SOMATO PUBLICATIONS

Global Research in Gynecology and Obstetrics

Research Article

Effect of a Decision Aid on Treatment Choice and Satisfaction in Women with Heavy Menstrual Bleeding

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Abstract

Objectives: We evaluated the effect of a web-based decision aid in women with heavy menstrual bleeding on the choice of treatment and satisfaction rate.

Methods: Women with heavy menstrual bleeding were given access to a web-based decision aid before consulting a gynaecologist. During consultation a decision for treatment was made. Thereafter a questionnaire was sent to evaluate the satisfaction of shared decision making. These results were compared to a preliminary zero-measurement of a control group who did not receive the web-based decision aid.

Results: In the control group 75% opted for a non-invasive treatment compared to 67.4% in the intervention group (p=0.404). The total score of satisfaction of the intervention group is not significantly higher (p=0.118).

Conclusion: Using a web-based decision aid for heavy menstrual bleeding showed no statistically significant difference in the choice of treatment. More than two-thirds of the patients can be treated by their general practitioner as they received non-invasive treatment. This will reduce health care cost as the treatment can be shifted to primary health care.

Introduction

The principles of shared decision making are known since 1982 [1], but the last decade this patient centered care has increased its prominence in health care policy [2-5]. Shared decision making (SDM) has been defined as: 'an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options, to achieve informed preferences" [6]. The principle of shared decision making is providing information about different options and to discuss the advantages and disadvantages together. After the process of information provision, the health care profes-

sional supports the deliberation and decision making process of the patient [6]. Multiple studies showed that patients prefer to be more involved in decision making for a treatment. Thereby clinicians also prefer patients to be more involved in decision making [7,8]. The use of a patient decision aid tool is a way to improve shared decision making. The implementation of shared decision making tools, will contribute to uniform information provision according to the most up to date evidence [7,9]. The use of a decision aid improves the quality of shared decision making. The knowledge of patients will increase, the uncertainty and stress about choosing a treatment will decrease and also a reduction in cost has been seen [10]. The implementation of shared decision making also results in choosing a different type of treatment by the patient [11].

Shared decision-making is also becoming more important in the care and treatment of women with heavy menstrual bleeding [12,13]. The aim of this study was to evaluate the effect of a web-based decision aid in women with heavy menstrual bleeding on the choice of actual treatment. Besides, the extent to which patients were involved in the process of decision-making from patients perspective was studied and the number of patient consultations were evaluated. We hypothetisized that the use of a patient decision does not influence the actual choice of treatment, but improves patients satisfaction and reduces the number of consultations to the outpatient clinic.

Methods

A quasi-experimental design was performed. The institutional review board of the Zuyderland Medical Centre approved the study.

Participants

Participants were recruited from the Zuyderland Medical Centre, a non-university teaching hospital in The Netherlands. Women were eligible to participate in the study if they were 18 years or older, scheduled for their first appointment because of heavy menstrual bleeding, premenopausal and Dutch speaking. De definition used for 'heavy menstrual bleeding' is "Cyclic heavy blood loss in the reproductive phase of life, which affects the woman in daily life." Patients were not eligible to participate when heavy menstrual bleeding consist of irregular bleeding, postcoital bleeding or only dysmenorrhea complaints without heavy menstrual bleeding. A preliminary zero measurement was performed in a control group with similar inclusion- and exclusion criteria before implementation of the decision-aid.

Study procedures

In this research, we used questionnaires to evaluate the satisfaction of shared decision making in patients. The Shared Decision Making- Questionnaire 9 (SDM-Q9) The Netherlands (NL) for patients (Appendix A) was used [14]. The questionnaire is validated for shared decision making in health care in the Netherlands. This questionnaire consists of nine statements related to decision making. For each statement the patient has to score their agreement or disagreement with the statement from zero until five. The highest score of the SDM-Q9 questionnaire can be 45.

A preliminary zero-measurement was performed before start of the intervention with the decision aid. From April 2017 until May 2017 the control group was recruited to complete the SDM-Q9 NL for patients after consultation with the gynaecologist. After completing the preliminary zero-measurement the patient decision aid for 'heavy menstrual bleeding' was implemented. Participating gynaecologist were trained by professionals in shared decision-making skills and the use of the patient decision aid prior to implementation of the patient decision aid.

