b>	13 (3.35)	8 (4.35)	5 (2.45)	0.300
<b>Number of breastfeeding-related difficulties</b>				
<b>0</b>	147 (37.89)	70 (38.04)	77 (37.75)	0.019 <sup>a</sup>
<b>1</b>	104 (26.80)	60 (32.61)	44 (21.57)	
<b>2 or more</b>	137 (35.31)	54 (29.35)	83 (40.69)	
<b>Exclusive breastfeeding</b>	347 (89.43)	172 (93.48)	175 (85.78)	0.014 <sup>a</sup>
<b>Cause for mixed feeding</b>				
<b>Insufficient feeding</b>	8 (2.06)	2 (1.09)	6 (2.94)	0.199
<b>Milk did not contain enough nutrients</b>	5 (1.29)	3 (1.63)	2 (0.98)	0.571
<b>Advised by healthcare professionals</b>	34 (8.76)	10 (5.43)	24 (11.76)	0.028 <sup>a</sup>
<b>Advised by nonhealthcare professionals</b>	5 (1.29)	3 (1.63)	2 (0.98)	0.571

CAMs, complementary and alternative medicines

<sup>a</sup>P-value statistically significant ( $P < 0.05$ ).

among CAMs users compared with non-users (40.69% vs. 29.35%;  $P = 0.019$ ). In the majority of cases ( $n = 347$ ; 89.43%), children were exclusively breastfed. Exclusive breastfeeding was significantly more frequent among CAMs non-users (93.48% vs. 85.78%;  $P = 0.014$ ). Forty-one women (10.57%) used mixed feeding, mainly following the advice of healthcare professionals ( $n = 34$ ; 8.76%) or owing to insufficient milk production ( $n = 8$ ; 2.06%).

Focusing on CAMs taken during breastfeeding and stratified according to the European Pharmacopoeia (Table 3), phytotherapeutic agents were found to be the most frequently used CAMs ( $n = 77$ ; 37.75%); however, only 19 women (9.31%) were able to classify them, and these agents were the class of CAMs with the lowest concordance between the classification by the women and by the European Pharmacopoeia (Cohen's kappa = 0.24). Other commonly taken CAMs were dietary supplements ( $n = 66$ ; 32.35%) and herbal preparations ( $n = 64$ ; 31.37%), with a significant concordance between the classification by the women and by the Pharmacopoeia (Cohen's kappa = 0.62 and 0.92, respectively). Of note, 162 women reported to take a CAM belonging only to

one class, whereas 40 women declared the use of CAMs from two different classes, and only two subjects said that they used three different types of CAMs.

The perceptions and beliefs of women concerning the efficacy and safety of CAMs are described in Table 4. Regarding efficacy, 35 (9.02%) and 158 (40.72%) women, respectively, believed that CAMs had higher or comparable efficacy than conventional medications, while 114 (29.38%) considered their efficacy to be lower. Perceptions of efficacy were comparable among CAMs users and non-users. Moreover, 150 (38.66%) and 133 (34.28%) women, respectively, were convinced that CAMs had higher or comparable safety than conventional medications, and only 31 (7.99%) women considered the use of CAMs to be unsafe. Women in the CAMs user group were significantly more likely than non-users to consider CAMs to be safe ( $P = 0.032$ ). In most cases, women said that they had no information about the potential risks of CAMs use ( $n = 254$ ; 65.64%), with no difference between CAMs users and non-users.

