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#### Antepartum and labour related predictors of nonparticipation, dropout, and lost to follow up in a treatment for women with negative birth experiences and/or posttraumatic stress following childbirth.

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Antepartum and labour related predictors of non-participation, dropout, and lost to follow up in a treatment for women with negative birth experiences and/or post-traumatic stress following childbirth.

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professor; Maria Jonsson<sup>1</sup> associate professor; Thomas Parling<sup>1,2</sup> PhD

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(RCT). The RCT was registered at *unonymized*. Date for registration *unony* 

retrospectively registered.

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Abstract	t
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3 4	1	Abstract
5 6	2	Objectives: Internet-based interventions are often hampered by high dropout rates. The
7 8	3	number of individuals who decline to participate or drop out are reported, but reasons for
9 10 11	4	dropout are not. Identification of barriers to participation and predictors of dropout may help
12 13	5	improve the efficacy of internet-based clinical trials. The aim was to investigate a large
14 15	6	number of possible predictors for non-participation and dropout in a randomized controlled
17 18	7	trial for women with a negative birth experience and/or post-traumatic stress following
19 20	8	childbirth.
21 22 22	9	Setting: A childbirth clinic at a university hospital in Sweden.
25 24 25	10	Participants: The sample included 1,523 women who gave birth between September 2013
26 27	11	and February 2018. All women who rated an overall negative birth experience on a Likert
28 29 20	12	scale, and/or had an immediate caesarean section (CS), and/or severe postpartum
30 31 32	13	haemorrhage ( $\geq$ 2,000 ml) were eligible.
33 34	14	Methods: Demographic, antepartum, and labour-related/postpartum predictors were
35 36	15	investigated for non-participation (eligible but denied participation), pre-treatment dropout
37 38 39	16	(prior to intervention start), treatment dropout, and loss to follow-up. Descriptive statistics
40 41	17	and logistic regression were used in the data analysis.
42 43	18	Results: A majority (80.3 %) were non-participants. Non-participation was predicted by
44 45 46	19	lower level of education, being foreign-born, no experience of counselling for fear of
40 47 48	20	childbirth, multiparity, vaginal delivery (vs. caesarean section and vacuum assisted delivery)
49 50	21	and absence of; preeclampsia, anal sphincter injury, and intrapartum foetal distress. Pre-
51 52	22	treatment dropout was predicted by absence of severe haemorrhage. Treatment dropout was
53 54 55	23	predicted by vaginal delivery (vs. immediate CS), vertex presentation and good overall birth
56 57	24	experience. Loss to follow-up was predicted by vaginal delivery (vs. immediate CS or
58 59 60	25	vacuum-assisted delivery) and absence of intrapartum foetal distress.

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3 4	1	<b>Conclusions:</b> Mothers with no obstetric complications were more likely to not participate and
5 6	2	dropout at different time points. Both demographic, antepartum and obstetrical variables are
/ 8 9	3	important to attend to while designing procedures to maximize participation in iCBT.
10 11	4	
12 13	5	KEYWORDS
14 15 16	6	Dropout; ICBT; internet-delivered; negative birth experience; non-participation;
17 18	7	posttraumatic stress
19 20	8	
21 22 22	9	
23 24 25		Strengths and limitations of this study
26 27		• A large number of participants from routine health care were included
28 29 30		• Demographic, antepartum, and labour-related/postpartum predictors were
31 32		investigated at four stages (recruitment, prior to treatment start, during
33 34		treatment, and at follow-up).
35 36 37		Neither psychological / psychiatric status or attitudes to internet delivered
38 39		interventions were investigated in this study but warrants further exploration.
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1	Introduction
2	The internet has created new opportunities for health care services. Internet-delivered
3	cognitive behavior therapy (iCBT) for various psychological disorders has been developed
4	and investigated in the past decades (1) and the field is growing quickly. The active
5	mechanisms in iCBT are the same as in CBT but differs in the way it is delivered (internet-
6	/computer-based) and increases the availability for evidence based psychological
7	interventions in the society. ICBT is convenient, flexible, and cost-effective for many
8	different psychological disorders (2) it is effective for treatment of depression and several
9	anxiety disorders, and for some diagnoses, iCBT is equally effective as face-to-face CBT
10	(3,4).
11	Several trials of internet interventions have had problems with high levels of non-
12	adherence, with a majority of the participants never completing treatment (5). Information
13	about dropouts in internet-based interventions is generally poorly reported in the literature
14	(5,6) and one study reported that of 75 reviewed trials, 40% failed to report information about
15	dropouts (7). However, when numbers are reported, they are typically high, especially in self-
16	guided interventions (8) (5). In a review of internet-based treatments, dropout ranged between
17	2 and 83%, with a weighted average of 31% (9). In a meta-analysis (10), dropout rates of 74%
18	were reported for unguided treatment for depression, whereas the corresponding figure for
19	therapist-supported treatments was 28%. Kuester et al. (11) found an average dropout rate of
20	23.2% in their meta-analysis of internet-based interventions for PTSD.

The literature is inconsistent regarding the definitions of participants who discontinue
before treatment completion (12). Operationalization of adherence varies across trials and
limits comparability (13). Eysenbach (14) defines low adherence in internet interventions as *"Nonuse attrition"* (when a participant completes an initial assessment battery but fails to

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start the intervention) and "*Dropout attrition*" (when a participant accesses the treatment, but prematurely discontinues it). Other terms, such as "non-compliance," "failure to engage," "premature termination," "attrition," and "dropout" have been used in the literature (12). Melville et al. (9) identified three categories of predictors of dropout: sociodemographic factors and contextual variables, psychological problems, and treatment-related variables – and described that dropout could occur at several different timepoints in iCBT. The following terms for dropout at different timepoints in internet interventions have been suggested: 1. Pretreatment dropout: when a participant drops out before starting the intervention. 2. Treatment dropout: when a participant drops out after having started the intervention. 3. Follow-up dropout: when a participant completes the intervention but drops out before follow-up measures are completed.

Studies seldom report reasons for non-participation or dropout (15). To better understand who will benefit from internet-based interventions and improve usability and efficacy, there is a need to identify factors related to dropout (16). Adherence to internet-interventions can be influenced by several sociodemographic factors, such as gender, age, and level of education (9,16–19). In a study 96 adult patients with posttraumatic stress reactions were allocated to ten sessions of iCBT or to a waiting list. The dropout rate in the iCBT group was 16%; technical problems and emotional distress due to the treatment interventions were the most frequently reported dropout reasons (20).

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The form of an intervention differs in internet treatments, considering amount of material, intensity and support. Some interventions are, e.g., fully therapist-supported with face-to-face sessions or via phone, some offer support via mail, and some do not offer support at all (self-help) (2). Systematic reviews have found that guided internet treatments in general tend to be more effective than non-guided ones (8). Studies seldom report data on the invited persons who decline participation (non-participants). In a randomized controlled trial (RCT)

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investigating expressive writing for postpartum physical and psychological health, recruitment was low (10.7% of the invited) (21). The recruited sample derived from a restricted sociodemographic range (high proportion of white Europeans, well-educated, employed, many in professional occupations, older, and more likely to be married). About 115 000 women give birth in Sweden every year (22). Childbirth is a subjective and multidimensional event that in some cases can lead to a negative childbirth experience. The prevalence of negative childbirth experiences varies (9-45%) in different communities (23-25). For some women (3-4%) the distress of a negative childbirth experience lead to the development of Posttraumatic Stress Disorder Following Childbirth (PTSD FC) (26–31). In Sweden there is no specific treatment recommendation for women with negative birth experiences and/or PTSD FC. So far, only a few randomised controlled trials have investigated the efficacy of different interventions for this population, it is therefore no or little information about how women with negative birth experiences commit and engage in iCBT and similar treatments. The aim of this study was to investigate a number of possible predictors for nonparticipation and dropout in an RCT for those with a negative birth experience and/or posttraumatic stress following childbirth (32). The main objective was to investigate demographic, antepartum, and labour-/postpartum related predictors for the following events a) non-participation (eligible women who did not give written consent), b) pre-treatment dropout (i.e., dropout prior to intervention, but after having given informed consent), c) treatment dropout (i.e., dropout during treatment), and d) loss to follow-up (i.e., those who did

not complete follow-up measures).

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	8
1	Methods
2	The STROBE cohort reporting guidelines were used for this publication (33).
3	Patient and public involvement
4	Patients or the public were not involved in the design, or conduct, or reporting, or
5	dissemination plans of this study.
6	
7	Study design
8	Investigation of single predictors for non-participation, pre-treatment dropout, treatment
9	dropout and loss to follow up, reflecting four consecutive time points (about 8 weeks
10	postpartum, about 10 weeks postpartum, between 10 and 16 weeks postpartum, and after 16
11	weeks postpartum respectively), for all eligible participants in a longitudinal RCT.
12	Participants
13	The current study is a secondary analysis of an RCT for women with negative birth
14	experiences, recruited in routine public health care. Approximately 17,000 women gave birth
15	at <i>anonymised</i> Hospital between September 2013 and February 2018, and a majority ( $n =$
16	1,203) rated their overall birth experience on a Likert scale (0–10), as a standard procedure
17	before discharge. Eligible women ( $n = 1,523$ ) had a negative birth experience (defined as $\leq 5$
18	on the Likert scale), and/or an immediate caesarean section, and/or a severe postpartum
19	haemorrhage ( $\geq$ 2,000 ml). Of 1,523 eligible women, about 20% (n = 300) gave written
20	consent to be part of the RCT (32). The 1,523 eligible women had a mean age of 31.5 years
21	(SD = 5.03), participants in the RCT study were 31.7 (4.6) years, and the non-participants age
22	were 31.4 (5.1) years; the majority reported being married or having a partner (84.6 %, $n =$
23	1,291), and 50.8% ( $n = 775$ ) had a university degree. Data on eligible participants are
24	presented in Table 1.

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2	Table	1

# Demographics for the eligible participants (total sample) consisting of those who participated

4	and the	non-participants.
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	Total	Participants	Non-participants
	<i>n</i> =1523	<i>n</i> =300	<i>n</i> =1223
	n(%)	n(%)	n(%)
elationship status			
Married/cohabit	1291 (95.1)	286 (21.1)	1005(74.1)
Single/other	66 (4.9)	8 (0.6)	58(4.3)
Education			
Elementary school	72(5.4)	1 (0.1)	71(5.3)
High school	489(36.6)	82 (6.1)	407(30.5)
University	775(58.0)	209 (54.2)	566(42.4)
Country of birth			
Sweden	953 (76.7)	261 (21)	692 (55.7)
Foreign born	289 (23.3)	25 (2)	264 (21.3)

6 of birth.

## 8 Sample size and power

9 There was no specific sample size calculation for this investigation other than the sample size
10 estimation for the RCT (21) (power was set to 0.8 with a medium effect size) where a total
11 sample size of 130 was needed.
12

9 13 **Procedure** 

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3 4	1	Women rated their birth experience as a routine measure at the hospital before
5	2	discharge. Those with negative birth experiences were contacted via telephone, about eight
7 8 9	3	weeks postpartum. During the telephone calls, the women were informed about the study and
) 10 11	4	those interested in participating were sent study information and a consent form by post.
12 13	5	Those who declined at this stage ( $n = 693$ ) were asked about their reason for doing so. In total
14 15 16	6	530 eligible women did not respond to the invitation, 300 women gave written consent
17 18	7	(participants) and 1,223 did not (non-participants). Of the 300 participants, 101 never
19 20	8	completed baseline measures (pre-treatment dropouts). The participants who filled out the
21 22	9	baseline questionnaires ( $n = 199$ ) were randomized to either treatment as usual (TAU, $n =$
23 24 25	10	100) or iCBT+TAU ( $n = 99$ ). The iCBT treatment consisted of six treatment modules
26 27	11	including psychoeducation and interventions, with therapist support on demand, tailored for
28 29	12	women with negative experiences of childbirth (see Appendix 1) (21). Regardless of
30 31 32	13	treatment allocation, local health care providers in accordance with international guidelines
32 33 34	14	treated all participants in the study. TAU included conventional support in accordance with
35 36	15	the existing practices at the Department of Obstetrics and Gynecology of the participating
37 38	16	hospital. Of the 99 allocated to treatment, a total of 41 were treatment completers (at least
39 40 41	17	three of six steps completed) and 58 were treatment dropouts. All randomized participants
42 43	18	(199) were asked to fill out questionnaires six weeks post randomization; 121 completed the
44 45 46	19	follow-up measures and 78 were lost to follow-up, please see figure 1.
47 48	20	Figure 1 about here

Material

Based on previous knowledge about possible causes for non-participation and dropout, predictor variables were categorized into three conceptual categories (demographic, antepartum, and labour-/postpartum related variables). Obstetric data were extracted from