The web-based patient decision aid has been developed by PATIENT+. PATIENT+ is established by medical clinicians to improve the quality of health care by implementing shared decision making [15]. The online web-based decision aid was developed according to the international Patient Decision Aid Standards (IPDAS) [16]. The intervention group was recruited from May 2017 until December 2018. The decision aid for heavy menstrual bleeding was implemented as standard care at the department of Obstetrics and Gynaecology of the Zuyderland Medical Centre. After referral by the general practitioner for 'heavy menstrual bleeding', eligible women received a participant information letter (Appendix B) and written informed consent of the patient was obtained (Appendix C). If informed consent was obtained a personal code for the associated decision aid was sent to the patient. The patient filled in the online web-based decision aid before the first appointment with the gynaecologist. During the first appointment the gynaecologist discussed the results with the patient and a shared deci-

sion for treatment was made. After this consult, the SDM-Q9 NL for patient was sent to the patient. The choice of treatment and number of consultations were retrieved from electronical patients files. The results were collected anonymous in a pre-established database.

Outcomes

The primary outcome was the choice of treatment, categorized in non-invasive or invasive. Secondary outcome parameters were total number of consultations and patients satisfaction about shared decision making concerning the complaint of heavy menstrual bleeding.

Data collection and statistical analysis

A quantitative data collection of the number of consultations and the satisfaction of shared decision making using this patient decision aid was performed. The choice of treatment in the control as well as the intervention group was registered.

The χ^2- test for categorical variables and the independent sample t-test was used to analyse continuous variables. Conditional logistic regression analysis was used to determine independent variables which were significant predictors for satisfaction in decision making. Analyses were performed using SPSS (version 22.0 for Windows, SPSS Inc., Chicago, IL, USA). A p-value <0.05 indicates a statistically significancy.

Results

In the control group 32 patients were included. After implementation of the decision aid, 216 decision aids were offered to patients scheduled for a consult because of heavy menstrual bleeding. Of these 216 patients, 139 patients (64.4%) filled in the decision aid. Of these 139 patients who filled in the decision aid we excluded four patients because of missing data. The data analysis concerns data regarding 32 women in the control group and 135 women in the intervention group. The mean age of the control group was 42.9 years and of the intervention group 44.8 years (p=0.174). Total consultations were not statistically different between the control (2.0) and the intervention (2.3) group (p=0.216).

Choice of treatment

The choice of treatment was categorized in non-invasive or invasive. Non-invasive treatment included no treatment, Non-Steroidal Anti-Inflammatory Drugs (NSAID), tranexamic acid and hormonal contraception. Invasive treatment included a therapeutic hysteroscopic procedure, an endometrial ablation (novasure) or a hysterectomy. There was no significant difference between the control group and intervention group in choice of treatment. (p=0.404) (Table 1) The five mentioned treatments were subdivided in non-invasive and invasive and also hysterectomy versus other methods was compared. There were no significant differences between both comparisons of treatment.

Evaluation of shared decision making

In total 60 of the 135 patients who used the decision aid, filled in the SDM-Q9 questionnaire. The intervention group scored higher on seven of the nine questions, but only item six and nine scored significantly higher in the intervention group than in the control group. The total score of the intervention group is not significantly higher than the control group. (p=0.118) (Table 2).

Discussion

In this study, no statistically significant difference was found in the choice of treatment and consultation rate between the control group and the intervention group in women with abnormal menstrual bleeding. Besides this, there was a trend towards a higher perceived level of involvement in decision making in patients as showed by the results of the SDM-Q9 questionnaire.

In previous research different outcomes were shown in the treatment choices after using a decision aid. In the RCT of Kennedy et al. [12] the intervention group who received information booklets plus an interview showed a decrease in hysterectomy rates in comparison to the control group who only received the booklets. In the systematic review of Boss et al. [17] nine studies who used a videodisc or interview as a decision aid showed a decrease in choice for surgery. However, seven studies indicate a lack of significant difference in preference for treatment. In the Cochrane review [7] a subanalysis of the studies who compared a decision aid with usual care showed a reduction in the number of patients choosing major elective surgery in the groups receiving the decision aid compared to usual care. In our intervention group, patients received information by a web-based decision tool before consultation of the gynaecologist. In the intervention group of this study, there is actually a trend towards more invasive treatment in

Table 1: Choice of treatment for abnormal menstrual bleeding.

