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CHAPTER 1

GENERAL INTRODUCTION AND OUTLINE OF THE THESIS

GENERAL INTRODUCTION

'Every woman should be able to skip the first and start with the second pregnancy and delivery'.

Pregnancy and delivery are well known risk factors for developing urinary incontinence (UI).[1] The first delivery has the largest effect with an additional increase in risk every subsequent delivery.[1] Stress (S) and mixed (M)UI are the most common types of UI associated with pregnancy and delivery.[1] SUI is defined as any involuntary leakage of urine on effort or exertion, or on sneezing or coughing.[2] MUI has both a stress and urgency component.[2] SUI may be due to the following causes: 1) a reduced urethral closure function; 2) damage to the urethrovaginal support system; and 3) high abdominal pressure compared to the ability of the support system.[3] During a rise in abdominal pressure the urethral closure pressure is maintained by both the intrinsic urethral sphincter mechanism and the urethral support mechanism.[4] The intrinsic urethral sphincter consists of the submucosa with the submucosal vascularization, the urethral smooth muscles, and the striated external urethral sphincter.[5,6] The urethral support system consists of the anterior vaginal wall, the levator ani muscle (LAM), the arcus tendineus fasciae pelvis, the endopelvic fascia, and the internal obturator muscle.[7,8] The LAM is attached to the arcus tendineus fascia pelvis on both sides and provides a hammock under the urethra and bladder neck.

During a rise in intra-abdominal pressure, by for instance coughing, jumping or laughing, the urethra is compressed against the hammock, which prevents a downward movement.[9] At the same time, the urethral sphincter closing mechanism is active as it moves the urethra in- and upward towards the pubic bone, with concurrent contraction of the compressor urethra (part of the external urethral sphincter), clamping the upward moving urethra, resulting in increase of the intra-urethral pressure.[9] If the function of the LAM is compromised in any way, and/or the intrinsic sphincter urethra is damaged, the total closing mechanism may be malfunctioning and involuntary loss of urine can occur.[6]

The exact aetiology of UI in pregnancy is uncertain, but anatomical and hormonal changes are considered to contribute to UI.[10] The growing foetus (and weight gain of the mother)[11] will increase the pressure on the bladder and hormonal changes will result in remodelling of fibres of all tissues to increase the visco-elasticity. As a

result of the increased visco-elasticity, connective tissue is weaker, the resting tone of the LAM is reduced, and there is less strength in the endopelvic fascia and arcus tendineus fasciae pelvis, with the ultimate aim to prepare for delivery.[6] During vaginal delivery the LAM stretches up to 3.3 times (pubococcygeal muscle) it's natural length[12], which can damage the LAM and the nerves.[13] Magnetic resonance imaging of the LAM at 9 to 12 months post-partum revealed that approximately 20% of all primiparous women have a defect in the LAM. Furthermore, post-partum women with SUI are twice as likely to have a defect in the LAM compared to continent primiparas.[14]

Pelvic floor muscle training (PFMT) is an accepted and effective treatment option for women with SUI.[15-17] PFMT aims to improve the supportive system of the pelvic floor muscle (especially the LAM) in order to act with an appropriate pre-contraction in case of expected leakage, both with voluntary (the Knack manoeuvre) and involuntary contractions.[18,19] PFMT may be provided individually or in a group. During group therapy, women can encourage each other to do their exercises and discuss experiences and coping strategies on how to implement PFMT in daily life. Recently, a meta-analysis on the effects of individual versus pelvic floor muscle group training (PFMGT) for women with UI, both provided by a specialized physical therapist, showed no significant difference in results between groups.[20] The latter is of particular interest as group therapy is less expensive when compared to individual therapy, and might therefore be a cost-effective strategy. A Cochrane review reported that the effect of PFMT for the treatment of UI in the peri-partum period is uncertain; however the reported results are based on small studies with very low to low quality evidence.[21-23]

The reported mean prevalence of UI in pregnancy and between 6 weeks and 1 year post-partum varies greatly, between 9 to 63% [24,25] and 11 to 63%[26,27], respectively. In The Netherlands in 2018, 168.500 babies were born and 75.500 women had their first delivery.[28] These numbers, although not stratified by delivery type, show the enormous number of potentially affected women with SUI or MUI. It is known that when SUI presents during pregnancy, the risk of having SUI 12 years after delivery is still significant[29] and that 75% to 92% of women with SUI at 3 months post-partum, still have UI even after 12 years.[30] Despite these high prevalence numbers, current Dutch guidelines for 1st, 2nd and 3rd line care of pregnant and post-partum women hardly pay attention to UI.[17,31]

At present the societal and health care costs for pregnant and post-partum women with UI are unknown. However, it is known that the lifetime risk of surgery for SUI is 14% by the age of 80.[32] The prevalence of SUI rises with age.[33] This fact, together with the ageing population[34] will result in increasing health care costs for SUI.[35] The Dutch Ministry of Health, Welfare and Sports state that "it will be a challenge to provide good, accessible and affordable care for everyone in the future".[36] Therefore, it is important to consider cost-effective strategies.

UI reduces physical quality of life and can be a barrier for exercise.[37] UI also has a negative impact on mental and social quality of life and reduces participation in work, sports and daily activities.[38-40] Women change or adapt their activities to avoid UI and subsequent embarrassment.[41] In the general population, an association exists between bothersome UI and help-seeking behavior.[42,43] However, it is unclear which factors contribute to help-seeking behavior in pregnancy and the first year post-partum. Therefore, we aimed to investigate a wide range of factors regarding pregnancy-related UI.. The reported studies contribute to the body of knowledge of health care professionals concerning the beliefs of peri-partum women regarding UI. This may support the development and divulgation of adequate information (strategies). Moreover, accurate prevalence numbers, knowledge about experienced bother in relation to peri-partum UI and help-seeking behavior, provides relevant information on the extent and impact of UI in this population, on which researchers and policy makers can base their future plans

AIM AND OUTLINE OF THE THESIS

The main objective of this thesis is to gain more knowledge on pregnancy related UI including prevalence, experienced bother, anticipated course, therapeutic effect of physical therapy and help-seeking behavior.

This thesis starts with the results of two systematic reviews and meta-analyses on the prevalence, incidence and bothersomeness of UI. **Chapter 2** presents the results regarding pregnant women and in **Chapter 3** the results for women between 6 weeks and 1 year post-partum are presented. **Chapter 4** describes the design of two randomized controlled trials (RCTs), which aim to evaluate the long term effect of PFMGT compared to care-as-usual in pregnant and post-partum women. The

protocols provide detailed information on the training protocol and assessment methods. **Chapter 5** presents the results of the two RCTs, as presented in chapter 4. In addition, to gain more knowledge on bother in relation to UI and help-seeking behavior of both pregnant, and women between 6 weeks and 1 year post-partum, two surveys on self-reported UI, level of experienced bother and beliefs were conducted. **Chapter 6** reveals the results of the survey among pregnant women. **Chapter 7** shows the results of the survey among women between 6 weeks and 1 year post-partum. **Chapter 8** reveals the results of a qualitative study. The objective was to gain more in depth knowledge regarding pregnant and up to 1 year post-partum women's beliefs, experiences and subsequent healthcare management as well as the views of health care professionals (HCPs). In **Chapter 9** the main findings and conclusions are discussed, and, finally, **Chapter 10** describes the scientific and societal impact of this thesis.

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CHAPTER 2

PREVALENCE, INCIDENCE AND BOTHERSOMENESS OF URINARY INCONTINENCE IN PREGNANCY: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Introduction and Hypothesis: Urinary incontinence (UI) is a common and embarrassing complaint for pregnant women. Reported prevalence and incidence figures show a large range, due to varying case definitions, recruited population and study methodology. Precise prevalence and incidence figures on (bothersome) UI are of relevance for health care providers, policy makers and researchers. Therefore, we conducted a systematic review and meta-analysis to investigate the prevalence and incidence of UI in pregnancy in the general population for relevant subgroups and assessed experienced bother.

Methods: All observational studies, published between January 1998 and October 2018 reporting on prevalence and/or incidence of UI during pregnancy were included. All women, regardless of weeks of gestation and type of UI presented in all settings were of interest. A random-effects model was used. Subgroup analyses were conducted by parity, trimester and subtype of UI.

Results: The mean (weighted) prevalence based on 44 included studies, containing a total of 88.305 women, was 41.0% (range of 9-75%). Stress urinary incontinence (63%) is the most prevalent type of UI. 26% of the women reported daily loss, whereas 40% reported loss on a monthly basis. Bother was experienced as mild to moderate.

