



European multicenter study of natural family planning (1989–1995): efficacy and drop-out

THE EUROPEAN NATURAL FAMILY PLANNING STUDY GROUPS

*Study Centre: Heinrich Heine University (Prof. Dr. G. Freundl), Düsseldorf, Germany**

Abstract

Background: Effectiveness studies in natural family planning (NFP) published over the past 20 years have shown a wide range of contraceptive efficacy and acceptability. This seems to be due in part to different NFP methodologies. Consequently, we decided to carry out an effectiveness study in Europe to examine one group of the most widely spread NFP methods, the symptothermal methods.

Methods: Between 1989 and 1995, 15 NFP groups from 10 European countries participated in a prospective European multicentre study. This paper reports on 1328 women aged between 19 and 45 years and willing to participate for at least 12 cycles. Two types of symptothermal methods were mainly used, the symptothermal double-check methods (1046 women, 16 865 cycles of exposure, 34 unintended pregnancies) and the symptothermal single-check methods (214 women, 1495 cycles of exposure, 13 unintended pregnancies). The study was an observational study with prospectively collected data. The pregnancy rates, drop-out rates and lost-to-follow-up rates are presented separately for both subgroups according to the Kaplan–Meier method.

Results: For the double-check methods, there was an unintended pregnancy rate of 2.6% at the end of the first 12 cycles of use (standard error or SE 0.55%), a drop-out rate for difficulties or dissatisfaction of 3.9% (SE 0.69%) and a lost-to-follow-up rate of 3.1% (SE 0.62%). In the single-check group, there was a total of 13 unintended pregnancies at the end of the first 12 cycles of study

*Writing committee, study organizations and coordinators listed at the end of the paper. Correspondence to: Professor Dr G. Freundl, Urdenbacher Allee 83, D-40593 Düsseldorf, Germany

participation, giving an unintended pregnancy rate of 8.5% (SE 2.52%), a drop-out rate for difficulties or dissatisfaction of 3.0% (SE 1.76%) and a lost-to-follow-up rate of 23.4% (SE 4.35%). No pregnancy was observed in women over 40 years of age. Most pregnancies occurred because of deliberate unprotected intercourse in the fertile phase ('user failure').

Conclusions: The symptothermal double-check methods have proved to be effective family planning methods in Europe. The low drop-out-rate for difficulties or dissatisfaction with NFP shows the good acceptability.

Introduction

Wide variations from country to country and between continents in the efficacy of contraceptive methods led us to study the effectiveness and acceptability of natural family planning (NFP) in Europe. Over several decades, natural methods have had a bad reputation resulting from large differences in efficacy in published NFP studies published until 1990 [1–7]. The development of NFP methods over time has resulted in several good indicators of fertility which can be combined to offer greater precision in detecting the bounds of the fertile phase in the cycle with better efficacy for the user [8,9]. Today, in industrial countries, symptothermal methods are widely used.

For the industrial countries, efficacy is generally considered to be the most important factor in the acceptability of a family planning method. This present project was designed as a prospective observational study to determine the efficacy, discontinuation rate and acceptability of the symptothermal methodologies as practiced by different NFP groups within Europe. It was a joint project of 15 NFP centers in 10 European countries, co-ordinated by the Deutsche Arbeitsgruppe NFP at the Heinrich Heine University of Düsseldorf. The participating centers, together with the respective project co-ordinators, are listed at the end of this paper.

Subjects and methods

Experimental design

Through this joint project, we hoped to collect enough cycle data to be able to study the efficacy of the symptothermal methods in the industrial countries. Moreover, this multicenter design with identical conditions for all participating centers, has many advantages compared with an *a posteriori* meta-analysis of data from different studies. We also wanted to give smaller European NFP groups the chance to participate directly and under comparable conditions in a joint project. Therefore, study participation was offered to all European NFP groups which claimed to use symptothermal methods of natural family planning and used a common protocol based on that of the prospective German NFP study which had been conducted before [10–12].

All European NFP groups work on the same principle: every center has trained NFP teachers, who introduce interested women or couples to natural family planning. Therefore, it was easy to recruit volunteers for this joint project as the NFP teachers can ask their clients directly. Thus, the number of the recruited volunteers depends on the number and the activity of the NFP teachers at the respective center. One problem of this design is that there is no objective control of the teachers and their strategies in choosing the volunteers.