	Control group n=32	Interventiongroup n=135	P-value χ^2- test
Choice of treatment (n, %)			
1. No treatment or medication	18 (56.3%)	75 (55.6%)	0.404
2. Intra uterine device	6 (18.8%)	16 (11.9%)	
3. Therapeutic hysteroscopic procedure	-	2 (1.5%)	
4. Endometrial ablation	7 (21.9%)	24 (17.8%)	
5. Hysterectomy	1 (3.1%)	18 (13.3%)	
Non-invasive versus Invasive (n, %)			
Non-invasive ([1,2])	24 (75.0%)	91 (67.4%)	0.404
Invasive ([3,4,5])	8 (25.0%)	44 (32.6%)	
Others versus hysterectomy(n, %)			
Others ([1,2,3,4])	31 (96.9%)	117 (86.7%)	0.102
Hysterectomy ([5])	1 (3.1%)	18 (13.3%)	

the intervention group in comparison to the control group. This might be due to stepped care in the control group. During the first consult without using the decision aid mostly non-invasive treatment will be discussed as in the intervention group, in which the decision aid was implemented, the patients already read about all the treatment options and their advantages and disadvantages before consultation. Patients might be more aware of the different treatment options and considered if they were willing to receive more invasive surgery with the knowledge that the treatment might be more effective.

No other studies that analysed the consultation rate between intervention group with a decision aid and a control group without a decision aid were published. Only Stacey et al. [7] mentioned that ten studies evaluated the effect of the decision aid on consultation length in comparison with usual care. The consultation length varied with a range from 8 minutes shorter to 23 minutes longer. These results are not comparable with our study as we only analysed the consultation rate and not the length of consultation.

There are no previous studies that measure the satisfaction of a patient after using a decision aid with the SDM-Q9, but multiple protocols were published that will study this [18]. The questions in the SDM-Q9 focus on what the influence of the doctor is on certain matters. For example questions four asks if the doctor precisely explained the advantages and disadvantages of the treatment options. In our research the decision aid was used by the patients before they had a consultation with the doctor. The patient therefore received a lot of information for the first time via the decision aid and not via the doctor. This might have influenced the results for the measurement of satisfaction for the intervention group negatively.

Table 2: Results SDM-Q9 questionnaire for patients.

	Control group N=32 (mean, sd)	Intervention group N=60 (mean, sd)	P-value t-test
1. My doctor made clear that a decision needs to be made.	3.3 (1.9)	3.5 (1.9)	0.681
2. My doctor wanted to know exactly how I want to be involved in making the decision.	3.2 (1.9)	3.8 (1.8)	0.130
3. My doctor told me that there are different options for treating my medical condition.	4.2 (1.7)	4.5 (1.2)	0.278
4. My doctor precisely explained the advantages and disadvantages of the treatment options.	3.6 (2.0)	4.2 (1.4)	0.115
5. My doctor helped me understand all the information.	4.7 (0.9)	4.6 (1.1)	0.856
6. My doctor asked me which treatment option I prefer.	3.2 (2.2)	4.1 (1.8)	0.049
7. My doctor and I thoroughly weighed the different treatment options.	3.1 (2.0)	3.7 (1.9)	0.160
8. My doctor and I selected a treatment option together.	2.3 (2.3)	3.1 (2.1)	0.111
9. My doctor and I reached an agreement on how to proceed.	4.6 (1.2)	3.9 (1.9)	0.034
SDM-Q9 – SOM	32.1 (10.0)	35.5 (9.7)	0.118

In two studies of Calderon et al. [19] and Ballesteros et al. [20] the psychometric properties of the SDM-Q9 questionnaire for shared decision-making was analysed. They report that the SDM-Q9 presents appropriate psychometric properties and is therefore useful for assessing different aspects of shared decision-making in patients and is helpful as an indicator of the degree of quality and satisfaction with health care and patient-physician relationship. Therefore we conclude that the SDM-Q9 gives us a real analysis of the satisfaction of patients after using a decision aid.

Due to the high differences in population and interventions between studies, a comparison with the current literature is difficult. To determine whether a decision aid is enhancing shared decision making can be measured in various ways as also the results of shared decision making can be interpreted in multiple outcomes. Due to no standard outcomes it is difficult to study the effect of a decision aid or the impact of shared decision making.

Strengths and limitations

This study is using a decision aid that was established by medical professionals. Thereby a recommended and qualified questionnaire was used to evaluate the satisfaction of shared decision making. This is the first study that analyses the effect on choice of treatment and satisfaction of patients using the web-based decision aid for 'heavy menstrual bleeding' of PATIENT+. A limitation of this study is the small number of patients in the control group and the intervention group that filled in de SDM-Q9 questionnaire. Therefore these results should be interpreted with caution. Due to the small numbers of patients in this study we advice that more research should be done to evaluate the effect on choice of treatment and satisfaction of the decision aid and shared decision making

in patient with heavy menstrual bleeding. Thereby, there might be selection bias in this study because only 60 of the 135 patients who received the decision aid filled in the SDM-Q9 questionnaire.