Conclusions: UI is very prevalent and rising with the weeks of gestation in pregnancy. SUI is the most common type and in most cases it was a small amount. Bother for UI is heterogeneously assessed and experienced as mild to moderate by pregnant women.

INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine.[1] It is a common and embarrassing problem, evoking substantial individual morbidity, loss in quality of life and socio-economic costs.[2,3] In addition to the loss of bladder control, the need to wear incontinence pads often harms the individuality and self-confidence of young pre-partum women.[4] UI ranges from occasionally leaking urine when coughing or sneezing (stress UI (SUI)) to UI preceded by urgency (urgency UI (UUI)), or a combination of both (mixed UI (MUI)). In the peri-partum period women often experience UI for the first time. In general, SUI is more related to the peri-partum period, whereas the prevalence of UUI and MUI increases with age.[5] Pregnancy and (vaginal) delivery are important risk factors in the development of UI in life.[2,6] Moreover, when SUI presents during pregnancy, the risk of having SUI at 12 years post-partum is significant.[7]

The prevalence and incidence of UI in pregnancy is widely researched. However, these prevalence and/or incidence figures vary greatly throughout published reports, depending on local setting, case definitions applied, recruited population (trimester of pregnancy and parity), and study methodology.[8-10] Former systematic reviews focused on the prevalence of pelvic floor disorders (PFDs) among community-dwelling women[11], the prevalence of UI in nulliparous women[12] or in female athletes.[13] To our knowledge, no systematic review and meta-analysis on the prevalence and incidence of UI in pregnancy is available. Reliable prevalence and incidence rates on UI in pregnancy are not only needed to indicate the burden of the health problem, but also to better inform health professionals, policy makers and researchers in order to set priorities and to assist in planning management of UI.[14]

Furthermore, it is known that not all pregnant women are bothered by experiencing UI. It is reported that the crude UI prevalence rate is higher and probably overestimated compared to the prevalence rate of significant or bothersome UI.[3] As bothersome UI is associated with help-seeking behaviour this discrepancy may have crucial consequences for research planning, health care providers and policy makers.[15] However, a clear and widely accepted definition of bothersome UI still does not exist, which results in the use of heterogeneous terminology and measurement instruments.

Therefore, the primary aim of this systematic review and meta-analysis was to examine the pooled overall prevalence and incidence of UI in pregnancy in the general population, specified for relevant subcategories (trimester of pregnancy, parity, type of UI, frequency and amount). A secondary aim was to provide an overview of the measurement instruments and their outcomes for bother in relation to UI as used in included studies.

METHODS

The MOOSE statement for reporting systematic reviews and meta-analyses was followed.[16] The research protocol was published in the PROSPERO database (registration number CRD42018111991).

Search strategy

We performed a systematic review and meta-analysis of observational studies reporting on the prevalence and/or incidence of UI during pregnancy and experienced bother in relation to UI. We searched the electronic databases of PubMed, EMBASE and CINAHL.

We used the following search terms to search all databases: pregnancy, pregn*, prepartum, pre-partum, pre partum, peripartum, peri-partum, peri partum, nulliparous, primiparous, primigrav*, primipar*, multiparous, multigrav*, multipar*, urinary incontinence, urine loss, pelvic floor disorders, pelvic floor dysfunctions, leaking urine, incontinence, prevalence, incidence, epidemiology, bothersomeness, bother* and quality of life. In the Appendix the complete search strategy for PubMed is provided. This search string was adapted for use in the other databases.

Eligibility criteria

Observational studies published between January 1, 1998 and January 1, 2019 in Dutch, English, Portuguese, German and French were included. All studies examining prevalence and/or incidence of UI among adult primi- and multigravid women, regardless of weeks of gestation, type of UI, setting and country were of interest. Outcomes of interest were prevalence and/or incidence of (bothersome) UI. Exclusion criteria were: articles not available in full or not reporting an overall

UI prevalence of any frequency, and studies examining only twin pregnancies. When articles did not report a prevalence or incidence figure or response rate, an attempt was made for estimation from the information provided. Throughout this article we use the term bother (in relation to UI) as umbrella term for related constructs (impact on daily life or quality of life (QOL)).

Study selection

Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources were screened independently by two reviewers (HM and EB) to identify studies that potentially meet the inclusion criteria. The full text of these potentially eligible studies were retrieved and independently assessed for eligibility by two reviewers. Any disagreement on eligibility was resolved through discussion with a third reviewer (BB). All the included articles were reference checked.

Data extraction and risk of bias

Information on each study was extracted in a standardised data extraction form, based on the Cochrane Public Health Data Extraction and Assessment template.[17] To assess the risk of bias, the Joanna Briggs critical appraisal tool for studies reporting prevalence data was used.[18,19] The checklist consists of nine questions, with the response options yes, no, unclear or not applicable. Overall risk of study bias was rated as low (defined as 8-9 criteria answered as 'yes'), moderate (4-7 criteria answered as 'yes') or high risk (≤3 criteria answered as 'yes'). The response option not applicable (occasionally scored in criteria 5) was considered to be a 'yes'. Two reviewers extracted data independently. Inconsistencies were identified and resolved through discussion including a third author if necessary.

Characteristics regarding measurement instruments for bother were extracted in a separate standardised extraction form. The form contains items like measurement instrument, related construct and measurement results.

Summary measures, statistical analyses and heterogeneity

We used a random effects model to pool the inverse variance (IV) weighted prevalence of UI in individuals to avoid undue influence on the summary estimate

from smaller and less precise studies or studies with a very small prevalence. Pooled prevalence and incidence values were reported with 95% confidence intervals (CI). The degree of heterogeneity was determined by the I^2 statistic, with $I^2 > 75\%$ labelled as considerable heterogeneity.[20]

We performed subgroup analyses based on trimester, parity, type and frequency of UI, as these factors may explain why studies show varying prevalence figures. Trimesters 1, 2 and 3 were defined as weeks 1-13, 14-26 and 27 to at term (42 weeks) respectively. STATA Statistical Software, release 15, was used for analysis.

In order to determine the overall experienced bother in relation to UI across included studies, the total scores of the different measurement instruments for bother were converted to a (standardized) 0 to 100 scale, with 0 indicating no bother and 100 indicating extremely bothered. We classified 1 to 20 as no to mild bother, 20 to 40 as mild to moderate bother, 40 to 60 as moderate to severe, 60 to 80 as severe to very severe, and 80 to 100 as extremely severe bother.

RESULTS

Study selection

Among the 1338 papers initially identified, 44 met the eligibility criteria (Figure 1), resulting in a total of 88,305 participants. All included studies were observational and published between 1998 and January 1, 2019.

Risk of bias

The risk of bias items for each study are shown in Table 1. High, moderate and low risk of bias were considered to be present in 3, 34 and 7 studies respectively. Risk of bias items with the lowest ratings were 8 and 9, and risk of bias items with the highest ratings were 1 and 4.

Study characteristics

17 studies originated from Asia, 15 from Europe, 8 from the USA, 3 from Africa and 1 from Oceania. The majority of women were included from a (tertiary) hospital. Other studies included women from a civil registration system[21], midwifery area[22], hospital and maternity unit[23] or obstetric/child health clinic.[24,25] Table 1 summarizes the study characteristics of included studies.

