

„Be-Up: Geburt aktiv“

Effects of the birthing room environment on vaginal births and client-centred outcomes in low risk women at term: a multicentre randomised clinical trial (RCT)

Background: Research indicates that by changing the hospital birth environment, maternal self-determination during labour will be facilitated. A pilot study by Hodnett 2009 indicates that a redesigned birthing room, which fosters maternal mobility, relaxation, coping with pain, self-determination and personal comfort, may help to increase the rate of vaginal births.

Thus the study will answer the question whether women who aim at a normal birth and who labour in a redesigned birthing room will be more likely to have a normal birth (compared with controls), have less medical interventions, less complications, better health, and are more satisfied with their birth experience.

Aim: This multicentre RCT tests the effect of a redesigned birthing room (intervention) on the probability of vaginal birth (VB) in 17 obstetric units (hospitals). So far there is no RCT, which was adequately powered, to study the independent effect of the birthing environment. By increasing VB, the rate of caesarean sections will be reduced, which in Germany is higher than recommended by the WHO and associated with increased maternal and infant morbidity. This trial is in line with the recently proclaimed German national health goal “Health in Childbirth” (Gesundheit rund um die Geburt).

Design: Active controlled superiority trial; two-arm parallel design; birthing room with special design features (intervention) which are absent in the control birthing room; independent centrally controlled and concealed randomisation; no blinding possible; data verification by external monitors; 3 months follow-up; power: 90%, significance level: 5%, dropout rate: <10%; health economic evaluation.

Methods: In 17 hospitals 3,800 primiparae and multiparae will be assigned by chance to one of two parallel trial groups: either the intervention or the control group. Pregnant women are included if at admission they present with a singleton fetus in cephalic presentation at term planning a VB.

The intervention birthing room will be environmentally redesigned: the delivery bed won't be visible, and there will be equipment that facilitates mobility, coping with pain, self-determination. The control birthing room will be a typical birthing room with a delivery bed which is centrally positioned. Professionals will care for the women according to hospital standards.

Data will be documented during labour and after birth. The women will fill in questionnaires on the postpartum unit and at 3 months after birth. Additionally, a cost analysis will be done.

Expected outcome: An increase of VB by 5% from baseline of 72% (nationally 421,241 VB in hospitals) to 77% would result in an additional 21,062 women per year, who experience a VB instead of a CS. Expected benefits are improved physical/emotional client-centred outcomes, more self-determination during birth, less medical interventions, less subsequent CS in future pregnancies, less health care costs for interventions.

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German Clinical Trials Register (Deutschen Register Klinischer Studien): DRKS00012854

Further information on the study:

<https://be-up-studie.de> (see English language button)