Appendix 5 Table over included studies, interventions for fear of childbirth

Bilaga 5: Included studies; interventions for fear of childbirth

Abbreviations

n= number of participants; Na= not available; RCT= randomized controlled trial; I=intervention group; C=control group; CI=confidence interval; p= probability value; ITT= intention to treat; ns= not statistically significant;

W-DEQ= Wijma Delivery Expectancy Questionnaire (33 items from 0=''not at all'' to 5=''extremely'', min=0, max= 30, higher score= more depressed); W-DEQ-A= prenatal W-DEQ; W-DEQ-B = postnatal W-DEQ;

EPDS=Edinburgh Postnatal Depression Scale (10 items from 0 to 3, min=0, max= 165, higher score= more fear;

EQ-5D-3L = healthrelated quality of life on a EuroQol 5-dimensional scale (five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression; 3 levels: no problems, some problems, and extreme problems).

Tables

Author **Year** **Country** **Ref #**	Saisto 2001 Finland [1]
Study design **Setting** **Recruitment**	RCT Between August 1996 and July 1999, Helsinki University Central Hospital obstetrically low-risk and physically healthy pregnant women referred to the outpatient clinic because of fear of vaginal delivery
Population	n=85+91= 176; mean age (SD): I=31.2 (5.1), C=31.9 (4.8) ; nulliparous: I=51.8%, C=50.5%; gestational age in weeks at enrollment (SD): I=24.9 (1.7), C=24.9 (1.8); fear of childbirth, nr of affirmatives on screening questions, mean (SD): I=6,0 (1.7), C=5.7 (1.8).
Inclusion criteria	The cut-off point for diagnosis of fear of childbirth was five or more affirmative answers on 10 screening questions or request for cesarean. Exclusion criteria: contraindication to vaginal delivery at the time of randomization
Follow up	Patient records postpartum (for outcome caesarian section)
Intervention **Participants (n)** **Drop-outs (n)**	intensive therapy (routine obstetric check-ups combined with cognitive therapy regarding previous obstetric experiences, feelings, and misconceptions); 3-4 session with CBT-trained obstetrician. Randomized n= 85 analysed n= 85 (for outcome caesarian section) n= 0 (for outcome caesarian section)
Comparison **Participants (n)** **Drop-outs (n)**	conventional therapy (standard information distribution and routine obstetric check-ups, as well as provision of written information about the pros and cons of vaginal delivery versus cesarean) Randomized n= 91, analysed n= 91 n= 0 (for outcome caesarian section)
Outcomes	**Fear of childbirth** - available but with high risk of bias **Delivery** - Cesarean for psychological reasons, n (%): I=20/85= 24%; C=26/91= 29% **Mental health** - available but with high risk of bias **Experience of treatment**

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	- na
	Quality of life
	- na
	Obstetric complications
	- na
	Pain relief and other medications during delivery
	- na
Comments **Risk of bias**	High risk of bias for patient reported outcomes. Moderate risk of bias for outcomes from patient records.