Each volunteer was asked to keep a cycle chart on which, in addition to the usual signs and symptoms of fertility, the sexual activity should also be recorded, as well as her family planning intention for the following cycle (achieving or avoiding a pregnancy). At recruitment, the biosocial data of each woman and information about the particular NFP method used were collected. In cases of drop-out, the reasons for discontinuation were recorded. To participate in this study, the women should meet the following inclusion criteria:

- 19–45 years of age;
- Use of a symptothermal method of natural family planning;
- Willingness to participate for 12 or more cycles;
- Willingness to indicate on each cycle chart the pregnancy intention for the next cycle;
- Willingness to indicate the sexual behavior and practice on the cycle chart;
- No sterilization or use of intrauterine devices, no postpartum or post-pill situation (3 normal cycles since delivery, miscarriage, breast feeding or use of the oral contraceptive pill).

Each NFP center had a co-ordinator who was asked to collect the charts monthly and to evaluate them according to the NFP rules of the respective center. The co-ordinators sent client data, cycle data and drop-out data every two months to the study center in Düsseldorf. The incoming data were checked for plausibility, and, every three months, the monitor in the study center sent a reminder about missing data and asked for correction of non-plausible data.

Between January 1, 1989 and July 31, 1994, 1361 women were recruited from 15 NFP organizations in 10 European countries. The end date was one year later, on July 31, 1995, with the last data input on September 30, 1995. As the recruitment phase was rather long, most of the women had already left the study when the last women were recruited. Study participation ends with the beginning of the menstruation after the last cycle of each subject (except for the pregnancies). By this design, also those women who had been most recently recruited, had the chance to stay in the study for at least 12 cycles. Data from 21 220 cycles of the women mentioned above were collected, with 49 unintended pregnancies.

In Europe each NFP group has its individual NFP method based on a particular combination and interpretation of the clinical indicators [13]. We obtained a sufficient data base for two types of methods, symptothermal double-check methods and symptothermal single-check methods. This paper presents the results found for users of these particular methods. Therefore, the study is an observational study of two NFP methods with prospectively collected data.

All symptothermal double-check methods provide a double-check to determine the beginning of the fertile phase (cervical mucus observation and some kind of calculation rule) and a double-check at the end of the fertile phase (temperature measurement and mucus observation). The symptothermal single-check methods provide one indicator (cervical mucus observation) to determine the beginning and one indicator (the basal body temperature) to determine the end of the fertile phase.

Data handling

The program for data collection and for the organization and administration of the study was written and tested at the study center in Düsseldorf [14]. Interim analyses could be obtained at any time. During input, the program directly checked the data for consistency and generated error reports which were sent to the respective national project co-ordinator.

Statistical analysis

The cycle data were analyzed and efficacy calculations performed using the *Statistical Analysis System* (SAS). While the Pearl Index is widely used to describe the failure rate in contraception studies, such as NFP studies, other methods, like the 'perfect/imperfect use' analysis [15] and the life-table method, originally introduced to estimate survival rates in cancer studies, are presently preferred [16,17]. Using a similar approach, namely the Kaplan–Meier method, we can assess the probability of events of interest, like unintended pregnancies correlated to the duration of use; 'survival curve' estimates by either the life-table method or the Kaplan–Meier method give us the percentage of unintended pregnancies over time [18]. In the present evaluation we calculated the contraceptive effectiveness and the lost-to-follow-up rate using the Kaplan–Meier method.

Results

Data of 21 220 cycles from 1361 women from 15 centers were collected. Some women did not fulfil the conditions of the study, and some of the data collected in this study were not usable because of missing information. Therefore, the final data base consists of 19 048 cycles from 1328 women; 49 unintended and 173 intended pregnancies are recorded. The data analysis shows that mainly two different types of

NFP methods were used in the participating NFP centers, symptothermal double-check methods and symptothermal single-check methods. For the remainder of this paper, we therefore deal with the 1046 women with 16 865 cycles of exposure, using the double-check methods, and with 214 women with 1495 cycles of exposure, who used the single-check methods. The volunteers using single-check methods are mainly represented by the French-speaking groups of the Centre de Liaison de Equipe de Recherche (CLER). A small group of women (68 women, 688 cycles) used some kind of mucus method or other symptothermal methods and were excluded from this analysis because of the small numbers of cycles. Table 1 shows the individual contributions of the different method groups from each center and the cumulative contributions.

Characteristics of the volunteers

Figure 1 shows the age distribution for the users of the double-check methods and the users of the single-check method. Approximately 50% of the women were between 25 and 36 years old. However, the two groups differ significantly according to the age distribution (χ^2 -test: $p < 0.001$). The users of the double-check methods were younger, 60.0% of them were NFP beginners, and 38.3% had different degrees of previous NFP experience. Only 6.6% of the single-check users were NFP beginners, while 86.9% were experienced (for some women, the level of NFP experience was not known). Table 2 shows these and further demographic characteristics of both groups. As they differ significantly by age and socioeconomic status, we describe the results for both groups separately and will draw some conclusions in the discussion.