The perceived benefits and side effects reported by women who used CAMs during breastfeeding are described in

**Table 3**

Classification of complementary and alternative medicines (CAMs) ( $n = 248$ ) taken by the 204 CAMs users during breastfeeding, and concordance between classification by the study participants and the European Pharmacopoeia

	Women's classification, $N$ (%)	European Pharmacopoeia classification, $N$ (%)	Cohen's kappa	Landis and Koch classification
<b>Dietary supplements</b>	98 (48.04)	66 (32.35)	0.62	Good
<b>Herbal preparations</b>	65 (31.86)	64 (31.37)	0.92	Very good
<b>Homeopathic preparations</b>	29 (14.22)	14 (6.86)	0.51	Moderate
<b>Phytotherapeutic agents</b>	19 (9.31)	77 (37.75)	0.24	Fair
<b>Traditional practices</b>	8 (3.92)	11 (5.39)	0.83	Very good
<b>Natural preparations</b>	7 (3.43)	2 (0.98)	0.44	Moderate
<b>Domestic preparations</b>	6 (2.94)	6 (2.94)	0.48	Moderate
<b>Others</b>	13 (6.37)	-	-	
<b>Acupuncture</b>	3 (1.47)	-	-	

**Table 4**

Attitude of women towards the efficacy and safety of complementary and alternative medicines (CAMs)

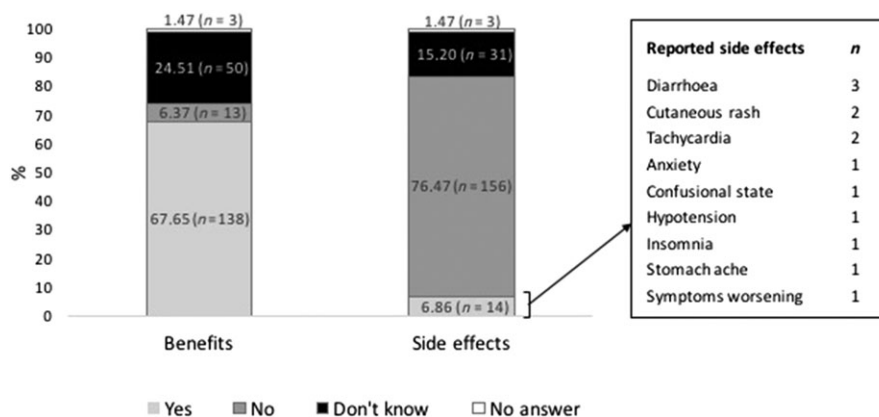
	Breastfeeding women, overall ( $n = 388$ )	CAMs non-users during breastfeeding ( $n = 184$ )	CAMs users during breastfeeding ( $n = 204$ )	$P$ -value
<b>Perceived efficacy of CAMs compared with traditional drugs</b>				
<b>Higher</b>	35 (9.02)	14 (7.61)	21 (10.29)	0.306
<b>Comparable</b>	158 (40.72)	67 (36.41)	91 (44.61)	
<b>Lower</b>	114 (29.38)	59 (32.07)	55 (26.96)	
<b>Don't know</b>	75 (19.33)	41 (22.28)	34 (16.67)	
<b>No answer</b>	6 (1.55)	3 (1.63)	3 (1.47)	
<b>Perceived safety of CAMs compared with traditional drugs</b>				
<b>Higher</b>	150 (38.66)	62 (33.70)	88 (43.14)	0.032 <sup>a</sup>
<b>Comparable</b>	133 (34.28)	61 (33.15)	72 (35.29)	
<b>Lower</b>	31 (7.99)	14 (7.61)	17 (8.33)	
<b>Don't know</b>	68 (17.53)	44 (23.91)	24 (11.76)	
<b>No answer</b>	6 (1.55)	3 (1.63)	3 (1.47)	
<b>Had information on potential risks</b>				
<b>Yes</b>	128 (32.99)	58 (31.52)	70 (34.31)	0.841
<b>No – Don't know</b>	254 (65.46)	123 (66.85)	131 (64.22)	
<b>No answer</b>	6 (1.55)	3 (1.63)	3 (1.47)	

<sup>a</sup> $P$ -value statistically significant ( $P < 0.05$ ).

