

A randomized trial among women with heavy menstruation – impact of a decision aid on treatment outcomes and costs

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Abstract

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Objective To evaluate the effects of a decision aid for menorrhagia on treatment outcomes and costs over a 12-month follow-up.

Design Randomized trial and pre-trial prospective cohort study.

Setting and participants Gynaecology outpatient clinics in 14 Finnish hospitals, 363 (randomized trial) plus 206 (cohort study) patients with menorrhagia.

Intervention A decision aid booklet explaining menorrhagia and treatment options, mailed to patients before their first clinic appointment.

Main outcome measures Health related quality of life, psychological well-being, menstrual symptoms, satisfaction with treatment outcome, use and cost of health care services.

Results All study groups experienced overall improvement in health-related quality of life, anxiety, and psychosomatic and menstrual symptoms, but not in sexual life. Treatment in the intervention group was more active than in the control group, with more frequent course of medication and less undecided treatments. However, there were no marked disparities in health outcomes, satisfaction with treatment outcome and costs. Total costs (including productivity loss) per woman because of menorrhagia over the 12-month follow-up were 2760€ and 3094€ in the intervention and control group, respectively ($P = 0.1$). The pre-trial group also had a significantly lower rate of uterus saving surgery compared with the control group, but no difference in costs because of menorrhagia treatment.

Conclusion Despite some differences in treatment courses, a decision aid for menorrhagia in booklet form did not increase the use of health services or treatment costs, nor had it impact on health outcomes or satisfaction with outcome of treatment.

Introduction

Decision aids are tools that help patients make informed choices and participate in treatment decision-making, especially when more than one treatment option exists. They help to guide the patient and her/his doctor towards treatment that best addresses the patient's values and needs.¹ Decision aids come in a variety of formats, including leaflets, audiotapes, decision boards, group presentations, computer programs, interactive videos, websites and structured interviews,^{1,2} or combinations of these.³ The key component is information necessary for informed choice presented in a structured, unbiased and comprehensive format. It must allow for the patient's preferences, and help to incorporate these into the decision-making process.

Previous studies on decision aids have covered a wide range of circumstances, from participating in a screening test to decisions on life-threatening health conditions.^{1,2} So far, only a few studies have included cost evaluation.³⁻⁵ Among women with menorrhagia, two types of decision aids have been compared, an information pack, and that plus a structured interview conducted by a nurse.³ The decision aids had no effect on women's health status. Those who received an information pack plus interview reported greater satisfaction with overall results compared with other women. Moreover, the decision aid plus interview was cost saving because of a lower hysterectomy rate.³

A decision aid given to women with menorrhagia leads to an increase in specific treatment decisions and decrease in use of newly introduced treatments.⁶ In the present study, we analysed the health and cost outcomes of using a decision aid booklet in a randomized trial with 1-year follow-up.

Participants and methods

Recruitment

Potentially eligible women were identified from referral documents in gynaecology outpatient clinics of 14 hospitals (four university teaching hospitals, five central and five local hospitals).

Preliminarily chosen women (age 35–54 years, cause of referral: menorrhagia or fibroids) all had heavy menstruation as the main gynaecological complaint. Final selection was based on the questionnaire information provided before the clinic appointment. Details on recruitment, selection procedure and participant flow are presented elsewhere⁶ (see also Fig. 1). The mean age of the study sample was 44.4 years (range 35–54 years), 47% were sterilized, 55% had education less than 12 years, 63% perceived their menstrual flow as very heavy (vs. moderate heavy), 24% had irregular periods and 46% suffered also from pelvic pain or pressure.

The trial participants were recruited between January 1997 and September 1999. Between November 1995 and December 1996 we formed a pre-trial sample without an intervention to record changes in treatment modalities and assess the magnitude of any carry-over effect of disseminating information.

The study was approved by the ethics committees of STAKES and participating hospitals. Women were informed that their treatment in gynaecology clinics would accord with clinical standards. All signed an informed consent form.

