**AUB KQ1 Evidence Table (Reference ID #415, #379)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Vuorma et al., 2004Vuorma et al., 2003**Country:**Finland**Enrollment** **period:** January 1997 to September 1999**Intervention** **setting:** Gynecology outpatient clinics at 14 hospitals**Funding:**STAKES, National Research and Development Centre for Welfare and Health, and Public Health Doctoral Programmes of Helsinki and Tempere universities**Author industry relationship disclosures:**None**Study Design:** RCT**Blinding:** None  | **Intervention:**Information group- mailed a decision-aid booklet explaining menorrhagia and risks and benefits of treatment options.**Comparator:**Usual care**Groups:****G1:** Information**G2:** Control**Followup:**12 months | **Inclusion criteria:** * Aged 35 to 54 years
* Referral for menorrhagia or fibroids
* Heavy menstruation as main gynecological complaint

**Exclusion criteria:** Symptoms other than heavy menstrual bleeding main cause for medical care**N at enrollment:** **G1:** 184**G2:** 179**N at followup:** **G1:** 156**G2:** 159**Age, mean years (SE):****G1:** 44.5 (0.31)**G2:** 44.3 (0.31)**BMI:**NR **Parity:**NR **Race/ethnicity:**NR**Education <12 years, n (%):****G1:** 104 (57)**G2:** 94 (53) | Inconvenience due to heavy bleeding,a mean (SE):**G1:** 19.2 (0.34)**G2:** 19.5 (0.35)Menstrual pain,b mean (SE):**G1:** 4.9 (0.27)**G2:** 4.7 (0.27)Periods perceived as very heavy, n (%):**G1:** 112 (61)**G2:** 115 (64)Irregular periods, n (%):**G1:** 42 (23)**G2:** 46 (26)Pelvic pain or pressure, n (%):**G1:** 86 (47)**G2:** 80 (45)Anxiety,c mean (SE):**G1:** 36.1 (0.80)**G2:** 35.9 (0.81)Inconvenience due to heavy bleeding,ad mean (SE):**G1:** 19.1 (0.38)**G2:** 19.5 (0.37)Menstrual pain,bd mean (SE):**G1:** 4.8 (0.29)**G2:** 4.7 (0.29)Anxiety,cd mean (SE):**G1:** 36.0 (0.85)**G2:** 35.8 (0.85)Rand-36 scores,d mean (SE):General health:**G1:** 66 (1.5)**G2:** 67 (1.5)Physical functioning:**G1:** 86 (1.3)**G2:** 85 (1.3)Emotional well-being:**G1:** 69 (1.6)**G2:** 69 (1.5)Social functioning:**G1:** 75 (1.9)**G2:** 74 (1.8)Energy:**G1:** 55 (1.8)**G2:** 55 (1.8)Pain:**G1:** 68 (1.8)**G2:** 69 (1.8)Role functioning/physical:**G1:** 65 (3.0)**G2:** 67 (3.0)Role functioning/emotional:**G1:** 64 (3.1)**G2:** 72 (3.1)Perceived health VAS, mean (SE):**G1:** 73 (1.4)**G2:** 73 (1.4)Psychosomatic symptoms,de mean (SE):**G1:** 31.8 (0.59)**G2:** 32.1 (0.58)Sexual satisfaction,df women with partners, mean (SE):**G1:** 23.7 (0.42)**G2:** 24.2 (0.42)Sexual problems,dg women with partners, mean (SE):**G1:** 4.70 (0.20)**G2:** 4.33 (0.20)Partner satisfaction,dh women with partners, mean (SE):**G1:** 17.1 (0.27)**G2:** 17.1 (0.27) | Satisfaction with communication with personnel in gynecology outpatient clinics,i median (IQR):**G1:** 36 (30, 39)**G2:** 36.5 (31, 40) **G1 vs. G2:** p=0.6Change in anxiety level at 3 months, median (IQR):**G1:** 1 (-5, 5)**G2:** -1 (-4, 4) **G1 vs. G2:** p=0.3Increase in treatment methods mentioned (max 6) between follow-up and baseline, mean (SE):**G1:** 0.48 (0.102)**G2:** 0.45 (0.102)**G1 vs. G2:** p=0.8Treatment planned after 3 months, n (%):Hysterectomy:**G1:** 99 (54)**G2:** 85 (49)**G1 vs. G2:** p=0.2Minor surgery or LNG-IUS:**G1:** 38 (21)**G2:** 52 (29)**G1 vs. G2:** p=0.06Change in birth control method:**G1:** 4 (2)**G2:** 3 (2)**G1 vs. G2:** p=1.0Oral medication:**G1:** 33 (18)**G2:** 15 (8)**G1 vs. G2:** p=0.007No treatment decision:**G1:** 8 (4)**G2:** 20 (11)**G1 vs. G2:** p=0.02No visit to outpatient clinic:**G1:** 