Conclusion

There is no statistically significant difference in the choice of treatment or consultation rate while using a web-based decision aid for abnormal menstrual bleeding. A trend towards more invasive treatment might be explained due to stepped care in the control group. More than two-thirds of all patients can be treated by their general practitioner as these patients either received no treatment, medication or insertion of an IUD. This will reduce health care cost as the treatment for heavy menstrual bleeding can be shifted to primary health care in more than half of the patients. The intervention group had a higher rate of satisfaction by using the web-based decision aid, but no statistically significance was found.

Practice implications

Women with abnormal menstrual bleeding always firstly consultate their general practitioner. More than two-thirds can be treated by the general practitioner, because they do not choose for invasive treatment. This implicates that the decision aid probably can better be used by general practitioners with a reduction of health care costs due to less referrals to the hospital.

Ethical Approval

The Zuyderland Medisch Centrum NL METC approved this research.

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References

1. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1982) Making Health Care Decisions, The Ethical and Legal Implications of Informed Consent in the Patient–Practitioner Relationship. Washington DC.
2. O'Connor, AM., Wennberg, JE., Legare, F., Llewellyn-Thomas, HA., Moulton, BW., Sepucha, KR., et al. (2007) Toward the "tipping point": decision aids and informed patient choice. Health Aff (Millwood), 26(3): 716–725.
3. Elwyn, G., Coulter, A., Laitner, S., Walker, E., Watson, P., Thomson, P. (2010) Implementing shared decision making in the NHS. Brit Med J, 341:c5146.
4. The Secretary State of Health, Command of Her Majesty (2010) Equity and excellence: liberating the NHS. TSO, London.
5. Senate and House of Representatives (2010) Patient Protection and Affordable Care Act., Washington.
6. Elwyn, G., Frosch, D., Thomson, R., Joseph-Williams, N., Lloyd, A., Kinnersley, P., et al. (2012) Shared decision making: A model for clinical practice. J Gen Intern Med, 27(10): 1361-1367.
7. Stacey, D., Legare, F., Col, NF., C.L Bennett, CL., M.J. Barry, K.B. Eden., et al. (2014), Decision aids for people facing health treatment or screening decisions. Cochrane Database Syst Rev, 28(1):CD001431.
8. Van, der, Weijden, T., Boivin, A., Burgers, J., SChunemann, HJ., Elwyn, G. (2012), Clinical practice guidelines and patient decision aids. An inevitable relationschip. J Clin Epidemiol, 65(6): 584-589.
9. Stiggelbout, AM, Van, der, Wijden, T., Frosch, D., Legare, F., Montori, VM., Trvena, L., et al. (2012) Shared decision making: really putting patients at the centre of healthcare. BMJ, 344: e256.
10. O' Connor, AM., Rostom, A., Fiset, V., Tetroe, J., Entwistle, V., Llewellyn-Thomas, H., et al. (1999) Decision aids for patients facing health treatment or screening decisions. Brit Med J, 319(7212): 731-734.
11. Knops, AM., Legemate, DA., Goossens, A., Bossuyt, PM., Ubbink, DT. (2013) Decision aids for patients facing a surgical treatment decision: a systematic review and meta-analysis. Ann Surg, 257(5): 860-866.
12. Kennedy, AD., Sculpher, MJ., Coulter, A., Dwyer, N., Rees, M., Abrams, KR., et al. (2002), Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs: a randomized controlled trial. JAMA, 288(21): 2701–2708.
13. Zandstra, D., Busser, JAS., Aarts, JWM., Nieboer, TE.(2017) Interventions to support shared decision making for women with heavy menstrual bleeding: a systematic re-

view, Eur J Obstet Gynecol Reprod Biol, 211: 156–163.