Author **Year** **Country** **Ref #**	Rouhe et al. 2013 Finland [2] see also [3,4]
Study design **Setting** **Recruitment**	RCT Maternity unit of Helsinki University Central Hospital 2007 to 2009 Screening of 12 000 consecutive and unselected Finnish- and Swedish-speaking pregnant women who participated in routine ultrasound screening at the gestational age of 11–13 weeks
Population	n= 371; mean age (SD): I=29.3 (4.6); C=29.4 (4.8) ; nulliparous= 100%; gestational age in weeks at intervention start (SD): I=27.6 (3.9); C=not applicable; fear of childbirth, W-DEQ-A mean (SD): I=113 (11); C=113 (12)
Inclusion criteria	W-DEQ-A ≥ 100, nulliparous exclusion criteria= manifest psychosis and severe depression
Follow up	- Postpartum (3 months after delivery) - data on the deliveries were derived from the hospital obstetric patient records.
Intervention **Participants (n)** **Drop-outs (n)**	psychoeducative group therapy, six sessions during pregnancy and one after childbirth Randomized n= 131, analysed n= 131 (ITTanalysis) Did not participate: n= 41
Comparison **Participants (n)** **Drop-outs (n)**	care by community nurses and referral if necessary Randomized n= 240, analysed n= 240 (ITT analysis) Received special care for fear of childbirth: n= 106
Outcomes	**Fear of childbirth** - W-DEQ-A, mean (SD)= na - W-DEQ-B (postpartum, answered by I=77 and C=124), mean (SD) I=63.0 (32); C=73.7 (29); p= 0.02 **Delivery** - spontaneous vaginal delivery, n (%): I=83 (63.4); C=114 (47.5), P = 0.005 - caesarean sections, n (%): I=30 (22.9); C=78 (32.5); p= 0.05 - Elective caesarean sections, n (%): I=14 (10.1); C=31 (12.9); p= 0.62 - Emergency caesarean sections, n (%): I=16 (12.2); C=47 (19.6), p= 0.05 -vacuum extraction, n (%): I=18 (13.7); C=48 (20.0); p= 0.16 - Induction of labour, n (%): I=30 (22.9); C=50 (20.8); p= 0.692 **Mental health** -na

	Experience of treatment
	- na
	Quality of life
	-na
	Obstetric complications
	- Bleeding in ml, mean (SD):
	I=534 (484); C=589 (538), p= 0.35
	Gestational age at delivery (weeks), mean (SD):
	I=39.7 (1.5); C=39.6 (1.6); p >0.99
	Birthweight (g), mean (SD):
	I=3532 (550); C=3486 (518); p= 0.44
	Apgar (1 minute) < 7, n (%):
	I=14 (10.7); C=25 (10.4); p >0.99
	Postpartum interventions (suturing of deep lacerations or surgical evacuation of placenta or membranes postpartum), n (%):
	I=15 (14.9); C=16 (9.9); p= 0.24
	Pain relief and other medications during delivery
	- Epidural or spinal analgesia, n (%):
	I=85 (84.2); C=138 (85.2); p >0.99
Comments	
Risk of bias	Moderate

Author	Rouhe et al.
Year	2015a
Country	Finland
Ref #	[4] see also [2,3]
Study design	RCT
Setting	Finland, data from obstetrical patient records and questionnaires
Recruitment	na, reported elsewhere.
Population	n= 371; mean age (SD)=na (reported elsewhere) ; nulliparous= 100%; gestational age at intervention start= na (reported elsewhere); fear of childbirth= na (reported elsewhere)
Inclusion criteria	W-DEQ-A ≥ 100, nulliparous
	exclusion criteria= manifest psychosis and severe depression
Follow up	- T1= mean gestational age 20 ± 2 weeks
	- T2= mean gestational age 36 ± 2 weeks
	- T3= 3 months postnatally
	- Data on the deliveries were derived from the hospital obstetric patient records.
Intervention	psychoeducative group therapy, six sessions during pregnancy and one after childbirth
Participants (n)	Randomized n= 131, analysed n= 131 (ITTanalysis)
Drop-outs (n)	na (reported elsewhere)
Comparison	care by community nurses and referral if necessary
Participants (n)	Randomized n= 240, analysed n= 240 (ITT analysis)
Drop-outs (n)	Received special care for fear of childbirth: n= 106
Outcomes	**Fear of childbirth**
	- na
	Delivery
	-Spontaneous vaginal delivery with no complications, n(%):
	I=78 (63.4); C=112 (47.5); p = 0.005
	- elective caesarean sections with no complications:
	I=14 (10.7); C=31 (12.9%) (NS)
	- complicated caesarean sections, n (%):

I=16 (12.2); C=49 (20.4); p < 0.05
Mental health
- emotional well-being in general (VAS; 0 = I am feeling bad; 10= I am feeling perfectly fine), mean:
I=7.3; C=7.1; p=ns
Experience of treatment
- na
Quality of life
- satisfaction with life scale (SWLS; min= 5; max=30, higher scores= more satisfaction), answered by
I=77 and C=124), mean:
I=22.7; C=21.9; p= ns
Obstetric complications
- hemorrhage episodes, medial mL (range):
I=400 (150 to 3000); C=450 (10 to 5050); p = 0.024
Pain relief and other medications during delivery
- na