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1	each participant's medical records and questionnaire information was taken from the
2	anonymised database. The Care Base Internet Platform, including its web-based part
3	(anonymised), was developed within the anonymised program. The aim of the anonymised
4	research program is to prevent and reduce psychosocial malfunctioning in patients and
5	relatives. The anonymised eService is currently being used for interventions and data
6	collection http://www. anonymised
7	Demographic variables
8	Country of birth (born in anonymised /foreign-born), level of education (university/high
9	school/elementary school), relationship status (married/partner or single/other status), and age
10	at delivery (years).
11	Antepartum variables
12	Previous caesarean section (no/yes), counselling for fear of childbirth (no/yes),
13	preeclampsia during pregnancy (International Classification of Disease 10th revision (ICD-10
14	code O14; no/yes), length of pregnancy (number of days based on second trimester
15	ultrasound), and parity (first child/second child/third child or more).
16	Labour-related/postpartum variables
17	Mode of delivery (vaginal delivery/emergency caesarean section/immediate caesarean
18	section/vacuum-assisted delivery/elective caesarean section), foetal presentation (vertex
19	presentation/others), manual placenta removal (ICD-10 code O73; no/yes), epidural
20	anaesthesia (ICD-10 code ZXH50; no/yes), intrapartum foetal distress (ICD-10 code O68;
21	no/yes), anal sphincter injury (ICD-10 code O70; no/yes), labour dystocia (ICD-10 code O62;
22	no/yes), severe postpartum haemorrhage ( $\geq$ 2,000 ml; no/yes), anaemia (ICD-10 code D59;
23	no/yes), blood transfusion (ICD-10 code Z51.3; no/yes), number of children in the pregnancy
24	(one/two or more), child transferred to neonatal intensive care unit (NICU; no/yes),

3 4	1	breastfeeding problems (ICD-10 code O92; no/yes) and overall birth experience (more severe
5 6	2	0-2 vs. less severe 3-5).
7 8	3	Dependent variables
9 10 11	4	Non-participation ( $n = 1,223$ ) vs participation ( $n=300$ ): eligible women who did not /
12 13	5	did return a signed informed consent form.
14 15 16	6	Pre-treatment dropouts ( $n = 101$ ) vs pre-treatment completers ( $n=199$ ): women who
10 17 18	7	gave written consent but did not / did proceed to complete the baseline measurements.
19 20	8	Treatment dropouts ( $n = 58$ ) vs treatment completers ( $n=41$ ): women in the iCBT arm
21 22 22	9	who reported activity in 0 to 2 treatment steps of the treatment vs 3 to 6 treatment steps.
23 24 25	10	Lost to follow-up ( $n = 78$ ) vs completed follow-up: all randomized women in either
26 27	11	treatment arm (iCBT+TAU and TAU) who never completed the post-treatment measures vs
28 29	12	those who completed them $(n = 121)$ .
30 31 32	13	Statistical analysis
33 34	14	Logistic regression was used to determine predictors of non-participation, pre-treatment
35 36	15	dropout, treatment dropout, and loss to follow-up. Odds ratios with 95% confidence intervals
37 38 39	16	and beta values including SE are reported. Missing data were not handled. All available data
40 41	17	was used leading to slight differences regarding number of participants in the analyses.
42 43	18	Reasons given for non-participation were categorized. SPSS version 26 was used for all
44 45 46	19	analyses.
47 48 49	20	Ethics
50 51	21	The Regional Ethics Review Board in anonymised approved the study (2012/495/1 and
52 53 54 55 56 57 58 59	22	amendment 2016/11/16).
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#### **Results**

#### Predictors of non-participation

Women with lower levels of education, multiparas and foreign-born were more often non-participants (Table 2). Women who had not been counselled for fear of childbirth, no preeclampsia during pregnancy, no sphincter injury, no intrapartum foetal distress, and those ikely t. with vaginal delivery were more likely to decline participation, please see Table 2 (and Table

A2 for  $\beta$ ,SE).

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$\begin{array}{ccc} 3 & 1 \\ 4 & 2 \end{array}$	Table 2.	. 10	1	, , <b>.</b>	1 1 .		clud		
5 2	Odds ratio with 95% CI de	erived from	1 logistic regression fo	or potentia	al predictors	T	in 28	т	· · · C 11
6		NC N	on-participants	Pre-tro	eatment dropout $OP 05\%$ CI	l re	on 05 %	L( N	OB $05\%$ CI
7		IN 1224	OK 95% CI	<u>IN</u> 294	0R 95% CI	<u>IN</u>		IN 100	000000000000000000000000000000000000
8	Country of birth	1234	3.93(2.38-6.13)****	284	1.09(0.45-2.64)	98	1.43 (0.3%	198	1.8/(0.69-5.08)
9 10	Sweden/ouner	1226		239/23		89/9 00	elat	101/1/	
11		1330	10	290	1.0	99 71		199	1.0
12	University High school	190	1.0	200	1.0	/1 27		140 50	1.0 1.22(0.60, 2.55)
13	Fign school	489	$1.03(1.30-2.44)^{1.1}$	01	1.33(0.89-2.02)	27 1	1.32(0.30-0.26)	30 1	1.33(0.09-2.33)
14 15	Belationship status	12	20.2(3.02-189.9)****	1	na	1	nanc	1 107	na
15 16	married ashabit/ather	1201/66	2 06(0 07 1 27)	292	1 25(0 20 5 25)	97	ded	197	20
17		1291/00	2.00(0.97-4.57)	200	1.23(0.29-3.33)	93/2		100	11a
18	Age, years	1202/100	0.99(0.90-1.01) 0.90(0.52, 1, 10)	21/264	0.97(0.92 - 1.02) 0.78(0.26, 1.68)	99		199	0.93(0.89-1.02) 0.97(0.22, 2.22)
19	Courselling for for of	1502/189	0.80(0.53-1.19)	200	0.78(0.30-1.08)	89/9	1.42(0.3 <b>3-9</b> .90) G· <del>G</del>	1///19	0.8/(0.33-2.32)
20	Counselling for fear of	1525	0 50(0 25 0 72)***	300	1 0((0 55 2 05)	99		10/20	0.99(0.20, 1.07)
21	Childbirth, no/yes	13/0/14/	$0.50(0.35-0.73)^{***}$	254/46	1.06(0.55-2.05) 1.20(0.51,2.95)	8//12	0.08(0.18-2.32)	109/30	0.88(0.39-1.97)
22	Preeclampsia, no/yes	1440/83	$0.59(0.30-0.96)^{*}$	2/6/24	1.20(0.51-2.85)	90/9	1.40(0.33-0.32)	184/15	1.39(0.48-4.00)
24	Pregnancy, days	1507	1.00(0.99-1.00)	299	0.99(0.98-1.01)	99	1.01(0.98-1.94)	198	1.00(0.98-1.02)
25		1505	1	299		99		198	1
26	1 <sup>st</sup> Child	838		200		68		134	I 1.07(0.54.2.10)
27	2 <sup>nd</sup> child	448	$1.65(1.22-2.22)^{**}$	/1	0.9/(0.55-1.73)	22	1.80(0.63-4.96)	48	1.0/(0.54-2.10)
28 20	3 <sup>rd</sup> child or more	219	2.15(1.40-3.30)***	28	1.52(0.68-3.40)	9	1.68(0.39-7.26)	10	1.63(0.58-4.60)
30	Mode of delivery	1523	1	300	1	99	chn	199	1
31	Vaginal delivery	/83		129	I 1 0(0 54 1 00)	40		82	
32	Emergency CS	289	0./1(0.51-1.0)	63	1.0(0.54-1.88)	20	0.33(0.10-1.03)	40	0./4(0.34-1.58)
33	Immediate CS <sup>1</sup>	186	$0.54(0.3/-0.79)^{**}$	49	0.63(0.30-1.30)	19	$0.19(0.0640.63)^{**}$	36	$0.42(0.18-0.99)^{*}$
34 25	Vacuum assisted	198	0.62(0.43-0.91)*	48	0.96(0.48-1.91)	15	0.29(0.84 - 1.91)	31	$0.26(0.10-0.71)^{**}$
35 36	Elective CS	67	1.01(0.52-1.99)	11	0.17(0.02-1.41)	5	1.33(0.13-13g3/)	10	2.5/(0.62-10.65)
37	Foetal presentation	1510		300	0.52(0.25.1.12)	99		199	1.00(0.(1.0.70)
38	Vertex / other	1287/223	1.02(0./1-1.46)	256/44	0.53(0.25-1.13)	82/17	0.31(0.11-0.94)*	165/34	1.28(0.61-2.70)
39	Manual placenta removal	1523		300		99	liog	199	
40							jrap		
41 42							ohiq		
43			_ · ·	1			lue		
44			For peer review only -	nttp://bm	jopen.bmj.com/site/al	bout/guid	aeiines.xntml <b>de</b>		

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				1		-2022-063 pyright,		
no / yes Epidural anaesthesia	1379/144 1523	1.41(0.88-2.26)	278/22 300	0.42(0.14-1.26)	93/6 99	0.33(0.08-1.90)	181/18 199	0.99(0.36-2.66)
no / yes Intrapartum foetal distress	813/710 1523	0.86(0.67-1.10)	151/149 300	1.12(0.69-1.80)	49/50 99		102/97 199	1.52(0.86-2.70)
no / yes Anal sphincter injury	1234/289 1523	0.67(0.50-0.91)*	228/72 300	0.76(0.43-1.36)	71/28 99	0.50(0.2 <sup>55</sup> – 55 – 55 – 55 – 55 – 55 – 55 – 55	148/51 199	0.50(0.25-0.99)*
no / yes Labour dystocia	1447/76 1523	0.48(0.29-0.79)**	275/25 300	0.92(0.38-2.21)	88/11 99	1.27(0.3 20 20 20 20 20 20 20 20 20 20 20 20 20	182/17 199	1.09(0.40-3.00)
no / yes Severe haemmorhage <sup>1</sup>	885/638 1523	0.87(0.67-1.11)	166/134 300	1.26(0.78-2.04)	55/44 99	0.74(0.355-0056) ar upper	114/85 199	0.75(0.42-1.34)
no / yes Anaemia	1329/194 1523	1.19(0.80-1.76)	266/34 300	0.38(0.15-0.96)*	83/16 99	0.49(0.15 rei add dat ed ta A fr	171/28 199	1.00(0.44-2.28)
no / yes Blood transfusion	1274/249 1523	0.85(0.61-1.18)	246/54 300	0.57(0.29-1.12)	79/20 99		158/41 199	0.66(0.32-1.38)
no / yes Children in the pregnancy	1340/183 1508	1.01(0.69-1.49)	265/35 299	0.65(0.29-1.45)	87/12 99	0.31(0.09-1.09) A tra	173/26 198	0.53(0.21-1.32)
Child transferred to NICU	14/6/32 1523	1.35(0.52-3.55)	294/5 300 241/50	0.48(0.05-4.40)	97/2 99 78/21		194/4 199 162/27	0.51(0.05-4.96)
Breastfeeding problems	1235/208 1523 1505/18	0.85(0.00-1.14)	300 296/54	0.65(0.07-6.36)	99 98/1		102/37 199 196/3	0.77(0.07-8.67)
Overall birth experience <sup>1</sup> 0-2/3-5	1203 305/898	1 02(0 74-1 42)	234 58/176	0.72(0.38-1.35)	72 20/52	0 27(0 0920 79)*	148 40/108	0.90(0.43-1.88)
1 <sup>1</sup> inclusion criteria. 2 * p<.05, **p<.01, ***p 3 4 5	<.001	For peer review only	- http://bmj	jopen.bmj.com/site/ał	bout/guid	elines.xhtml		0.50(0.15 1.00)

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2 3 4	1	Reasons why women declined to take part despite eligibility.	
5 6	2	Of the contacted women, 693 actively declined participation and their	answers were
7 8	3	categorized into different subgroups (Table 3).	
9 10 11	4		
12 13	5	Table 3.	
14 15	6	Reasons for non-participation ( $n = 693$ ) given during telephone interview ei	ght weeks
16 17 18	7	postpartum	
19 20		Reason for non-participation	Ν
21 22		Feels fine, does not need any support	326
23 24		Does not speak Swedish	134
25 26		Not interested (no further information)	77
27 28		Feels fine, has already received professional support	35
29 30 21		Does not feel fine, receiving/waiting for other professional support	35
32 33		Does not have the time	30
34 35		Does not have a computer	16
36 37		Not interested, will not have more kids anyway	14
38 39		Not interested, does not want to think about the delivery	13
40 41		Misunderstood the Likert scale (inclusion), had a positive experience	10
42 43		Not comfortable with internet/computer, prefers face-to-face therapy	3
44 45 46	8		
40 47 48	9		
49 50	10	Predictors of pre-treatment dropout	
51 52	11	The only significant predictor of pre-treatment dropout was no severe	postpartum
53 54 55	12	haemorrhage (i.e., less than 2000 ml; Table 2).	
56 57 58 59 60	13	Predictors of treatment dropout	

Table 3.		
Reasons for non-participation ( $n = 693$ ) given during telephone interview effects	ght weeks	
postpartum		
Reason for non-participation	Ν	%
Feels fine, does not need any support	326	(47)
Does not speak Swedish	134	(19)
Not interested (no further information)	77	(11)
Feels fine, has already received professional support	35	(5)
Does not feel fine, receiving/waiting for other professional support	35	(5)
Does not have the time	30	(4)
Does not have a computer	16	(2)
Not interested, will not have more kids anyway	14	(2)
Not interested, does not want to think about the delivery	13	(2)
Misunderstood the Likert scale (inclusion), had a positive experience	10	(1.4)
Not comfortable with internet/computer, prefers face-to-face therapy	3	(0.4)

- s of pre-treatment dropout
  - only significant predictor of pre-treatment dropout was no severe postpartum age (i.e., less than 2000 ml; Table 2).
  - s of treatment dropout

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For those randomized to the treatment group, dropout was significantly predicted by mode of delivery, foetal presentation, and overall birth experience (Table 2). Participants with vaginal delivery, vertex presentation and less severe overall birth experience were more likely to drop out from treatment.