Randomization

Eligible women were allocated to either the information group or ordinary care group by a STAKES researcher (SV) within 2 days of the baseline questionnaire arriving at STAKES. Randomization was performed in blocks with a varying block size separately for each hospital, using sequentially numbered, opaque, sealed envelopes. Outpatient clinic staff was aware of each woman's participation in the study only if she mentioned it.

Intervention

The information group received a decision aid booklet (25 A5 pages) about menorrhagia and its treatment options. The content drew on scientific literature^{7,8} and up-to-date guidance for general practitioners on menorrhagia treatment.⁹ All relevant treatment options were covered,

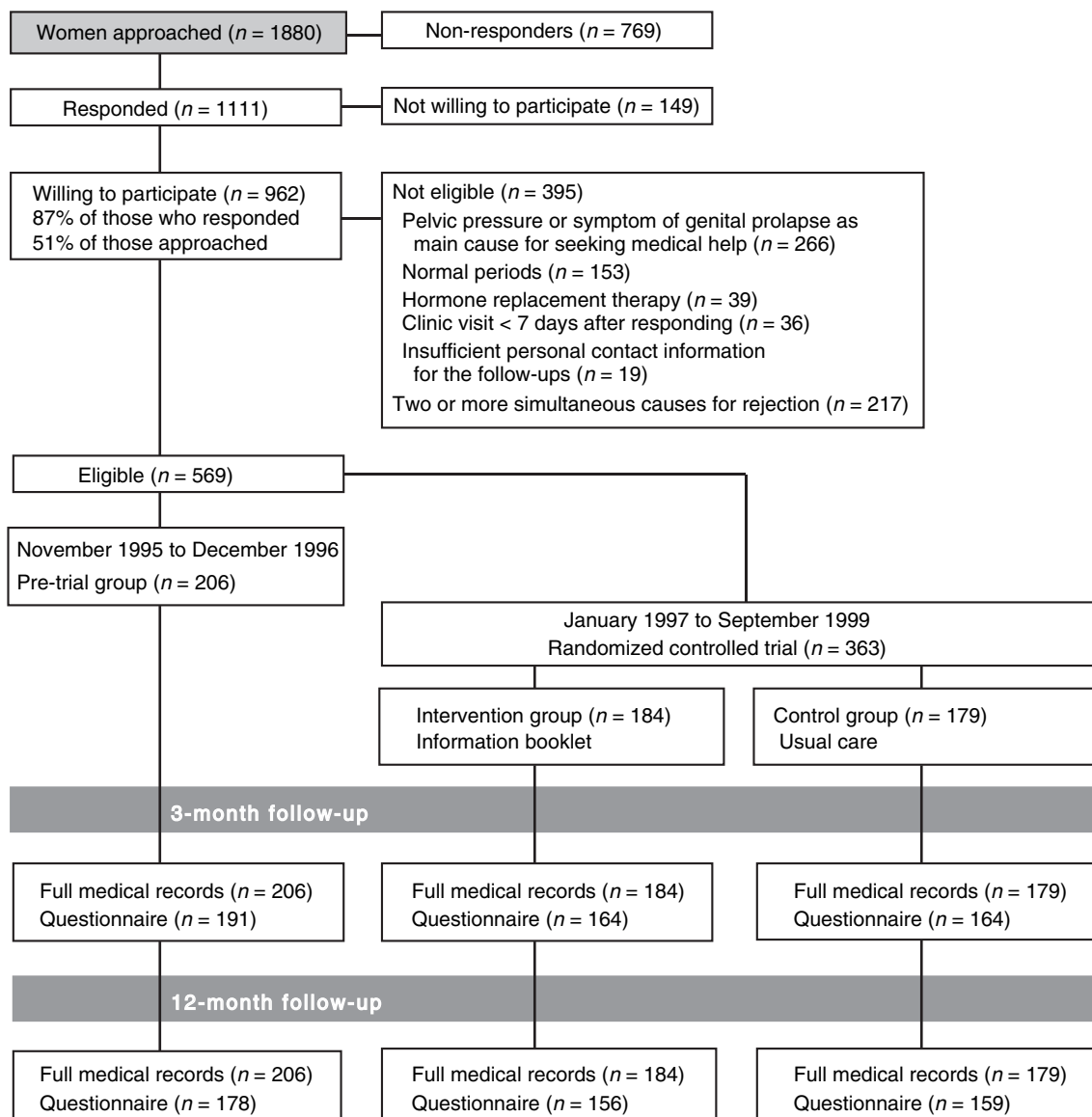


Figure 1 Trial profile.