Comments	
Risk of bias	Moderate

Author	Rouhe et al.
Year	2015b
Country	Finland
Ref #	[3] see also [2,4]
Study design	RCT
Setting	In 2007 to 2009
Recruitment	Screening for fear of childbirth among nulliparous women at the time of routine ultrasonography screening at the gestational age of 11–13 weeks.
Population	n= 371 ; mean age (SD)= ; nulliparous= 100%; gestational age at intervention start= 28th week of pregnancy; fear of childbirth:
Inclusion criteria	W-DEQ-A ≥ 100, nulliparous
Follow up	- T1= mid-pregnancy (at 20±2 gestational weeks), n (I+C) = 107+177 - T2= end of the third trimester (at 36±2 gestational weeks), n (I+C) = 82+121 - T3= 3 months after delivery (at 3 months±2 weeks postpartum), n (I+C) = 77+123
Intervention **Participants (n)** **Drop-outs (n)**	psychoeducative group therapy, six sessions during pregnancy and one after childbirth Randomized n= 131 Did not complete intervention: n= 131-90= 41
Comparison **Participants (n)** **Drop-outs (n)**	conventional care Randomized n= 240 Received special care for fear of childbirth: n= 106
Outcomes	**Fear of childbirth** - W-DEQ-A, mean (SD): na - W-DEQ-B (postpartum, n=201), mean (SD): I=63.0 (32); C=73.7 (29); p= 0.016, Cohen's d=0.35 **Delivery** -Spontaneous vaginal delivery n (%): I=na (63.4); C=na (47.5); p = 0.005 - caesarean sections, n (%): I=na (22.9); C=na (32.5); p= 0.05 **Mental health** - T1 EPDS, mean (SD):

I=8.3 (5.8); C=8.9 (5.0)
- T2 EPDS, mean (SD):
I=7.5 (5.2); C=8.1 (4.7)
- T3 EPDS (n=201), mean (SD):
I=6.4 (5.4); C=8.0 (5.9); p=0.04, Cohen's d= 0.28

Experience of treatment
- na
Quality of life
- na
Obstetric complications
- na
Pain relief and other medications during delivery
- na

Comments Risk of bias	Moderate

Author Year Country Ref #	Fenwick et al. 2015 Australia [5] see also [6, 7, 8]
Study design Setting Recruitment	RCT Australia, BELIEF study recruited by research midwives in antenatal clinics of three metropolitan teaching hospitals in south-east Queensland, Australia between May 2012 and June 2013.
Population	n=339; mean age (SD) = na, reported elsewhere; nulliparous= na, reported elsewhere; gestational age at intervention start= na; fear of childbirth=na.
Inclusion criteria	WDEQ > 66; between 12 to 24 weeks gestation; aged 16 years and older; able to read, write and understand English; capacity to consent
Follow up	6 weeks postpartum
Intervention Participants (n) Drop-outs (n)	telephone psycho-education; two telephone calls of 10 to 104 minutes by a midwife Randomized n= 170, analysed n= 91 n= 79 (Lost to follow-up= 51; withdrew=28)
Comparison Participants (n) Drop-outs (n)	usual maternity care Randomized n= 169, analysed n= 93 n= 76 (Lost to follow-up= 58; withdrew=16; removed < 66 WDEQ= 2)
Outcomes	Secondary outcomes of the BELIEF study. **Fear of childbirth** - na **Delivery** - Spontaneous vaginal delivery, n(%) I = 44 (48.4); C = 39 (41.9); 95% CI=0.72 – 2.31; p= 0.38 - Forceps/ vacuum, n (%): I=16 (17-6); C=15 (16.1); 95% CI=0.51 – 2.40; p= 0.79 - Caesarean section, n (%): I=31 (34.1; C=39 (41.9; 95% CI=0.39 – 1.30; p= 0.27 - Elective caesarean section, n (%): I=15 (16.5); C=16 (17.2); 95% CI=0.43 – 2.05; p=0.88 - Emergency caesarean section, n (%); I=16 (17.6); C=23 (24.7); 95% CI=0.31 – 1.32; p= 0.23 - Induction of labour, n (%):

