ORIGINAL PAPER

Measuring the effectiveness of homeopathic care through objective and shared indicators

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Objective: **To test a methodology to evaluate, at population level, the effectiveness of homeopathic treatment through standard objective public health indicators.**
Methods and settings: **Indicators of hospitalization and drug use were obtained from the Health Statistical Documentation System of Tuscany for two homeopathic centers in the Local Health Authority of Pisa, Italy. We compared homeopathic users with the general population in the same area and by comparing patients before and after homeopathic treatment.**
Results: **The homeopathic patients used less drugs than the reference population, this effect was more evident for patients with repeated homeopathic consultations. A significant decrease in drug use was found on comparing the same patients before and after homeopathic treatment. Hospitalization indicators tended to favour patients who had received homeopathic treatment but were not always statistically significant.**
Conclusions: **This paper demonstrates a new methodological approach to assess the effectiveness of a therapeutic modality, without *ad-hoc* clinical trials. This methodology can be used by public health institutions in which non-conventional medicines are integrated into the public health care system.** *Homeopathy* (2011) **100**, 212−219.

Keywords: Public health care system; Health indicators; Effectiveness; Homeopathy

Introduction

There is a significant literature on research in homeopathy. Many publications are Randomized Clinical Trials (RCT)[1−5] or observational studies.[6−9] Some studies are experimental[10−14] or basic research;[15−17] while others are systematic reviews or meta-analyses.[18−21] The most credible studies are those based on well-defined designs such as the RCT. Studies that do not follow such designs are considered of poor quality and, consequently, their results dubious.

What it is often neglected is that the theoretical frameworks on which RCTs are based were originally designed for drug trials: patients with the same illness are selected, and the remission of symptoms is the main outcome measure. Such methods may not be appropriate to different systems of care like homeopathy.

Concepts of health and effectiveness in non-conventional medicines like homeopathy may differ from conventional ones. In a homeopathic consultation the individual's set of symptoms, of which the one representing the reason for seeking care is just one, is observed. Important in this concept of effectiveness is to observe that a process of healing takes place for the patient, which implies that the well-being of the patient must be observed over an extended time-period. From this point of view, remission of the symptom is a natural consequence of improved well-being. As Relton says: *In interpreting the homeopathy evidence it is important to understand that the existing clinical experimental (randomized controlled trial) evidence base provides evidence as to the effectiveness of homeopathic medicines, but not the effectiveness of treatment by a homeopath.*[22]

There is a need for new methodologies that are accepted by the whole scientific community (including both conventional and non-conventional medicine) with the specific aim of measuring effectiveness of homeopathic medicine.

Aims and objectives

We aimed to evaluate the effectiveness of homeopathic treatment through standard objective public health indicators of well-being. Measuring the well-being of an individual and its improvement or worsening is a challenge. Well-being comprises several aspects ranging from the way the patient feels, to the doctor's assessment of his/her health status, to the results of objective medical tests. It includes objective as well as subjective indicators of health.

We started from these considerations and developed a methodology to assess the effectiveness of the homeopathic approach considering both objective and subjective aspects. Data was collected on subjects since their first visit to homeopathic centers, building an integrated database from both data, at individual level, acquired and stored by Regional Statistical System. The Regional Health Care Plan of Tuscany is unusual in Italy in incorporating non-conventional medicine.[23,24] In the present article we focus on objective health data only, related to a given set of homeopathic patients.

Our approach is tested and presented here as an autonomous method, although part of the broader methodological concept. Specifically we compared objective health data of homeopathic patients with those for the general population. Much reliable objective health data is available for the general populations and already used to compute health indicators, to compare costs[25] or subjective data.[26]

We measured the difference in objective health indicators:

— between a population identified as homeopathic users and a reference population in the same geographical area,
— within the population identified as homeopathic users, before and after homeopathic care.

We emphasize that, in order to respect homeopathic point of view, we start from a different (and broader) approach in the classification of patients: subjects are not classified by disease variables, but only by basic demographic variables, such as age and sex.

In the following sections we define the criteria we adopted to classify homeopathic users; illustrate the used indicators and their values; finally, we report and discuss the results and the limitations of our study.