including benefits and risks (see Box). The booklet encouraged women to consider different aspects of each treatment and the outcomes they preferred. It was mailed to the women at least 7 days before their gynaecology outpatient clinic visit.

Data collection

One-year follow-up information was collected by two methods: (i) a follow-up questionnaire

(three reminders) 12 months after entering the study, and (ii) examination of medical records, which were accessible to every woman based on their informed consent. The questionnaire response rate at 12 months was 87% (85, 89 and 86%, intervention, control and pre-trial group respectively). The dropouts ($n = 76$) did not differ from other women in any baseline variable, nor in actual treatments.

Box Content of the decision aid booklet (intervention)

Menstrual cycle
 Causes of heavy menstruation
 Indications for treatment
 Diagnosis
 Treatment modalities
 Active observation
 Non-hormonal medical treatments (non-steroid anti-inflammatory drugs, tranexamic acid)
 Hormonal medical treatments (progestines, contraceptive pills)
 Hormonal intrauterine system
 Removal of copper intrauterine device and progestine capsules
 Minor surgery = destruction of endometrial lining, removal of single fibroid
 Hysterectomy = removal of uterus
 Encouraging women to consider the outcome they want from treatment and the issue important to them, and to discuss these with the outpatient clinic physician
 Table of medical treatments

Variables

Health outcomes were measured using standard validated scales when available. The primary outcome was general health status measured using RAND-36,^{10,11} and a visual analogue scale (VAS 0–100). Worst and best possible perceived health formed each end of the scale. In both scales, higher score indicates better health. Anxiety was measured by 20-item state anxiety scale.¹² Psychosomatic symptoms were measured by an 18-item questionnaire scale.¹³ Sexuality-related factors were assessed by the McCoy sex scale.¹⁴ In these scales, higher score indicates more symptoms or problems or higher satisfaction.

Menstrual pain, perceived inconvenience because of bleeding, regularity of the cycle, and the existence of pelvic pain or pressure were asked.¹⁵

Using a VAS (0–100), women were asked to score their satisfaction with the outcome of treatment. The worst and best possible outcome formed each end of the scale.

Data on use of hospital services (operations, inpatient days, procedures, outpatient visits), medication, and sick-leave days during the past year were derived from the medical records and questionnaires. Information on other doctor

visits because of menorrhagia and other causes was obtained from the questionnaire. Women's own costs included travel costs for health care services and sanitary pads. For pricing the hospital services, average Finnish prices of diagnosis related groups (DRG group) were used, and the costs of primary health services were based on Finnish standard cost information.¹⁶ Unit costs of examinations other than those carried out in gynaecology outpatient clinics were obtained from the Social Insurance Institution. The productivity loss as a result of sick-leave days was defined as the average daily gross wage of women in Finland (1999), including social security contributions (83€ per day). We also did a sensitivity analysis using a lower estimate of productivity loss (one-third of average wage rate). The price of the decision aid was 10€. Given that the time horizon of the analysis was only 1 year, cost items were not discounted. Costs were analysed from the societal perspective and converted to the 1999 price level.

Statistical analysis

The target sample size of 180 women per group was calculated to give 80% power to detect 10% difference between study groups with an α -error of 0.05 in the RAND-36 dimension with the widest standard deviation, 'emotional role functioning'. The population level of this dimension in Finland is 78 among women aged 35–54 years.¹⁰

In all analyses, the intention to treat principle was used. In composite scales (instruments of HRQoL, anxiety, psychosomatic symptoms, inconvenience because of heavy bleeding), missing information on a single item was replaced with the mean of non-missing item values if less than half of the items were missing.¹⁷ Otherwise, missing data were excluded from the analyses. If only some of the data concerning the use of health services were missing, missing responses were interpreted to indicate no use.