I=34 (37.4); C=27 (29.1); 95% CI=0.76 – 2.75;p= 0.25

Mental health

- EPDS Mean (SD), range:

I=6.2 (5), 0–22; C=5.5 (4.7), 0–23; 95% CI=-0.67 – 2.14; p= 0.30

Experience of treatment

- na

Quality of life

- na

Obstetric complications

- Preterm birth, n (%), range weeks:

I=7 (7.7), 32–36; C=3 (3.2), 28–35

- Admit to nursery, n (%):

I=16 (17.6); C=18 (19.4); 95% CI=0.42 – 1.87; p= 0.75

Pain relief and other medications during delivery

-Narcotic in labour, n (%):

I=26 (28.6); C=29 (31.2); 95% CI=0.44 – 1.66; p= 0.65

- Epidural analgesia, n (%):

I=33 (36.3); C=33 (35.5); 95% CI=0.53 – 1.94; p= 1.00

Comments	
Risk of bias	Moderate

Author	Toohill et al.
Year	2017
Country	Australia
Ref #	[6] see also [5,7,8]
Study design	RCT
Setting	Australia, clinics across three maternity hospitals in Queensland, BELIEF Study
Recruitment	Women screened for childbirth fear May 2012 to June 2013 at the maternity hospitals
Population	n=339; age mean (SD): I=28.5 (na), C=28.7 (na); nulliparous= 56%; gestational age at intervention start= 24 weeks ; W-DEQ-A mean (SD): I=80.0 (12.4), C=76.3 (10.6)
Inclusion criteria	W-DEQ A ≥ 66
Follow up	- T1: 36 weeks of gestation, n (I+C)= 170 + 169 - T2: 6 weeks postpartum, n (I+C)= 91+ 93
Intervention	telephone psycho-education; two telephone calls of 10 to 104 minutes by a midwife
Participants (n)	Randomized n= 170
Drop-outs (n)	n=na
Comparison	Usual antenatal care
Participants (n)	Randomized n=169
Drop-outs (n)	n=na
Outcomes	**Fear of childbirth** - T1 W-DEQ-A, mean (SD), range: I=61.0 (19.7), 12 to 117; C=66.5 (18.2), 22 to 121 - W-DEQ-B, mean (SD): na **Delivery** - Vaginal birth, unassisted, n(%): I=44 (48.4); C=39 (41.9) -Vaginal birth, assisted n(%): I=16 (17.6); C=15 (16.1) - Unplanned caesarean section, n(%): I=16 (17.6); C=23 (24.7)

	- Planned caesarean section, before labour commenced, n(%):
	I=11 (12.1); C=13 (14.0)
	- Planned caesarean section, after labour commenced, n(%):
	I=4 (4.0); C=3 (3.2)
	- Caesarean section, n(%):
	I=31 (34.1); C=39 (41.9)
	- Vaginal delivery, any, n(%):
	I = 60 (66%); C = 54 (58); OR 2.34
	Mental health
	- na
	Experience of treatment
	- na
	Quality of life
	- na
	Obstetric complications
	- na
	Pain relief and other medications during delivery
	- na
Comments	
Risk of bias	Moderate