Predictors of loss to follow-up

In the analyses of loss to follow-up, absence of intrapartum foetal distress and vaginal delivery (compared with immediate CS and vacuum delivery) predicted loss to follow up (Table 2). An additional analysis showed that being randomised to iCBT+TAU was a significant predictor of loss to follow up OR = 1.84 (95 % CI: 1.04-3.28), B=0.61, SE=0.29, p= .037, where 46 of 99 in iCBT+TAU and 32 of 100 in TAU were lost to follow up.

#### Discussion

The current study provides an explorative analysis of predictors for non-participation and drop out at different timepoints in an RCT examining iCBT for women with negative birth experiences and/or posttraumatic stress following childbirth (21). Significant predictors for non-participation and dropout were found at different stages in the recruitment process of an RCT. Women with higher education level, without previous children and those born in anonymised were more likely to enter into the study. Thereafter, women who had been counselled for fear of birth, experienced complications during the childbirth and with an overall severe birth experience were more likely to stay in the study.

A majority (80.3%) of the eligible women declined participation and our first
conclusion was that a large number of those eligible did not see themselves as being in need
of iCBT or wanted to take part in a clinical trial. When they were contacted by telephone
during the recruitment period, the most frequent reason for declining was "I feel fine/have no

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need of any support." Explanations could be that the cut-off for the screening instrument was over-inclusive and/or that the other inclusion criteria (immediate caesarean section and severe postpartum haemorrhage) did not necessarily result in a negative birth experience. The content validity of the one-item Likert scale in the current trial could be discussed, as women may take different aspects of their birth experience into account. Also, the time-point for the rating could be discussed. In the current trial, all women rated their birth experience shortly after giving birth; it is difficult to determine the timepoint that would yield the most accurate rating of the birth experience. However, using a Likert scale as a tool for self-assessment of overall birth experience is well-established in clinical practice and used in research (34,35). A person's perception of their birth experience can change over time and it is important to consider the specific timepoint used in measurement (33). Larsson et al. (36) used a VAS scale (range 1–10) for self-assessment of birth experience at two days, three months, and nine months postpartum. They found that the participants' negative birth experiences decreased over time and suggested that use of a VAS scale was an adequate way to find women in need of follow-up after a negative birth experience. The analysis included the inclusion criteria (immediate caesarean section, overall birth experience, and severe haemorrhage) as predictors. Non-participation was predicted by vaginal delivery vs. immediate caesarean section. Childbirth without severe haemorrhage predicted pre-treatment dropout. It is known that severe postpartum haemorrhage is a significant risk factor for developing PTSD (37,38). Treatment drop out was predicted by a less severe overall birth experience and vaginal delivery vs. immediate CS. These predictors were inclusion criteria and should be interpreted with caution as mentioned above. The results regarding these predictors must therefore be interpreted with caution. However, the results might be useful for future hypothesis in further research. The three inclusion criteria in this

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study are experiences that potentially can have serious effects on the mental health of a birth

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giving woman. It may be of value to understand more about what type of care (e.g.,

counselling, therapy), what type of format (e.g., face to face or ICBT) and what level of support (therapist support or pure self-help) is demanded. Three socio-demographic variables predicted non-participation: lower level of education, multiparity, and being foreign-born. Lower level of education as a greater risk for dropout is consistent with dropout in other iCBT trials (16). Multiparity was also identified as an important predictor of non-participation. The physical and psychological changes of the postpartum period are challenging for first-time mothers and they have lower levels of maternal confidence and higher levels of stress compared with multiparous women (39), which might increase their likelihood of participation. An alternative explanation is that multiparous women have less time to commit to clinical trials compared with first-time mothers. This trial's intervention addressed Swedish-speaking women; foreign-born women might see language as a barrier to participation. Five antepartum and labour-related/postpartum variables also predicted nonparticipation. Women without experience of the following were more likely to be non-participants; counselling for fear of childbirth, preeclampsia, anal sphincter injury, intrapartum foetal distress, and vacuum-assisted delivery (vs. vaginal delivery). Women who had been counselled for fear of childbirth had already professionally addressed peripartum psychological problems and might therefore have been more open to support. Preeclampsia, intrapartum foetal distress, and anal sphincter injuries are all severe conditions and motivators for participation. Preeclampsia and severe postpartum haemorrhage are significant threats to the mother and may have devastating or lethal outcomes. Further, both preeclampsia and intrapartum foetal distress are potential threats to the health of the foetus, thus acting as significant stressors for the woman. Instrumental deliveries may be caused by emergency obstetric complications potentially threatening the mother or the child and are very stressful

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situations for the woman in their own right (30). The labour related / post-partum predictors
 show a consistent pattern where women who did not experience these stressful events may not
 have had enough motivation to seek out help or support.

Pre-treatment dropout was predicted by the absence of severe haemorrhage which is mentioned above. Vertex foetal presentation (vs. other presentation) predicted treatment dropout. This is consistent with the significant predictors for non-participation where those with vertex presentation might not experience this as a stressful event enough to stay in the treatment. It might also be that those with vertex presentation who were randomized to the treatment did not find it helpful or that it did not address their problem fully in order to stay in the treatment.

Predictors for loss to follow-up were vaginal delivery vs. instrumental delivery and absence of intrapartum foetal distress. Occurrence of such events are threats to the foetus which in turn can be very stressful for the mother. Absence of these events might lead to lost interest in devoting time and energy to proceed with the follow-up assessment. Absence of immediate CS was also a significant predictor of loss to follow up and is discussed in relation to the other inclusion criteria/predictors. Finally, randomisation to iCBT+TAU (compared with TAU) was a significant predictor of lost to follow up. A majority of those who were lost to follow up from the iCBT+TAU group were also those who were treatment droputs.

19 Closer inspection of variables associated with non-participation and dropout can yield 20 insights that can be used in both future research and clinical practice. Knowledge of sub-21 groups that are more likely to continue and complete study participation provides information 22 about motivational factors and should be applied during the initial recruitment for similar 23 trials. Participants where not asked why they dropped out. We believe that dropout can 24 depend on different factors such as lack of energy and/or interest of being part of a clinical

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trial; dropout can also depend on the participant's experience of not needing the intervention anymore. In this trial women with lover level of education, multipara and foreign born where more often non-participants, perhaps the way of inclusion and the intervention itself must be better adapted to attract those sub-groups in the future. Translation to other languages, using simple language and pictorial material could be ways of improving adherence.

Analyses of predictors of non-participation and dropout are important for evaluating the
efficacy of the interventions (6). This explorative study found predictors of non-participation
and dropout that should be taken into account in future development of similar interventions.
Awareness of characteristics among women who drop out and those who continue, and
complete interventions is important and should get more attention during initial recruitment
for similar trials.

#### 12 Strengths

The current study is the first to present data on non-participation and dropouts in iCBT for women with negative birth experiences and/or posttraumatic stress following childbirth. The main strength of this study was the size of the sample and the routine public health care setting as well as consecutive recruitment. All women who gave birth were asked to rate their birth experience on a self-assessed Likert-scale and all women with a low rating were invited. This process increased the likelihood of the results being generalizable to similar clinical contexts. The exploration of dropout predictors from a large cluster of demographic variables and medical/clinical characteristics was another strength. A third strength was that reasons for dropout were explored at different stages in the study process, which allowed analysis of specific timepoints when participants were more likely to end their participation. Analyses of different timepoints for dropout could simplify the analyses of underlying reasons for withdrawal (9). Limitations

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Our study has several limitations that should be noted. Psychological problems and/or treatment-related variables were not available for analyses. Such variables are likely to be strong predictors of non-participation and dropout (9) and should be integrated in future studies. Neither discomfort with the internet or computers were analysed as factors for non-participation or dropout in the current trial. The impact of computer-related factors on adherence has been described previously (17). Further, recruitment to the study was before discharge from the hospital when the experience of birth is fresh. Thus, the eligible sample might have been different if we had asked them at a later time point. However, the assessment of the birth experience was in close conjunction to immediate CS and severe haemorrhage (the two other inclusion criteria). Conclusions In this sample, drawn from a large population, predictors were found for nonparticipation and dropout at different stages in the recruitment process and during the study of an RCT. In summary, both demographic and obstetrical variables are important to attend to for both clinical and research purposes, while designing procedures to maximize participation in iCBT for postpartum women. First time mothers with high level of education and those who had adverse obstetric experiences were more likely to join and stay in the internet intervention. **Conflicts of Interest** All authors of this manuscript declare No known competing interest. **Authorship Contribution statement** All listed authors fulfil ICMJE authorship criteria. Author abbreviations are found in brackets

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after type of contribution. Writing - original draft (JS), Writing - review & editing (JS, ASS,

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> FV, ML, ISP, AS, MJ, TP), Conceptualization (ASS, ML, ISP, AS, MJ, TP), Methodology (ASS, ML, ISP, AS, MJ, TP), Formal analysis (JS, ASS, FV, AS, TP), Investigation (JS, ASS, FV, ML, MJ), Data curation (JS, ASS, FV, ML, ISP, AS, MJ, TP), Supervision (ASS, ML, TP), Funding acquisition (ASS, MJ), and Project administration (ASS, ML, ISP, MJ). TP is the guarantor. **Transparency** The manuscript's guarantor affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as originally planned have been explained. **Funding.** This project was funded by The Regional Research Council (Regionala Forskningsrådet, RFR) grants nr 368901, 308451, and 480141; http://www.researchweb.org/ is/sverige) and Swedish research council funding for clinical research in medicine (ALF) grants nr N/A. Role of the funding sources The funders of the study had no influence on the study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the article for publication. All authors confirm the independence from funders and all authors, external and internal, had full access to all of the data (including statistical reports and tables) in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. **Data sharing** is available on reasonable request from researchers who provide a methodologically sound proposal. Individual participant data that underlie the results reported in this article, after deidentification will be shared. Proposals should be directed to agneta.skoog\_svanberg@kbh.uu.se . To gain access, data requestors will need to sign a data access agreement.

1		8
2 3 4	1 2	
5 6 7	3	Abbreviations
8 9	4	ICD-10: International Classification of Disease 10th revision
10 11 12	5	iCBT: Internet-based cognitive behavior therapy
12 13 14	6	RCT: Randomized controlled trial
$\begin{array}{c} 14\\ 15\\ 16\\ 17\\ 18\\ 19\\ 20\\ 21\\ 22\\ 23\\ 24\\ 25\\ 26\\ 27\\ 28\\ 29\\ 30\\ 31\\ 32\\ 33\\ 34\\ 35\\ 36\\ 37\\ 38\\ 39\\ 40\\ 41\\ 42\\ 43\\ 44\\ 45\\ 46\\ 47\\ 48\\ 49\\ 50\\ 51\\ 52\\ 53\\ 54\\ 55\\ 56\\ 57\\ 58\\ 59\\ 60\\ \end{array}$	7 8 9	TAU: Treatment as usual

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17 18	9	
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25 26 27	13	Figure caption.
28 29	14	
30 31 32	15	Figure 1. Flowchart
33 34 35		
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Figure 1. Flowchart

# Appendix 1 Week by week content of the iCBT treatment

Week	Content
1st	Information, psychoeducation, breathing retraining
2nd	Vignettes, common symptoms, fear and avoidance
3rd	Depressive symptoms, significance of relations, "reflective listening"
4th	Exposure, talking about the childbirth
5th	Managing anxiety and depressive symptoms, psychological health, values, recovery
6th	Summary, repetition and relapse prevention

Note. Every week contains homework assignments based on the content of the module

