GYNECOLOGY

Effectiveness of app-based self-acupressure for women with menstrual pain compared to usual care: a randomized pragmatic trial

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BACKGROUND: Primary dysmenorrhea is common among women of reproductive age. Nonsteroidal anti-inflammatory drugs and oral contraceptives are effective treatments, although the failure rate is around 20% to 25%. Therefore additional evidence-based treatments are needed. In recent years, the use of smartphone applications (apps) has increased rapidly and may support individuals in self-management strategies.

OBJECTIVE: We aimed to investigate the effectiveness of app-based self-acupressure in women with menstrual pain.

MATERIALS AND METHODS: A 2-armed, randomized, pragmatic trial was conducted from December 2012 to April 2015 with recruitment until August 2014 in Berlin, Germany, among women aged 18 to 34 years with self-reported cramping pain of 6 or more on a numeric rating scale (NRS) for the worst pain intensity during the previous menstruation. After randomization, women performed either app-based self-acupressure (n = 111) or followed usual care only (n = 110) for 6 consecutive menstruation cycles. The primary outcome was the mean pain intensity (NRS 0−10) on the days with pain during the third menstruation. Secondary outcomes included worst pain intensity during menstruation, duration of pain, 50% responder rates (reduction of mean pain by at least 50%), medication intake, sick leave days, and body efficacy expectation assessed at the first, second, third, and sixth menstruation cycles.

RESULTS: We included 221 women (mean age, 24.0 years; standard deviation [SD], 3.6 years). The mean pain intensity difference during the third menstruation was statistically significant in favor of acupressure (acupressure: 4.4; 95% confidence interval [CI], 4.0−4.7; usual care 5.0; 95% CI, 4.6−5.3; mean difference −0.6; 95% CI, − 1.2 to −0.1; $P = .026$). At the sixth cycle, the mean difference between the groups (−1.4; 95% CI, −2.0 to −0.8; $P < .001$) reached clinical relevance. At the third and sixth menstruation cycles, responder rates were 37% and 58%, respectively, in the acupressure group, in contrast to 23% and 24% in the usual care group. Moreover, the worst pain intensity (group difference −0.6; 95% CI, −1.2 to −0.02; and −1.4; 95% CI, −2.0 to −0.7), the number of days with pain (−0.4; 95% CI, −0.9 to −0.01; and −1.2; 95% CI, −1.6 to −0.7) and the proportion of women with pain medication at the third and sixth menstruation cycles (odds ratio [OR], 0.5; 95% CI, 0.3−0.9] and 0.3 (95% CI, 0.2−0.5) were lower in the acupressure group. At the third cycle, hormonal contraceptive use was more common in the usual care group than in the acupressure group (OR, 0.5; 95% CI, 0.3−0.97) but not statistically significantly different at the sixth cycle (OR, 0.6; 95% CI, 0.3−1.1]). The number of sick leave days and body efficacy expectation (self-efficacy scale) did not differ between groups.

On a scale of 0 to 6, mean satisfaction with the intervention at the third cycle was 3.7 (SD 1.3), recommendation of the intervention to others 4.3 (1.5), appropriateness of acupressure for menstrual pain 3.9 (1.4), and application of acupressure for other pain 4.3 (1.5). The intervention was safe, and after the sixth cycle, two-thirds of the women (67.6%) still applied acupressure on all days with pain.

CONCLUSION: Smartphone app−delivered self-acupressure resulted in a reduction of menstrual pain compared to usual care only. Effects were increasing over time, and adherence was good. Future trials should include comparisons with other active treatment options.

Key words: acupressure, dysmenorrhea, mHealth, pain

Primary dysmenorrhea[1] affects up to 81% of women of reproductive age,[2,3] with approximately 15% experiencing severe pain.[2] Menstrual pain has a relevant impact on quality of life[4] and results in a substantial economic loss.[5,6]

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Nonsteroidal anti-inflammatory drugs and oral contraceptives are effective treatments,[7] although the failure rate is around 20% to 25%[5,8,9] because of side effects[7,10] and lack of effectiveness in some cases.[10-12] Additional evidence-based treatments are needed.[13] Of women with menstrual pain, 70% are reported to practice self-management.[10] A few studies have investigated the effect of self-acupressure for dysmenorrhea, mostly as an add-on to therapist-administered acupressure.[13-16] Although results showed a beneficial effect for self-acupressure,[17-21] the evidence is unclear due to risk of bias (mostly due to performance and attrition bias).[13]

In recent years, the use of smartphone applications (apps)[22] has increased rapidly. Mobile and electronic health solutions are already widely used in the general public and are seen as a valuable tool for various health problems[22-25] and self-management.[26] Mobile health (mHealth) solutions might have improved the autonomy and participation of users already,[26] for example by facilitating the search for information and health services, as well as by structuring of information and data. Health data is increasingly being collected via smartphones and portable devices (so-called wearables) and can be shared with doctors and other service

providers. Individual behavior can be positively influenced with the help of behavioral change techniques and used, for example, for smoking cessation or weight control.[27,28] Only a few mHealth solutions have been investigated in randomized controlled trials to date, and the majority of available apps do not report any health care professional involvement in their development[22,25] Nevertheless, a strong increase in mHealth solutions and increasing integration into usual care is expected. App-based self-acupressure might be innovative to support women with menstrual pain; however, its effectiveness in a usual care setting remains unclear.

In this study, we aimed to investigate whether app-based self-acupressure is more effective in reducing pain than usual care for women with menstrual pain.

Materials and Methods

Study design

We performed a 2-armed, randomized, pragmatic trial with a treatment duration and observation time of 6 menstruation cycles per woman. The design of the trial and the development of the smartphone app "AKUD" were shaped by stakeholder engagement (see previous publication[29]). A statistician not involved in the study used "ranuni" random number generator of the SAS/STAT software version 9.2 (SAS Institute, Cary, NC) to generate the randomization list (1:1 ratio). The list was transferred into a secured database (Microsoft Office Access 2010; Microsoft Corporation, Redmond, WA) and hidden behind the interface so that it was not accessible to anyone involved in the random allocation or treatment. Eligible women were randomized by clicking a button of the database interface. The result could not be changed, which ensured allocation concealment.

This study followed the standards of the Declaration of Helsinki[30] and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use good clinical practice (ICH-GCP) guidelines, and were approved by the respective Ethics Committee (Charité—Universitätsmedizin Berlin EA1/027/12). All patients gave oral and written informed consent. The trial was registered at clinicaltrials.gov (NCT01582724), and the study protocol was published.[29]

Participants and setting

Women were recruited in Berlin, Germany, from December 2012 to August 2014, using information materials (posters, flyers, and leaflets), the intranet platforms of Charité—Universitätsmedizin Berlin, and students' e-mail lists. In adition, the study was advertised on 2 Berlin subway lines for 5 months. Telephone interviews were used for participant prescreening. To facilitate recruitment, a financial compensation of 30 EUR was introduced after 8 months.

Participants were eligible for the trial if they fulfilled the following inclusion criteria: female sex; 18 to 25 years of age (criterion broadened to 18—34 years after 8 months of recruitment to facilitate recruitment); having dysmenorrhea, defined as self-reported cramping pain during every menstrual cycle; no prior history of a gynecologic disease that could be a reason for dysmenorrhea; having had menstruation in the last 6 weeks and a menstrual cycle duration between 3 and 6 weeks; moderate or severe pain, defined as a score equal to or greater than 6 on a numeric rating scale (NRS, 0—10) for the worst pain intensity during the last menstruation; and providing written and oral informed consent. Participants had to own a smartphone (iOS or Android) and to agree to enter study data through the app. Patients were not eligible for the trial if they fulfilled any of the following exclusion criteria: already using or planning to use acupressure, acupuncture, shiatsu, or/and tuina massage in the following 8 months; or known pregnancy or planned pregnancy in the following 8 months.

Intervention and control group

Both treatment groups received the app AKUD (Software development: Smart Mobile Factory, Berlin, Germany), which included a visualization of the menstrual cycle, questionnaires, and diaries for both groups.

Acupressure specific features were available only for the acupressure group. These included explanations of the acupressure procedure, drawings, videos, and photos of the acupressure points, as well as a timer to guide the 1-minute acupressure of each point. The acupressure intervention (points, duration, setting) resulted from a written Delphi consensus with international acupuncture experts from China, Germany, and the United States.[29] The acupuncture points SP6 (Sanyinjiao), LI4 (Hegu), and LR3 (Taichong) were used on both sides. In the acupressure group, a health care professional introduced the acupressure based on the instruction of the app at the baseline visit (Table 1). The women were reminded by the app every noon to apply acupressure starting 5 days before the anticipated menstruation. Users could switch off the reminders within the app. To keep the intervention standardized, the app received no major updates.

Women in the control group did not receive any study specific intervention. After the sixth menstruation cycle, that is, at the end of the study, the acupressure features were activated within the app and a personal face-to-face introduction to acupressure was offered.

The acupressure and the control groups could continue with usual care during the study, which was defined as all medical and nonmedical treatments with the exception of tuina, shiatsu, and acupuncture because of the use of similar pressure points.

Outcome measurements

The primary outcome measure was the mean pain intensity on the days with pain during the third menstruation on a numerical rating scale (NRS) from 0 (no pain) to 10 (worst possible pain) assessed retrospectively after the third menstruation.[31] The NRS and the time point were chosen based on the stakeholder process in preparation of the trial[29] and previous literature on acupressure on dysmenorrhea.[14] The NRS is easy to apply and well suited for implementation in a smartphone app, and 3 months seemed long enough to