Figure 1. Most women ( $n = 138$ ; 67.65%) ascribed benefits to the use of these products. Regarding safety, only 14 (6.86%) women declared having experienced side effects during CAMs use. In particular, the most frequent side effects were diarrhoea, tachycardia and cutaneous rash. Other side effects included epigastric pain, worsening of symptoms, hypotension, insomnia, anxiety and confusion. One woman declared to have experienced a side effect, but did not further specify it.

Data on CAMs use over the whole lifetime and during pregnancy were also collected (Table S1). Of 388 women, 235 (60.57%) declared having used at least one CAMs before pregnancy; this percentage was significantly higher among users of CAMs during breastfeeding compared with non-users (67.16% vs. 53.26%,  $P = 0.019$ ).

Furthermore, 185 women (47.68%) declared having used at least one CAMs during pregnancy. Use of CAMs during



**Figure 1**

Benefits and side effects reported by women using complementary and alternative medicines during breastfeeding

pregnancy was found to be significantly more common among CAMs users during breastfeeding compared with non-users [67.16% vs. 53.26% of users of CAMs before pregnancy ( $P = 0.019$ ); 53.45% vs. 42.39% of users of CAMs during pregnancy ( $P = 0.005$ )]. Based on women's classification, the CAMs most frequently used during pregnancy were homeopathic ( $n = 106$ ; 27.32%), phytotherapeutic ( $n = 56$ ; 14.43%) and domestic ( $n = 31$ ; 7.99%) preparations.

According to the 185 CAMs users during pregnancy, CAMs were mainly used to treat back pain ( $n = 41$ ; 22.16%), nausea ( $n = 39$ ; 21.08%) and constipation ( $n = 30$ ; 16.22%) (Figure S1). The most frequent adviser for CAMs use during pregnancy was the midwife ( $n = 58$ ; 31.35%); however, 51 (27.57%) women said that they had self-medicated with CAMs.

## Discussion

To the best of our knowledge, this was the first Italian study conducted with the aim of characterizing users of CAMs during breastfeeding. Our results demonstrated that the use of CAMs during breastfeeding is a widespread practice among Italian women, particularly among primiparae. Use of CAMs was mainly due to the occurrence of lactation-related disorders, such as breast fissures, engorgement and flat or inverted nipples. The occurrences of engorgement and flat or inverted nipples were significantly different between the groups, and women experiencing more than one difficulty were more likely to take a CAM. If they are not properly managed, these issues may seriously hamper the initiation and continuation of breastfeeding. Most of these conditions should be managed by correcting breastfeeding positioning and attachment [17], an approach that requires the availability of information and the appropriate education of healthcare staff [18]. However, in our sample, women were instead often driven by healthcare professionals towards CAMs use and also mixed feeding, and about half of them resorted to self-medication or followed the advice from friends, television, the internet and so forth (Figure S1).

Furthermore, CAMs were clearly perceived as being safer than conventional drugs, as they were viewed as culturally

acceptable, easy to access and more affordable [19]. According to our survey, the majority of women perceived the efficacy of CAMs as being comparable or even superior to conventional drugs, in terms of both efficacy and safety. This is probably the most important reason for women becoming CAMs users [20], even if, in the present study, 14 women reported having experienced adverse effects possibly related to CAMs use, including diarrhoea, tachycardia and cutaneous rash. Nevertheless, we could not determine whether these events were attributable to CAMs use or to concomitant conditions and/or conventional medications. Thus, we also could not perform a causality assessment.

Furthermore, most women reported never to have received precise scientific information regarding CAMs use during breastfeeding. These results were comparable with those of a population-based survey conducted in Australia, where 70.1% of participants reported lacking information regarding the use of herbal products during breastfeeding, 43.4% perceived herbs as safer than conventional medicines, and only 28.6% reported informing their doctor of their CAMs use during lactation [1].

The substantial lack of information on CAMs was confirmed as many women were unable to classify correctly the CAMs they were taking. In particular, as shown in Table 3, the lowest level of awareness was in regard to phytotherapeutic agents: the majority of CAMs users reported use of phytotherapeutic agents during breastfeeding, although most of them believed they were taking other classes of CAMs (mainly dietary supplements and herbal preparations).