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<u>Beta values.</u> Nc N	, and SE derived from	logistic r			⊩2022-063214 oi opyright, includ						
Beta values, Nc N	, and SE derived from	logistic r			<b>—</b> • <b>—</b>						
NC N	Odds ratio with 95% CI, Beta values, and SE derived from logistic regression, for potential predictors										
IN	Non-participants		N OR 95% CI				c to follow up				
	<i>B</i> , S.E	IN	<i>B</i> , S.E	IN		IN	<i>B</i> , S.E				
1234 953/281	3.93(2.58-6.15)*** 1.38, 0.22	284 259/25	1.09(0.45-2.64) 0.09, 0.45	98 89/9	1.43 (0.35, 9, 74) 0.35, 9, 74	198 181/17	1.87(0.69-5.08 0.63, 0.51				
1336		290		99	ownl Sup	199					
775	1.0	208	1.0	71	and erieu	148	1.0				
489	1.83(1.38-2.44)*** 0.61, 0.15	81	1.53(0.89-2.62) 0.43, 0.28	27	1.32(0.5	50	1.33(0.69-2.5 0.28, 0.33				
72	26.2(3.62-189.9)*** 3.27, 1.01	1	na	1	http:// niag. A	1	na				
1357 1291/66	2.06(0.97-4.37) 0.72, 0.38	292	1.25(0.29-5.35) 0.256, 0.74	97 95/2	ntainin	197 192/5	na				
1510	0.99(0.96-1.01) -0.12, 0.013	300	0.97(0.92-1.02) -0.034, 0.86	99	0.95(0.8 -1.95) -0.52, -0.52	199	0.95(0.89-1.02 -0.048, 0.03				
1491 1302/189	0.80(0.53-1.19) -0.23, 0.21	295 31/264	0.78(0.36-1.68) -0.25, 0.39	98 89/9	1.42(0.3 <b>5</b> -6. <b>6</b> 6) 0.35, <b>9</b> .7 <b>4</b>	196 177/19	0.87(0.33-2.32 -0.14, 0.50				
1523 1376/147	0.50(0.35-0.73)*** -0.69, 0.19	300 254/46	1.06(0.55-2.05) 0.06, 034	99 87/12	0.68(0.18-2.52) -0.40,8.62	199 169/30	0.88(0.39-1.9 <sup>°</sup> -0.13, 0.41				
1523 1440/83	0.59(0.36-0.96)* -0.53, 0.25	300 276/24	1.20(0.51-2.85) 0.18, 0.44	99 90/9	1.46(0.39-6.22) 0.38, 0.745	199 184/15	1.39(0.48-4.00 0.33, 0.54				
1507	1.00(0.99-1.00) -0.003, 0.004	299	0.99(0.98-1.01) -0.008, 0.008	99	1.01(0.98-1. <b>0</b> 4) 0.01, 0.01	198	1.00(0.98-1.02 0.002, 0.01				
1505		299		99	се В	198					
838	1	200	1	68	1 1	134	1				
	1234 953/281 1336 775 489 72 1357 1291/66 1510 1491 1302/189 1523 1376/147 1523 1440/83 1507 1505 838	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$	$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	1294       3.95(2.36-0.15)**       254       1.09(0.45-2.04)       96       1.43 (0.50, 145)         953/281       1.38, 0.22       259/25       0.09, 0.45       89/9       0.35, 0.76, 0.76         1336       290       99       99       97       1.64 (0.54, 145)       1.64 (0.54, 145)         489       1.83(1.38-2.44)***       81       1.53(0.89-2.62)       27       1.32(0.54, 145)         72       26.2(3.62-189.9)***       1       na       1       ngg.         72       3.27, 1.01       .043, 0.28       0.28, 0.74       95/2         1510       0.99(0.96-1.01)       300       0.97(0.92-1.02)       99       0.95(0.84, -1.95)         1510       0.99(0.96-1.01)       300       0.97(0.92-1.02)       99       0.95(0.84, -1.95)         1491       0.80(0.53-1.19)       295       0.78(0.36-1.68)       98       1.42(0.33, 6.66)         1302/189       -0.23, 0.21       31/264       -0.25, 0.39       89/9       0.35, 97, 74         1523       0.50(0.35-0.73)***       300       1.06(0.55-2.05)       99       0.68(0.10, 2, 52)         1376/147       -0.69, 0.19       254/46       0.06, 0.34       87/12       -0.40, 30, 64         1507       1.00(0.99	1294       339(2.38-0.13)       1284       1.09(0.43-2.04)       98       1.43 (0.24 million)       198         953/281       1.38, 0.22       259/25       0.09, 0.45       89/9       0.35, 0.46       181/17         1336       290       99       99       199       199         775       1.0       208       1.0       71       1.de test       148         489       1.83(1.38-2.44)***       81       1.53(0.89-2.62)       27       1.32(0.53-448)       50         72       26.2(3.62-189.9)***       1       na       1       ng.       1       1         1357       2.06(0.97-4.37)       292       1.25(0.29-5.35)       97       nat       197         1291/66       0.72, 0.38       0.256, 0.74       95/2       192/5       199       -0.12, 0.013       -0.034, 0.86       -0.52, 9.05       199         1491       0.80(0.53-1.19)       295       0.78(0.36-1.68)       98       1.42(0.32-6.66)       196         1302/189       -0.23, 0.21       31/264       -0.25, 0.39       89/9       0.35, 9.74       177/19         1523       0.59(0.36-0.96)*       300       1.20(0.51-2.85)       99       0.46(0.37-6.82)       199				

Page 33 of 37					BMJ Open		jopen-202 1 by copyr		
1 2 3 4	2 <sup>nd</sup> child	448	1.65(1.22-2.22)** 0.50_0.15	71	0.97(0.55-1.73)	22	ig 2-06321 1.80(0.622-4.196) 0.58 dat 529	48	1.07(0.54-2.10) 0.06 0.34
5 6 7	3 <sup>rd</sup> child or more	219	2.15(1.40-3.30)*** 0.77, 0.081	28	$\begin{array}{c} 0.20, 020 \\ 1.52(0.68 - 3.40) \\ 0.42, 0.41 \end{array}$	9	1.68(0.3 <b>9</b> -7. <b>2</b> 6) 0.52, <b>0</b> .7 <b>2</b>	16	1.63(0.58-4.60) 0.49, 0.53
8	Mode of delivery	1523		300		99	embo Ses r	199	
9 10	Vaginal delivery	783	1	129	1	40	elat 20	82	1
11 12 13	Emergency CS	289	0.71(0.51-1.0) -0.34, 0.17	63	1.0(0.54-1.88) 0.003, 0.32	20	0.33(0.1 - 1.1, g. 50) -1.1, g. 500	40	0.74(0.34-1.58) -0.31, 0.39
14 15	Immediate CS <sup>1</sup>	186	0.54(0.37-0.79)** -0.61, 0.19	49	0.63(0.30-1.30) -0.46, 0.37	19	0.19(0.06) -1.64, a) and a	36	0.42(0.18-0.99)* -0.86, 0.43
16 17 18	Vacuum assisted	198	0.62(0.43-0.91)* -0.475, 0.19	48	0.96(0.48-1.91) -0.04, 0.35	15	0.29(0.8 - 1.23, - 1.2	31	0.26(0.10-0.71)** -1.33, 0.51
19 20	Elective CS	67	1.01(0.52-1.99) 0.01, 0.34	11	0.17(0.02-1.41) -1.75, 1.06	5	1.33(0.13 37) 0.29, 1.18	10	2.57(0.62-10.65) 0.95, 0.73
21	Foetal presentation	1510	1.02(0.71-1.46)	300	0.53(0.25-1.13)	99	0.31(0.1 🔄 0.🚰)*	199	1.28(0.61-2.70)
22 23	Vertex / other	1287/223	0.20, 0.18	256/44	-0.63, 0.38	82/17	-1.16, 🗐 .5 👸	165/34	0.24, 0.38
24 25 26	Manual placenta removal no / yes	1523 1379/144	1.41(0.88-2.26) 0.346, 0.24	300 278/22	0.42(0.14-1.26) -0.88, 0.57	99 93/6	0.33(0.0g-1.90) -1.11,9.88	199 181/18	0.99(0.36-2.66) -0.014, 0.51
27 28 29	Epidural anaesthesia no / yes	1523 813/710	0.86(0.67-1.10) -0.15, 0.13	300 151/149	1.12(0.69-1.80) 0.11, 024	99 49/50	0.95(0.4 -0.049	199 102/97	1.52(0.86-2.70) 0.42, 0.29
30 31 22	Intrapartum foetal distress no / yes	1523 1234/289	0.67(0.50-0.91)* -0.39, 0.15	300 228/72	0.76(0.43-1.36) -0.27, 0.29	99 71/28	0.50(0.2 + 1.21) -0.69 @.4 *	199 148/51	0.50(0.25-0.99)* -0.70, 0.36
33 34	Anal sphincter injury no / yes	1523 1447/76	0.48(0.29-0.79)** -0.73, 0.25	300 275/25	0.92(0.38-2.21) -0.82, 045	99 88/11	1.27(0.35-4.66) 0.24, 0.66	199 182/17	1.09(0.40-3.00) 0.09, 0.52
35 36	Labour dystocia	1523	0.87(0.67-1.11)	300	1.26(0.78-2.04)	99	0.74(0.33-1 <b>.§</b> 6)	199	0.75(0.42-1.34)
37	no / yes	885/638	-0.14, 0.13	166/134	0.23, 0.25	55/44	-0.3, 0.41	114/85	-0.29, 0.30
38 39 40 41	Severe haemmorhage <sup>1</sup>	1523	1.19(0.80-1.76)	300	0.38(0.15-0.96)*	99	0.49(0.17-1 <b>:ii</b> 4) ographi	199	1.00(0.44-2.28)
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no / yes	1329/194	0.17, 0.20	266/34	-0.95, 0.47	83/16	-0.72, £0.55	171/28	0.004, 0.42
Anaemia	1523	0.85(0.61-1.18)	300	0.57(0.29-1.12)	99	0.50(0.1 - 1 1 1 1	199	0.66(0.32-1.38)
no / yes	1274/249	-0.16, 0.17	246/54	-0.56, 0.35	79/20	-0.69, <b>@</b> .5 <b>ද</b>	158/41	-0.41, 0.37
Blood transfusion	1523	1.01(0.69-1.49)	300	0.65(0.29-1.45)	99	0.31(0.0 )	199	0.53(0.21-1.32)
no / yes	1340/183	0.011, 0.20	265/35	-0.43, 0.41	87/12	-1.19, a g	173/26	-0.64, 0.47
Children in the pregnancy	1508	1.35(0.52-3.55)	299	0.48(0.05-4.40)	99	nated not	198	0.51(0.05-4.96)
1 child / 2 children	1476/32	0.30, 0.49	294/5	-0.72, 1.12	97/2	to te	194/4	-0.68, 1.16
Child transferred to NICU	1523	0.83(0.60-1.14)	300	1.21(0.67-2.20)	99	0.73(0.2	199	1.07(0.52-2.22)
no / yes	1255/268	-0.19, 0.16	241/59	0.20, 0.30	78/21	-0.32, 2 2	162/37	0.069, 0.37
Breastfeeding problems	1523	0.86(0.28-2.64)	300	0.65(0.07-6.36)	99	ata nata	199	0.77(0.07-8.67)
no / yes	1505/18	-0.15, 0.57	296/54	-0.43, 1.16	98/1	ninii ninii	196/3	-0.26, 1.23
Overall birth experience <sup>1</sup>	1203	1.02(0.74-1.42)	234	0.72(0.38-1.35)	72	0.27(0.0 20.27)*	148	0.90(0.43-1.88)
0-2 / 3-5	305/898	0.023, 0.17	58/176	-0.34, 0.32	20/52	-1.31, 🚽 .5 💆	40/108	-0.11, 0.38
µ<.03, p<.01, p	<.001					.bmj.com/ on June 14, 2025 at Agence Bibliographiqu , and similar technologies.		
		For peer review only	/ - http://bmj	jopen.bmj.com/site/a	bout/guid	elines.xhtml e		
# Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

# **Instructions to authors**

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the STROBE cohortreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

			Page
		Reporting Item	Number
Title and abstract		Internet-based Cognitive Behavior Therapy (iCBT) for women with negative birth experiences and/or posttraumatic stress following childbirth: Prevalence and predictors of non-participation and dropout	
Title	<u>#1a</u>	Indicate the study's design with a commonly used term in the title or the abstract	Title page
Abstract	<u>#1b</u>	Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract page
Introduction			
Background / rationale	<u>#2</u>	Explain the scientific background and rationale for the investigation being reported	5-7
Objectives	<u>#3</u>	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	<u>#4</u>	Present key elements of study design early in the paper	8

		BMJ Open	Page 3
Setting	<u>#5</u>	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Eligibility criteria	<u>#6a</u>	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	8-10
Eligibility criteria	<u>#6b</u>	For matched studies, give matching criteria and number of exposed and unexposed	n.a
Variables	<u>#7</u>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	10-12
Bias	<u>#9</u>	Describe any efforts to address potential sources of bias	18-23
Study size	<u>#10</u>	Explain how the study size was arrived at	9
Quantitative variables	<u>#11</u>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	10-12
Statistical methods	<u>#12a</u>	Describe all statistical methods, including those used to control for confounding	12
Statistical methods	<u>#12b</u>	Describe any methods used to examine subgroups and interactions	n.a.
Statistical methods	<u>#12c</u>	Explain how missing data were addressed	12
Statistical methods	<u>#12d</u>	If applicable, explain how loss to follow-up was addressed	12
Statistical methods	<u>#12e</u>	Describe any sensitivity analyses	n.a
Results			
Participants	<u>#13a</u>	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give	fig 1, table 2

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		applicable.	
Participants	<u>#13b</u>	Give reasons for non-participation at each stage	Fig 1
Participants	<u>#13c</u>	Consider use of a flow diagram	Fig 1
Descriptive data	<u>#14a</u>	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	Table
Descriptive data	<u>#14b</u>	Indicate number of participants with missing data for each variable of interest	Table
Descriptive data	<u>#14c</u>	Summarise follow-up time (eg, average and total amount)	10
Outcome data	<u>#15</u>	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	Table
Main results	<u>#16a</u>	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table
Main results	<u>#16b</u>	Report category boundaries when continuous variables were categorized	Table
Main results	<u>#16c</u>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a
Other analyses	<u>#17</u>	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a
Discussion			

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Key results	<u>#18</u>	Summarise key results with reference to study objectives	18-22
Limitations	<u>#19</u>	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	22-23
Interpretation	<u>#20</u>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	18-23
Generalisability	<u>#21</u>	Discuss the generalisability (external validity) of the study results	18-23
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CCst u.. ng <u>https://www.</u> BY. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

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Antepartum and labour related single predictors of nonparticipation, dropout, and lost to follow up in a randomised controlled trial comparing internet-based cognitive behaviour therapy with treatment as usual for women with negative birth experiences and/or post-traumatic stress following childbirth.