Material and methods

Definition of homeopathic users

Correctly identifying users of homeopathy is crucial to measuring the real effects of homeopathic medicine. If a change in health status observed, one may be able to interpret this change — at least partially — as an effect of the therapy.

A person who consults an homeopath only once cannot be immediately considered to be receiving homeopathic treatment. We need to detect repeated consultations by the same person before considering him/her as a 'homeopathic user'. Homeopathic therapy may imply continuing contact between doctor and patient, even in absence of functional symptoms or pathologic events.

The population we observed is composed of all those people who attended a homeopathic consultation at one of the two public homeopathic centers of Pisa Local Health Authority n.5 (USL 5), from January 2007 to July 2008. The duration of treatment for each subject is obviously not the same, our observational period was fixed (19 months). Only at the end of the data collection (July 31, 2008) we were able to classify subjects according to their frequency of attendance at homeopathic centers (fidelity), previous use of homeopathy (old/new user), and age and gender.

The flow diagram (Figure 1) illustrates the process by which we identified patients included in the analysis. Of 643 patients who accessed the two public homeopathic centers of Pisa we excluded 75 patients with brief duration of treatment. The remaining 568 users were classifiable in several categories: 145 had previous homeopathic treatment before attending the public homeopathic centers of Pisa, this information was acquired during the first visit. We refer to them as 'old' users. The other 423 were classified as 'new' users. This classification permits us to separate users new to this therapeutic approach from those who had already used it, and could still be subject of its effects, a 'carry-over' effect.

We further classified new users according to their fidelity. Homeopathy aims to improve the well-being of the patient over a relatively long time-period, so we need to distinguish between patients with regular attendance and occasional or rare attenders.

We decided to use the data collected to find a proper interval of exposure to homeopathy. We computed the average duration of attendance for those people who have been followed for an adequate period of time as the ratio between the number of days elapsed between the first and the last consultation, and the total number of consultations, and choose the third quartile (4 months, 120 days) to distinguish people with tight fidelity from broad fidelity. Tight fidelity users are those who consulted more than twice in a period of at least 4 months. Broad fidelity users are those with less frequent contacts.

Since the groups and subgroups were similar by age and gender, we decided to perform the analyses on different subgroups, specified time by time, depending on the goal and comparison groups.

Health indicators as objective measures of health condition

To test the effectiveness of homeopathic therapy, we compared the health condition of our homeopathic users with the general population in the same area. The measures used are a subset of health indicators, collected by the Tuscan Regional Health Authority (Agenzia Regionale di Sanità — ARS). These indicators give a description of the health status of people in order to be able to identify its need and to make the attainment of targets in health as
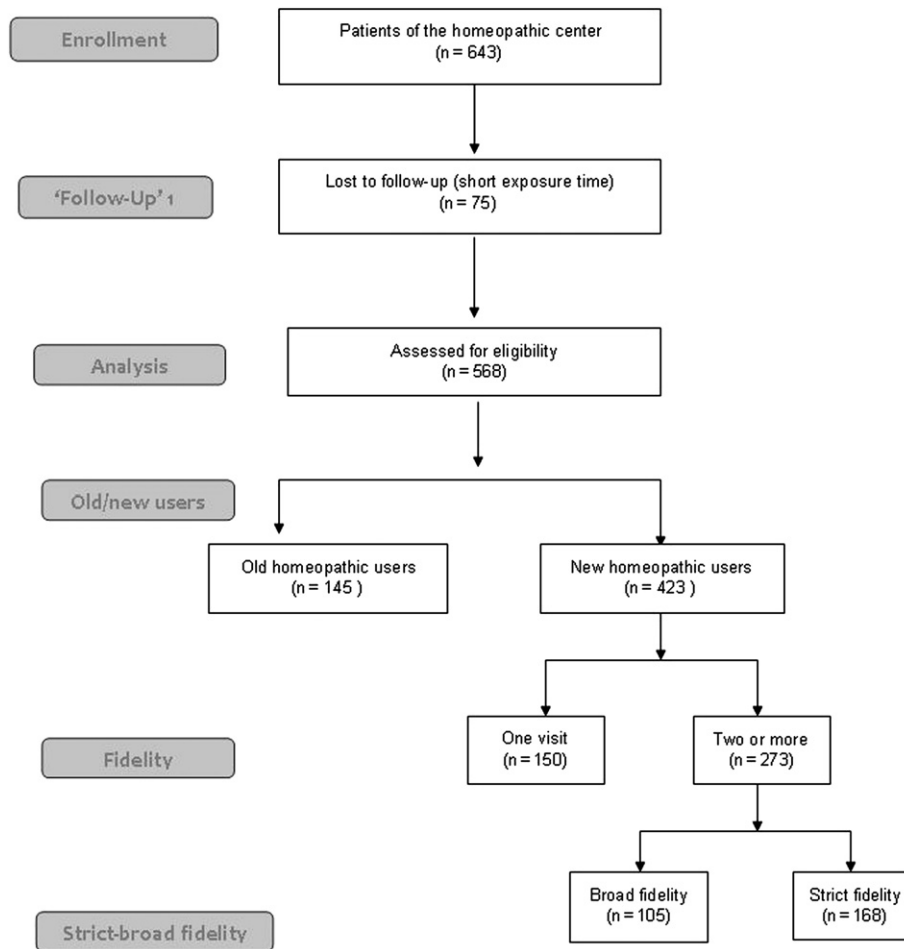
Figure 1 Flow diagram.