These results highlight the poor (or lack of) breastfeeding counselling by healthcare practitioners, a procedure that should be performed correctly in order to prevent the development of lactation-related disorders and enhance the awareness of breastfeeding women about making a conscious and informed choice of appropriate products or procedures to empower the breastfeeding experience.

Improvement in knowledge about CAMs is particularly relevant considering that more than 60% of breastfeeding women reported recurrent use of CAMs and more than 47% of them also reported CAMs use during pregnancy, often self-prescribed. The lower prevalence of CAMs use during pregnancy compared with recurrent use may indicate that

women pay greater attention towards the use of these products, and of conventional medications in general, during this time.

A survey conducted in the United States reported that women often do not share their use of, or willingness to use, herbal remedies with their healthcare providers owing to a fear of offending providers or to the belief that clinicians will be ignorant about their use [5]. In this light, healthcare providers should maintain an open and respectful approach when counselling pregnant and nursing women about the use of herbal products, and they should provide reliable advice and guidance on exposure to products that might be harmful [5].

According to a review conducted to determine the safety and efficacy of herb use during breastfeeding, most studies were of poor methodological quality [21]. It is also important to note that many CAMs products contain alcohol or caffeine as excipients, which should be avoided in both pregnancy and the breastfeeding period [4]. This is an important safety issue considering that, as reported in our sample, the majority of participating women did not know which types of product (and consequently compounds) they were consuming. Furthermore, it is important to emphasize that, although there was a high prevalence of well-educated women (57.24% reported having a university degree), participants' ability to classify CAMs was low.

### Limitations

Our study had several limitations. First, the survey was based on a non-random, self-reported procedure for the questionnaire phase, which might have affected the generalizability of our findings. In particular, our analysis included a significant proportion of well-educated women, so the results might not have been representative of the population as a whole. Secondly, the items that interrogated the previous use of CAMs might have been affected by recall bias. Thirdly, our survey did not provide information on comorbidities and the concomitant use of conventional drugs, so we could not evaluate the association of these factors with CAMs use, and we could not discern whether reported adverse events were related to CAMs or to concomitant medications. Fourthly, the results of the present study might have been influenced by the heterogeneity of the CAMs included, especially in terms of safety. Furthermore, our survey did not provide information on the socioeconomic status of CAMs users, so we could not establish whether there was an association between socioeconomic classes and CAMs use. Finally, we did not include any dummy questions/variables to evaluate the extent of the variability of the sample size included, in terms of illiteracy rate.

### Conclusions

Despite the prevalence of CAMs use among pregnant and breastfeeding women, our research confirmed that there is inconclusive safety evidence in this population, as pregnant and breastfeeding women may use these products without realizing that they may pose a threat to themselves and their infants.

However, it is important both for mothers and healthcare professionals to acknowledge that CAMs have not been evaluated in high-quality clinical trials, and there is limited evidence to support the safety of their use during such critical periods. Our data suggest that a significant proportion of women use CAMs as part of a self-care approach, and this should not be encouraged in a modern and sustainable healthcare system. Therefore, it is crucial to increase the awareness of patients and healthcare professionals alike about breastfeeding, breastfeeding complications and the correct use of natural products and complementary/alternative practices in order to minimize potential adverse effects [4].

Further studies are needed to develop the best evidence on the efficacy and safety of nonpharmaceutical treatments, which already represent an important resource for symptom control, in particular during pregnancy and breastfeeding.

### Competing Interests

There are no competing interests to declare.

