P05.09 - Virtual Reality & Feasibility and Efficacy of first Trimester Ultrasound: a randomized controlled trial (VR FETUS study)

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Aim – To investigate the feasibility and efficacy of 1st trimester Three-Dimensional (3D) Virtual Reality (VR) ultrasound (US).

Methods – Randomized controlled trial with 2 arms: intervention (1st trimester 2D and 3D VR US) vs control. Questionnaires are used for psychological burden, quality of life and health expenses.

Conclusion – 1st trimester 3D VR US may improve detection of anomalies in a high risk population. Also, this trial should reveal the cost-effectiveness of 3D VR US.

Objective

Fetal anomalies can be detected in the 1st trimester of pregnancy. Three-dimensional (3D) virtual reality (VR) ultrasound (US) is a reliable and validated technique for the evaluation of fetal development and can be used in clinical care. The aim of this study is to investigate whether 3D VR US in the first trimester of pregnancy is of additional value in terms of diagnostic accuracy and health-related Quality of Life (QoL), as reflected by psychological burden, and cost-effectiveness.

Methods

The VR FETUS Study is a randomized controlled trial with 2 treatment arms. The control group receives care as usual. The intervention group will receive an additional 1st trimester 2D and 3D VR US. Following each visit, participants will fill in questionnaires.

Results

Primary outcome: Detection of congenital anomalies using 1st trimester 3D VR and second trimester 2D US. Neonatal investigation will be applied as the golden standard. Based on an estimated detection rate of 65% for 3D VR first trimester and 70% for 2D second trimester US and an α=0.05 and β=0.80, estimated n = 4,000 inclusions is necessary. Secondary outcome: health-related QoL (as reflected by psychological burden) and cost-effectiveness.

Conclusion

Use of 3D VR US in clinical care may improve 1st trimester detection of anomalies. Moreover, this randomized controlled trial should reveal the benefits of 3D VR US for the pregnant population with respect to health-related quality of life and cost-effectiveness.

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