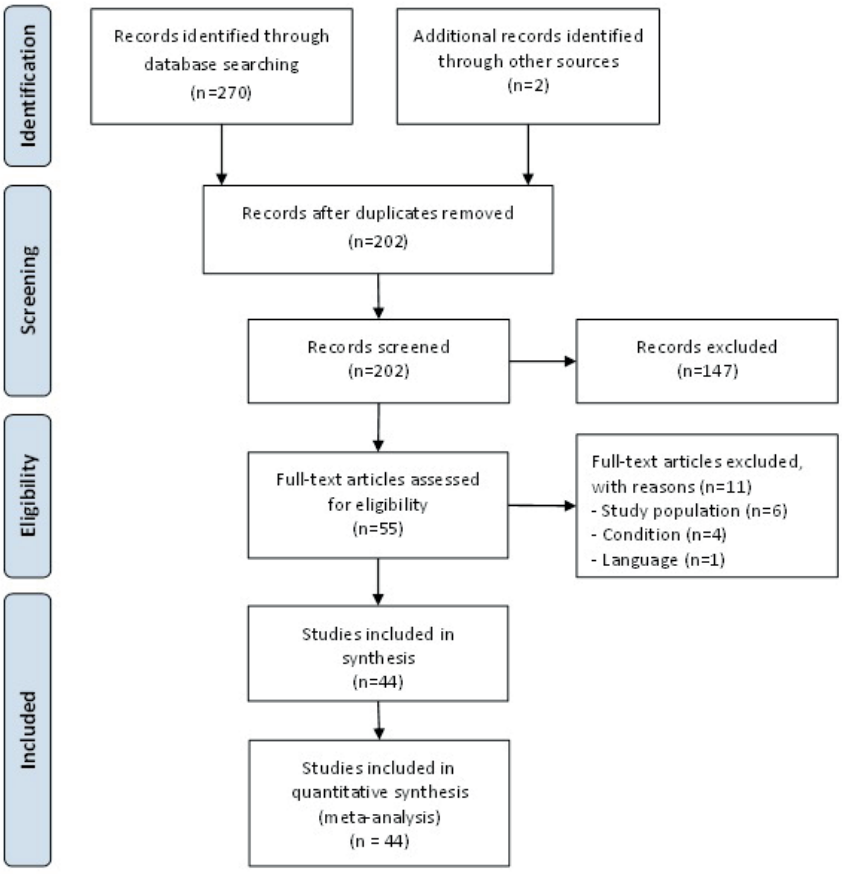

Figure 1 Study flow diagram

13 studies reported on (measurement instruments for) bother, whereas one study (73) reported on two measurement instruments. The result of only one measurement instrument was reported for this study, as the second one (SF-36) was incomplete. Table 2 provides an overview of the measurement instruments as used in included studies, with the original and the converted (0-100 scale) measurement results.

Six different measurement instruments for bother were used, of which the ICIQ-UI SF was most frequently used. Two studies reported the results of the ICIQ-UI SF as categories.[26,27] One measurement instrument was self-constructed and non-validated.[28]

Table 1 Characteristics and outcomes of included studies

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Abdullah et al. 2016[28]	Malaysia	Nulliparous pregnant women in 3rd trimester	UI not specified	3rd trimester	Questionnaire based on ICIQ-UI-SF (Face-to-face interview by trained personnel)	<20 y: n=25 21-30 y: n=254 >30 y: n=27	-	306	3rd trimester	105 (34.4)	SUI: 68 (64.8) UUI: 7 (6.7) MUI: 26 (24.8) Unknown: 4 (1.3)	2,5,9
Adaji et al. 2010[29]	Nigeria	All pregnant women	UI not specified	All trimesters	ICIQ-UI-SF (illiterate women assisted by trained nurse)	(15-42)	0: 46 (22.5) 1-4: 131 (64.2) >4: 27 (13.2)	204	1st: 9 (4.4) 2nd: 101 (49.8) 3rd: 93 (45.8)	43 (21.1)	SUI: 26 (60.5) UUI: 11 (25.6) MUI: 4 (9.3) Enuresis: 1 (2.3) Unexplained: 1 (2.3)	3,5, 8,9
Balik et al. 2016[30]	Turkey	All pregnant women 28-40 wks gestation Exclusion criteria: Diabetes mellitus POP Renal disease	UI not specified	3rd trimester	ICIQ-UI-SF IIQ-7 UDI-6	(5.7; 18-44)	0: 90 (36) ≥1: 160 (64)	250	3rd trimester $\bar{X}$: 35.45 wks (SD 2.98; range 28-40)	93 (37.2)	SUI: 39 (41.9) UUI: 12 (12.9) MUI: 42 (45.2)	3,5,7, 8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Bekele et al. 2016[31]	Ethiopia	All pregnant women Exclusion criteria: Severely sick Kidney or urethral infection Contra-indication for vaginal palpation	Complaint of any involuntary leakage of urine at least once during current pregnancy.	All trimesters	Questionnaire adapted	26 (16-40)	0: 132 (31.3) 1-3: 243 (57.6) ≥4: 47 (11.1)	422 (92.5)	1st: 41 (9.7) 2nd: 101 (23.9) 3rd: 280 (66.4)	48 (11.4)	SUI: 28 (58) UUI: 6 (12.5) MUI: 12 (24.5) Unknown: 2 (5.0)	6,7,8
Beksac et al. 2017[32]	Turkey	Nulliparous pregnant women No UI before pregnancy Exclusion criteria: Systemic disorders (DM, obesity, hyper-tension, urinary system problems) Previous pelvic floor surgery	UI not specified	11-14 wks gestation ± 24 wks gestation ± 37 wks gestation	UDI-6	(3.73; 19-35)	Nullipara	61	11-14 wks gestation ± 24 wks gestation ± 37 wks gestation	11-14 wks: 3 (4.9) 24 wks: 6 (9.9) 37 wks: 16 (26.3)	SUI: 11-14 wks: 2 (3.3), 24 wks: 4 (6.6), 37 wks: 10 (16.4) UUI: 11-14 wks: 1 (1.6), 24 wks: 2 (3.3), 37 wks: 4 (6.6) MUI: 11-14 wks: 0, 24 wks: 0, 37 wks: 2(3.3)	2,3,5, 8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Bø et al. 2012[33]	Norway	All pregnant women < 20 wks gestation Living in districts Planning to give birth at one of two study hospitals	UI not specified	28 ± 2 wks gestation	ICIQ-UI-SF	29.3 (4.9)	0: 351 (46.1) ≥1: 410 (53.9)	772 (93.8)	$\bar{X}$: 28 ± 2 wks gestation	310 (41.7)	SUI: 218 (71.0) UUI: 28 (9.1) MUI: 36 (11.7) Missing: 28 (8.2)	8
Brown et al. 2010[34]	Australia	Nulliparous pregnant women ≥ 18 yrs ≤ 24 wks gestation	Leakage of urine at least once per month	≤ 24 wks gestation 31 wks gestation	Validated questionnaire (≤24 wks gestation-questionnaire) 31 wks gestation-computer assisted telephone interviews) Sandvik questionnaire	18-24: n=213 (14.1%) 25-29: n=430 (28.5%) 30-34: n=583 (38.7%) ≥35: n=281 (18.6%)	Nullipara	- ≤24 wks gestation: 1507 (22.0) - 31 wks gestation: 1454	≤ 24 wks: $\bar{X}$: 15.03 (SD 3.09, range 6-24) 31 wks: $\bar{X}$: 31 (SD 0.03; range 27-38)	≤24 wks: 256 (17.0) 31 wks: 813 (55.9) [Incidence: ≤24 wks: 146 (16.4) 31 wks: 561 (63.2)]	SUI: ≤ 24 wks: 125 (8.3), 31 wks: 536 (36.9) UUI: ≤ 24 wks: 38 (2.5), 31 wks: 86 (5.9) MUI: ≤ 24 wks: 93 (6.2), 31 wks: 191 (13.1)	8,9

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Chan et al. 2013[35]	China	Nulliparous pregnant women ≥ 18 yrs Singleton pregnancy Chinese No UI before pregnancy	Presence of either SUI or UUI	1st, 2nd, 3rd trimester	PFDI	30.6 (3.8)	Nullipara	328 (74.2)	All trimesters: 328 (100)	1st: 38 (11.5) 2nd: 112 (34.1) 3rd: 134 (41.8)	SUI: 1st: 30 (9.1), 2nd: 106 (32.35), 3rd: 124 (37.8) UUI: 1st: 16 (4.9), 2nd: 17 (5.2), 3rd: 47(14.3) MUI: 1st: 8 (2.4), 2nd: 11 (3.3), 3rd: 34 (10.4)	-
Daly et al. 2018[36]	Ireland	Nulliparous pregnant women ≥ 18 yrs ≤ 24 wks gestation	Reporting any leakage	During pregnancy (<24 wks)	Questionnaire, adapted from existing valid questionnaire Sandvik questionnaire	18-24: n=81 (9.4%) 25-29: n=205 (23.8%) 30-34: n=357 (41.5%) 35-39: n=189 (22.0) ≥40: n=28 (3.3%)	Nullipara	860 (46.7)	<24 wks	330 (38.7) [Incidence: 120 (21.7)]	SUI: 147 UUI: 40 MUI: 128 Incidence: SUI: 71 UUI: 9 MUI: 33	8

