**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** |
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| **Author:**  Vuorma et al., 2004  Vuorma 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=0.6  Change in anxiety level at 3 months, median (IQR):  **G1:** 1 (-5, 5)  **G2:** -1 (-4, 4)  **G1 vs. G2:** p=0.3  Increase 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=0.8  Treatment planned after 3 months, n (%):  Hysterectomy:  **G1:** 99 (54)  **G2:** 85 (49)  **G1 vs. G2:** p=0.2  Minor surgery or LNG-IUS:  **G1:** 38 (21)  **G2:** 52 (29)  **G1 vs. G2:** p=0.06  Change in birth control method:  **G1:** 4 (2)  **G2:** 3 (2)  **G1 vs. G2:** p=1.0  Oral medication:  **G1:** 33 (18)  **G2:** 15 (8)  **G1 vs. G2:** p=0.007  No treatment decision:  **G1:** 8 (4)  **G2:** 20 (11)  **G1 vs. G2:** p=0.02  No visit to outpatient clinic:  **G1:** 2 (1)  **G2:** 4 (2)  **G1 vs. G2:** p=0.4  Actual treatment received up to 12 months after first visit, n (%):  Hysterectomy:  **G1:** 98 (53)  **G2:** 88 (49)  **G1 vs. G2:** p=0.4  Minor surgery or LNG-IUS:  **G1:** 30 (16)  **G2:** 46 (26)  **G1 vs. G2:** p=0.03  Other:  **G1:** 54 (29)  **G2:** 44 (25)  **G1 vs. G2:** p=0.3  No treatment and no visit to outpatient clinic:  **G1:** 2 (1)  **G2:** 1 (1)  **G1 vs. G2:** p=0.4  Number of surgical procedures used within 1 year, mean (SE):  **G1:** 0.70 (0.04)  **G2:** 0.73 (0.04)  **G1 vs. G2:** p=0.6  Rand-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=0.7  Physical 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=0.9  Emotional 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=0.7  Social 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=0.5  Energy:  **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=0.9  Pain:  **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=0.9  Role 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=0.5  Role 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=0.01  Perceived 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=0.6  Psychosomatic 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=0.5  Inconvenience 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=0.9  Menstrual 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=0.8  Anxiety,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=0.4  Sexual 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=0.4  Sexual 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=0.8  Partner 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=0.9  Satisfaction 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:  Low  Allocation concealment:  Low  Selective reporting:  Low  Blinding patients/personnel:  High  Blinding outcome assessment:  High  Incomplete outcome reporting:  Low  Other:  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.