14. Rodenburg-Vandenbussche, S., Pieterse, AH., Kroonenberg, PM., Scholl, I., Van, Der, Wijden, T., Luyten, GP., et al. (2015) Dutch Translation and Psychometric Testing of the 9-item Shared decision making questionnaire (SDM-Q-9) and Shared Decision Making Questionnaire-Physician Version (SDM-Q-Doc) in Primary and Secondary Care. PLos One, 10(7): e0132158
15. http://patientplus.info/overpatientplus/
16. Elwyn, G., O'Connor, AM., Bennett, C., Newcombe, RG., Politi, M., Durand MA., et al. (2009) Assessing the quality of decision support technologies using the international patient decision aid standards instrument (IPDASi). PLoS One, 4(3): e4705.
17. Boss, EF., Mehta, N., Nagarajan, N., Links, A., Benke, JR., Z. Berger et al, (2013), Shared decision-making and choice for elective surgical care: a systematic review. Otolaryngol Head Neck Surg, 154(3): 405-420.
18. Savelberg, W., Moser, A., Smidt, M., Boersma, L., Haekens, C., Van, Der, Weijden, T. (2015) Protocol for a pre-implementation and post-implementation study on shared decision-making in the surgical treatment of women with early-stage breast cancer. Brit Med J, 5(3).
19. Calderon, C., Jimenez-Fonseca, P., Ferrando, PJ. (2018) Psychometric properties of the Shared Decision-Making Questionnaire (SDM-Q-9) in oncology practice. Int J Clin Health Psychol, 18(2): 143-151.
20. Ballesteros, J., Moral, E., Brieva, L., Ruiz-Beato, E., Prefasi, D., Maurino, J. (2017) Psychometric properties of the SDM-Q-9 questionnaire dor shared decision-making in multiple sclerosis: item response theory modelling and confirmatory factor analysis. Healt Qual Life Outcomes, 15(1): 79.

Appendix

Appendix A: SDM-Q9 NL for Patients

SDM-Q
versie voor patiënten

Vragenlijst Over Gedeelde Besluitvorming (SDM-Q-9)

Vanwege welke reden heeft u uw arts bezocht (bijvoorbeeld welke klachten, welke diagnose)?

Welke beslissing is er genomen (bijvoorbeeld welke behandeling)?

De volgende uitspraken hebben betrekking op uw ervaringen bij het bovengenoemde artsbezoek. Kruist u a.u.b. aan in hoeverre elke uitspraak van toepassing is.

1. Mijn arts heeft me duidelijk gemaakt dat er een beslissing genomen moet worden.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

2. Mijn arts wilde precies van me weten hoe ik betrokken zou willen worden bij het nemen van de beslissing.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

3. Mijn arts heeft me verteld dat er voor mijn klachten verschillende behandelingsmogelijkheden zijn.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

4. Mijn arts heeft me de voor- en nadelen van de behandelingsmogelijkheden precies uitgelegd.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

5. Mijn arts heeft me geholpen alle informatie te begrijpen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

6. Mijn arts heeft me gevraagd welke behandelingsmogelijkheid mijn voorkeur heeft.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

7. Mijn arts en ik hebben de verschillende behandelingsmogelijkheden grondig afgewogen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

8. Mijn arts en ik hebben samen een behandelingsmogelijkheid uitgekozen.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

9. Mijn arts en ik hebben een afspraak gemaakt over het verdere vervolg.

helemaal niet van toepassing	grotendeels niet van toepassing	eerder niet van toepassing	eerder wel van toepassing	grotendeels van toepassing	helemaal van toepassing
☐	☐	☐	☐	☐	☐

February 2012, Translated by M. Koelewijn-van Loon&AM Stiggelbout.
Translation of the original "9-Item Shared Decision Making Questionnaire (SDM-Q-9)"
Authorised by Martin Härter & Isabelle Scholl (University Medical Center Hamburg-Eppendorf, Germany)

Appendix B: Patient information letter

PROEFPERSONEN INFORMATIE VOOR DEELNAME AAN EEN WETENSCHAPPELIJK ONDERZOEK

Geachte mevrouw,

Wij vragen u vriendelijk om mee te doen aan een medisch-wetenschappelijk onderzoek **"Samen Beslissen, met de keuzehulpen hevig menstrueel bloedverlies, uterusextirpatie en myomen".** U beslist zelf of u wilt meedoen. Voordat u die beslissing neemt, is het belangrijk om meer te weten over het onderzoek. Lees deze informatie rustig door. Bespreek het met partner, vrienden of familie. Hebt u na het lezen van de informatie nog vragen? Dan kunt u terecht bij de onderzoeker. Haar contactgegevens staan vermeld onderaan deze brief.