Group differences were analysed by comparing means and proportions. Statistical significance was tested by the chi-squared test, and Fisher's exact test for proportions, and Student's *t*-test for means. The Mann–Whitney

U-test was used to compare medians of satisfaction with the outcome of treatment score. Two-tailed tests, and a 0.05 critical value of statistical significance were used.

Results

The sample comprised 569 women: 363 in the randomized trial (184 in the intervention group, 179 in the control group) and 206 in the pre-trial sample (Fig. 1).

A thorough comparison of the baseline characteristics of the participants in the three groups has been presented elsewhere.⁶ The only statistically significant difference between the intervention and control group was that women in the former had fewer doctor visits for causes other than menorrhagia during the 12 months prior to randomization (3.01 vs. 3.79, $P = 0.04$).⁶ In the pre-trial group, the proportion of women perceiving their periods as very heavy was lower (54% vs. 64%, $P = 0.04$) than in the control group.

At the 1-year follow-up there was an overall positive change in several dimensions of RAND-36, i.e. perceived health (VAS), and psychological and menstrual health outcomes, but not in sexual life (Tables 1 and 2). The intervention group reported a greater increase in the dimension of emotional role functioning than the control group (12.6 vs. 1.9, $P = 0.01$). None of the changes in other dimensions of RAND-36, in perceived health (VAS), anxiety, psychosomatic symptoms, sexuality, menstrual symptoms or satisfaction with the outcome of treatment differed between the intervention and control group (Tables 1 and 2).

Table 3 shows the use of health care services by group during the 12-month study period. In the intervention compared with the control group there was a statistically insignificant tendency towards a lower rate of diagnostic procedures (55 vs. 89 procedures, mean 0.35 and 0.56, $P = 0.07$ *t*-test for mean), lower rate of uterus saving surgery (16 vs. 26 procedures, 0.10 and 0.16, $P = 0.08$) and higher rate of medical treatment episodes (51 vs. 34 episodes, 0.33 and 0.21, $P = 0.06$).

Table 4 shows data on direct costs and productivity losses because of menorrhagia during the 1-year follow-up. There were no differences in direct menorrhagia treatment costs between the intervention and control group (1952€ vs. 2042€, respectively, $P = 0.5$). The productivity loss was slightly lower in the intervention group (807€ vs. 1052€, $P = 0.08$) but there was no difference in the total estimated costs (2760€ vs. 3094€, $P = 0.1$) (Table 4).

Table 5 shows data on health care costs for causes other than menorrhagia, with no differences between the intervention and control group. Using a lower estimate of productivity loss did not change the cost disparities between the groups (Table 6).

In the pre-trial group compared with the control group, there was a greater increase in the dimensions of physical role functioning and emotional role functioning of the RAND-36 ($P = 0.03$ and 0.007, respectively), but no difference in any other health outcomes (Tables 1 and 2). The pre-trial group also had a significantly lower rate of uterus saving surgery (26 vs. 10 procedures, $P = 0.002$ *t*-test for mean) (Table 3), but no difference in costs because of menorrhagia treatment (Table 4). The costs due to hospital inpatient stays for causes other than menorrhagia were lower in the pre-trial than the control group (135€ vs. 855€, respectively, $P = 0.05$) (Table 5), helping to produce a significant difference also in total costs because of causes other than menorrhagia (841 vs. 2070, $P = 0.03$). Excluding one participant with severe mental disease and another with multiple endocrinological diseases and asthma eliminated the differences.