Use-effectiveness and discontinuation rates: double-check methods

Because of the long-term study participation of quite a number of women using the double-check method, it was possible to calculate the 'survival' curves for 36 cycles of use. The 1046 women using a symptothermal double-check method contributed a total of 16 865 cycles of exposure, and individually up to 36 cycles of study participation (the longest participation for any volunteer in the study was 79 cycles).

For the double-check method, we registered 34 unintended pregnancies, 22 of them occurring within the first 12 cycles of study participation. The cumulative rate of unintended pregnancies in the first 12 cycles is 2.6%. The drop-out rate due to dissatisfaction or difficulties with the NFP method was 3.9% at 12 woman-cycles of use. The lost-to-follow-up rate was 3.1% after 12 cycles of exposure and only 8.1% after 36 cycles of exposure (see Table 3, Part A for all these data, which have been calculated using the Kaplan–Meier method).

The low lost-to-follow-up rate in the double-check group accounts for the quality of follow-up and the reliability of the data in this group (see Table 3, Part A). Many volunteers stayed longer than the requested minimum of 12 cycles in this study. Ending study participation includes, for example, those women who left the study but

Table 1: Contribution of data by method

<i>Country</i>	<i>Variable</i>	<i>Valid data</i>	<i>Double-check</i>	<i>Single-check</i>	<i>Other methods</i>
Austria	Women	247	247	0	0
	Cycles (uip)	3 473 (11)	3 473 (11)	0 (0)	0 (0)
Belgium 1	Women	71	71	0	0
	Cycles (uip)	1 284 (1)	1 284 (1)	0 (0)	0 (0)
Belgium 2	Women	12	5	0	7
	Cycles (uip)	116 (1)	50 (1)	0 (0)	66 (0)
Belgium 3	Women	52	50	0	2
	Cycles (uip)	971 (1)	934 (1)	0 (0)	37 (0)
Czech Rep.	Women	64	64	0	0
	Cycles (uip)	679 (2)	679 (2)	0 (0)	0 (0)
France	Women	260	23	212	25
	Cycles (uip)	1 764 (14)	188 (0)	1 475 (13)	101 (1)
Germany	Women	399	399	0	0
	Cycles (uip)	7 362 (10)	7 362 (10)	0 (0)	0 (0)
Great Britain	Women	104	98	1	5
	Cycles (uip)	1 449 (5)	1 362 (5)	16 (0)	71 (0)
Ireland 1	Women	29	12	0	17
	Cycles (uip)	432 (2)	213 (1)	0 (0)	219 (1)
Ireland 2	Women	3	3	0	0
	Cycles (uip)	29 (0)	29 (0)	0 (0)	0 (0)
Italy	Women	40	40	0	0
	Cycles (uip)	673 (0)	673 (0)	0 (0)	0 (0)
Spain 1	Women	20	19	0	1
	Cycles (uip)	357 (1)	333 (1)	0 (0)	24 (0)
Spain 2	Women	5	2	1	2
	Cycles (uip)	70 (0)	41 (0)	4 (0)	25 (0)
Spain 3	Women	11	3	0	8
	Cycles (uip)	131 (1)	40 (1)	0 (0)	91 (0)
Switzerland	Women	11	11	0	1
	Cycles (uip)	258 (0)	204 (0)	0 (0)	54 (0)
Total	Women	1 328	1 046	214	68
	Cycles (uip)	19 048 (49)	16 865 (34)	1 495 (13)	688 (2)

uip, unintended pregnancies

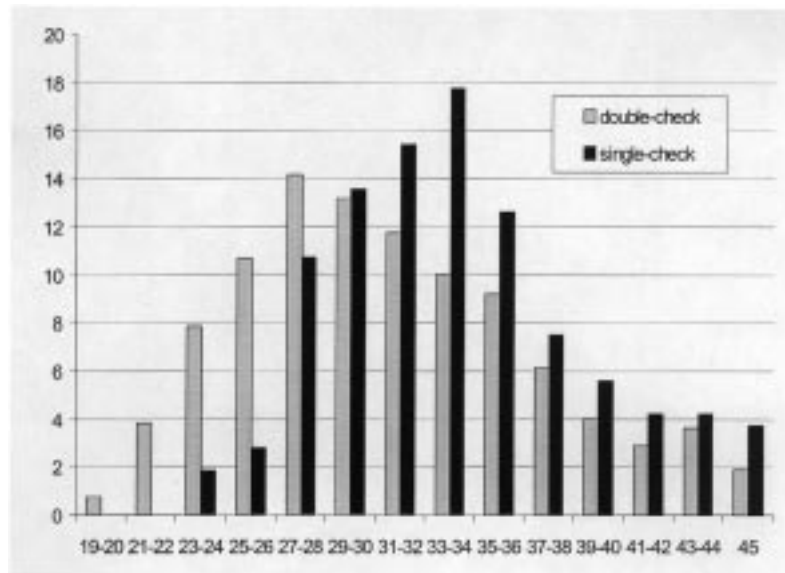


Figure 1. Age distribution of volunteers for the two methods; horizontal axis: age classes in years, vertical axis: frequencies in per cent