2 (1)**G2:** 4 (2)**G1 vs. G2:** p=0.4Actual treatment received up to 12 months after first visit, n (%): Hysterectomy:**G1:** 98 (53)**G2:** 88 (49)**G1 vs. G2:** p=0.4Minor surgery or LNG-IUS:**G1:** 30 (16)**G2:** 46 (26)**G1 vs. G2:** p=0.03Other:**G1:** 54 (29)**G2:** 44 (25)**G1 vs. G2:** p=0.3No treatment and no visit to outpatient clinic:**G1:** 2 (1)**G2:** 1 (1)**G1 vs. G2:** p=0.4Number of surgical procedures used within 1 year, mean (SE):**G1:** 0.70 (0.04)**G2:** 0.73 (0.04)**G1 vs. G2:** p=0.6Rand-36 scores, mean change (SE):General health:**G1:** 2.2 (1.23)**G2:** 2.8 (1.22)**G1 vs. BL:** p=0.07**G2 vs. BL:** p=0.03**G1 vs. G2:** p=0.7Physical functioning**G1:** 2.4 (1.33)**G2:** 2.2 (1.32)**G1 vs. BL:** p=0.04**G2 vs. BL:** p=0.1**G1 vs. G2:** p=0.9Emotional well-being:**G1:** 4.7 (1.40)**G2:** 5.3 (1.39)**G1 vs. BL:** p=0.001**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.7Social functioning:**G1:** 5.2 (1.98)**G2:** 7.1 (1.96)**G1 vs. BL:** p=0.01**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.5Energy:**G1:** 8.9 (1.72) **G2:** 8.8 (1.71)**G1 vs. BL:** p<0.001**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.9Pain:**G1:** 6.5 (1.96)**G2:** 6.2 (1.95)**G1 vs. BL:** p=0.002**G2 vs. BL:** p=0.001**G1 vs. G2:** p=0.9Role functioning/physical:**G1:** 9.2 (3.41)**G2:** 6.3 (3.38)**G1 vs. BL:** p=0.007**G2 vs. BL:** p=0.07**G1 vs. G2:** p=0.5Role functioning/emotional:**G1:** 12.6 (3.13) **G2:** 1.9 (3.09)**G1 vs. BL:** p<0.001**G2 vs. BL:** p=0.5**G1 vs. G2:** p=0.01Perceived health VAS, mean change (SE):**G1:** 2.6 (1.38)**G2:** 3.6 (1.36)**G1 vs. BL:** p=0.09**G2 vs. BL:** p=0.003**G1 vs. G2:** p=0.6Psychosomatic symptoms,e mean change (SE):**G1:** 3.4 (53) **G2:** 3.8 (0.53)**G1 vs. BL:** p<0.001**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.5Inconvenience due to heavy bleeding,a mean change (SE):**G1:** 10.4 (0.58)**G2:** 10.5 (0.57)**G1 vs. BL:** p<0.001**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.9Menstrual pain,b mean change (SE):**G1:** 4.7 (0.29)**G2:** 4.6 (0.29)**G1 vs. BL:** p<0.001**G2 vs. BL:** p<0.001**G1 vs. G2:** p=0.8Anxiety,c mean change (SE):**G1:** 2.0 (0.78)**G2:** 1.0 (0.78)**G1 vs. BL:** p=0.012**G2 vs. BL:** p=0.199**G1 vs. G2:** p=0.4Sexual satisfaction,f women with partners, mean change (SE):**G1:** 0.29 (0.37)**G2:** -0.14 (0.36) **G1 vs. BL:** p=0.487**G2 vs. BL:** p=0.688**G1 vs. G2:** p=0.4Sexual problems,g women with partners, mean change (SE):**G1:** -0.23 (0.18) **G2:** -0.15 (0.18) **G1 vs. BL:** p=0.224**G2 vs. BL:** p=0.444**G1 vs. G2:** p=0.8Partner satisfaction,h women with partners, mean change (SE):**G1:** -0.08 (0.18) **G2:** -0.13 (0.18)**G1 vs. BL:** p=0.659**G2 vs. BL:** p=0.436**G1 vs. G2:** p=0.9Satisfaction with outcome of treatment VAS, median (IQR):**G1:** 94 (75, 100)**G2:** 95 (75, 100)**G1 vs. G2:** p=0.9 | **Overall quality:** Poor**Risk of bias:** Randomization: LowAllocation concealment:LowSelective reporting:LowBlinding patients/personnel:HighBlinding outcome assessment:HighIncomplete outcome reporting:LowOther:Low |

**Table Notes and Comments**: a Scale 5-25; b Scale for menstrual pain was calculated by multiplying the intensity of pain (0 for no pain to 6 for heaviest possible pain) by the frequency of pain (0 for never to 2 for every period); c Scale 20-80, higher score indicates higher level of anxiety; d Data from subset of women who gave 12-month follow-up information G1 (n=156) and G2 (n=159); e Scale 18-72; f Scale 5-35; g Scale 2-14; h Scale 3-21; i Scale 8-40.