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De Oliveira et al. 2013[37]	Brazil	All pregnant women Singleton pregnancy Exclusion criteria: Clin. or obst. interference during pregnancy UTI or renal inf. last 4 wks Neurological diseases Cognitive deficit Illiterate women Premature birth Absence of prenatal care	Women reporting not having any UI were defined as continent. Women who reported symptoms of incontinence were defined as "incontinent".	3rd trimester: last four weeks of pregnancy	ICIQ-UI-SF (interview)	27	1: 200 (40.4) 2-3: 206 (41.6) ≥4: 89 (18.0)	495	3rd trimester	352 (71%)		5,7, 8,9

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Dinc et al. 2018[38]	Turkey	All pregnant women Any gestational age Exclusion criteria: 1 UTI History of urological/ gyne-cological surgery	UI not specified	All trimesters	Self-developed questionnaire (face-to-face interviews)	(5.07; 17-42)	0: 393 (52.4) 1: 248 (33.1) >1: 107 (14.3) Missing n=2	750	1st: 128 (17.1) 2nd: 311 (41.45) 3rd: 311 (41.45)	300 (40.0) By trimester: 1: 38 (29.7) 2: 100 (32.2) 3: 162 (52.1)	SUI: 241 (80.3) UUI: 12 (4.0) MUI: 47 (15.7)	5,8,9
Dolan et al. 2004[39]	UK	Nullipara	Any UI within last 3 months	34-40 wks gestation	Self-developed urinary incontinence questionnaire KHQ 34-40 wks: interview, other postal	26 (5.26)	Nullipara	492	34-40 wks	Antenatal: 175 (35.6) Pre-pregn: 17 (3.5)	SUI: antenatal: 75 (49.0) UUI: antenatal: 4 (2.6) MUI: antenatal: 74 (48.4) Unexplained:22	6,7, 8,9
Groutz et al. 1999[40]	Israel	Nulliparous, primiparous and grand multi-parous women	Stress UI: involuntary leakage of urine with coughing, laughing, sneezing, or any other physical effort	2nd or 3rd day post-partum	Interview	20-43	0: 100 1: 100 ≥5: 100	300	1-40 wks	127 (42.3) By parity: 1: 28 (22.0) 2: 49 (38.6) ≥5: 50 (39.4)		3,4,5, 6,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Hansen et al. 2012[41]	Denmark	Primipara ≥18 yrs	Any urinary leakage	UI during pregnancy (last 3 months)	ICIQ-UI-SF Interference daily life	28.2 (4.8)	Nullipara	1018 (63)	3rd trimester	327 (32.1)	SUI: 243 (23.9) UUI: 31 (3.0) MUI: 53 (5.2)	8
Herath et al. 2017[42]	Sri Lanka	Nulliparous pregnant women Second and third trimester Exclusion criteria: Condition which prohibits physical exercise	UI not specified	2nd and 3rd trimester	Not validated questionnaire (interviewer-administered questionnaire)	26.4 (4.4; 18-43)	Nullipara	1017	2nd trim: 189 (18.6) 3rd trim: 828 (81.4)	192 (18.9)	SUI: 94 (9.2) UUI: 79 (7.8) MUI: 19 (1.9)	9
Højberg et al. 1999[43]	Denmark	All pregnant women 16 wks of gestation	Involuntary loss of urine within the last year	16 wks of gestation	Self-developed questionnaire	15-24: n=1347 (17%) 25-29: n=3253 (42%) 30-34: n=2365 (30%) ≥35: n=830 (11%)	0: 4103 (53) 1: 2643 (34) 2: 851 (11) ≥3: 198 (2)	7795 (97)	16 wks	693 (8.9) By parity: 0: 136 (3.9) 1: 361 (13.8) ≥2: 169 (16.2)	SUI: 385 (55.2) UUI: 53 (7.6) MUI: 185 (26.6) Unclassified: 17 (0.2) Missing n=53	8

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Huebner et al. 2010[44]	Germany	Primipara Singleton pregnancy Cephalic pre-sentation Vaginal delivery Duration of pregnancy ≥38 wks gestation	UI not specified	1st & 2nd half of pregnancy	Self-developed questionnaire	28.1 (4.7)	Nullipara	411 (67.4)		1st half pregnancy: 15 (3.6) 2nd half pregnancy: 108 (26.3)		5,6,8
Hvidman et al. 2002[21]	Denmark	Nulli- and pri-miparous women	UI not specified	During 1st and 2nd pregnancy	Not validated questionnaire	28.1	- 0: 352 (54.9) - 1: 290 (45.1)	642 (60.3)	1st: 27 (4.2) 2nd: 61 (9.5) 3rd: 133 (20.7)	- Nulliparous: 70 (19.9) - Primiparous: 72 (24.8) [Incidence: - Nulliparous: 59 (16.8) Primiparous: 24 (8.4)]	-	5,6,8

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Jean-Michel et al. 2018[45]	USA	Pregnant women ≤ 25 yrs - Presenting to the labor and delivery triage unit for routine obstetric care or admitted to the maternity ward. Exclusion criteria: <12 wks gestation	UI not specified	3 mths preceding study enrollment	3IQ	20.3 (2.6)	0: 63 (64) ≥1: 35 (36)	98 (82.4)	$\overline{X}$: 34.5 wks (SD 7.5) 1st : 1 2nd: 18 3rd: 79	51 (52.0)	SUI: 32 (63) UUI: 16 (31) MUI: 0 Unclassified: 3 (6)	3,5,6, 8
Kocaöz et al. 2010[46]	Turkey	All pregnant women	UI not specified		ICIQ-UI-SF Wagner's QoL scale (Face-to-face interviews)	28.1 (1.29)	0: 175 (44.5) 1: 150 (52.3) 2: 53 (16.5) 3: 10 (3.4) ≥4: 5 (1.7)	393	1st: 27 (6.9) 2nd: 47 (11.9) 3rd: 319 (81.2)	106 (26.97) By trimester: 1st: 3 (11.1) 2nd: 9 (19.1) 3rd: 94 (29.5)	SUI: 58 (54.7) UUI: 27 (25.5) MUI: 17 (16.0) Unclassified: 4 (3.8)	5,8,9
Kok et al. 2016[47]	Turkey	All pregnant women ≥ 18 yrs Exclusion criteria: High risk pregnancy	All responses other than 'never' on the questions 'how often do you leak urine?' and 'How much urine do you usually leak?'	Any gestational age	ICIQ-UI-SF I-QoL	30.2 (4.44) ≤29: n=129 (44.9%) ≥30: n=158 (55.1%)	0: 112 (39.0) ≥1: 127 (44.3) Missing: 48 (16.7)	287	$\overline{X}$: 29.5 wks (SD 8.29)	61 (21.3) By trimester: 1st: 2 (3.3) 2nd: 5 (8.2) 3rd: 54 (88.2)	SUI: 44 (72.1) UUI: 16 (26.1) MUI: 1 (1.8)	2,3,7, 8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Liang et al. 2012[48]	Taiwan	Nullipara ≥ 36 wks pregnancy delivered Singleton pregnancy Exclusion criteria: Severe cardio-pulmonary or renal diseases Preeclampsia Insulin dependent DM Neuro-genic diseases Surgery for POP or UI	Experiencing leakage of urine at least once a month	2nd or 3rd day post-partum	Liang et al. LUTS questionnaire (face-to-face interview)	29.4 (4.1)	Nullipara	1501	1st -3rd	563 (37.5)	SUI: 1st trim: 147 (9.8), 2nd trim: 208 (13.9), 3rd trim: 400 (26.7) UUI: 1st trim: 16 (1.1), 2nd trim: 33 (2.2), 3rd trim: 71 (4.7) MUI: 1st trim: 32 (2.1), 2nd trim: 46 (3.1), 3rd trim: 91 (6.1)	5,8,9

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Lin et al. 2018[10]	Taiwan	All women delivering after 28 wks gestation Exclusion criteria: Multiple gestation Severe cardio-pulmonary or renal diseases Pre-eclampsia Insulin -dependent diabetes mellitus Neurogenic diseases UI before pregnancy	SUI; losing urine on coughing, sneezing, or physical exertion	During pregnancy	Interview in obstetric ward LUTS questionnaire SF-12 IIQ-7 UDI-6	32.6 (4.3)	$\bar{x}$: 1.7 (SD: 0.7)	866	1st -3rd	446 (51.5)		8,9