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Manuscript ID	bmjopen-2022-063214.R1
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Antepartum and labour related single predictors of non-participation, dropout, and lost to follow up in a randomised controlled trial comparing internet-based cognitive behaviour therapy with treatment as usual for women with negative birth experiences and/or post-traumatic stress following childbirth.

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Word count: 3007

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Abstract	t
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3 4	1	Abstract
5 6	2	Objectives: Internet-based interventions are often hampered by high dropout rates. The
7 8	3	number of individuals who decline to participate or drop out are reported, but reasons for
9 10 11	4	dropout are not. Identification of barriers to participation and predictors of dropout may help
12 13	5	improve the efficacy of internet-based clinical trials. The aim was to investigate a large
14 15	6	number of possible predictors for non-participation and dropout in a randomized controlled
17 18	7	trial for women with a negative birth experience and/or post-traumatic stress following
19 20	8	childbirth.
21 22 22	9	Setting: A childbirth clinic at a university hospital in Sweden.
25 24 25	10	Participants: The sample included 1,523 women who gave birth between September 2013
26 27	11	and February 2018. All women who rated an overall negative birth experience on a Likert
28 29 20	12	scale, and/or had an immediate caesarean section (CS), and/or severe postpartum
30 31 32	13	haemorrhage ( $\geq$ 2,000 ml) were eligible.
33 34	14	Methods: Demographic, antepartum, and labour-related/postpartum predictors were
35 36	15	investigated for non-participation (eligible but denied participation), pre-treatment dropout
37 38 39	16	(prior to intervention start), treatment dropout, and loss to follow-up. Descriptive statistics
40 41	17	and logistic regression were used in the data analysis.
42 43	18	Results: A majority (80.3 %) were non-participants. Non-participation was predicted by
44 45 46	19	lower level of education, being foreign-born, no experience of counselling for fear of
40 47 48	20	childbirth, multiparity, vaginal delivery (vs. caesarean section and vacuum assisted delivery)
49 50	21	and absence of; preeclampsia, anal sphincter injury, and intrapartum foetal distress. Pre-
51 52	22	treatment dropout was predicted by absence of severe haemorrhage. Treatment dropout was
53 54 55	23	predicted by vaginal delivery (vs. immediate CS), vertex presentation and good overall birth
56 57	24	experience. Loss to follow-up was predicted by vaginal delivery (vs. immediate CS or
58 59 60	25	vacuum-assisted delivery) and absence of intrapartum foetal distress.

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2		
3 4	1	<b>Conclusions:</b> Mothers with no obstetric complications were more likely to not participate and
5 6	2	dropout at different time points. Both demographic, antepartum and obstetrical variables are
/ 8 9	3	important to attend to while designing procedures to maximize participation in iCBT.
10 11	4	
12 13	5	KEYWORDS
14 15 16	6	Dropout; ICBT; internet-delivered; negative birth experience; non-participation;
17 18	7	posttraumatic stress
19 20	8	
21 22 22	9	
23 24 25		Strengths and limitations of this study
26 27		• A large number of participants from routine health care were included
28 29 30		• Demographic, antepartum, and labour-related/postpartum predictors were
31 32		investigated at four stages (recruitment, prior to treatment start, during
33 34		treatment, and at follow-up).
35 36 37		Neither psychological / psychiatric status or attitudes to internet delivered
38 39		interventions were investigated in this study but warrants further exploration.
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1	Introduction
2	The internet has created new opportunities for health care services. Internet-delivered
3	cognitive behavior therapy (iCBT) for various psychological disorders has been developed
4	and investigated in the past decades (1) and the field is growing quickly. The active
5	mechanisms in iCBT are the same as in CBT but differs in the way it is delivered (internet-
6	/computer-based) and increases the availability for evidence based psychological
7	interventions in the society. ICBT is convenient, flexible, and cost-effective for many
8	different psychological disorders (2) it is effective for treatment of depression and several
9	anxiety disorders, and for some diagnoses, iCBT is equally effective as face-to-face CBT
10	(3,4).
11	Several trials of internet interventions have had problems with high levels of non-
12	adherence, with a majority of the participants never completing treatment (5). Information
13	about dropouts in internet-based interventions is generally poorly reported in the literature
14	(5,6) and one study reported that of 75 reviewed trials, 40% failed to report information about
15	dropouts (7). However, when numbers are reported, they are typically high, especially in self-
16	guided interventions (8) (5). In a review of internet-based treatments, dropout ranged between
17	2 and 83%, with a weighted average of 31% (9). In a meta-analysis (10), dropout rates of 74%
18	were reported for unguided treatment for depression, whereas the corresponding figure for
19	therapist-supported treatments was 28%. Kuester et al. (11) found an average dropout rate of
20	23.2% in their meta-analysis of internet-based interventions for PTSD.

The literature is inconsistent regarding the definitions of participants who discontinue
before treatment completion (12). Operationalization of adherence varies across trials and
limits comparability (13). Eysenbach (14) defines low adherence in internet interventions as *"Nonuse attrition"* (when a participant completes an initial assessment battery but fails to

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start the intervention) and "*Dropout attrition*" (when a participant accesses the treatment, but prematurely discontinues it). Other terms, such as "non-compliance," "failure to engage," "premature termination," "attrition," and "dropout" have been used in the literature (12). Melville et al. (9) identified three categories of predictors of dropout: sociodemographic factors and contextual variables, psychological problems, and treatment-related variables – and described that dropout could occur at several different timepoints in iCBT. The following terms for dropout at different timepoints in internet interventions have been suggested: 1. Pretreatment dropout: when a participant drops out before starting the intervention. 2. Treatment dropout: when a participant drops out after having started the intervention. 3. Follow-up dropout: when a participant completes the intervention but drops out before follow-up measures are completed.

Studies seldom report reasons for non-participation or dropout (15). To better understand who will benefit from internet-based interventions and improve usability and efficacy, there is a need to identify factors related to dropout (16). Adherence to internet-interventions can be influenced by several sociodemographic factors, such as gender, age, and level of education (9,16–19). In a study 96 adult patients with posttraumatic stress reactions were allocated to ten sessions of iCBT or to a waiting list. The dropout rate in the iCBT group was 16%; technical problems and emotional distress due to the treatment interventions were the most frequently reported dropout reasons (20).

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The form of an intervention differs in internet treatments, considering amount of material, intensity and support. Some interventions are, e.g., fully therapist-supported with face-to-face sessions or via phone, some offer support via mail, and some do not offer support at all (self-help) (2). Systematic reviews have found that guided internet treatments in general tend to be more effective than non-guided ones (8). Studies seldom report data on the invited persons who decline participation (non-participants). In a randomized controlled trial (RCT)

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investigating expressive writing for postpartum physical and psychological health, recruitment was low (10.7% of the invited) (21). The recruited sample derived from a restricted sociodemographic range (high proportion of white Europeans, well-educated, employed, many in professional occupations, older, and more likely to be married). About 115 000 women give birth in Sweden every year (22). Childbirth is a subjective and multidimensional event that in some cases can lead to a negative childbirth experience. The prevalence of negative childbirth experiences varies (9-45%) in different communities (23-25). For some women (3-4%) the distress of a negative childbirth experience lead to the development of Posttraumatic Stress Disorder Following Childbirth (PTSD FC) (26–31). In Sweden there is no specific treatment recommendation for women with negative birth experiences and/or PTSD FC. So far, only a few randomised controlled trials have investigated the efficacy of different interventions for this population, it is therefore no or little information about how women with negative birth experiences commit and engage in iCBT and similar treatments. The aim of this study was to investigate a number of possible predictors for nonparticipation and dropout in an RCT for those with a negative birth experience and/or posttraumatic stress following childbirth (32). The main objective was to investigate demographic, antepartum, and labour-/postpartum related predictors for the following events a) non-participation (eligible women who did not give written consent), b) pre-treatment dropout (i.e., dropout prior to intervention, but after having given informed consent), c) treatment dropout (i.e., dropout during treatment), and d) loss to follow-up (i.e., those who did

not complete follow-up measures).

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### Methods The STROBE cohort reporting guidelines were used for this publication (33). Patient and public involvement Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this study. Study design Investigation of single predictors for non-participation, pre-treatment dropout, treatment dropout and loss to follow up, reflecting four consecutive time points (about 8 weeks postpartum, about 10 weeks postpartum, between 10 and 16 weeks postpartum, and after 16 weeks postpartum respectively), for all eligible participants in a longitudinal RCT. **Participants** The current study is a secondary analysis of an RCT for women with negative birth experiences, recruited in routine public health care. Approximately 17,000 women gave birth at Uppsala university Hospital between September 2013 and February 2018, and most of them rated their overall birth experience on a Likert scale (0-10), as a standard procedure before hospital discharge. Eligible women (n = 1,523) had a negative birth experience (defined as $\leq$ 5 on the Likert scale), and/or an immediate caesarean section, and/or a severe postpartum haemorrhage ( $\geq 2,000$ ml). Of 1,523 eligible women, about 20% (n = 300) gave written consent to be part of the RCT (32). The 1,523 eligible women had a mean age of 31.5 years (SD = 5.03), participants in the RCT study were 31.7 (4.6) years, and the non-participants age were 31.4 (5.1) years; the majority reported being married or having a partner (84.6 %, n =1,291), and 50.8% (n = 775) had a university degree. Data on eligible participants are presented in Table 1.

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# Demographics for the eligible participants (total sample) consisting of those who participated

*n*=1223

n(%)

1005(74.1)

58(4.3)

71(5.3)

407(30.5)

566(42.4)

#### Total Participants Non-participants n=1523 *n*=300 n(%) *n*(%) Relationship status Married/cohabit 1291 (95.1) 286 (21.1) 66 (4.9) 8 (0.6) Single/other Education Elementary school 72(5.4) 1 (0.1) High school 489(36.6) 82 (6.1) University 775(58.0) 209 (54.2)

and the non-participants.

