**AUB KQ1 Evidence Table (Reference ID #1441)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)** | **Outcome Measure(s)** | **Overall Quality****Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**Protheroe et al., 2007**Country:**United Kingdom**Enrollment** **period:** July 2003 to January 2005**Intervention** **setting:** 19 general practices**Funding:**Grant from Medical Research Council**Author industry relationship disclosures:**None**Study Design:** RCT**Blinding:** NR | **Intervention:**Self-directed, interactive computerized decision aid (Clinical Guidance Tree) and patient information leafletTreatment options included watchful waiting, nonhormonal drug treatments (mefenamic acid, tranexamic acid, NSAIDS and ethamsylate), hormonal medications (COC and progestogens), LNG-IUS (Mirena) and surgical options (transcervical endometrial resection, abdominal or vaginal hysterectomy) **Comparator:**Control: Patient information leaflet alone**Groups:****G1**: Decision aid**G2**: Control**Followup:**6 months | **Inclusion criteria:** * Aged 30-55 years
* Menorrhagia and consulted their general practitioner in the previous week

**Exclusion criteria:** * Heavy menstrual bleeding caused by physical pathology such as confirmed or provisional diagnosis of cancer, endometriosis, fibroids, polyps and cysts
* Inability to understand English
* Considered unsuitable by their general practitioner (including terminal illness, mental health problems)

**N at enrollment:** **G1:** 74**G2:** 72**N at followup (%):** **G1:** 60 (81) **G2:** 56 (78)**Age years, mean ± SD:****G1:** 41 ± 5.2**G2:** 41 ± 5.4**BMI:**NR**Parity:**NR**Race/ethnicity:**NR**Achieved higher education, n (%):****G1:** 17 (23)**G2:** 15 (21) | Decisional Conflict Scale total score,b mean ± SD:**G1:** 51 ± 20.6**G2:** 50 ± 19.4Spielberger State-Trait Anxiety Inventory score,c mean ± SD:**G1:** 12.7 ± 4.2**G2:** 13.4 ± 4.2 Menorrhagic Specific Utility Scale score,b mean ± SD:**G1:** 36.2 ± 19.6**G2:** 39.9 ± 21.8Knowledge (% of correct answers), mean ± SD:**G1:** 36.7 ± 18.8**G2:** 36.5 ± 21.0Baseline treatment preference, n (%):Had a treatment preference at baseline: **G1:** 47 (63)**G2:** 45 (62)Tablets:**G1:** 20 (27)**G2:** 22 (30.5)Surgery:**G1:** 22 (30)**G2:** 18 (25)Hormone intrauterine device:**G1:** 5 (6.5)**G2:** 5 (7)Unsure:**G1:** 27 (36.5)**G2**: 27 (37.5) | Decisional Conflict Scale total scoreb at 2 weeks, mean ± SD:**G1:** 23.4 ± 14.3 (n=69)**G2:** 40.5 ± 18.3 (n=69)**G1 vs. G2:** p<0.001Decisional Conflict Scale total scoreb at 2 weeks, adjusted difference (95% CI): **G1 vs. G2:** -16.6 (-21.5, -11.7)Spielberger State-Trait Anxiety Inventory score,c mean ± SD:2 weeks:**G1:** 11.6 ± 3.7 (n=59)**G2:** 12.2 ± 3.7 (n=61)**G1 vs. G2:** p=0.166 months:**G1:** 11.2 ± 4.2 (n=47)**G2:** 13.3 ± 4.9 (n=52)**G1 vs. G2:** p=0.067Spielberger State-Trait Anxiety Inventory score,c adjusted difference (95% CI):2 weeks:**G1 vs. G2:** -1.0 (-2.4, 0.4)6 months:**G1 vs. G2:** -1.8 (-3.7, 0.1) Menorrhagic Specific Utility Scale score, mean ± SD:**G1:** 59.3 ± 30.0 (n=60)**G2:** 50.9 ± 25.1 (n=56)**G1 vs. G2:** p=0.033Menorrhagic Specific Utility Scale score, adjusted difference (95% CI):**G1 vs. G2:** 10.9 (0.9, 21.0)Knowledge (% of correct answers), mean ± SD:**G1:** 59.7 ± 18.4 (n=54)**G2:** 48.8 ± 19.6 (n=54)**G1 vs. G2:** p=0.014Knowledge (% of correct answers), adjusted difference (95% CI):**G1 vs. G2:** 9.3 (1.9, 16.6)**Bleeding:**NR**Quality of life:**NR**Pain:**NR**Sexual function:**NR**Patient satisfaction:**NR**Fertility:**NR**Time to conception:**NR**Additional interventions,**a **n (%):**Treatment at 6 months:**G1:** 40 (71) **G2:** 45 (80) **G1 vs. G2:** p=0.268Treatment preference at two weeks:**G1:** 49 (88)**G2:** 38 (68)**G1 vs. G2:** p=0.011Post intervention preference matches treatment received:**G1:** 23 (58) n=40**G2:** 20 (44) n=45**G1 vs. G2:** p=0.198Hospital appointment:**G1:** 19 (34)**G2:** 21 (38)**G1 vs. G2:** p=0.659Surgical treatment:**G1:** 7 (13)**G2:** 3 (5)**G1 vs. G2:** p=0.139Mirena:**G1:** 13 (23)**G2:** 15 (27)**G1 vs. G2:** p=0.625Medical treatment:**G1:** 20 (36)**G2:** 27 (48) **G1 vs. G2:** p=0.198 | **Overall quality:**Poor**Risk of bias:**Randomization:LowAllocation concealment:LowSelective reporting:UnclearBlinding patients/personnel:HighBlinding outcome assessment:HighIncomplete outcome reporting:LowOther:Unclear |

**Table Notes:** a For G1 and G2 total n=56 in each group unless otherwise noted; b Scale 0-100; c Scale 6-24, where higher score indicates higher anxiety.