Discussion

In spite of no marked difference in health outcomes between the study groups at the 1-year follow-up, there was an overall improvement in health outcomes among all these women with menorrhagia. The only exception was sexual life, which showed no improvement. The decision aid for menorrhagia did not affect health care costs, despite some differences in treatments courses.⁶

Table 1 Health outcome scores at baseline and score change after 12 months

RAND-36 ¹	Baseline values		Change at 12 months		p1	p2
	Mean	SE	Change	SE		
General health						
Intervention	66	1.5	2.2	1.23	0.7	0.07
Control	67	1.5	2.8	1.22	–	0.03
Pre-trial	67	1.4	2.3	1.15	0.8	0.04
Physical functioning						
Intervention	86	1.3	2.4	1.33	0.9	0.04
Control	85	1.3	2.2	1.32	–	0.1
Pre-trial	87	1.3	1.8	1.25	0.8	0.2
Emotional well-being						
Intervention	69	1.6	4.7	1.40	0.7	0.001
Control	69	1.5	5.3	1.39	–	0.000
Pre-trial	67	1.5	6.3	1.30	0.6	0.000
Social functioning						
Intervention	75	1.9	5.2	1.98	0.5	0.01
Control	74	1.8	7.1	1.96	–	0.000
Pre-trial	73	1.8	6.7	1.84	0.9	0.000
Energy						
Intervention	55	1.8	8.9	1.72	0.9	0.000
Control	55	1.8	8.8	1.71	–	0.000
Pre-trial	53	1.7	9.1	1.60	0.9	0.000
Pain						
Intervention	68	1.8	6.5	1.96	0.9	0.002
Control	69	1.8	6.2	1.95	–	0.001
Pre-trial	68	1.7	9.5	1.89	0.2	0.000
Role functioning/physical						
Intervention	65	3.0	9.2	3.41	0.5	0.007
Control	67	3.0	6.3	3.38	–	0.07
Pre-trial	61	2.9	16.5	3.10	0.025	0.000
Role functioning/emotional						
Intervention	64	3.1	12.6	3.13	0.01	0.000
Control	72	3.1	1.9	3.09	–	0.5
Pre-trial	63	2.9	13.1	2.85	0.007	0.000
Perceived health, VAS (scale 0–100)						
Intervention	73	1.4	2.6	1.38	0.6	0.09
Control	73	1.4	3.6	1.36	–	0.003
Pre-trial	72	1.3	5.2	1.29	0.4	0.000

Values are given for those who gave 12-month follow-up information ($n = 493$).

¹Scale 1 – 100 in each dimension, higher scores indicating better health; positive change means improvement in health status.

p1, significance of change between groups, control group as reference, *t*-test; p2, significance of change within a group, *t*-test.

The overall improvement in health outcomes, but with no marked difference between the study groups, is in line with the previous results.³

Sexual life was not used as an outcome measure in any of the 30-plus trials on decision aids included in the Cochrane review.² Some of those studies focused on treatment decisions that affect sexual life, e.g. prostate cancer and breast cancer treatments. In a randomized trial comparing

hysterectomy and hormonal intrauterine system in the treatment of menorrhagia, there was no difference in sexual life between the study groups at the 1-year follow-up.¹⁸ One possible explanation is that a good partnership is more important for sexual life than gynaecological health.

In this study, the intervention group tended towards a lower rate of treatment and investigation episodes during the 1-year follow-up

Table 2 Psychological and menstrual health outcome scores at baseline and score change after 12 months