	Country of birth			
	Sweden	953 (76.7)	261 (21)	692 (55.7)
	Foreign born	289 (23.3)	25 (2)	264 (21.3)
5	Note. Missing data; n=166	o for relationship s	tatus, <i>n</i> =187 for edu	acation, and <i>n</i> =281 for country
6	of birth.			
7				
8	Sample size and power			
9	There was no specific sam	ple size calculation	on for this investigat	ion other than the sample size
10	estimation for the RCT (2	1) (power was set	to 0.8 with a mediu	m effect size) where a total
11	sample size of 130 was ne	eded.		
12				
13	Procedure			

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2 3 4	1	Women rated their birth experience as a routine measure at the hospital before
5 6	2	discharge. Those with negative birth experiences were contacted via telephone, about eight
7 8	3	weeks postpartum. During the telephone calls, the women were informed about the study and
9 10 11	4	those interested in participating were sent study information and a consent form by post.
12 13	5	Those who declined at this stage ( $n = 693$ ) were asked about their reason for doing so. In total
14 15	6	530 eligible women did not respond to the invitation, 300 women gave written consent
16 17 18	7	(participants) and 1,223 did not (non-participants). Of the 300 participants, 101 never
19 20	8	completed baseline measures (pre-treatment dropouts). The participants who filled out the
21 22	9	baseline questionnaires ( $n = 199$ ) were randomized to either treatment as usual (TAU, $n =$
23 24	10	100) or iCBT+TAU ( $n = 99$ ). The iCBT treatment consisted of six treatment modules
25 26 27	11	including psychoeducation and interventions, with therapist support on demand, tailored for
28 29	12	women with negative experiences of childbirth (see supplementary Table 1) (21). Regardless
30 31	13	of treatment allocation, local health care providers in accordance with international guidelines
32 33 34	14	treated all participants in the study. TAU included conventional support in accordance with
35 36	15	the existing practices at the Department of Obstetrics and Gynecology of the participating
37 38	16	hospital. Of the 99 allocated to treatment, a total of 41 were treatment completers (at least
39 40 41	17	three of six steps completed) and 58 were treatment dropouts. All randomized participants
41 42 43	18	(199) were asked to fill out questionnaires six weeks post randomization; 121 completed the
44 45	19	follow-up measures and 78 were lost to follow-up, please see figure 1.
46 47	20	
48 49	20	Figure 1 about here
50 51	21	
52 53 54	22	Material
55 56	23	Based on previous knowledge about possible causes for non-participation and dropout,
57 58 59	24	predictor variables were categorized into three conceptual categories (demographic,

antepartum, and labour-/postpartum related variables). Obstetric data were extracted from

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1	each participant's medical records and questionnaire information was taken from the U-
2	CARE database. The Care Base Internet Platform, including its web-based part (U-CARE
3	eService), was developed within the U-CARE program. The aim of the U-CARE research
4	program is to prevent and reduce psychosocial malfunctioning in patients and relatives. The
5	U-CARE eService is currently being used for interventions and data collection http://www. u-
6	care.uu.se.
7	Demographic variables
8	Country of birth (born in Sweden /foreign-born), level of education (university/high
9	school/elementary school), relationship status (married/partner or single/other status), and age
10	at delivery (years).
11	Antepartum variables
12	Previous caesarean section (no/yes), counselling for fear of childbirth (no/yes),
13	preeclampsia during pregnancy (International Classification of Disease 10th revision (ICD-10
14	code O14; no/yes), length of pregnancy (number of days based on second trimester
15	ultrasound), and parity (first child/second child/third child or more).
16	Labour-related/postpartum variables
17	Mode of delivery (vaginal delivery/emergency caesarean section/immediate caesarean
18	section/vacuum-assisted delivery/elective caesarean section), foetal presentation (vertex
19	presentation/others), manual placenta removal (ICD-10 code O73; no/yes), epidural
20	anaesthesia (ICD-10 code ZXH50; no/yes), intrapartum foetal distress (ICD-10 code O68;
21	no/yes), anal sphincter injury (ICD-10 code O70; no/yes), labour dystocia (ICD-10 code O62;
22	no/yes), severe postpartum haemorrhage ( $\geq$ 2,000 ml; no/yes), anaemia (ICD-10 code D59;
23	no/yes), blood transfusion (ICD-10 code Z51.3; no/yes), number of children in the pregnancy
24	(one/two or more), child transferred to neonatal intensive care unit (NICU; no/yes),

1	breastfeeding problems (ICD-10 code O92; no/yes) and overall birth experience (more severe
2	0-2 vs. less severe 3-5).
3	Dependent variables
4	Non-participation ( $n = 1,223$ ) vs participation ( $n=300$ ): eligible women who did not /
5	did return a signed informed consent form.
6	Pre-treatment dropouts ( $n = 101$ ) vs pre-treatment completers ( $n=199$ ): women who
7	gave written consent but did not / did proceed to complete the baseline measurements.
8	Treatment dropouts ( $n = 58$ ) vs treatment completers ( $n=41$ ): women in the iCBT arm
9	who reported activity in 0 to 2 treatment steps of the treatment vs 3 to 6 treatment steps.
10	Lost to follow-up ( $n = 78$ ) vs completed follow-up: all randomized women in either
11	treatment arm (iCBT+TAU and TAU) who never completed the post-treatment measures vs
12	those who completed them $(n = 121)$ .
13	Statistical analysis
14	Logistic regression was used to determine predictors of non-participation, pre-treatment
15	dropout, treatment dropout, and loss to follow-up. Odds ratios with 95% confidence intervals
16	and beta values including SE are reported. Missing data were not handled. Among the
17	predictor variables there were 3 demographics that had missing data above 5%; country of
18	birth, education, and relationship status (18,5%, 12%, and 10,8% missing respectively). We
19	decided not to impute these demographic missing data from antepartum, and labour-
20	related/postpartum variables, as we think it would have resulted in arbitrary imputations. In
21	addition, since the analyses are not multivariate but bivariate the consequences are less. All
22	available data was used leading to slight differences regarding number of participants in the
23	analyses. Reasons given for non-participation were categorized. SPSS version 26 was used for
24	all analyses.
25	Ethics

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The Regional Ethics Review Board in Uppsala, Sweden, approved the study (2012/495/1 and amendment 2016/11/16).

#### **Results**

# **Predictors of non-participation**

Women with lower levels of education, multiparas and foreign-born were more often non-participants (Table 2). Women who had not been counselled for fear of childbirth, no preeclampsia during pregnancy, no sphincter injury, no intrapartum foetal distress, and those with vaginal delivery were more likely to decline participation, please see Table 2 (and supplementary Table 2 for  $\beta$ ,SE).

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3 4	1	Table 2.						14 o cluc		
5	2	Odds ratio with 95% CI d	lerived from	n logistic regression f	or potenti	al predictors		ling 28	T	
6			NO	on-participants	Pre-tro	eatment dropout	Tre	eatment dropour	LC	ost to follow up
7			<u>N</u>	OR 95% CI	<u>N</u>	<u>OR 95% CI</u>	<u>N</u>		<u>N</u>	OR 95% CI
8		Country of birth	1234	3.93(2.58-6.15)***	284	1.09(0.45-2.64)	98	1.43 (0.3.3 g.	198	1.87(0.69-5.08)
9 10		Sweden/other	953/281		259/25		89/9	er 2 rela	181/17	
10		Level of education	1336		290		99	ted	199	
12		University	775	1.0	208	1.0	71		148	1.0
13		High school	489	1.83(1.38-2.44)***	81	1.53(0.89-2.62)	27	1.32(0.5353628)	50	1.33(0.69-2.55)
14		Elementary school	72	26.2(3.62-189.9)***	1	na	1	naan	1	na
15		Relationship status	1357		292		97	ieu d d	197	
16 17		married-cohabit/other	1291/66	2.06(0.97-4.37)		1.25(0.29-5.35)	95/2	nata a f		na
17		Age, years	1510	0.99(0.96-1.01)	300	0.97(0.92-1.02)	99	0.95(0.86 <b>E PPS</b> )	199	0.95(0.89-1.02)
10		Previous CS yes/no	1302/189	0.80(0.53-1.19)	31/264	0.78(0.36-1.68)	89/9	1.42(0.33	177/19	0.87(0.33-2.32)
20		Counselling for fear of	1523		300		99		199	
21		childbirth, no/yes	1376/147	0.50(0.35-0.73)***	254/46	1.06(0.55-2.05)	87/12	0.68(0.18 - 2. 🕏 )	169/30	0.88(0.39-1.97)
22		Preeclampsia, no/yes	1440/83	0.59(0.36-0.96)*	276/24	1.20(0.51-2.85)	90/9	1.46(0.34 6. 2)	184/15	1.39(0.48-4.00)
23		Pregnancy, days	1507	1.00(0.99-1.00)	299	0.99(0.98-1.01)	99	1.01(0.9🛱 1.🚰)	198	1.00(0.98-1.02)
24 25		Parity	1505		299		99	an	198	
25 26		1 <sup>st</sup> child	838	1	200	1	68	1 <b>G</b>	134	1
27		2 <sup>nd</sup> child	448	1.65(1.22-2.22)**	71	0.97(0.55-1.73)	22	1.80(0.65 4.%)	48	1.07(0.54-2.10)
28		3 <sup>rd</sup> child or more	219	2.15(1.40-3.30)***	28	1.52(0.68-3.40)	9	1.68(0.39 7.26)	16	1.63(0.58-4.60)
29		Mode of delivery	1523		300	· · · · ·	99	iect Jun	199	
30		Vaginal delivery	783	1	129	1	40	1 <b>in 1</b>	82	1
31		Emergency CS	289	0.71(0.51-1.0)	63	1.0(0.54-1.88)	20	0.33(0.1 <b>2</b> 1.03)	40	0.74(0.34-1.58)
32 33		Immediate $CS^1$	186	0.54(0.37-0.79)**	49	0.63(0.30-1.30)	19	0.19(0.06-8.63	36	0.42(0.18-0.99)*
34		Vacuum assisted	198	0.62(0.43-0.91)*	48	0.96(0.48-1.91)	15	0.29(0.84-1.())	31	0.26(0.10-0.71)**
35		Elective CS	67	1 01(0 52-1 99)	11	0 17(0 02-1 41)	5	1 33(0 13-13 <b>@</b> 7)	10	2 57(0 62-10 65)
36		Foetal presentation	1510	1.01(0.02 1.00)	300	0.17(0.02 1.11)	99		199	
37		Vertex / other	1287/223	1 02(0 71-1 46)	256/44	0 53(0 25-1 13)	82/17	0 31(0 11-0 9 <b>±</b> )*	165/34	1 28(0 61-2 70)
38		Manual placenta removal	1523	1.02(0.71 1.10)	300	0.00(0.20 1.10)	99		199	1.20(0.01 2.70)
39		Manual placenta tentova	1525		500			lĝo	177	
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	,	1070/144	1 41 (0 00 0 0 0 0)	270/22	0.40(0.14.1.00)	02/6	0632£	101/10	
	no / yes Enidural anaesthesia	13/9/144	1.41(0.88-2.26)	278/22	0.42(0.14-1.26)	93/6 99	0.33(0.06≝1.940) ≘. S	181/18 199	0.99(0.36-2.66)
	no / yes	813/710	0.86(0.67-1.10)	151/149	1.12(0.69-1.80)	49/50	0.95(0.43 2. 2)	102/97	1.52(0.86-2.70)
	Intrapartum foetal distress	1523	· · · · · ·	300	( )	99		199	
	no / yes	1234/289	0.67(0.50-0.91)*	228/72	0.76(0.43-1.36)	71/28	0.50(0.218 長望)	148/51	0.50(0.25-0.99)*
	Anal sphincter injury	1523		300		99	eigr rela	199	
	no / yes	1447/76	0.48(0.29-0.79)**	275/25	0.92(0.38-2.21)	88/11	1.27(0.35 4 4 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	182/17	1.09(0.40-3.00)
	Labour dystocia	1523		300		99		199	
	no / yes	885/638	0.87(0.67-1.11)	166/134	1.26(0.78-2.04)	55/44	0.74(0.33) (0.66)	114/85	0.75(0.42-1.34)
	Severe haemmorhage <sup>1</sup>	1523	1 10(0 20 1 76)	300	0.29(0.15.0.06)*	99 92/16		199	1 00(0 44 2 28)
	ΠΟ / yes Anaemia	1529/194	1.19(0.80-1.70)	200/34	0.38(0.13-0.90)	83/10 99		1/1/28	1.00(0.44-2.28)
	no / ves	1274/249	0 85(0 61-1 18)	246/54	0 57(0 29-1 12)	79/20	ິລີ⊃ີສ 0.50(0.19ap 1295)	158/41	0 66(0 32-1 38)
	Blood transfusion	1523	0.00 (0.01 1.10)	300	0.07(0.23 1.12)	99		199	0.00(0.02 1.00)
	no / yes	1340/183	1.01(0.69-1.49)	265/35	0.65(0.29-1.45)	87/12	0.31(0.0¢1.00)	173/26	0.53(0.21-1.32)
	Children in the pregnancy	1508		299		99	Al tr	198	
	1 child / 2 children	1476/32	1.35(0.52-3.55)	294/5	0.48(0.05-4.40)	97/2	na <b>ni b</b>	194/4	0.51(0.05-4.96)
	Child transferred to NICU	1523		300		99	ng,	199	
	no / yes	1255/268	0.83(0.60-1.14)	241/59	1.21(0.67-2.20)	78/21	0.73(0.28 1.9)	162/37	1.07(0.52-2.22)
	Breastfeeding problems	1523		300	0 (5(0 07 ( 2()	99	sim	199	0.77(0.07, 0.(7))
	no / yes Overall hirth evenerioneel	1202/18	0.86(0.28-2.64)	296/54	0.65(0.07-6.36)	98/1	natiar or	196/3	0.//(0.0/-8.6/)
	$0_{-2}/3_{-5}$	1205	1.02(0.74 1.42)	234 58/176	0.72(0.38-1.35)	72 20/52	0.27(0.00 0 75)*	148	0.90(0.43-1.88)
1	Note The first category is	the referen	$\frac{1.02(0.74-1.42)}{1.02}$	$\frac{30/170}{\text{s/no} \text{ is stat}}$	$\frac{0.72(0.38-1.33)}{1.000}$	20/32	$\frac{0.27(0.0940.78)}{2}$	40/108	0.90(0.43-1.88)
2	<sup>1</sup> inclusion criteria.		ice, for e.g. when yes	5/110 15 Stat			<sup>2601</sup> <i>y</i> . <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b> <b>1</b>		
3	* p<.05, **p<.01, ***p	<.001					ies.		
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1	Reasons why women declined to take part despite eligibility.		
2	Of the contacted women, 693 actively declined participation and their	answers v	vere
3	categorized into different subgroups (Table 3).		
4			
5	Table 3.		
6	Reasons for non-participation ( $n = 693$ ) given during telephone interview effects	ght weeks	
7	postpartum	-	
	Reason for non-participation	Ν	%
	Feels fine, does not need any support	326	(47)
	Does not speak Swedish	134	(19)
	Not interested (no further information)	77	(11)
	Feels fine, has already received professional support	35	(5)
	Does not feel fine, receiving/waiting for other professional support	35	(5)
	Does not have the time	30	(4)
	Does not have a computer	16	(2)
	Not interested, will not have more kids anyway	14	(2)
	Not interested, does not want to think about the delivery	13	(2)
	Misunderstood the Likert scale (inclusion), had a positive experience	10	(1.4)
	Not comfortable with internet/computer, prefers face-to-face therapy	3	(0.4)
8			
9			
0	Predictors of pre-treatment dropout		
1	The only significant predictor of pre-treatment dropout was no severe	postpartur	n
2	haemorrhage (i.e., less than 2000 ml; Table 2).		
13	Predictors of treatment dropout		

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For those randomized to the treatment group, dropout was significantly predicted by mode of delivery, foetal presentation, and overall birth experience (Table 2). Participants with vaginal delivery, vertex presentation and less severe overall birth experience were more likely to drop out from treatment.