easy as possible, facilitated by a set of standard and comparable regional health indicators.[25]

The use of such indicators has several advantages:

— they are well accepted and shared by the scientific community;
— they do not require *ad-hoc* clinical trials;
— they are collected independently;
— they are not subject to systematic error (or bias) because their source is not a questionnaire but the administrative registration of medical events;
— they are regularly updated.

It is possible to calculate the same indicators on subgroups of patients, allowing, for instance, the comparison of the results between different therapeutic systems. For our purposes comparisons were made between the general population and homeopathic users, by age group and geographical area.

Among all regional indicators, we selected the most general indicators because they do not involve clinical definitions or classifications, but only the main demographic variables (age, gender, area of residence). We used the following indicators:

drug usage indicator: the prevalence of use of drugs per 1000 inhabitants;
hospitalization indicator A: subjects admitted to hospital at least once over the year per 1000 inhabitants;

hospitalization indicator B: admissions to hospital per 1000 inhabitants.

All these indicators are available for the regional population, by age class, the most disaggregated level is the USL area. For our study the reference indicators are values for USL area 5. Note that the drug usage indicator does not consider the nature of the drug or diagnosis, and the hospitalization indicators include all causes of hospital admission.

Regardless of the therapeutic approach, we can assume that the less drugs you use the better is your health; the lower is the hospitalization the higher is your well-being. Lower drug use and the lower hospitalization also imply reduction in the public health expenditures. But for our aim of assessing effectiveness of homeopathic therapy, these indicators are viewed as proxy variables of well-being.

Data and comparisons

We were able to obtain individual data from the Statistical Documentation System of the USL 5 to calculate the value of the indicators. From the Regional Statistical Board we obtained the administrative data on drug prescriptions (date, number and costs) and hospitalization (date and number of admissions) for each user of the homeopathic centers. We obtained drug-use data from 30th January, 2006 to the end of July 2008 (31 months), and hospitalization data

from 1st June 2006 to the end of July 2008 (26 months). It is important to notice that the data used are objective: they are collected independently by the Statistical Documentation System of the USL 5 and have been used for the calculation of all the indicators for both population, reference and homeopathic patients. Data were transformed and used to create the integrated database.

Comparison with the reference population

The 2006 USL 5 general population was our reference population (Table 3). Obviously this population includes our homeopathic users, but this is not a problem for the results of our analysis, because the number of our patients are relatively very small and not likely to substantially change the value of indicators. If the indicators are affected, they will be underestimated.

The hypotheses we tested are the following:

$$\begin{cases} H_0 : & R = 1; \\ H_1 : & R \neq 1. \end{cases}$$

The null hypothesis (H_0) is that the ratio R (ratio between the indicator in the reference population and in homeopathic patients) is equal to 1, that is, there is no difference between the two populations.