Doel van het onderzoek

Het doel van dit wetenschappelijk onderzoek is nagaan of de inzet van keuzehulpen binnen de afdeling gynaecologie van het Zuyderland Medisch Centrum leidt tot een grotere tevredenheid van patiënten en artsen ten aanzien van gezamenlijke besluitvorming.

Wat betekent meedoen

Het onderzoek houdt in dat u toegang krijgt tot een online keuzehulp. Deze keuzehulp kunt u gebruiken ter voorbereiding op uw geplande consult bij de gynaecoloog. Tevens krijgt u na afloop van uw consult eenmalig via de e-mail een vragenlijst toegestuurd met de vraag deze in te vullen.
Het gebruik van de keuzehulp zal ongeveer 30 minuten van uw tijd kosten. Het invullen van de vragenlijst na afloop van het consult bij de gynaecoloog zal ongeveer 10 minuten duren.
Naast de verkregen informatie uit de vragenlijst worden nog een aantal van uw gegevens verzameld. Het betreft hierbij gegevens met betrekking tot uw leeftijd, burgerlijke staat, opleiding en arbeidssituatie.

Wat u ervoor moet doen

Van u wordt enkel verwacht de keuzehulp te gebruiken voorafgaand aan uw consult met de gynaecoloog en de vragenlijst na afloop van dit consult in te vullen. Er zijn geen beperkingen aan uw dagelijkse bezigheden.

Welke bijwerkingen kunt u verwachten?

Er zijn geen bijwerkingen te verwachten.

Wat zijn de risico's van het onderzoek?

Er zijn geen risico's van het onderzoek bekend.

Wat gebeurt er als u niet wenst deel te nemen aan het onderzoek?

Deelname aan het onderzoek is geheel vrijwillig en u kunt zonder opgaaf van reden stoppen met het onderzoek. Het al dan niet deelnemen aan het onderzoek heeft geen verdere gevolgen voor de verdere behandeling of de relatie met uw behandelende arts. Daarnaast krijgt u ook toegang tot de online keuzehulp indien u niet wenst deel te nemen aan het onderzoek.

Welke medisch-ethische toetsingscommissie heeft dit onderzoek goedgekeurd?

De toetsingscommissie (METC) van het Zuyderland Medisch Centrum heeft dit onderzoek goedgekeurd.

Vragen

Mocht u na het lezen van deze informatiebrief nog vragen hebben over dit onderzoek dan kunt u daarmee terecht bij de arts-onderzoeker, Dr. M. Wassen, tel. 045-5767808.

Met vriendelijke groet,

Dr. M.L.H. Wassen,
Gynaecoloog Zuyderland Medisch Centrum
Dr. H. van der Hoffplein 1

6162 BG Geleen

Appendix C: Informed consent letter

Toestemmingsverklaring

Titel van het onderzoek: "Samen Beslissen, met de keuzehulpen hevig menstrueel bloedverlies, uterusextirpatie en myomen"

Ik heb de informatiebrief voor de proefpersoon gelezen. Ik ben ingelicht over de risico's en ongemakken die redelijkerwijs te voorzien zijn.

Ik kon aanvullende vragen stellen. Mijn vragen zijn genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe.

Ik weet dat meedoen helemaal vrijwillig is. Ik weet dat ik op ieder moment kan beslissen om toch niet mee te doen. Daarvoor hoef ik geen reden te geven.

Als ik dat doe, zal dat geen enkele invloed hebben om mijn verdere behandeling (indien van toepassing)

Ik weet dat aan mijn huisarts verteld wordt dat ik meedoe aan dit onderzoek. (indien van toepassing)

Ik weet dat aan de specialist(en) die mij behandelt verteld wordt dat ik meedoe aan dit onderzoek. (indien van toepassing)

Ik weet dat sommige mensen mijn gegevens kunnen zien onder voorwaarde dat de vertrouwelijkheid van mijn gegevens gewaarborgd wordt:
het onderzoeksteam
de medisch ethische toetsingscommissie
de apotheker

Ik geef toestemming om mijn gegevens te gebruiken, voor de doelen die in de informatiebrief staan.

Ik weet dat mijn onderzoeksgegevens 15 jaar na afloop van dit onderzoek bewaard worden.

Ik wil meedoen aan dit onderzoek.

Naam proefpersoon:

Handtekening: Datum: __ / __ / __

Indien u mee wilt doen aan het onderzoek gelieve deze brief ondertekend mee te nemen naar uw eerstvolgende poli-afspraak en af te leveren bij de poli-medewerkers Gynaecologie en Obstetrie.