Author	Toohill et al.
Year	2014
Country	Australia
Ref #	[7] see also [5,6,8]
Study design	RCT
Setting	Australia, clinics across three maternity hospitals in Queensland, BELIEF Study
Recruitment	Women screened for childbirth fear May 2012 to June 2013 at the maternity hospitals
Population	n= 339; mean age (SD): I=29 (5.9), C=29.2 (4.98) ; nulliparous, n (%): I=58 (57.4), C=58 (59.8); gestational age at recruitment, mean weeks (SD): I=18.2 (3.17), C=17.9 (2.8) ; W-DEQ-A, mean (SD): I=80.9 (13.1), C=75.7 (9.7).
Inclusion criteria	W-DEQ A ≥ 66, second trimester, able to communicate sufficiently in English, aged 16 years or older. Exclusion: women anticipating or experiencing a perinatal death (e.g., congenital abnormality incompatible) or stillbirth
Follow up	36 weeks' gestation.
Intervention **Participants (n)** **Drop-outs (n)**	telephone psycho-education; two telephone calls of 10 to 104 minutes by a midwife Randomized n= 170, analysed n= 101 n=170-101= 69
Comparison **Participants (n)** **Drop-outs (n)**	usual care offered by public maternity services Randomized n= 169, analysed n= 97 n= 169-97= 72
Outcomes	**Fear of childbirth** - W-DEQ-A, mean change (SD): I=19.52 (18.59), n= 98; C=96 9.28 (16.32), n=96; mean change difference (95% CI)= 10.24 (5.29 to 15.19), $p < 0.001$ - W-DEQ-A, n that improved > 20 (%): I=48 (47.5), n= 98; C=25 (25.8), n= 96 - W-DEQ-B, mean (SD): na **Delivery** - na

	Mental health
	- EPDS, mean change (SD): I=1.26 (4.98), n=101; C=0 .61 (5.30), n= 97; mean change difference (95% CI)= .65 (-0.79 to 2.09), p= 0.38
	Experience of treatment
	- na
	Quality of life
	- na
	Obstetric complications
	- na
	Pain relief and other medications during delivery
	- na
Comments	
Risk of bias	Moderate

Author	Turkstra et al.
Year	2017
Country	Australia
Ref #	[8] see also [5-7]
Study design	RCT
Setting	Australia, clinics across three maternity hospitals in Queensland, BELIEF Study
Recruitment	Women screened for childbirth fear at the maternity hospitals
Population	n= 339; mean age (SD): I=30.2 (5.82), C=30.5 (4.98); nulliparous= na; gestational age at recruitment= na ; W-DEQ-A, mean (SD): I=82.4 (13.7), C=75.3 (9.11)
Inclusion criteria	W-DEQ A ≥ 66, second trimester, able to communicate sufficiently in English, aged 16 years or older.
Follow up	6 weeks postpartum
Intervention **Participants (n)** **Drop-outs (n)**	telephone psycho-education; two telephone calls of 10 to 104 minutes by a midwife Randomized n= 170, analysed n= 89 n=170- 89= 81
Comparison **Participants (n)** **Drop-outs (n)**	usual care offered by public maternity services Randomized n= 169, analysed n= 95 n= 169-97= 74
Outcomes	**Fear of childbirth** - na **Delivery** - vaginal, unassisted, n (%): I=42 (47%); C=41 (43%) - vaginal, assisted, n (%): I=16 (18%); C=15 (16%) - caesarean, n (%): I=31 (35%); C=39 (41%) **Mental health** - na **Experience of treatment** - na **Quality of life (as-treated analysis)** - EQ-5D-3L, mean (SD): I=0.86 (0.15); C=0.88 (0.15) - EQ-5D-3L change, mean (SD): I=0.010 (0.16); C=0.016 (0.18)

	- EQ-5D-3L mobility (moderate/severe), n (%): I=8 (9%); C=9 (10%) - EQ-5D-3L self-care (moderate/severe), n (%): I=0 (0%); C=0 (0%) - EQ-5D-3L activities (moderate/severe), n (%): I=24 (27%); C=21 (22%) - EQ-5D-3L pain/discomfort (moderate/severe), n (%): I=30 (34%); C=29 (31%) - EQ-5D-3L anxiety/depression (moderate/severe), n (%): I=27 (30%); C=20 (21%) **Obstetric complications** -na **Pain relief and other medications during delivery** -na
Comments	
Risk of bias	Moderate

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