To have comparable data, variables per observation time, values have been weighted using the year-per-person index. Only patients with a sufficient exposure time were included in the analysis. For the drug usage indicator, we selected only those patients who had an interval of 3 months at least; for the hospitalization indicators, an interval of at least 10 months. Because of these time limitations, the drug

usage indicator is calculated on a group of 265 of 273 patients, and hospitalization indicators on a group of 169 patients; we excluded hospitalizations due to pregnancy.

Before−after comparison

We also analysed the within group effect of homeopathic therapy, comparing indicators before and after homeopathic care. The main selection criteria are the same used for the calculation of the regional indicators: we computed the individual difference between drug usage and hospitalizations before and after homeopathic treatment, weighting for duration of observation. We had 240 patients for the events related to the use of drugs, and 169 for events related to hospitalization.

The null hypothesis (H_0) is that the mean of differences ($\overline{d}$) is equal to 0, that is, there is no difference in the level of the indicator before and after homeopathic treatment; formally, we can expressed it as:

$$\begin{cases} H_0 : & \overline{d} = 0; \\ H_1 : & \overline{d} \neq 0. \end{cases}$$

Results

There were 168 tight fidelity users who consulted more than twice in a period of at least 4 months, and 105 broad fidelity users with less frequent contacts. Thus, of 423 new users, 273 are fidelity users, while the remaining 150 (with only one visit in the observational period) could not be classified. Figure 2 shows the path of a (hypothetical) patient who entered our study. Table 1 gives the demographics of all homeopathic users, Table 2 describes the
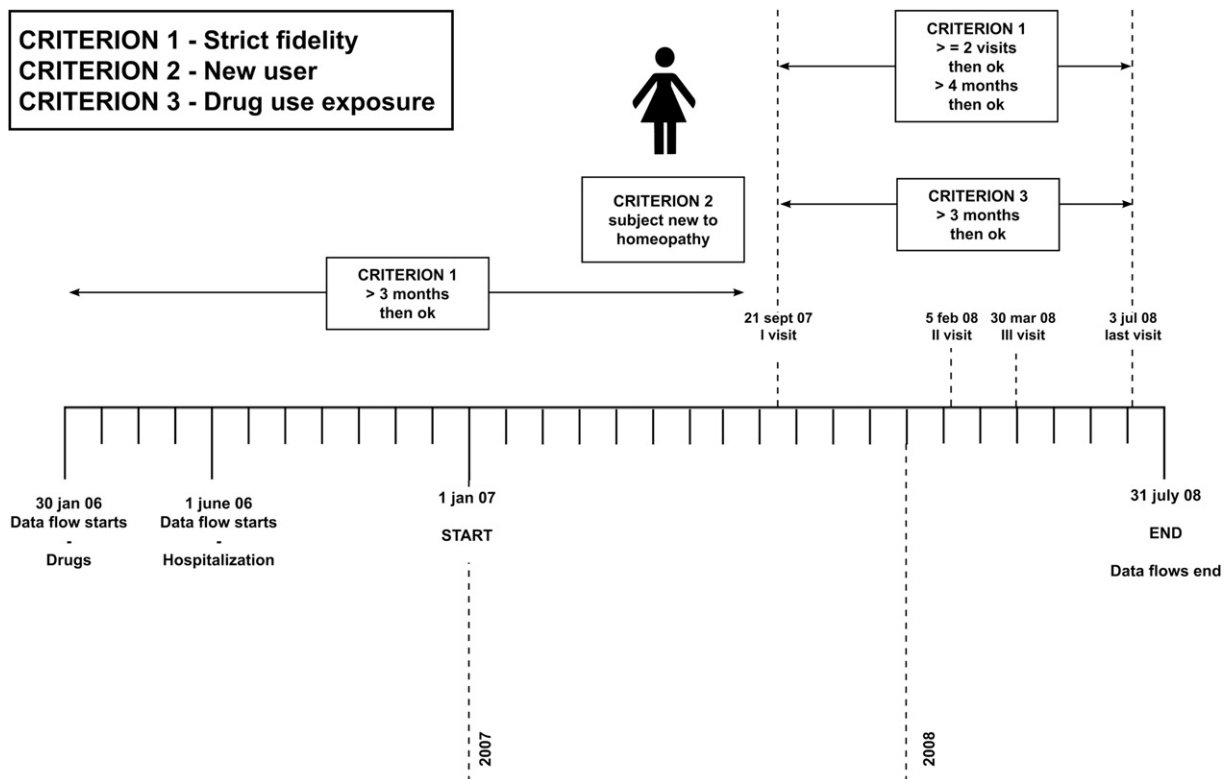

Figure 2 Hypothetical path of a patient in this study.