indicated that they would continue to use NFP to avoid pregnancy, and some women who had no further need for family planning (e.g. after hysterectomy). After 12 cycles, 17.6% belonged to this subgroup. Some women changed their family planning intention to ‘trying for pregnancy’ and therefore discontinued the study.

Use-effectiveness and discontinuation rates: single-check method

One of the study requirements was the intention to participate in the study for at least 12 cycles, and, unlike the double-check group, most women using single-check methods did discontinue after this time. Therefore, we cut the calculations for the Kaplan–Meier curve of the single-check methods after 12 cycles (Table 3, Part B). A total of 214 women using the single-check methods of CLER contributed 1495 cycles of exposure up to 12 cycles of study participation. There was a total of 13 unintended pregnancies within the first 12 cycles. No pregnancies occurred in women older than 40 years.

The cumulative rate of unintended pregnancy in the first 12 cycles was 8.5%. The drop-out rate for dissatisfaction or difficulties was 3.0%. The lost-to-follow-up rate in this group was very high: 23.4% after 12 cycles of exposure (see Table 3, Part B for all these data). The high lost-to-follow-up rate is due to the fact that CLER discontinued the volunteers all at the same time and did not inform the study center of the state of every participant at the time of discontinuation.

Table 2. Sociodemographic characteristics of the 1260 volunteers: double-check method, 1046; single-check method, 214

	<i>Double-check method (%)</i>	<i>Single-check method (%)</i>
Experience with NFP* (<i>n</i> = 1029 vs. <i>n</i> = 200) ^a		
Beginners	60.04	6.54
Experienced	38.34	86.92
Family status* (<i>n</i> = 997 vs. <i>n</i> = 214) ^a		
Married	74.82	98.60
Not married	23.47	1.40
Separated	0.90	0.00
Divorced	0.80	0.00
Occupation* (<i>n</i> = 1013 vs. <i>n</i> = 212) ^a		
Working	47.80	39.80
Staying at home	38.50	58.49
Still in school	13.70	1.71
Educational level* (<i>n</i> = 983 vs. <i>n</i> = 211) ^a		
High	53.92	45.97
Medium	37.03	46.45
Low	9.05	7.58
Spacer/limiter (<i>n</i> = 995 vs. <i>n</i> = 210) ^a		
Spacer	68.04	69.05
Limiter	31.96	30.95
Number of children* (<i>n</i> = 964 vs. <i>n</i> = 213) ^a		
No children	36.00	8.45
One child	13.59	10.33
Two children	23.96	23.94
At least three children	26.45	57.28
Religion* (<i>n</i> = 1011 vs. <i>n</i> = 210) ^a		
Catholic	81.11	97.62
Protestant	10.78	0.95
Others	2.37	0.48
None	5.74	0.95

^aWhere these numbers do not add up to the total, the remainder are women for whom there is no information; **p* < 0.05, significant difference

Table 3. Use-effectiveness and drop-out rates for double-check and single-check methods as calculated from the Kaplan–Meier curves (rates and standard errors in per cent)