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Luo et al. 2017[49]	China	All pregnant women Singleton pregnancy Exclusion criteria: UI before pregnancy Abdominal and vaginal surgery DM Hyper-tension Placenta previa Threatened abortion Amniotic fluid ab-normalities Fetal growth restriction Vaginal bleeding Exclusion criteria: Failure to complete all invest-igation content and unreliable pelvic ultrasound data	UI not specified	Any gestational age	ICIQ-UI-SF	30.5 Nullipara: 28.4 (3.8) Para: 32.7 (3.70)	0: 179 (52.3) ≥1: 163 (47.7)	342	Nullipara: 1st: 64 (35.8) 2nd: 60 (33.5) 3rd: 55 (30.7) Para: 1st: 58 (35.6) 2nd: 57 (35.0) 3rd: 48 (29.4)	135 (39.5)		3,8,9

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Mallah et al. 2014[50]	Iran	Vaginal delivery Nullipara Healthy women Exclusion criteria: UI before pregnancy History of pelvic trauma, anus and rectal surgery Previous urinary/ gastro-intestinal tract impairment	UI not specified	1st - 3rd trimester	Self-developed questionnaire VAS severity	28.1 (3.7, 19-32)	Nullipara	441		1st trim: 44 2nd trim: 85 3rd trim: 194		2,5,6, 7,8,9
Marshall et al. 1998[51]	UK	All women 2 or 3 days past delivery	UI not specified	2nd or 3rd day post-partum	Self constructed questionnaire		0: 3562(45.9) 2-4: 3826 (49.3) ≥5: 374 (4.8)	7762	1st -3rd	3570 By parity: 0: 1755 2-4: 1683 ≥5: 132		4,6,8, 9
Martin-Martin et al. 2014[52]	Spain	Pregnant women Singleton pregnancy Exclusion criteria: UI before pregnancy	UI not specified	3rd trimester	(Modified) ICIQ-UI-SF (questionnaire given end of 3rd trimester)	31 (5.1)	0: 224 (58.8) ≥1: 160 (41.9)	381 (82.6)	3rd trimester	118 (31)	SUI: 84 (71%) UUI: 4 (3.4%) MUI: 25 (21.5%) Unclassified: 5 (4.3%)	6,7,8

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Martinez Franco et al. 2014[53]	Spain	Pregnant women <13 wks gestation >28 wks gestation	UI not specified	1rd and 3rd trimester	ICIQ-UI-SF PFDI-20	30.8 (16-42)	0: 122 (54.5) 1: 91 (40.6) 2: 8 (3.6) 3: 3 (1.3)	224	1st: 58 (25.9) 3rd: 166 (74.1)	77 (34.4) By trimester: 1st: 11 (19.0) 3rd: 66 (39.8)	SUI: 37 (48) UUI: 7 (9.1) MUI: 25 (32.5) Unclassified: 8 (10.4)	3,5,8,9
Martins et al. 2010[54]	Brazil	Pregnant women Exclusion criteria: High-risk pregnancy Parents who did not give consent to pregnant women	UI regardless of amount	Any gestational age	Questionnaire designed and validated for this research (interview)	24.26 (14-45)	0: 248 (49.6) 1: 133 (26.6) 2: 67 (13.4) 3: 32 (6.4) ≥4: 20 (4.0)	500 (100)	All trimesters	319 (63.3)	SUI: 196 (39.2) UUI: 201 (40.2)	8
		<18 yrs Prenatal care at private clinics										
Mørkved et al. 1999[55]	Norway	All women who delivered at hospital	UI not specified	Before pregn. During pregn.	Structured interview 8 wks post-partum	28 (19-40)	$\bar{x}$: 1.8 (1-5) 1: 52 (36.1) 2: 54 (37.5) 3: 31 (21.5) ≥4: 7 (4.9)	144 (72)	All trimesters	60 (42) By parity: 1: 18 (35) 2: 20 (37) 3: 17 (55) ≥4: 5 (70)		3,8

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Nigam et al. 2016[56]	India	All pregnant women > 34 wks pregnancy Exclusion criteria: High risk pregnancy	UI not specified	34 wks gestation	Questionnaire (based on ICIQ-UI-SF) Interview	≤20: n=19 21-25: n=194 26-30: n=162 31-35: n=25	0: 153 (38.25) ≥ 1: 247 (61.75)	400	Late 3rd trim	301 (75.3)	SUI: 219 (72.7) UUI: 16 (4.0) MUI: 66 (21.9)	7,8,9
Okunola et al. 2018[26]	Nigeria	Pregnant women 18-45 yrs Exclusion criteria: DM UI prior to pregnancy UTI Use of parasympatho-mimmetic or sympatholytic drug Urological/ gyn-aecological surgery	UI not specified	Any gestational age	ICIQ-UI-SF Illiterate participants were assisted by 2 trained nurses	29.9 (5.3)	0: 150 (33.9) ≥1: 292 (66.1)	442 (85.5)	1st: 12 (2.7) 2nd: 83 (18.8) 3rd: 47 (78.5)	124 (28.1) By parity: 0: 43 (28.7) ≥1: 81 (27.7)	SUI: 77 (17.4) UUI: 30 (6.8) MUI: 17 (3.9)	5,8

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Raza-Khan et al. 2006[57]	USA	All pregnant women Exclusion criteria: Maternal history of preexisting DM Active cardiac disease excl. mitral valve prolapse Neurological disease Urinary tract surgery Congenital genito-urinary abnormalities	Any MESA answer of 'sometimes' or 'often'	3rd trimester	MESA Hunskaar Severity Index	28 (17-41)	0: 37 (32.7) 1: 47 (41.6) 2: 18 (15.9) 3: 10 (8.8) 4: 1 (0.9)	113	3rd trimester: $\bar{X}$: 34.8 (2.6)	83 (74)	SUI: 36 (32) UUI: 4 (4) MUI: 42 (37) Unclassified: n=1	3,8,9