Table 1 Patients by new-old users, fidelity, gender and age group

Gender	Fidelity	Age group								Total
		0	*1–4*	*5–14*	*15–44*	*45–64*	*65–74*	*75–84*	*>84*	
Female	No (one-off)	2	15	13	55	11	3	0	0	99
	Yes	6	29	19	91	32	7	2	0	186
	Total new users	8	44	32	146	43	10	2	0	285
	Total old users	0	2	10	49	43	6	1	1	112
	Total eligible users	8	46	42	195	86	16	3	1	397
Male	No (one-off)	2	12	19	9	6	2	1	0	51
	Yes	8	30	21	20	7	1	0	0	87
	Total new users	10	42	40	29	13	3	1	0	138
	Total old users	0	1	7	15	9	1	0	0	33
	Total eligible users	10	43	47	44	22	4	1	0	171

Table 2 New to homeopathy fidelity users by broad and tight fidelity and age group

Gender	Fidelity	Age group								Total
		0	*1–4*	*5–14*	*15–44*	*45–64*	*65–74*	*75–84*	*>84*	
Female	Tight	4	15	14	56	19	4	2	0	114
	Broad	2	14	5	35	13	3	0	0	72
	Total	6	29	19	91	32	7	2	0	186
Male	Tight	5	18	13	13	4	1	0	0	54
	Broad	3	12	8	7	3	0	0	0	33
	Total	8	30	21	20	7	1	0	0	87

273 fidelity users. We found no association (χ^2 test) between socio-demographic variables and type of homeopathic user, so we exclude a bias in our data due to age and/or gender selection.

For patients with just one visit in the observational period, we could not test if there were changes in health status. But we found no statistical significant difference between these patients and the fidelity group in terms of gender and age.

Comparison with reference population

Drug usage Table 4 shows the drug usage indicator for the USL 5 population and for the subgroups we identified among homeopathic users (statistical significance is indicated using * for *p*-value <0.05, ** for *p*-value <0.01 *** for *p*-value <0.005). For fidelity new users we detect significant lower values in drug usage indicator in most age groups. This is particularly marked for tight fidelity new users and for female fidelity new users. For this indicator we can reject the null hypothesis for which the observed population is equal to the expected population.

Hospitalizations Tables 5 and 6 show hospitalization indicators for the USL 5 population, and for the subgroups. As for the drug usage indicator, given the small size of the observed cases, the significance of the differences was calculated directly from the binomial distribution. As can be seen, although ratios are lower than in general population, no significant difference was found: but group sizes were small and observation relatively brief. We cannot reject the null hypothesis that the population of homeopathic users is equal to the reference population.

For the hospitalization B indicator (total number of admissions) some differences is significant. It is of interest that this indicator for tight fidelity new users is lower in several age groups.

Comparison before–after homeopathy

Table 7 shows the results for drug use before and after homeopathic care. Differences were calculated at individual level. No difference is detected for all fidelity new users, but, for tight fidelity new users there is a significant reduction in drug use, while a significant increase is detected for broad fidelity new users. No differences are detected by gender. Relevant results are reported in Table 8, revealing that major differences are detected in the number of drugs prescribed. These differences are significant for all new fidelity users and, more pronounced for tight fidelity ones. There is a greater reduction for female than for male patients. The reduction in the number of drugs prescribed is reflected in reduction of drugs costs as shown in Table 9.