	Baseline values		Change at 12 months		p1	p2
	Mean	SE	Change	SE		
Anxiety (scale 20–80)¹						
Intervention	36.0	0.85	2.0	0.78	0.4	0.012
Control	35.8	0.85	1.0	0.78	–	0.199
Pre-trial	36.4	0.80	2.0	0.74	0.4	0.007
Psychosomatic symptoms (scale 18–72)¹						
Intervention	31.8	0.59	3.4	0.53	0.5	0.000
Control	32.1	0.58	3.8	0.53	–	0.000
Pre-trial	32.4	0.55	3.6	0.50	0.8	0.000
Menstrual symptoms¹						
Inconvenience due to heavy bleeding (scale 5–25)						
Intervention	19.1	0.38	10.4	0.58	0.9	0.000
Control	19.5	0.37	10.5	0.57	–	0.000
Pre-trial	19.1	0.35	10.5	0.53	1.0	0.000
Menstrual pain (scale 0–12)						
Intervention	4.8	0.29	4.7	0.29	0.8	0.000
Control	4.7	0.29	4.6	0.29	–	0.000
Pre-trial	4.3	0.27	4.2	0.27	0.4	0.000
Sexuality²						
Sexual satisfaction (scale 5–35)³						
Intervention	23.7	0.42	0.29	0.37	0.4	0.487
Control	24.2	0.42	–0.14	0.36	–	0.688
Pre-trial	23.6	0.39	0.10	0.34	0.6	0.752
Sexual problems (scale 2–14)¹						
Intervention	4.70	0.20	–0.23	0.18	0.8	0.224
Control	4.33	0.20	–0.15	0.18	–	0.444
Pre-trial	4.35	0.19	–0.22	0.17	0.8	0.148
Partner satisfaction (scale 3–21)³						
Intervention	17.1	0.27	–0.08	0.18	0.9	0.659
Control	17.1	0.27	–0.13	0.18	–	0.436
Pre-trial	17.0	0.25	–0.48	0.17	0.2	0.009
Satisfaction with outcome of treatment						
VAS (scale 0–100)³ median (Q1, Q3)						
Intervention			94	(75, 100)	0.9	–
Control			95	(75, 100)	–	–
Pre-trial			92	(70, 100)	0.7	–

Values are given for those who gave 12-month follow-up information ($n = 493$).

Positive change meaning improvement of symptoms, greater satisfaction.

¹Higher score indicating more symptoms/problems.

²Those with partner ($n = 450$).

³Higher score indicating higher satisfaction. Q1 and Q3 are quartiles.

p1, significance of change between groups, control group as reference, t -test; p2, significance of change within a group, t -test.

compared with the control group. This accords with our earlier report, which found a significant difference in the proportion of end-point treatments between the intervention and control group.⁶

In Kennedy's *et al.* study,³ the information pack plus interview resulted in reduced costs,

but not the information pack alone. In two earlier studies based on other medical conditions, the higher costs occurring in the intervention group resulted from an expensive interactive multimedia decision aid.^{4,5} In the present study, the cost of the low-tech decision aid was insignificant compared with the other

Table 3 Use of health care services and medication by group

Resource use	Intervention group (<i>n</i> = 156)	Control group (<i>n</i> = 159)	Pre-trial group (<i>n</i> = 178)	<i>P</i> -values ¹	
				C vs. I	C vs. PT
Number of diagnostic procedures					
D&C	28 (0.18)	41 (0.26)	43 (0.24)	0.1	0.7
Hysteroscopy	14 (0.09)	25 (0.16)	31 (0.17)	0.09	0.7
Hysteroscopy and D&C, concomitant	12 (0.08)	21 (0.13)	23 (0.13)	0.1	0.9
Colposcopy	1 (0.01)	0 (0)	1 (0.01)	0.4	0.4
Diagnostic laparoscopy	0 (0)	2 (0.01)	0 (0)	0.08	0.07
Sum of the procedures above	55 (0.35)	89 (0.56)	98 (0.55)	0.07	0.9
Number of treatment procedures and control visits					
Outpatient clinic visits without any procedure	327 (2.10)	320 (2.01)	365 (2.05)	0.5	0.8
Hysterectomy (%) Chi sq-test	79 (0.51)	77 (0.48)	95 (0.53)	0.7	0.4
Sterilization (%) Fischer's exact test	2 (0.01)	2 (0.01)	1 (0.01)	1.0	0.5
Thermal ablation	8 (0.05)	11 (0.07)	3 (0.02)	0.4	0.02
Resection of endometrium ²	7 (0.05)	14 (0.09)	5 (0.03)	0.1	0.02
Myomectomy (via laparoscopy or laparotomy)	1 (0.01)	1 (0.01)	2 (0.01)	1.0	0.6
Sum of three procedures above	16 (0.10)	26 (0.16)	10 (0.06)	0.08	0.002
Re-admissions due to complication	5 (0.03)	2 (0.01)	3 (0.02)	0.3	0.8
Other treatments					
Medical treatment, number of episodes	51 (0.33)	34 (0.21)	44 (0.25)	0.06	0.6
Hormonal IUS (has or had during follow-up)	21 (0.13)	24 (0.15)	18 (0.10)	0.5	0.1
Number of doctor visits					
Due to menorrhagia ³	303 (1.94)	316 (1.99)	316 (1.78)	0.8	0.3
Due to other causes ⁴	520 (3.33)	478 (3.01)	566 (3.18)	0.5	0.7