<i>Ordinal cycle number</i>	<i>Women exposed</i>	<i>Unintended pregnancy</i>	<i>Dissatisfied drop-out</i>	<i>Trying for pregnancy</i>	<i>Intended pregnancy</i>	<i>Ending study participation</i>	<i>Lost to follow-up</i>
(A) Double-check method							
1	1046	0.10 (0.10)	0.00	0.00	0.01 (0.01)	0.96 (0.30)	0.10 (0.10)
3	992	0.49 (0.21)	0.67 (0.25)	0.49 (0.22)	1.48 (0.38)	2.93 (0.53)	0.50 (0.22)
6	874	1.25 (0.36)	1.86 (0.44)	1.70 (0.42)	3.59 (0.60)	5.48 (0.73)	1.04 (0.33)
12	589	2.57 (0.55)	3.91 (0.69)	4.45 (0.75)	12.39 (1.16)	17.55 (1.36)	3.12 (0.62)
18	353	4.81 (0.89)	5.38 (0.88)	5.70 (0.90)	16.24 (1.41)	26.10 (1.69)	4.53 (0.84)
24	229	5.17 (0.95)	9.19 (1.37)	8.33 (1.27)	21.01 (1.77)	35.34 (2.09)	5.27 (0.99)
36	80	5.68 (1.07)	14.73 (2.48)	9.48 (1.69)	25.69 (2.37)	49.85 (2.81)	8.08 (1.71)
(B) Single-check method							
1	214	0.00	0.87 (0.62)	0.00	2.37 (1.03)	3.74 (1.30)	2.80 (1.13)
3	169	4.97 (1.62)	0.87 (0.62)	1.04 (0.73)	3.92 (1.36)	11.49 (2.26)	7.99 (1.93)
6	127	6.82 (1.91)	1.47 (0.85)	2.39 (1.19)	6.95 (1.99)	25.10 (3.24)	12.04 (2.45)
12	36	8.52 (2.52)	3.03 (1.76)	4.09 (1.67)	11.96 (2.90)	80.22 (3.50)	23.38 (4.35)

Dissatisfied drop-out: drop-out because of dissatisfaction or difficulties

Figure 2 shows the evolution over time of the frequencies of unintended pregnancies. From this figure, we can see the steep increase in this rate for the first six months in the single-check method, compared with the double-check method. There is a significant advantage with the double-check methods, as the log-rank test shows.

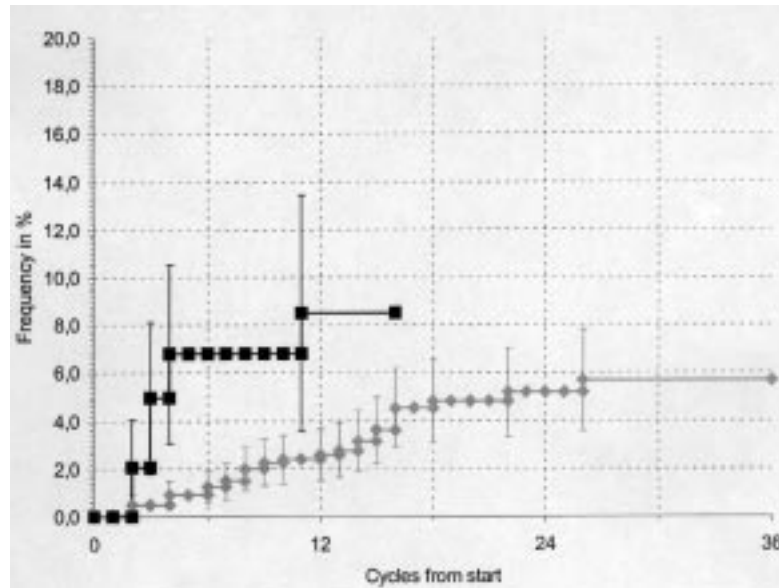


Figure 2. Kaplan–Meier curve for the event ‘unintended pregnancies’. The upper curve (black squares) is from single-check data; the lower curve (grey diamonds) from double-check data

Discussion

Our results confirm the original findings of the interim report [13,19]: the symptothermal double-check methods of natural family planning are very effective family planning methods. This is due to the greatly increased precision of interpretation of the clinical indicators of fertility and continuous improvements in the method rules over the past 20 years. Additionally, standardized teaching programs and materials have been developed. Obviously, there are improvements in both the method-effectiveness and use-effectiveness as compared with the former NFP methods [1–7,9,11,20].

This confounds the long-held belief that natural methods, in general, are ineffective, and, indeed, the pregnancy rate of the double-check method in this study compares favorably with current contraceptive methods, such as IUDs. This low pregnancy rate is all the more significant, in that two thirds of the women in the study

were spacing and not limiting their family size. Women in Europe aspiring to self-determination and natural methods for fertility control can be confident they are not exposed to an increased risk of unintended pregnancy. The low drop-out rate for dissatisfaction or difficulties with NFP and the low pregnancy rate also negate the other long-held belief that abstinence is a major obstacle to the use of NFP. There is some sexual activity also in the fertile phase (protected and unprotected intercourse and other forms of genital contact). However, the low pregnancy rate indicates a conscious and risk-related sexual behavior. This issue will be addressed in a later paper; the analysis of the German data concerning sexual behavior was published 1995 [see 21].