Table 3 Reference population: 2006 residents in USL 5 by gender and age group

Gender	Age group								Total
	0	*1–4*	*5–14*	*15–44*	*45–64*	*65–74*	*75–84*	*>84*	
Female	1407	5327	12,455	61,453	44,713	20,193	16,453	6525	168,526
Male	1488	5805	13,303	64,213	42,490	17,370	10,836	2826	158,331
Total	2895	11,132	25,758	125,666	87,203	37,563	27,289	9351	326,857

Table 4 Drug usage indicator for reference population (USL 5) and homeopathic users by age group and gender

n	Group	Age group						
		0–4	*5–14*	*15–24*	*25–34*	*35–44*	*45–54*	*55–64*
326,857	USL 5 − Pisa	823.70	595.70	583.40	611.60	679.40	782.10	923.70
265	Fidelity new users	435.48***	465.12*	326.95**	500.03	474.03***	712.56	567.94***
97	Broad fidelity new users	566.54***	nc	nc	nc	570.69	nc	nc
168	Tight fidelity new users	471.51***	361.11***	353.98*	337.84***	464.65***	530.30***	617.98***
168,526	Female USL 5 − Pisa	808.40	581.70	633.50	707.70	575.80	852.60	962.20
181	Female fidelity new users	484.20***	349.59**	233.42***	489.25**	502.70***	815.43	542.55***
158,331	Male USL 5 − Pisa	837.90	608.80	536.80	520.80	602.30	710.30	881.50
84	Male fidelity new users	385.47***	577.80	nc	nc	nc	nc	nc

* For *p*-value <0.05.
** For *p*-value <0.01.
*** For *p*-value <0.005.

Table 5 Hospitalization A indicator for reference population (USL 5) and homeopathic users by age group and gender

n	Group	Age group							
		0	*1–4*	*5–14*	*15–44*	*45–64*	*65–74*	*75–84*	*>84*
326,857	USL 5 − Pisa	230.02	80.99	56.48	93.00	110.87	174.49	231.49	284.21
169	Fidelity new users	nc	55.55	18.56	50.47	45.77	nc	nc	nc
40	Broad fidelity new users	nc	95.11	nc	57.56	nc	nc	nc	nc
129	Tight fidelity new users	nc	39.16	20.11	48.13	57.05	nc	nc	nc
168,526	Female USL 5 − Pisa	255.88	91.59	62.49	62.13	113.06	207.15	280.11	332.16
119	Female fidelity new users	nc	106.33	35.63	62.57	39.37	nc	nc	
158,331	Male USL 5 − Pisa	201.38	69.63	50.03	125.25	108.79	146.45	199.81	263.66
50	Male fidelity new users	nc	0.00	0.00	0.00	nc	nc		

In summary the results show a significant reduction in drug use, numbers and expenditure for tight fidelity users and especially for female fidelity new users (as shown in Tables 8 and 9). No differences were found for hospitalization data.

Discussion

Research on the effectiveness of homeopathy is controversial. The purpose of our research is to describe a general methodology to evaluate the effectiveness of homeopathic care, respecting peculiarities of this approach, proposing a method that can be applied also for other therapies. The methodology proposed could be applied using only administrative data, already collected by public health system.

In this paper, two main areas of objective health indicators were investigated as proxies for well-being: drug usage and hospitalization. In general, results were significant for the drug usage indicator: our population of homeopathic care users uses fewer drugs than the standard population of Pisa − USL 5; this is found true for female patients and, more interesting, for strict fidelity users. Furthermore, it can be seen that the number of drugs and the drugs expenditure reduce significantly after homeopathic treatment. This result echoes the study carried of Rossi,[26] in which a reduction in the use and costs of conventional drugs is found in relation to patients suffering from chronic respiratory disease. For hospitalization, results are not all significant, and *n* is small but all show a trend favouring homeopathy.

We were aware that, for infrequent events such as hospitalization the duration of observation did not allow us enough events. In the case of the number of admissions to hospital (before−after homeopathy) we could not draw any conclusions.