### References

- 1 Sim TF, Sherriff J, Hattingh HL, Parsons R, Tee LB. The use of herbal medicines during breastfeeding: a population-based survey in Western Australia. *BMC Complement Altern Med* 2013; 13: 317.
- 2 Ernst E. Herbal medicinal products during pregnancy: are they safe? *BJOG* 2002; 109: 227–35.
- 3 Kennedy DA, Lupattelli A, Koren G, Nordeng H. Herbal medicine use in pregnancy: results of a multinational study. *BMC Complement Altern Med* 2013; 13: 355.
- 4 Amer MR, Cipriano GC, Venci JV, Gandhi MA. Safety of popular herbal supplements in lactating women. *J Hum Lact* 2015; 31: 348–53.
- 5 Low Dog T. The use of botanicals during pregnancy and lactation. *Altern Ther Health Med* 2009; 15: 54–8.
- 6 Jackson PC. Complementary and alternative methods of increasing breast milk supply for lactating mothers of infants in the NICU. *Neonatal network: NN* 2010; 29: 225–30.
- 7 Forinash AB, Yancey AM, Barnes KN, Myles TD. The use of galactogogues in the breastfeeding mother. *Ann Pharmacother* 2012; 46: 1392–404.
- 8 Adams C, Cannell S. Women's beliefs about 'natural' hormones and natural hormone replacement therapy. *Menopause* 2001; 8: 433–40.
- 9 Marcus DM, Snodgrass WR. Do no harm: avoidance of herbal medicines during pregnancy. *Obstet Gynecol* 2005; 105: 1119–22.
- 10 Zaffani S, Cuzzolin L, Benoni G. Herbal products: behaviors and beliefs among Italian women. *Pharmacoepidemiol Drug Saf* 2006; 15: 354–9.
- 11 Lapi F, Vannacci A, Moschini M, Cipollini F, Morsuillo M, Gallo E, *et al.* Use, attitudes and knowledge of complementary and alternative drugs (CADs) among pregnant women: a preliminary survey in Tuscany. *Evid Based Complement Alternat Med* 2010; 7: 477–86.

- 12 European Pharmacopoeia. Available at [http://www.omeomed.net/sub\\_index/link.php#Farmacopea](http://www.omeomed.net/sub_index/link.php#Farmacopea) (last accessed 8 February 2018).
- 13 Boynton PM. Administering, analysing, and reporting your questionnaire. *BMJ* 2004; 328: 1372–5.
- 14 Boynton PM, Greenhalgh T. Selecting, designing, and developing your questionnaire. *BMJ* 2004; 328: 1312–5.
- 15 Richardson J. Design and conduct a survey. *Complement Ther Med* 2005; 13: 47–53.
- 16 Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977; 33: 159–74.
- 17 Gilmour C, Hall H, McIntyre M, Gillies L, Harrison B. Factors associated with early breastfeeding cessation in Frankston, Victoria: a descriptive study. *Breastfeeding Rev* 2009; 17: 13–9.
- 18 Law SM, Dunn OM, Wallace LM, Inch SA. Breastfeeding Best Start study: training midwives in a 'hands off' positioning and attachment intervention. *Matern Child Nutr* 2007; 3: 194–205.
- 19 Kuo GM, Hawley ST, Weiss LT, Balkrishnan R, Volk RJ. Factors associated with herbal use among urban multiethnic primary care patients: a cross-sectional survey. *BMC Complement Altern Med* 2004; 4: 18.
- 20 McHughes M, Timmermann BN. A review of the use of CAM therapy and the sources of accurate and reliable information. *J Manag Care Pharm* 2005; 11: 695–703.
- 21 Budzynska K, Gardner ZE, Dugoua JJ, Low Dog T, Gardiner P. Systematic review of breastfeeding and herbs. *Breastfeed Med* 2012; 7: 489–503.

## Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

<http://onlinelibrary.wiley.com/doi/10.1111/bcp.13639/supinfo>

**Figure S1** Use of complementary and alternative medicines (CAMs) during pregnancy: reasons and advice for their use. GP, general practitioner

**Table S1** Use of complementary and alternative medicines (CAMs) before and during pregnancy, overall and stratified according to CAM use during breastfeeding

**Appendix S1** Questionnaire