Predictors of loss to follow-up

In the analyses of loss to follow-up, absence of intrapartum foetal distress and vaginal delivery (compared with immediate CS and vacuum delivery) predicted loss to follow up (Table 2). An additional analysis showed that being randomised to iCBT+TAU was a significant predictor of loss to follow up OR = 1.84 (95 % CI: 1.04-3.28), B=0.61, SE=0.29, p = .037, where 46 of 99 in iCBT+TAU and 32 of 100 in TAU were lost to follow up.

Discussion

The current study provides an explorative analysis of predictors for non-participation and drop out at different timepoints in an RCT examining iCBT for women with negative birth experiences and/or posttraumatic stress following childbirth (21). Significant predictors for non-participation and dropout were found at different stages in the recruitment process of an RCT. Women with higher education level, without previous children and those born in Sweden were more likely to enter into the study. Thereafter, women who had been counselled for fear of birth, experienced complications during the childbirth and with an overall severe birth experience were more likely to stay in the study.

A majority (80.3%) of the eligible women declined participation and our first
conclusion was that a large number of those eligible did not see themselves as being in need
of iCBT or wanted to take part in a clinical trial. When they were contacted by telephone
during the recruitment period, the most frequent reason for declining was "I feel fine/have no

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need of any support." Explanations could be that the cut-off for the screening instrument was over-inclusive and/or that the other inclusion criteria (immediate caesarean section and severe postpartum haemorrhage) did not necessarily result in a negative birth experience. The content validity of the one-item Likert scale in the current trial could be discussed, as women may take different aspects of their birth experience into account. Also, the time-point for the rating could be discussed. In the current trial, all women rated their birth experience shortly after giving birth; it is difficult to determine the timepoint that would yield the most accurate rating of the birth experience. However, using a Likert scale as a tool for self-assessment of overall birth experience is well-established in clinical practice and used in research (34,35). A person's perception of their birth experience can change over time and it is important to consider the specific timepoint used in measurement (33). Larsson et al. (36) used a VAS scale (range 1–10) for self-assessment of birth experience at two days, three months, and nine months postpartum. They found that the participants' negative birth experiences decreased over time and suggested that use of a VAS scale was an adequate way to find women in need of follow-up after a negative birth experience. The analysis included the inclusion criteria (immediate caesarean section, overall birth experience, and severe haemorrhage) as predictors. Non-participation was predicted by vaginal delivery vs. immediate caesarean section. Childbirth without severe haemorrhage predicted pre-treatment dropout. It is known that severe postpartum haemorrhage is a significant risk factor for developing PTSD (37,38). Treatment drop out was predicted by a less severe overall birth experience and vaginal delivery vs. immediate CS. These predictors

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might be useful for future hypothesis in further research. The three inclusion criteria in this
study are experiences that potentially can have serious effects on the mental health of a birth
giving woman. It may be of value to understand more about what type of care (e.g.,

were inclusion criteria and must therefore be interpreted with caution. However, the results

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counselling, therapy), what type of format (e.g., face to face or ICBT) and what level of
 support (therapist support or pure self-help) is demanded.

Three socio-demographic variables predicted non-participation: lower level of education, multiparity, and being foreign-born. Lower level of education as a greater risk for dropout is consistent with dropout in other iCBT trials (16). Multiparity was also identified as an important predictor of non-participation. The physical and psychological changes of the postpartum period are challenging for first-time mothers and they have lower levels of maternal confidence and higher levels of stress compared with multiparous women (39), which might increase their likelihood of participation. An alternative explanation is that multiparous women have less time to commit to clinical trials compared with first-time mothers. This trial's intervention addressed Swedish-speaking women; foreign-born women might see language as a barrier to participation.

Five antepartum and labour-related/postpartum variables also predicted non-participation. Women without experience of the following were more likely to be non-participants; counselling for fear of childbirth, preeclampsia, anal sphincter injury, intrapartum foetal distress, and vacuum-assisted delivery (vs. vaginal delivery). Women who had been counselled for fear of childbirth had already professionally addressed peripartum psychological problems and might therefore have been more open to support. Preeclampsia, intrapartum foetal distress, and anal sphincter injuries are all severe conditions and motivators for participation. Preeclampsia and severe postpartum haemorrhage are significant threats to the mother and may have devastating or lethal outcomes. Further, both preeclampsia and intrapartum foetal distress are potential threats to the health of the foetus, thus acting as significant stressors for the woman. Instrumental deliveries may be caused by emergency obstetric complications potentially threatening the mother or the child and are very stressful situations for the woman in their own right (30). The labour related / post-partum predictors

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show a consistent pattern where women who did not experience these stressful events may not
 have had enough motivation to seek out help or support.

Pre-treatment dropout was predicted by the absence of severe haemorrhage which is mentioned above. Vertex foetal presentation (vs. other presentation) predicted treatment dropout. This is consistent with the significant predictors for non-participation where those with vertex presentation might not experience this as a stressful event enough to stay in the treatment. It might also be that those with vertex presentation who were randomized to the treatment did not find it helpful or that it did not address their problem fully in order to stay in the treatment.

Predictors for loss to follow-up were vaginal delivery vs. instrumental delivery and absence of intrapartum foetal distress. Occurrence of such events are threats to the foetus which in turn can be very stressful for the mother. Absence of these events might lead to lost interest in devoting time and energy to proceed with the follow-up assessment. Absence of immediate CS was also a significant predictor of loss to follow up and is discussed in relation to the other inclusion criteria/predictors. Finally, randomisation to iCBT+TAU (compared with TAU) was a significant predictor of lost to follow up. A majority of those who were lost to follow up from the iCBT+TAU group were also those who were treatment droputs.

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18 Closer inspection of variables associated with non-participation and dropout can yield 19 insights that can be used in both future research and clinical practice. Knowledge of sub-20 groups that are more likely to continue and complete study participation provides information 21 about motivational factors and should be applied during the initial recruitment for similar 22 trials. Participants where not asked why they dropped out. We believe that dropout can 23 depend on different factors such as lack of energy and/or interest of being part of a clinical 24 trial; dropout can also depend on the participant's experience of not needing the intervention

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anymore. In this trial women with lover level of education, multipara and foreign born where
 more often non-participants, perhaps the way of inclusion and the intervention itself must be
 better adapted to attract those sub-groups in the future. Translation to other languages, using
 simple language and pictorial material could be ways of improving adherence.

5 Analyses of predictors of non-participation and dropout are important for evaluating the 6 efficacy of the interventions (6). This explorative study found predictors of non-participation 7 and dropout that should be taken into account in future development of similar interventions. 8 Awareness of characteristics among women who drop out and those who continue, and 9 complete interventions is important and should get more attention during initial recruitment 10 for similar trials.

11 Strengths

The current study is the first to present data on non-participation and dropouts in iCBT for women with negative birth experiences and/or posttraumatic stress following childbirth. The main strength of this study was the size of the sample and the routine public health care setting as well as consecutive recruitment. All women who gave birth were asked to rate their birth experience on a self-assessed Likert-scale and all women with a low rating were invited. This process increased the likelihood of the results being generalizable to similar clinical contexts. The exploration of dropout predictors from a large cluster of demographic variables and medical/clinical characteristics was another strength. A third strength was that reasons for dropout were explored at different stages in the study process, which allowed analysis of specific timepoints when participants were more likely to end their participation. Analyses of different timepoints for dropout could simplify the analyses of underlying reasons for withdrawal (9). Limitations

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Our study has several limitations that should be noted. Psychological problems and/or treatment-related variables were not available for analyses. Such variables are likely to be strong predictors of non-participation and dropout (9) and should be integrated in future studies. Neither discomfort with the internet or computers were analysed as factors for non-participation or dropout in the current trial. The impact of computer-related factors on adherence has been described previously (17). Further, recruitment to the study was before discharge from the hospital when the experience of birth is fresh. Thus, the eligible sample might have been different if we had asked them at a later time point. However, the assessment of the birth experience was in close conjunction to immediate CS and severe haemorrhage (the two other inclusion criteria). In some analyses there might have been a lack of power, due to the varying N, that prevented significant predictors to be found. Conclusions In this sample, drawn from a large population, predictors were found for non-participation and dropout at different stages in the recruitment process and during the study of an RCT. In summary, both demographic and obstetrical variables are important to attend to for both clinical and research purposes, while designing procedures to maximize participation

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in iCBT for postpartum women. First time mothers with high level of education and those

who had adverse obstetric experiences were more likely to join and stay in the internet

intervention.

**Conflicts of Interest** 

All authors of this manuscript declare No known competing interest.

# Authorship Contribution statement

All listed authors fulfil ICMJE authorship criteria. Author abbreviations are found in brackets

3 after type of contribution. Writing - original draft (JS), Writing - review & editing (JS, ASS,

FV, ML, ISP, AS, MJ, TP), Conceptualization (ASS, ML, ISP, AS, MJ, TP), Methodology

5 (ASS, ML, ISP, AS, MJ, TP), Formal analysis (JS, ASS, FV, AS, TP), Investigation (JS,

6 ASS, FV, ML, MJ), Data curation (JS, ASS, FV, ML, ISP, AS, MJ, TP), Supervision (ASS,

ML, TP), Funding acquisition (ASS, MJ), and Project administration (ASS, ML, ISP, MJ). TP is the guarantor.

9 Transparency The manuscript's guarantor affirms that the manuscript is an honest,
10 accurate, and transparent account of the study being reported; that no important
11 aspects of the study have been omitted; and that any discrepancies from the study as
12 originally planned have been explained.

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design; in the collection, analysis, and interpretation of data; in the writing of the report;
and in the decision to submit the article for publication. All authors confirm the
independence from funders and all authors, external and internal, had full access to all

21 of the data (including statistical reports and tables) in the study and take responsibility

22 for the integrity of the data and the accuracy of the data analysis.

**Data sharing** is available on reasonable request from researchers who provide a

<sup>9</sup> 24 methodologically sound proposal. Individual participant data that underlie the results

2		
3 4	1	reported in this article, after deidentification will be shared. Proposals should be directed
5 6 7	2	to agneta.skoog_svanberg@kbh.uu.se . To gain access, data requestors will need to sign
7 8 9	3	a data access agreement.
10 11	4	Ethics statement The Regional Ethics Review Board in Uppsala, Sweden, approved the
12 13	5	study (2012/495/1 and amendment 2016/11/16).
15		Acknowledgements
16 17 18		We would like to thank statistician Per Wikman for help with structuring the database.
19 20 21	6	
22 23	7	Abbreviations
24 25 26	8	ICD-10: International Classification of Disease 10th revision
20 27 28	9	iCBT: Internet-based cognitive behavior therapy
29 30	10	RCT: Randomized controlled trial
31	11	
32 33	12	TAU: Treatment as usual
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30 31 32 33	15	Figure 1. Flowchart
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Figure 1. Flowchart

Supplementary Table 1.