Values are given as numbers (means) and *t*-test values for means of women who gave 12-month follow-up information (*n* = 493).

I, intervention group; C, control group; PT, pre-trial group; D&C, dilatation and curettage; hormonal IUS, hormonal intrauterine system.

¹*T*-test for difference in means between groups, control group as reference.

²Includes hysteroscopic resection or destruction of endometrium, polyp of fibroid removal.

³To general practitioner in health centre and private gynaecologist.

⁴To general practitioner in health centre and private physician.

cost components of treatment. In general, the decrease of treatment costs is not considered as the main aim of a decision aid, but improved patients' activity and participation when treatment decisions are made.

All women had menorrhagia as the main actual health problem. Use of two information sources, medical records and a questionnaire, reduced the potential information gap from one follow-up source. Information on operative treatment, inpatient stays and outpatient visits was obtained from medical records. In general, the two sources provided similar information. However, five women who had hysterectomy, and four who had minor surgery, failed to report the operation in the questionnaires. The response rate was high (87% in questionnaire) and validated health

outcome scores were used. The pre-trial group enabled some time trend evaluation during a period of changes in clinical practice in the treatment of menorrhagia.

It is possible that women whose actual symptom(s) was other than heavy menstruation decided not to respond. The respondents could easily notice in the baseline questionnaire that it focused on heavy menstruation, because the term heavy periods/heavy menstrual bleeding was used (instead of menstrual complaint, for example). Some women who returned the questionnaire but were not willing to participate gave this as the reason. No other signs of self-exclusion were detected. The study population is highly representative of Finnish women aged 35 years or over whose actual health problem is heavy menstruation.

Table 4 Total costs (€) per woman due to menorrhagia by group over 12-month follow-up

Cost component	Intervention group (<i>n</i> = 156)	Control group (<i>n</i> = 159)	Pre-trial group (<i>n</i> = 178)	P-values ¹	
				C vs. I	C vs. PT
Treatment and controls in gynaecology clinics ²					
Surgery/procedure	1448 (81)	1547 (81)	1467 (77)	0.4	0.5
Outpatient clinic visits	240 (12)	237 (12)	235 (11)	0.8	0.9
Medical treatments (hormonal IUS + oral medications)	41 (4.7)	38 (4.7)	31 (4.4)	0.7	0.3
Doctor visits elsewhere than gynaecology outpatient clinics due to menorrhagia ³	81 (6.5)	84 (6.4)	72 (6.1)	0.8	0.2
Tests	52 (3.9)	46 (3.9)	36 (3.7)	0.3	0.08
Women's own costs: travel, sanitary pads	81 (6.8)	91 (6.7)	72 (6.4)	0.3	0.05
Intervention (information booklet)	10	0	0		
Costs (sum of above mentioned)	1952 (86)	2042 (86)	1914 (81)	0.5	0.3
Productivity loss due to menorrhagia ⁴	807 (99)	1052 (98)	825 (93)	0.08	0.09
Total costs due to menorrhagia	2760 (162)	3094 (161)	2739 (152)	0.1	0.1

Values are given as mean (SE) of women who gave 12-month follow-up information (*n* = 493).

I, intervention group; C, control group; PT, pre-trial group.

¹T-test for difference between groups, control group as reference.

²Includes diagnostic tests and procedures.

³General practitioner in health centre, private physician and private gynaecologist.

⁴83€ per day, 100% gross wage. If unemployed or retired, productivity loss is 0.