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Rocha et al. 2017[58]	Portugal	≥18 yrs Singleton pregnancy Exclusion criteria: (Para)sympatica DM UI before pregnancy UTI/ genital infections Urogynaecological surgery Actual(this pregnancy)pre-term labor Fetal death	UI not specified	Directly post-partum	Adapted ICIQ-UI-SF	29.3 (5.7)	0: 108 (45.6) 1: 126 (53.2) ≥2: 3 (1.3	237	3rd trimester	123	SUI: 101 (82.1) UUI: 12 (10) MUI: 10 (7.9)	3,8,9
Rogers et al. 2017[59]	USA	Pregnant >18 yrs Nulliparous Singleton fetus No serious medical problem < 36 wks gestation	UI score > 0 on ISI	1rd - 3rd trimester	ISI QUID IIQ-7	24.2 (5.1)	Nullipara	623	1st: 124 (19.9) 2nd: 403 (64.7) 3rd: 96 (15.4)	1st: 40 (33) 2nd: 176 (44) 3rd: 407 (69)	SUI 1st: 10 (25) 2nd: 60 (34) 3rd: 135 (34) UUI 1st: 19 (48) 2nd: 81 (47) 3rd: 194 (48)	2,5,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%)[a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Sharma et al. 2009[60]	India	All pregnant women	UI not specified	1st - 3rd trimester	Questionnaire designed for this study (Interview)	26.5 (18-39)	0: 80 (33.3) 1-3: 133 (55.4) 4-8: 27 (11.3)	240	1st: 29 (12.1) 2nd: 89 (37.8) 3rd: 122 (50.1)	62 (25.8) By trimester: 1st: 7 (24.1) 2nd: 21 (23.6) 3rd: 34 (27.9)	SUI: 46 (19.2) UUI: 7 (2.9) MUI: 9 (3.8)	2,3,5,7,8
Solans-Domènech et al. 2010[27]	Spain	Healthy nulliparous pregnant women Exclusion criteria: UI before pregnancy Neurological disease Cognitive disorders Urological pathology(non infectious) Abortion Impaired mobility Previous urogynaecologic surgery Current treatment with drugs (benzodiazepines, diuretics)	UI not specified	1st - 3rd trimester	ICIQ-UI-SF ISI		Nullipara	1128	1st - 3rd trimester	441 (39.1) By trimester: 1st: 84 (8.3) 2nd: 319 (31.8) 3rd: 322 (28.5) [Incidence: 441 (39.1) By trimester: 1st: 84 (8.3) 2nd: 282 (28.1) 3rd: 141 (15.2)]	SUI: 1st trim: 57 (67.9), 2nd trim: 250 (79.8), 3rd trim: 255 (79.2) UUI: 1st trim: 15 (17.9), 2nd trim: 25 (7.8), 3rd trim: 22 (6.8) MUI: 1st trim: 3 (3.6), 2nd trim: 20 (6.3), 3rd trim: 18 (5.6)) Unclassified: 1st: 9 (10.7), 2nd trim: 20 (6.3), 3rd trim: 22 (6.8)	9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Sottner et al. 2006[61]	Czech Republic	Nullipara	UI not specified	1rd - 3rd trimester (questions asked 2nd day after delivery)	Questionnaire designed for this study		Nullipara	339 (71.5)	All trimesters *(each trimester same sample)*	1st: 56 (16.5) 2nd: 118 (34.8) 3rd: 218 (64.3)	SUI: 177 (52.2) UUI: 115 (33.9) Before pregnancy: SUI: 52 (15.3) UUI: 18 (5.3)	4,6,8
Spellacy et al. 2001[62]	USA	Healthy pregnant women ≥18 yrs	UI not specified	3rd trimester	Self-developed questionnaire (3rd trim: face to face Interview)	25.4 (5.34)	0 - 4	50	3rd trimester	31 (62)		2,3,6,7,8,9
Tanaw-attana-charoen et al. 2013[63]	Thailand	Pregnant women Exclusion criteria: Multiple pregnancy UI before pregnancy Urethra/bladder surgery LUTS and infection during pregnancy DM Hypertension with diuretic treatment Incomplete medical record	UI not specified	≥36 wks gestation	Modified ICIQ-UI-SF	<20: n=17 (4.1%) 20-29: n=222 (53.8%) 30-39: n=165 (40.0%) 40-49: n=9 (2.2%)	0: 182 (44.1) ≥1: 231 (55.9)	413	≥36 wks	222 (53.8)	SUI: 221 (53.5) UUI: 83 (20.0) MUI: 82 (19.8)	6,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
Thomason et al. 2007[64]	USA	Primipara Exclusion criteria: Genital anomalies Diabetes with risk of UTI Prior urinary tract infection/surgery Pregnant Delivered by CS UI before pregnancy	Have you involuntarily lost or leaked any amount of urine?	≥35 wks gestation (questions asked 6-9 months post-partum)	Self-constructed questionnaire	- Primiparous continent: 29.7 - Primiparous incontinent: 29.8	Nullipara	121 (75.6)	≥35 wks gestation	62 (51)		3,8
Valeton et al. 2011[65]	Brazil	Pregnant women ≥ 28 wks gestation 14-30 yrs Exclusion criteria: UTI/gynecological infection Urogynecology surgery Use of parasympa-thomimetic/ sympatholytic drugs DM Premature labor in	Symptoms of involuntary loss of urine	3rd trimester	- Self-reported UI - KHQ	23.2 (3.69)	0: 177 (51.6) 2: 105 (30.6) ≥3: 61 (17.8)	343	3rd trimester	105 (30.6) By parity: 0: 89 (26) 2: 103 (30) ≥3: 151 (44)		7,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measu-rement(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate (%))	Trimester of pregnancy n (%) [a]	UI prevalence n(%) [Incidence: n (%)]	Type of UI n (%)	Risk of bias items [b]
		current pregnancy Fetal death Delivered infant in another institution										
Wesnes et al. 2007[23]	Norway	All pregnant women	Everybody answering yes on the entry questions regarding UI before or during pregnancy or answering affirmatively about frequency, amount or volume before or during pregnancy, were defined as incontinent.	30 wks (3rd trimester)	Questionnaire	(14-47)	0: 19.981 (46.2) ≥1: 23.298 (53.8)	43.279 (45)	3rd trimester	25.121 (58.1) [Incidence: 13.978 (45.6) SUI: 9.634 (31.5) UUI: 1.231 (4.0) MUI: 3.113 (10.2)]	SUI: 15.961 (36.9) UUI: 2.083 (4.8) MUI: 7.077 (16.4)	8
Zhu et al. 2012[66]	China	Primipara ≥28 wks gest.	UI not specified	37-42 wks gestation	BFLUTS	26.4 (4.0)	Primiparous	10.098	Late pregnancy	2.696 (26.7)	SUI: 1.878 (18.6) UUI: 202 (2.0) MUI: 434 (4.3) Other UI: 182 (1.8)	5,8,9

[a] Unless otherwise stated .
[b] Each number represents the items where risk of bias exists (based on the Joanna Briggs critical appraisal tool [18]. 1= Was the sample frame appropriate to address the target population?, 2= Were study participants sampled in an appropriate way?, 3= Was the sample size adequate?, 4= Were the study subjects and the setting described in detail?, 5= Was the data analysis conducted with sufficient coverage of the identified sample?, 6= Were valid methods used for the identification of the condition? , 7= Was the condition measured in a standard, reliable way for all participants?, 8= Was there appropriate statistical analysis?, 9= Was the response rate adequate, and if not, was the low response rate managed appropriately?

UI=urinary incontinence, SUI= stress urinary incontinence, UUI= urgency urinary incontinence, MUI= mixed urinary incontinence , ICIQ-UI-SF= International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form, wks= weeks, POP=pelvic organ prolapse, IIQ-7= Incontinence Impact Questionnaire, UDI-6= urogenital distress inventory, DM= diabetes mellitus, y= years, clin= clinical, Obst= obstetric, UTI= urinary tract infection, inf=infection, QoL= quality of life, I-QoL= incontinence quality of life, PFDI-20= pelvic floor distress inventory, ISI= Incontinence severity index, QUID= Questionnaire for urinary diagnosis, 3-IQ= 3 incontinence questionnaire, mths= months, PFDI= Pelvic Floor Distress Inventory, KHQ= Kings Health Questionnaire, sec= second, trim= trimester, MESA= Medical, Epidemiological, and Social Aspects of Aging Questionnaire, BFLUTS= Bristol Female Lower Urinary Tract Symptom questionnaire.

Table 2 Measurement of bother and results

Measurement instrument	Background information on measurement instrument	Study	Original measurement result (mean)	Trimester/ weeks	(Converted) measurement results (0-100)
ICIQ-UI SF (0-21)	To assess symptoms of UI and impact on QoL. (4 questions, question 4 is on moment of UI and is not within the calculation of the total).	54	4.1	AT	19.3
		58	6.3	(28 wks +/- 2 wks) T3	30.0
		44	12.1	(last 4 wks pregn) T3	57.6
		63	6.2	T3	29.5
		73	6.6	(T1 and T3) AT	31.4
		26, 27	Results reported in categories. No total score.		
ICIQ-UI SF Question 3 (QoL) (0-10)	Question 3 of the ICIQ-UI SF is on the interference in daily life of UI.	69	Nulliparous 2.7	AT	26.7
			Multiparous 3.6	AT	35.8
			3.1	AT	31.3
		72	3.5	T3	34.8
I-QOL	Quality of life in persons with UI. 3 subscales: 1. Avoidance and limiting behaviour, 2. Psychosocial impact, 3. Social embarrassment. (22 questions)	67	82.4	AT	17.7
IIQ	Interference of UI of women's daily life and the bothersomeness. 4 subscales: 1. Physical activity, 2. Travel, 3. Social relationships, 4. Emotional health. (31 questions)	77	9.5 (T1: 8.2, T2: 7.1, T3: 13.3)	AT (T1, T2, T3)	9.5

Measurement instrument	Background information on measurement instrument	Study	Original measurement result (mean)	Trimester/ weeks	(Converted) measurement results (0-100)
Wagner's quality of life scale	Questions on daily lives and psychosocial characteristics. (28 questions)	66	9.9	AT	11.8
Self-constructed non-validated questionnaire		28			

ICIQ-UI SF= International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form, I-OOL= Incontinence Quality of Life, IIQ-7= Incontinence Impact Questionnaire, N=number, AT= All trimesters, T1= Trimester 1, T2= Trimester 2, T3= Trimester 3.

Synthesis of results

Overall prevalence

44 studies involving a total of 88.305 women were used to calculate the overall prevalence of UI. The weighted average of UI prevalence among pregnant women was 41.0% (CI 95% 34.0-48.0%; I^2: 99.77%), regardless of trimester, parity or type of UI (Figure 2). The lowest prevalence of UI found in the included studies was 9%[43] and the highest prevalence 75%[56]. Prevalence figures for low, moderate and high risk of bias studies were 38% (95% 18.0-58.0), 41% (95% 36.0-46.0), 47% (95% 39.0-54.0) respectively.

