Statistical Analysis Plan – the ADAPT study

The ADAPT study consists of two studies in one – the Intervention-study (randomized controlled study with group-based intervention vs control group), and the Observational study of the entire cohort.

Intervention-study – outcomes

Intervention vs control group

Primary outcome

- ICIQ-B Quality-of-Life Domain (items 19a–23a), score range 0–26, where higher scores indicate greater symptom burden and negative impact on daily life.

- Endpoint: Change in score from baseline (1-1.5 month postpartum) to last follow-up (9-12 months postpartum), compared between the Intervention and the Control group.

Secondary outcomes

- Total ICIQ-B score from questionnaires at baseline and follow-ups (e.g., 3, 6, 9-12 months).

- Anal incontinence symptoms derived from relevant ICIQ-B items and clinical follow-ups.

- Clinical outcomes at late follow-up (9-12 months postpartum) e.g. prolapse (modified POP-Q, hiatus length, height of perineal body), endoanal ultrasound (EAUS) assessment of the anal sphincter complex.

- Number of clinical follow-ups

- Additional questionnaire outcomes including urinary incontinence (UI-SF), prolapse symptoms (PFDI-20), heaviness, pain (KAPTAIN), body image (FGSIS), sexual function (ICIQ-VS) and psychological symptoms (EPDS) for all relevant timepoints.

Tertiary outcomes

- Endovaginal ultrasound (EVUS) assessment of Levator Ani Avulsion: presence, severity, and association with symptoms and quality of life at late clinical follow-up (9-12 months) postpartum

Intervention-study - analyses

Descriptive Analyses

- Continuous variables will be summarized using median and range, and IQR (InterQuartile Range) where relevant.

- Categorical variables will be summarized as counts and percentages.

- Baseline characteristics will be presented for each study group.

- Clinical outcomes at early follow-up (approx. 8-14 days postpartum) e.g. wound dehiscence and infection

Comparative Statistical Analyses

Primary analysis

- Group comparison of change in ICIQ-B QoL domain score from baseline to 9-12 months postpartum.

- If data are approximately normally distributed, an independent t-test will be used.

- If normality assumptions are not met, a Mann–Whitney U test will be applied.

- Two-sided significance level: $P \leq 0.05$

Secondary and tertiary analyses

- Continuous outcomes:

  - t-tests for normally distributed data.

  - Mann–Whitney U tests for non-normal data.

- Categorical outcomes:

  - χ^2 tests or Fisher's exact tests depending on cell counts.

- Repeated-measure outcomes (e.g., 3, 6, 9-12 months):

- Longitudinal models (e.g., linear or generalized linear mixed models) may be used to estimate group-by-time effects and account for within-subject correlation.

Observational study - outcomes

Cohort: all participants regardless of randomization-group.

Primary outcome

- Development/fluctuation of anal incontinence and related symptoms over time. From early clinical follow-up (8-14 days postpartum) to last clinical follow-up/questionnaire 9-12 months postpartum.

Secondary outcomes

- Development/fluctuation of pelvic symptoms over time e.g. urinary incontinence (UI-SF), prolapse symptoms (PFDI-20), heaviness, pain (KAPTAIN), body image (FGSIS), sexual function (ICIQ-VS) and psychological symptoms (EPDS)

- Clinical outcomes at late follow-up (9-12 months postpartum) e.g. prolapse (modified POP-Q, hiatus length, height of perineal body), endoanal ultrasound (EAUS) assessment of the anal sphincter complex.

Descriptive Analyses

- Continuous variables will be summarized using median and range, and IQR (InterQuartile Range) where relevant.

- Categorical variables will be summarized as counts and percentages.

- Baseline characteristics will be presented for the cohort.

- Clinical outcomes at early follow-up (approx. 8-14 days postpartum) e.g. wound dehiscence and infection

Univariable and multivariable analyses

- Associations between exposures (e.g. vacuum delivery, high birthweight, epidural, episiotomy) and outcomes such as anal and urinary incontinence, prolapse, repeated/number of clinical follow-ups etc. will be explored using appropriate regression models (linear, logistic, or ordinal).

- Models will adjust for clinically relevant confounders, such as age, BMI, parity, mode of delivery, tear grade.

Handling of Missing Data (intervention and cohort)

- Missing data patterns will be described for all key variables for both the intervention-study and observational study.

Qualitative Component (Intervention Group only)

- Semi-structured individual or focus-group interviews will explore participants' experiences with the intervention and explore women's experiences of sustaining a perineal tear and any associated symptoms.

- Data will be transcribed verbatim and analyzed using thematic or content analysis.

- Findings will be integrated with quantitative results to contextualize acceptability, perceived benefits, and implementation considerations.