For patients with just one visit in the observational period, we could not test for health changes. But we found no statistical significant difference between these patients and the fidelity group in terms of gender and age. Moreover,

Table 6 Hospitalization B indicator for reference population (USL 5) and homeopathic users by age group and gender

n	Group	Age group							
		0	*1–4*	*5–14*	*15–44*	*45–64*	*65–74*	*75–84*	*>84*
326,857	USL 5 − Pisa	276.16	96.04	70.65	112.48	152.42	256.45	345.50	397.66
265	Fidelity new users	nc	55.55	37.11	50.47*	45.77*	nc	nc	nc
97	Broad fidelity new users	nc	95.11	nc	57.56	nc	nc	nc	nc
168	Tight fidelity new users	nc	39.16	40.22	48.13*	57.05	nc	nc	nc
168,526	Female USL 5 − Pisa	307.05	107.48	78.26	76.32	162.43	315.48	436.54	478.75
181	Female fidelity new users	nc	106.33	71.27	62.57	39.37*	nc	nc	
158,331	Male USL 5 − Pisa	241.96	83.78	62.47	150.25	142.93	205.76	286.16	362.91
84	Male fidelity new users	nc	0.00	0.00	0.00*	nc	nc	nc	nc

* For *p*-value <0.05.

Table 7 Differences in drug-use indicator before−after homeopathy difference in drug use

Group	n	Mean	t-value	p	Significance
Fidelity new users	240	−0.015	−0.26	0.7922	
Broad fidelity − new users	94	0.228	2.26	0.0259	*
Tight fidelity − new users	146	−0.172	−2.58	0.0110	**
Female − fidelity new users	168	−0.045	−0.65	0.5178	
Male − fidelity new users	72	0.055	0.54	0.5939	

* For *p*-value <0.05.
** For *p*-value <0.01.

Table 8 Differences in number of prescriptions before−after homeopathy

Group	n	Mean	t-value	p	Significance
Fidelity new users	240	−0.995	−2.63	0.0092	**
Broad fidelity − new users	94	−0.075	−0.21	0.8358	
Tight fidelity − new users	146	−1.587	−2.77	0.0064	**
Female − fidelity new users	168	−0.935	−2.35	0.0199	**
Male − fidelity new users	72	−1.135	−1.32	0.1918	

** For *p*-value <0.01.

according to the results obtained by Endrizzi and Rossi[27,28] in a nearby geographical area, it seems that for many patients the reason for ceasing homeopathic treatment is improved health.

Regarding the comparison with the reference population, it is worth recalling that the regional population used as the reference included the homeopathic users: this would tend to lead to an underestimate of the effect size. We are also aware that people who use homeopathy or non-conventional therapies have different demographic characteristics compared to the general population. The last survey from the Italian National Institute of Statistics (ISTAT) regarding the health conditions and the use of health care services,[29] showed that the use of non-conventional therapies is higher among women, people coming from Northern Italy and of higher social class. In the case of homeopathy, the differences related to the educa-

Table 9 Differences in drug expenditure before−after homeopathy

Group	n	Mean	t-value	p	Significance
Fidelity new users	240	−16.07	−2.47	0.0141	**
Broad fidelity − new users	94	−5.85	−0.72	0.4733	
Tight fidelity − new users	146	−22.65	−2.44	0.0161	**
Female − fidelity new users	168	−15.96	−2.46	0.0149	**
Male − fidelity new users	72	−16.34	−1.05	0.2985	

** For *p*-value <0.01.

tional level are more marked. People who use homeopathy have a higher level of formal education and females are more represented than males; our data on USL 5 homeopathic users confirms this tendency. It could be argued that better health indicators could be imputed to effect of demographics and not due to the effectiveness of homeopathy; but there is no strong empirical evidence on the correlation among health and social variables.

Even if the comparison of indicators computed on the same subjects over time gives us an indirect confirmation of the effectiveness of homeopathy, our results require confirmation from studies based on users of other homeopathic centers; and, from outcomes of studies carried out for a longer period of time, and taking in consideration duration of formal education as a discriminatory variable in the calculation of indicators.

Conclusions

The main purpose of our study is to propose a new methodological approach easily applied where there is a well-structured flow of patients, allowing a clear definition of fidelity to a therapeutic care system. The assessment of effectiveness is crucial for public health institutions that integrate non-conventional medicines into the public health care system: our methodological approach implies a reduction in timing and costs and, moreover, it permits to monitor more patients. Our results suggest that use of homeopathy is associated with lower use of prescribed medication.

Acknowledgements

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