It is a problem to directly compare the efficiency of the double-check methods with the single-check methods, as both groups differ significantly in some social and economic characteristics and the latter group has a higher lost-to-follow up rate and a shorter study participation. Within 12 cycles of use, 2.6% of the women using double-check methods became pregnant without intention, as did 8.5% using single-check methods. This difference is even more remarkable, as we expected a higher motivation and a lower fecundity (i.e. lower pregnancy rate) in the single-check group because significantly more women were older, lived in a stable relationship, already had more than two children and had much more NFP experience at study entry (see Table 2).

One of the reasons for the increased efficacy of the double-check methods in our study may be the fact that this method requires more preovulatory fertile days (i.e. fertility may begin by the calendar check one day or more before the appearance of the cervical mucus symptom, thus reducing the risk of unplanned pregnancy from long sperm survival), and at the same time it requires less (unnecessary) post-ovulatory 'fertile' days in comparison with the single-check method. According to our data, there seems to be no major difference in the total length of the fertile phase between the two groups. Nearly all pregnancies resulted from unprotected intercourse in the fertile phase. This may be partly due to deliberate risk-taking [see 21]; however, it could also be due to less-precise rules or less-effective teaching in the single-check group.

According to our results, users of the double-check methods have the lowest rate of unintended pregnancies. This is the most important result since women want to use the most effective natural method. It also has important implications for NFP teacher training programs since NFP teachers offer personal advice and teaching to each client coming for natural methods. NFP teachers must be aware of the efficacy of each method and offer advice on the method of choice for the individual woman.

Our results compare favorably with those of other studies published recently. Barbato and Bertolotti [1] reported a Pearl Index of 3.6 for use-effectiveness and 0.4 for method-effectiveness for the symptothermal double-check methods in a prospective Italian study. Frank-Herrmann *et al.* [10,11] and Freundl *et al.* [12] gave interim results for the symptothermal double-check methods in Germany (758 women with 14 870 cycles of exposure). Here, the Pearl Index for use-effectiveness was 2.3 for NFP-only users, 2.1 for those who occasionally use barriers in the fertile phase, and 0.4 for method-effectiveness for both groups.

Compared with former effectiveness studies of NFP methods, these results may be very different. Kambic *et al.* [3] reported in 1981 on 247 women in the United States. The estimated failure rate according to life-table analysis in the first year was 16.4%. However, they did not distinguish between the different NFP methods. In 1982, Vessey *et al.* [20] reported a Pearl Index of 15.5 based on 161 woman-years of exposure in the Oxford Family Planning Association Study. In 1979, Klaus *et al.* [4] gave a net 12-cycle failure rate of 15.8% for users of the ovulation method, which is based on mucus observation only (excluding those using concurrent 'artificial' methods). In 1981, Rice *et al.* [5] analyzed data from 1014 women in five countries, who used a calculo-thermal method. The overall index was 6.2. It ranged from 2.8 among couples who had completed their family size to 13.3 among couples who were spacing. Those who used some additional form of contraception in the fertile phase had a Pearl Index of 10.3 in this study.

In developing countries, the cumulative pregnancy rates show that oral contraception in the first year of use can produce a lower rate of unintended pregnancies than the calendar method; at the end of the third year, however, the oral contraception was less effective and acceptable than the calendar method because of a lower continuation rate. The figures have been published in Flynn [22].

The double-check variations of the symptothermal methods are very effective natural methods as the results of this study show. Couples in industrial countries wishing to use an effective natural method should be encouraged to choose one of the symptothermal double-check methods. The chore of charting and the abstinence required by these methods are not too difficult to prevent effective use. This is proved by the low rate of unintended pregnancies and by the low rates of discontinuation for difficulties or dissatisfaction in our study.

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References

1. Barbato M, Bertolotti G. Natural methods of fertility control: a prospective study. *Int J Fertil (Suppl)*. 1988;33:4851.
2. Johnston JA. An analysis of continuity-discontinuity in natural family planning. An Australian factor analysis. *Int J Fertil*. 1981;26:231-8.
3. Kambic R, Kambic M, Brixius AM, Miller S. A thirty months clinical experience in natural family planning. *Am J Public Health*. 1981;71:1255-8.
4. Klaus H, Goebel M, Muraski B. Use-effectiveness and client satisfaction in six centers teaching the Billings ovulation method. *Contraception*. 1979;19:613-29.
5. Rice FL, Lanctot CA, Garcia-Devesa C. Biological effectiveness of the symptothermal method. An international study. *Int J Fertil*. 1981;26:222-30.