Week by week content of the iCBT treatment

Week	Content
1st	Information, psychoeducation, breathing retraining
2nd	Vignettes, common symptoms, fear and avoidance
3rd	Depressive symptoms, significance of relationships, "reflective listening"
4th	Exposure, talking about the childbirth
5th	Managing anxiety and depressive symptoms, psychological health, values, recovery
6th	Summary, repetition and relapse prevention

*Note.* Every week contained homework assignments based on the content of the module

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Supplementary Table 2. Odds ratio with 95% CI,	Beta values	, and SE derived from	logistic r	egression, for pote	ntial pre	t, including for dictors		
	No	on-participants	Pre-tre	eatment dropout	Tre	atment dropous	Los	st to follow up
	Ν	OR 95% CI	Ν	OR 95% CI	Ν	OR 95	Ν	OR 95% CI
		<i>B</i> , S.E		<i>B</i> , S.E		B, Set 2		<i>B</i> , S.E
Country of birth Sweden/other	1234 953/281	3.93(2.58-6.15)*** 1.38, 0.22	284 259/25	1.09(0.45-2.64) 0.09, 0.45	98 89/9	1.43 (0.38 5 86) 0.35, <b>Đ</b> .745	198 181/17	1.87(0.69-5.08) 0.63, 0.51
Level of education	1336		290		99	wnl ext a	199	
University	775	1.0	208	1.0	71	1.00 coade	148	1.0
High school	489	1.83(1.38-2.44)*** 0.61, 0.15	81	1.53(0.89-2.62) 0.43, 0.28	27	1.32(0.5	50	1.33(0.69-2.55) 0.28, 0.33
Elementary school	72	26.2(3.62-189.9)*** 3.27, 1.01	1	na	1	http:// S) · niag, A	1	na
Relationship status married-cohabit/other	1357 1291/66	2.06(0.97-4.37) 0.72, 0.38	292	1.25(0.29-5.35) 0.256, 0.74	97 95/2	ntgainin	197 192/5	na
Age years	1510	0.99(0.96-1.01) -0.12, 0.013	300	0.97(0.92-1.02) -0.034, 0.86	99	0.95(0.8 -1.95) -0.52, -0.52	199	0.95(0.89-1.02) -0.048, 0.03
Previous CS no / yes	1491 1302/189	0.80(0.53-1.19) -0.23, 0.21	295 31/264	0.78(0.36-1.68) -0.25, 0.39	98 89/9	1.42(0.3 0.35, 0.74	196 177/19	0.87(0.33-2.32) -0.14, 0.50
Counselling for fear of childbirth, no / yes	1523 1376/147	0.50(0.35-0.73)*** -0.69, 0.19	300 254/46	1.06(0.55-2.05) 0.06, 034	99 87/12	0.68(0.18-2.52) -0.40,5.62	199 169/30	0.88(0.39-1.97) -0.13, 0.41
Preeclampsia no / yes	1523 1440/83	0.59(0.36-0.96)* -0.53, 0.25	300 276/24	1.20(0.51-2.85) 0.18, 0.44	99 90/9	1.46(0.3 <b>9</b> -6.82) 0.38, 0.745	199 184/15	1.39(0.48-4.00) 0.33, 0.54
Length of pregnancy days	1507	1.00(0.99-1.00) -0.003, 0.004	299	0.99(0.98-1.01) -0.008, 0.008	99	1.01(0.98-1. <b>0</b> 4) 0.01, 0.01	198	1.00(0.98-1.02) 0.002, 0.01
Parity	1505		299		99	се Е	198	
1 <sup>st</sup> child	838	1	200	1	68	1 1	134	1
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Page 33 of 37					BMJ Open		ijopen-202 1 by copyr		
1 2 3 4	2 <sup>nd</sup> child	448	1.65(1.22-2.22)** 0.50, 0.15	71	0.97(0.55-1.73)	22	ignt, in 2-06321 1.80(0.62-4.96) 0.58.00.52	48	1.07(0.54-2.10) 0.06, 0.34
5 6 7	3 <sup>rd</sup> child or more	219	2.15(1.40-3.30)*** 0.77, 0.081	28	$\begin{array}{c} 0.20, 0.29\\ 1.52(0.68-3.40)\\ 0.42, 0.41\end{array}$	9	1.68(0.39-7.26) 0.52, 0.72	16	1.63(0.58-4.60) 0.49, 0.53
8	Mode of delivery	1523		300		99	embe Ense ses r	199	
9 10	Vaginal delivery	783	1	129	1	40	elate	82	1
11 12 13	Emergency CS	289	0.71(0.51-1.0) -0.34, 0.17	63	1.0(0.54-1.88) 0.003, 0.32	20	0.33(0.1 - 1.1, g. 589	40	0.74(0.34-1.58) -0.31, 0.39
14 15	Immediate CS <sup>1</sup>	186	0.54(0.37-0.79)** -0.61, 0.19	49	0.63(0.30-1.30) -0.46, 0.37	19	0.19(0.06 มีรู้อรู้)** -1.64, อุษัตต์	36	0.42(0.18-0.99)* -0.86, 0.43
16 17 18	Vacuum assisted	198	0.62(0.43-0.91)* -0.475, 0.19	48	0.96(0.48-1.91) -0.04, 0.35	15	0.29(0.8	31	0.26(0.10-0.71)** -1.33, 0.51
19 20	Elective CS	67	1.01(0.52-1.99) 0.01, 0.34	11	0.17(0.02-1.41) -1.75, 1.06	5	1.33(0.13 (3.13 (3.13 (0.13 (3.13) (3.13 (3.13)))))))))))))))))))))))))))))))))))	10	2.57(0.62-10.65) 0.95, 0.73
21	Foetal presentation	1510	1.02(0.71-1.46)	300	0.53(0.25-1.13)	99	0.31(0.1 🔄 0.🛃)*	199	1.28(0.61-2.70)
22 23	Vertex / other	1287/223	0.20, 0.18	256/44	-0.63, 0.38	82/17	-1.16, <b>3</b> .5	165/34	0.24, 0.38
24 25 26	Manual placenta removal no / yes	1523 1379/144	1.41(0.88-2.26) 0.346, 0.24	300 278/22	0.42(0.14-1.26) -0.88, 0.57	99 93/6	0.33(0.0g-1.90) -1.11, .89	199 181/18	0.99(0.36-2.66) -0.014, 0.51
27 28 29	Epidural anaesthesia no / yes	1523 813/710	0.86(0.67-1.10) -0.15, 0.13	300 151/149	1.12(0.69-1.80) 0.11, 024	99 49/50	0.95(0.4 <sup>1</sup> / <sub>2</sub> -2.22) -0.049 <sup>1</sup> / <sub>2</sub> 0.4 <sup>1</sup> / <sub>2</sub>	199 102/97	1.52(0.86-2.70) 0.42, 0.29
30 31 32	Intrapartum foetal distress no / yes	1523 1234/289	0.67(0.50-0.91)* -0.39, 0.15	300 228/72	0.76(0.43-1.36) -0.27, 0.29	99 71/28	0.50(0.2) -0.69,@.4\$	199 148/51	0.50(0.25-0.99)* -0.70, 0.36
33 34	Anal sphincter injury no / yes	1523 1447/76	0.48(0.29-0.79)** -0.73, 0.25	300 275/25	0.92(0.38-2.21) -0.82, 045	99 88/11	1.27(0.35-4.86) 0.24, 0.66	199 182/17	1.09(0.40-3.00) 0.09, 0.52
35 36 37	Labour dystocia no / yes	1523 885/638	0.87(0.67-1.11) -0.14, 0.13	300 166/134	1.26(0.78-2.04) 0.23, 0.25	99 55/44	0.74(0.33-1. <b>9</b> 6) -0.3, 0.41	199 114/85	0.75(0.42-1.34) -0.29, 0.30
38 39 40 41	Severe haemmorhage <sup>1</sup>	1523	1.19(0.80-1.76)	300	0.38(0.15-0.96)*	99	0.49(0.17-1. 1994) 0.49(0.17-1.	199	1.00(0.44-2.28)
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no / yes	1329/194	0.17, 0.20	266/34	-0.95, 0.47	83/16	-0.72, 20.55	171/28	0.004, 0.42
Anaemia	1523	0.85(0.61-1.18)	300	0.57(0.29-1.12)	99	0.50(0.1	199	0.66(0.32-1.38)
no / yes	1274/249	-0.16, 0.17	246/54	-0.56, 0.35	79/20	-0.69, <b>氧</b> ).5 <b>ខ្ល</b>	158/41	-0.41, 0.37
Blood transfusion	1523	1.01(0.69-1.49)	300	0.65(0.29-1.45)	99	0.31(0.0	199	0.53(0.21-1.32)
no / yes	1340/183	0.011, 0.20	265/35	-0.43, 0.41	87/12	-1.19, <b>a</b>	173/26	-0.64, 0.47
Children in the pregnancy	1508	1.35(0.52-3.55)	299	0.48(0.05-4.40)	99	næd næd	198	0.51(0.05-4.96)
1 child / 2 children	1476/32	0.30, 0.49	294/5	-0.72, 1.12	97/2	. Dov ent Sr to te	194/4	-0.68, 1.16
Child transferred to NICU	1523	0.83(0.60-1.14)	300	1.21(0.67-2.20)	99	0.73(0.2 a - a - b - b - b - b - b - b - b - b -	199	1.07(0.52-2.22)
no / yes	1255/268	-0.19, 0.16	241/59	0.20, 0.30	78/21	-0.32, T	162/37	0.069, 0.37
Breastfeeding problems	1523	0.86(0.28-2.64)	300	0.65(0.07-6.36)	99	nata national fro	199	0.77(0.07-8.67)
no / yes	1505/18	-0.15, 0.57	296/54	-0.43, 1.16	98/1	ninir ES)	196/3	-0.26, 1.23
Overall birth experience <sup>1</sup>	1203	1.02(0.74-1.42)	234	0.72(0.38-1.35)	72	0.27(0.0 <sup>5</sup> 0. <sup>7</sup> 0)*	148	0.90(0.43-1.88)
0-2 / 3-5	305/898	0.023, 0.17	58/176	-0.34, 0.32	20/52	-1.31, <b>5</b> .5	40/108	-0.11, 0.38

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<u>58/176</u> -0.34, 0.32 20/52 -1.31, **P**. 50 per bibliographique de libliographique de libriographique de libri *Note*. The first category is the reference, for e.g. when yes/no is stated, yes is the reference category. <sup>1</sup> inclusion criteria.

\* p<.05, \*\*p<.01, \*\*\*p<.001

## Reporting checklist for cohort study.

Based on the STROBE cohort guidelines.

## **Instructions to authors**

Protected by copyright, including for uses related Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cohortreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract		Internet-based Cognitive Behavior Therapy (iCBT) for women with negative birth experiences and/or posttraumatic stress following childbirth: Prevalence and predictors of non-participation and dropout	
Title	<u>#1a</u>	Indicate the study's design with a commonly used term in the title or the abstract	Title page
Abstract	<u>#1b</u>	Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract page
Introduction			
Background / rationale	<u>#2</u>	Explain the scientific background and rationale for the investigation being reported	5-7
Objectives	<u>#3</u>	State specific objectives, including any prespecified hypotheses	7
Methods			
Study design	<u>#4</u>	Present key elements of study design early in the paper	8

		BMJ Open	Page
Setting	<u>#5</u>	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	8
Eligibility criteria	<u>#6a</u>	Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up.	8-10
Eligibility criteria	<u>#6b</u>	For matched studies, give matching criteria and number of exposed and unexposed	n.a
Variables	<u>#7</u>	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	10-12
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	10-12
Bias	<u>#9</u>	Describe any efforts to address potential sources of bias	18-23
Study size	<u>#10</u>	Explain how the study size was arrived at	9
Quantitative variables	<u>#11</u>	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	10-12
Statistical methods	<u>#12a</u>	Describe all statistical methods, including those used to control for confounding	12
Statistical methods	<u>#12b</u>	Describe any methods used to examine subgroups and interactions	n.a.
Statistical methods	<u>#12c</u>	Explain how missing data were addressed	12
Statistical methods	<u>#12d</u>	If applicable, explain how loss to follow-up was addressed	12
Statistical methods	<u>#12e</u>	Describe any sensitivity analyses	n.a
Results			
Participants	<u>#13a</u>	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give	fig 1, table 2

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		applicable.	
Participants	<u>#13b</u>	Give reasons for non-participation at each stage	Fig 1
Participants	<u>#13c</u>	Consider use of a flow diagram	Fig 1
Descriptive data	<u>#14a</u>	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	Table
Descriptive data	<u>#14b</u>	Indicate number of participants with missing data for each variable of interest	Table
Descriptive data	<u>#14c</u>	Summarise follow-up time (eg, average and total amount)	10
Outcome data	<u>#15</u>	Report numbers of outcome events or summary measures over time. Give information separately for exposed and unexposed groups if applicable.	Table
Main results	<u>#16a</u>	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Table
Main results	<u>#16b</u>	Report category boundaries when continuous variables were categorized	Table
Main results	<u>#16c</u>	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a
Other analyses	<u>#17</u>	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a
Discussion			

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Key results	<u>#18</u>	Summarise key results with reference to study objectives	18-22
Limitations	<u>#19</u>	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	22-23
Interpretation	<u>#20</u>	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	18-23
Generalisability	<u>#21</u>	Discuss the generalisability (external validity) of the study results	18-23
Other Information			
Funding	<u>#22</u>	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	24

None The STROBE checklist is distributed under the terms of the Creative Commons Attribution License CCst u.. ng <u>https://www.</u> BY. This checklist can be completed online using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai