Correspondence

Study of contraceptive mobile app fails to provide convincing findings

This is the third study by the company Natural Cycles on their product, a mobile phone fertility tracking app, based on an algorithm that relies *primarily* on basal body temperature shifts and menstrual cycle lengths [1]. The first two studies by Bergund Scherwitzl et al. have already been criticized [2].

Although we appreciate the efforts in continuing to study this fertility awareness based method (FABM) we are disappointed that the current study has major limitations. Therefore, the estimates of unplanned pregnancy rates of the present study cannot be considered reliable for assessing the quality of the app, nor for comparison with other studies of FABMs or contraceptives.

We want to focus on three major limitations. First is the inappropriate calculation of unplanned pregnancy rates. Method efficacy needs to be calculated by taking all pregnancies into account. The authors distinguish both "perfect use efficacy of the application"… "and the rate of pregnancies caused by the algorithm itself". In both cases the method did not work, and therefore, the resulting pregnancies have to be considered all method-related. The perfect use rate was calculated only for a small subsample ($N=17$), and therefore, somewhat useless.

Second, the detection of unplanned pregnancy is very questionable as no precise definition is provided. Pregnancy is based on discontinuation which includes a likely pregnant due to a late luteal phase, very unlikely to be pregnant, and possibly pregnant. Furthermore, as the authors stated there was no intercourse reported in 47% of the cycles. The results are also confounded by recommending use of another method of contraception during the estimated fertile window. There is no analysis of pregnancy rates with another method or with periodic abstinence.

Third, we question whether the proprietary algorithm of Natural Cycles really works. The authors state that the algorithm can identify the ovulation day with high precision based on the temperature shift, cycle length, and LH surge [3]. However, the urine LH surge and the temperature shift vary in its timing relative to ovulation [4,5]. Currently available data are insufficient to establish the precision and accuracy of the Natural Cycles proprietary algorithm.

Other concerns are use of the imprecise term of "unplanned pregnancy", no inclusion/exclusion criteria, the large loss of participants (from 22,785 to 6944), and the typical use pregnancy rate of 8.3% after 1 year of use. The method-efficacy is probably far higher, assumingly around 6.7%. If we take into account the problems with pregnancy detection we assume even higher pregnancy rates. Further, there is an estimated discontinuation rate of 54% after 1 year. From those results, it cannot be concluded that Natural Cycles is an effective family planning method. We find that the study design has not improved recognizably in comparison to the preceding study. Finally, there is an obvious conflict of interest as the founders of the company with stock ownership performed the studies themselves and an ethical concern that this system was not studied with a tightly controlled design before it was launched for public use.

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