Table 5 Total costs (€) per woman due to causes other than menorrhagia by study group over 12-month follow-up (*n* = 493)

Cost component	Intervention group (<i>n</i> = 156)	Control group (<i>n</i> = 159)	Pre-trial group (<i>n</i> = 178)	P-values ¹	
				C vs. I	C vs. PT
Not menorrhagia-related causes					
Outpatient visits	178 (48)	184 (47)	97 (45)	0.9	0.2
Inpatient	385 (265)	855 (263) ²	135 (248)	0.2	0.05
Doctor visits due to other causes than menorrhagia ²	120 (12)	107 (12)	114 (11)	0.4	0.7
Women's own costs	115 (18)	98 (17)	109 (17)	0.5	0.6
Costs (sum of above mentioned)	798 (285)	1244 (282)	455 (266)	0.3	0.04
Productivity loss due to other causes than menorrhagia ^{3,4}	1049 (199)	826 (197)	386 (187)	0.4	0.1
Total costs due to causes other than menorrhagia	1847 (405)	2070 (401)	841 (379)	0.7	0.03

Values are given as means (SE).

I, intervention group; C, control group; PT, pre-trial group.

¹T-test for difference between groups, control group as reference.

²General practitioner in health centre and private physician.

³Including two women with exceptionally long inpatient spells, 150 and 60 days, due to causes other than menorrhagia.

⁴If unemployed or retired, productivity loss is 0.

The fact, that those women who gave questionnaire follow-up information, were healthier than non-respondents, may somewhat overestimate the impact of menorrhagia treatment in terms of health outcomes. It is, however, unlikely that this influences on the results of the impact of the decision aid.

A possible carry-over effect in information flow from the intervention group may have altered the physicians' practice of negotiating with their patients.⁶ Such a bias would have reduced any observed differences in outcome between the intervention and control group, so our conclusions can be considered conservative.

Table 6 Total costs of health care per woman at 12-month follow-up for those providing information (*n* = 493)

Cost component	Intervention group (<i>n</i> = 156)	Control group (<i>n</i> = 159)	Pre-trial group (<i>n</i> = 178)	P-values ¹	
				C vs. I	C vs. PT
Costs of health care					
Due to menorrhagia	1871 (86)	1951 (85)	1842 (81)	0.5	0.4
Due to other causes than menorrhagia	683 (282)	1146 (280)	346 (264)	0.2	0.04
Subtotal (sum of above)	2554 (295)	3097 (292)	2188 (276)	0.2	0.02
Women's own direct costs	196 (19)	189 (19)	182 (18)	0.8	0.8
Standard estimate of productivity loss ²					
Due to menorrhagia	807 (99)	1052 (98)	825 (93)	0.08	0.09
Due to other causes than menorrhagia	1049 (199)	826 (197)	386 (187)	0.4	0.1
Standard estimate of productivity loss ² (sum of above)	1856 (220)	1879 (218)	1210 (206)	0.9	0.03
Lower estimate of productivity loss ³	619 (73)	626 (72)	403 (69)	0.9	0.03
Total (health care and productivity loss)					
Standard estimate	4607 (431)	5164 (427)	3580 (403)	0.4	0.007
Low estimate	3369 (332)	3912 (329)	2773 (311)	0.2	0.01

I, intervention group, C, control group, PT, pre-trial group.

¹T-test for difference between groups, control group as reference.

²If unemployed or retired, productivity loss is 0.

³Third of average wage rate.

Outcomes of menorrhagia treatment in terms of quality of life appear to be very similar when hysterectomy, endometrial destruction¹⁹ or hormonal intrauterine device¹⁸ have been compared. We have shown earlier that a decision aid can influence treatment decisions.⁶ Better informed women, however, might have experienced other aspects of their treatment decision-making process that could not be captured in a questionnaire and thus are not reflected in health outcomes of treatment.

Improving the women's participation in treatment decision-making by providing them with a decision aid containing additional information on their actual health problem – menorrhagia – had some impact on treatment courses. However, the decision aid did not increase the use of health services or treatment costs, or had it impact on health outcomes, or on satisfaction with outcome of treatment.

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