6. Wade ME, McCarthy P, Braunstein GD. A randomized prospective study of the use-effectiveness of two methods of natural family planning. *Am J Obstet Gynecol.* 1981;141:368–76.
7. WHO. A prospective multicentre trial of the ovulation method of natural family planning. II. The effectiveness phase. *Fertil Steril.* 1981;36:591–8.
8. Barranco E, Sanchez MJ, Garcia I, Soler F, Chica MD. Current status of natural family planning in Granada (Spain). *Adv Contracept.* 1994;10(1):27–32.
9. Raith E, Frank P, Freundl G. *Natürliche Familienplanung heute. Für Ärzte, Berater und interessierte Anwender.* Berlin–Heidelberg: Springer. 1994.
10. Frank-Herrmann P, Freundl G, Baur S *et al.* Effectiveness and acceptability of the symptothermal method of natural family planning in Germany. *Am J Obstet Gynecol.* 1991;165:2052–4.
11. Frank-Herrmann P, Freundl G, Gnoth Ch *et al.* Natural family planning with and without barrier method use in the fertile phase: efficacy in relation to sexual behaviour, a German prospective long-term study. *Adv Contracept.* 1997;13:179–89.
12. Freundl G, Bremme M, Frank-Herrmann P, Baur S, Sottong U. Methoden- und Gebrauchssicherheit der symptothermalen Methode der natürlichen Familienplanung: Prospektive Studie mit inzwischens 10649 Zyklen. *Arch Gynecol Obstet.* 1993;254(1–4):281–5.
13. Freundl G. Prospective European multi-center study of natural family planning (1989–1992): Interim results. The European Natural Family Planning Study Groups. *Adv Contracept.* 1993;9:269–83.
14. Bremme M, Freundl G, Frank-Herrmann P. Computer based system for the input and retrieval of NFP data. Presented at the VI World Congress of the International Federation for Family Life Promotion (IFFLP). Nairobi, 1989.
15. Trussel J, Grummer-Strawn L. Further analyses of contraceptive failure of the ovulation method. *Am J Obstet Gynecol.* 1991;165:2054–60.
16. Kleinbaum DC, Kupper LL, Muller KE. *Applied Regression Analysis and Other Multivariate Methods.* Boston: PWS-Kent. 1988.
17. Potter RG. Application of life-table techniques to measurement of contraceptive effectiveness. *Demography.* 1966;3:297–304.
18. Matthews DE, Farewell V. *Using and Understanding Medical Statistics. Chapters 6 and 7.* Basel – München: Karger. 1985.
19. de Leizaola-Cordonnier A. Natural family planning effectiveness in Belgium. *Adv Contracept.* 1995;11:165–72.
20. Vessey M, Lawless M, Yeates D. Efficacy of different contraceptive methods. *Lancet.* 1982;330:841–2.
21. Gnoth C, Frank-Herrmann P, Freundl G, Kunert J, Godehardt E. Sexual behavior of natural family planning users in Germany and its changes over time. *Adv Contracept.* 1995;11(2):173–85.
22. Flynn AM. Natural family planning in developing countries. *Lancet.* 1992;340:309.

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Resumé

Généralités: Les études sur l'efficacité du planning familial naturel (PFN) publiées au cours de ces vingt dernières années ont décrit un large éventail de contraception efficace et acceptable. Cela est dû en partie, semble-t-il, aux différentes méthodologies de PFN. Nous avons donc décidé de mener une étude d'efficacité en Europe et d'examiner un groupe des méthodes du PFN les plus répandues, celui des méthodes symptothermiques.

Méthodes: Entre 1989 et 1995, quinze groupes de PFN de dix pays européens ont participé à une étude prospective multicentrique européenne. Le présent exposé se rapporte à 1328 femmes de 19 à 45 ans qui avaient accepté de participer pendant au moins 12 cycles. Deux types de méthodes symptothermiques essentiellement ont été utilisées, celles du double contrôle (1046 femmes, 16865 cycles, 34 grossesses non intentionnelles) et celles du contrôle simple (214 femmes, 1495 cycles, 13 grossesses non intentionnelles). Il s'agissait d'une étude d'observation, les données étant recueillies à des fins prospectives. Les taux de grossesses, d'abandon et de non-suivi sont présentées séparément, selon la méthode Kaplan-Meier.

Résultats: En ce qui concerne les méthodes du double contrôle, le taux de grossesses non intentionnelles était de 2,6% au terme des 12 premiers mois d'utilisation (erreur type ou ET de 0,55%), le taux d'abandon

pour raisons de difficultés ou insatisfaction de 3,9% (ET 0,69%) et le taux de non-suivi de 3,1% (ET 0,62%). Pour le groupe du contrôle simple, on a recensé au total 13 grossesses non intentionnelles au terme des 12 premiers cycles de participation à l'étude, soit un taux de 8,5% (ET 2,52%), un taux d'abandon pour raisons de difficultés ou insatisfaction de 3,0% (ET 1,76%) et un taux de non-suivi de 23,4% (ET 4,35%). Aucune grossesse n'a été enregistrée chez les femmes de plus de 40 ans. La plupart des grossesses résultaient de rapports sexuels délibérément non protégés durant la phase de fécondité (défaut d'utilisation).

Conclusions: Les méthodes symptothermiques à double contrôle se sont avérées des méthodes de planning familial efficaces en Europe. Le faible taux d'abandon du PFN pour raisons de difficultés ou insatisfaction témoigne d'une bonne acceptabilité.

Resumen

Antecedentes: Los estudios de eficacia en la planificación familiar natural (PFN) publicados durante los 20 últimos años indican una gran variedad en cuanto a la eficacia y aceptabilidad de métodos anticonceptivos. Esto se debe en parte, al parecer, a diferentes metodologías PFN. En consecuencia, decidimos realizar un estudio de eficacia en Europa a fin de examinar un grupo de los métodos PFN más difundidos, los métodos sintotérmicos.

Métodos: Entre 1989 y 1995, 15 grupos PFN de 10 países europeos participaron en un estudio multicentro europeo prospectivo. Este artículo se refiere a 1328 mujeres de 19-45 años que deseaban participar durante al menos 12 ciclos. Se utilizan principalmente dos tipos de métodos sintotérmicos, los métodos sintotérmicos de doble verificación (1046 mujeres, 16865 ciclos de exposición, 34 embarazos no intencionales) y los métodos sintotérmicos de una sola verificación (214 mujeres, 1495 ciclos de exposición, 13 embarazos no intencionales). El estudio fue un estudio de observación con datos recopilados prospectivamente. Las tasas de embarazo, de abandono y de no presentación al seguimiento se presentan de forma separada para los dos subgrupos según el método de Kaplan-Meier.

Resultados: Para los métodos de doble verificación hubo una tasa de embarazo no intencional del 2,6% al final de los 12 primeros ciclos de uso (error estándar o ES 0,55%), una tasa de abandono por motivo de dificultades o insatisfacción del 3,9% (ES 0,69%) y una tasa de no presentación al seguimiento del 3,1% (ES 0,62%). En el grupo de una sola verificación hubo un total de 13 embarazos no intencionales al final de los 12 primeros ciclos de participación en el estudio, que significaron una tasa de embarazo no intencional del 8,5% (ES 2,52%), una tasa de abandono por motivo de dificultades o insatisfacción del 3,0% (ES 1,76%) y una tasa de no presentación al seguimiento del 23,4% (ES 4,35%). No se observó ningún embarazo en mujeres de más de 40 años de edad. La mayoría de los embarazos ocurrieron debido a relaciones deliberadamente no protegidas en la fase fértil ("fallo de usuario").

Conclusiones: Los métodos sintotérmicos de doble verificación han demostrado ser métodos de planificación familiar eficaces en Europa. La baja tasa de abandono por motivo de dificultades o insatisfacción con la PFN muestra su buena aceptabilidad.

Writing Committee:

G. Freundl¹, Düsseldorf;
A. Flynn†, Birmingham;
P. Frank-Herrmann¹, Ch. Gnoth¹, Düsseldorf.

Study and data coordination:

NFP-Research Projects at the Heinrich Heine University of Düsseldorf.

Statistics:

E. Godehardt², J. Kunert², Ch. Gnoth¹, Düsseldorf.

Centers and Principal Investigators:

Austria: Dr R. Widhalm, Institut f. Ehe und Familie.
Belgium: Dr A. de Laizaola-Cordonnier, CAF (Centre 1),
M. van der Straten Waillet, CCL (Centre 2),
Dr A. Devos, NFP Vlanderen (Centre 3).
Great Britain: Dr A. Flynn†, NANFPT.
France: Dr R. Ecochard, CLER.
Germany: Dr P. Frank-Herrmann, NFP Working Group.
Ireland: D. Scally, CMAC (Centre 1),
M.-T. Joy, FPS (Centre 2).
Italy: Dr S. Girotto, Istituto per la RNF.
Spain: F. Soler, Codiplan (Centre 1),
J. de Irala, OSKARBI (Centre 2),
J. de Irala, ProVida (Centre 3).
Switzerland: L. Rovelli, Centre Metodi Naturali.
Czech Rep.: L. Laznickova, Pracovni skupina PPP.

†Dr. A Flynn died in August 1997

¹Department of Obstetrics and Gynecology in D-Benrath, Heinrich Heine University of Düsseldorf

²Biometric Research Group of the Department of Heart Surgery, Heinrich Heine University of Düsseldorf