Subcategories trimester of pregnancy, type of UI and parity

Five out of the 44 studies included women from trimester one or two, or two out of three pregnancy trimesters. 15 studies recruited women from the third trimester, with an overall UI prevalence of 47% (95%-CI: 37.0-58.0%). 24 studies recruited women from trimester 1-3, with an overall UI prevalence of 40% (95%-CI: 34.0-45.0%). Based on 24 studies, SUI accounts for 63% of UI cases, whereas UUI, MUI and unexplained UI, were 12%, 22% and 3% respectively.

When parity is taken into account, 42% of nulliparous women experience UI (based on 12 studies; 95% CI 33.0-51.0%; I^2=98.6%), whereas 4 studies reporting only on primiparous women, found an overall UI prevalence of 31% (95% CI 26.0-36.0%; I^2 90.6%). 27 studies included women with any parity, resulting in a pooled prevalence of 42% (95% CI 32.0-53.0%; I^2 99.8%).

Based on 12 out of 44 studies, the overall prevalence for UI in trimesters 1, 2 and 3 is 9% (95% CI 6.0-12.0%; I^2 97.7%), 19% (95% CI 12.0-25.0%; I^2 98.7%) and 34% (95% CI 23.0-46.0%; I^2 99.0%) respectively.

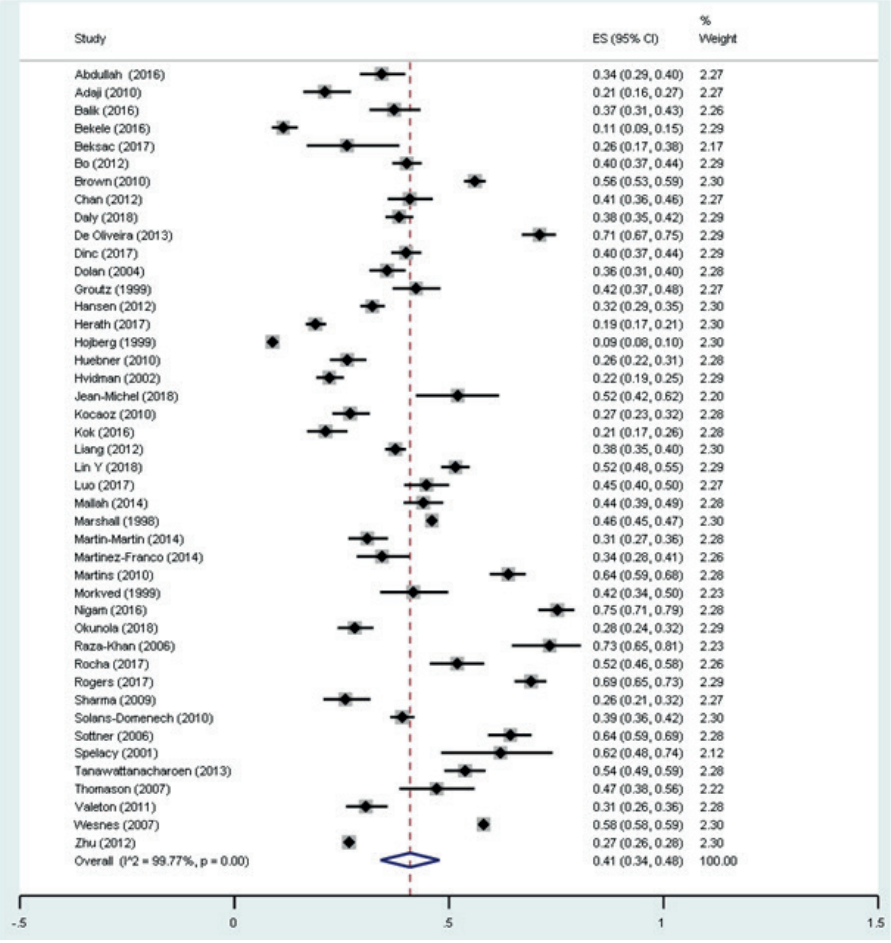

Figure 2 Pooled prevalence of UI during pregnancy

Subcategories frequency and amount of UI

Based on 10 studies, monthly UI accounts for 40% of UI cases (95% CI 23.0-57.0%; I^2 99.0%), weekly UI for 33% (95% CI 23.0-43.0%; I^2 94.8%) and daily UI for 26% (95% CI 20.0-32.0%; I^2 86.9%).

The majority of studies (n=9), reporting on the amount of urine loss (n=14), used the International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) to assess this parameter (none, small, moderate, large amount).[67] Three studies reported separately the ICIQ-UI SF amount item, showing that the majority (79.2-86.9%) of UI cases lose a small amount. Other descriptions of amount of urine lost were: drops or just a little, more like a trickle, more than a trickle[34,36], a few droplets, a stream[60] and drops, small splashes, more.[27,57]

Bother

13 studies reported on impact on daily life, quality of life or bother. It was heterogeneously assessed, however the ICIQ-UI SF was used in the majority of studies (n=7). In two studies question 3 of the ICIQ-UI SF on interference on daily life was reported as a measurement instrument for bother. Other measurement instruments that were used only once were the Incontinence Quality of Life (I-QOL), Incontinence Impact Questionnaire (IIQ-7), Wagner's quality of life questionnaire, and a self-constructed non-validated questionnaire. The overall bother of UI during pregnancy, on a 0 to 100 scale, ranges between 9.5 and 34.1, consistent with mild to moderate bother, whereas the experienced bother is higher in the 3rd trimester (between 13.3 and 57.6) (Table 3).

Case definition

The majority of studies (n=30) did not specify a case definition for UI. Four studies used as a case definition 'any leakage', or used a frequency (n=5), amount/ volume (n=1), timeframe (n=2) or UI type (n=3) criteria in their case definition, or a combination of those (n=3).

Table 3 Converted results 0-100 by measurement instrument

	Total (all instruments)	**ICIQ-UI SF (total score)**	**ICIQ-question 3 (QoL)**	**Other measurement instruments (I-Qol, IIQ-7, Wagner's QoL)**
All trimesters	9.5 - 34.1 (7 studies)	19.3 - 31.4 (2 studies)	31.3 (1 study)	9.5 - 34.1 (3 studies)
3rd trimester	13.3 - 57.6 (5 studies)	29.5 - 57.6 (3 studies)	34.8 (1 study)	13.3 (1 study)

ICIQ-UI SF= International Consultation on Incontinence Questionnaire -Urinary Incontinence Short Form, I-QOL=Incontinence Quality of Life, IIQ-7= Incontinence Impact Questionnaire, wks= weeks

Incidence

Few studies have examined incidence of UI during pregnancy, using different trimesters of pregnancy and case definitions. Therefore no pooling was done for this outcome. Five studies reported on new-onset UI during pregnancy among women who were continent 12 months before the index pregnancy[34,36] or who had no UI previous to pregnancy[21,23,27]. Daly *et al.* reported that 21.7% of nulliparous women experienced any new-onset urinary leakage in early pregnancy.[36] The frequency of leakage among new-onset UI was less than once per month in 55% of cases, on a monthly, weekly and daily basis in 26.7%, 13.3% and 5.0% of cases respectively. The majority (83.1%) experienced drops or just a little amount of leakage. Brown *et al*.[34] reported 146 incident cases for any UI in early pregnancy (≤24 weeks of gestation; 16.4%) compared to 561 cases in late pregnancy (31 weeks; 63.2%). It appeared that new cases of SUI accounted for more than two thirds of prevalent cases in early and late pregnancy, 70.4% and 73.9%, respectively. Hvidman *et al*. concluded that UI incidence during pregnancy was 16.8% among nulliparous and 8.4% among primiparous women.[21] Overall, incidence rates in early pregnancy among nulliparous women range between 16.4% and 21.7%.[34,36] When considering late pregnancy, the incidence rate increases to 45.6-63.2%.[23,34] The incidence rate of UI during first pregnancy, regardless of trimester, is 16.8-39.1%.[21,27]

DISCUSSION

The aim of this systematic review was to examine the pooled prevalence and incidence of UI during pregnancy and to provide an overview of measurement instruments, including the measurement results, to assess bother in relation to UI. The results show an overall mean prevalence of UI during pregnancy of 41%, with a range of 9-75%. The prevalence numbers rise with gestational period from 9% in the first trimester to 34% in the third. SUI is the most prevalent type of UI, accounting for 63% of cases. 26% of the women reported daily loss, whereas 40% reported loss on a monthly basis. Most of the cases reported a small amount of urine loss.

Incidence/new onset UI in nulliparous women in early pregnancy varied between 16.4% and 21.7%.[34,36] This variation might be explained by the different case definition used for UI (e.g. any UI[36] in contrast to UI at least once a month[34]). Incidence in late pregnancy increased to 63.2%.[34] Over 70% of new onset UI was

SUI. The high prevalence and rising incidence numbers of SUI during pregnancy might be due to several factors like physiological weight gain which results in increased intra-abdominal pressure on the bladder and pelvic floor muscles.[68] Additionally, it is known that pregnant women with SUI have significant less pelvic floor muscle strength and thickness[69] and/or a larger hiatal area at rest and during pelvic floor muscle contraction.[70] But also previous childbirth and high body mass index are risk factors for developing SUI.[71,72]

Most included studies showed a moderate risk of bias. Although several factors influence reported prevalence rates, e.g. case definition, studies with moderate or high risk of bias may distort prevalence and/or incidence rates. The prevalence rate among three studies with high risk of bias is 47% compared to 38% among studies with low risk of bias (in studies with a moderate risk of bias the prevalence is 41%). As studies with a low risk of bias tend to have a slightly lower prevalence, it is likely that the real prevalence of UI in pregnant women is in the range of 38-41%.

Only 13 out of 44 studies reported bother in relation to UI, these studies used a variety of measurement instruments. In an attempt to provide an overall assessment of experienced bother in relation to UI, we (arbitrarily) chose to standardize the measurement results of different bother scales to a 0 to 100 scale. Bother of UI during pregnancy ranges between 9.5 and 34.1 on a (standardized) 0 to 100 scale. The 0 to 100 scale can be regarded as a visual analogue scale (VAS). The VAS is a valid and reproducible method to measure the impact of UI on QOL.[73] No studies are known that report on cut-off points for QOL in pregnant women with UI. Therefore, cut-off points must be interpreted cautiously. One study comparing the VAS with a measure that assesses the impact on functioning in patients with pain identified three classes. Class 1, mild interference (score 1 – 34), class 2, moderate interference (score 35 – 64), and class 3, severe interference with daily life (score 65 – 100).[74] Based on these classes the overall bother of UI during pregnancy is mild, and in the third trimester mild to moderate. One study reporting on bother of UI in the last four weeks of pregnancy reported the highest bother of 57.[45] This might be due to the rising prevalence over time in pregnancy.[37,45,56,57,62-64]

The ICI provides an overview of (recommended) grade A (high quality) measurement instruments for bother in relation to UI[3] and advises to report prevalence figures

in combination with the experienced bother. The ICIQ-UI SF, IIQ and I-QOL, for example, are rated as grade A measurement instruments. Wagner's QOL and the VAS are not incorporated in the ICI overview, nor is the separate use of question 3 of the ICIQ-UI SF as a bother measure. A closer look at the measurement instruments shows that there are differences with regard to assessed constructs and domains. The ICIQ-UI SF is a quick way to assess frequency, severity and bother of UI. The IIQ, I-QOL, and Wagner's QOL scale assess bother of UI with a variety of subscales like: psychosocial impact, social embarrassment, relations, and physical activity and provide therefore more in depth information.

This systematic review revealed that the reporting of prevalence with a measure of bother is not common practice yet. To improve the reporting of UI prevalence, it is recommended that in research projects both prevalence and bother are measured with high quality measurement instruments in line with the recommendations of ICI. In clinical practice, measurement results of bother support healthcare professionals in the clinical reasoning process as it may provide information on diagnosis, prognosis or may evaluate one's own actions. At the same time, it standardizes communication with colleagues. Moreover, measurement results can be used to better inform patients about their situation and to involve them more easily in joint therapy decisions (shared decision making).

The construct bother in relation to UI seems difficult to grasp, as included studies used different definitions. The following terms were used: effect on daily activities/ everyday life, interference on daily life, health-related quality of life, severity, lifestyle changes, (perceived) impact on quality of life, distress, experienced discomfort and amount of bother. As the degree of bother is related to help-seeking behaviour for UI[75,76] it is of importance to define the construct bother (what does bother in relation to UI mean for pregnant women) and quantify bother. When bother is well defined and quantified, this will support researchers in selecting the appropriate measurement instrument and interpretation of the results.

Based on the prevalence figures, it would appear that UI in pregnancy is an enormous healthcare problem. However, not everyone seeks (medical) help for UI immediately. Several factors determine help-seeking behaviour of pregnant women, such as awareness of treatment possibilities and the experienced burden of UI.[76,77] Also the belief that UI will resolve by itself after delivery and the lack of knowledge that UI during pregnancy raises the odds for post-partum UI

substantially obstructs help-seeking.[78,79]

Management of UI should be directed to women who seek help for UI, but may also be directed towards women who experience bother or have risk factors for developing UI (prevention). Such uncertainties require further evaluation and data on duration of treatment effects of PFM(G)T.[80] Maternity care workers need to assess women for the presence, severity and bother of UI and, in consultation with them, develop a specially tailored plan of care to meet the women's needs.

The strength of this systematic review is the large number of included studies, which resulted in the availability of prevalence and incidence numbers for different subpopulation (countries, parity, trimester of pregnancy) and for different purposes (research planning, health care providers and policy makers). This review is the first one that focused on assessment methods for bother in relation to UI and degree of adherence to the recommendations of ICI with regard to this topic.

The limitations of this systematic review are, firstly, the presence of substantial clinical heterogeneity of the studies. Clinical heterogeneity is due to differences in: case definition (any UI or different frequencies of UI in a certain period of time), population (primigravida- multigravida) or periods researched (first, second, third trimester or any specific trimester). Secondly, the considerable statistical heterogeneity of the studies resulting in large CI's. Thirdly, as the Joanna Briggs critical appraisal tool does not recommend cut-off points for high, moderate or low risk of bias, we arbitrarily chose the cut-off points reported in this systematic review to explore possible differences in prevalence numbers if stratified for risk of bias. However, we did not include or exclude studies based on risk of bias.

CONCLUSION

UI is a very common symptom in pregnancy and the prevalence rises as weeks of gestation progress. SUI is the most common type and in most of the cases a small amount of urine was lost. The level of bother for UI is heterogeneously assessed and is experienced as mild to moderate by pregnant women.

APPENDIX:

Search strategy for PubMed:

((((((((((((((((((pregnancy[MeSH Terms]) OR pregnancy[Title/Abstract]) OR pregn*) OR prepartum[Title/Abstract]) OR 'pre-partum'[Title/Abstract]) OR 'pre partum'[Title/Abstract]) OR peripartum[Title/Abstract]) OR 'peri-partum'[Title/Abstract]) OR 'peri partum'[Title/Abstract]) OR nulliparous[Title/Abstract]) OR primiparous[Title/Abstract]) OR primigrav*[Title/Abstract]) OR primipar*[Title/Abstract]) OR multiparous[Title/Abstract]) OR multigrav*[Title/Abstract]) OR multipar*[Title/Abstract])) AND ((((((((((('urinary incontinence'[MeSH Terms]) OR urinary incontinence title/abstract) OR 'urine loss'[Title/Abstract]) OR 'pelvic floor disorders'[MeSH Terms]) OR 'pelvic floor disorders'[Title/Abstract]) OR 'pelvic floor dysfunctions'[Title/Abstract])) OR incontinence[Title/Abstract])) OR 'leaking urine'[Title/Abstract])))) AND ((((((((((((prevalence[MeSH Terms]) OR prevalence[Title/Abstract]) OR epidemiology[MeSH Terms]) OR epidemiology[Title/Abstract]) OR quality of life[MeSH Terms]) OR 'quality of life'[Title/Abstract]) OR bother*[Title/Abstract]) OR bothersomeness[Title/Abstract])))))))

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CHAPTER 3

PREVALENCE, INCIDENCE AND BOTHERSOMENESS OF URINARY INCONTINENCE BETWEEN 6 WEEKS AND 1 YEAR POST-PARTUM: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Introduction: Urinary incontinence (UI) is a common complaint for post-partum women. Reported prevalence and incidence figures show a large range, due to varying study methodology. The crude prevalence of post-partum UI may differ when accounting for bother. Precise prevalence and incidence figures on (bothersome) UI are of relevance for health care providers, research planning, and policy makers. Therefore, we conducted a systematic review and meta-analysis to investigate the prevalence and incidence of UI in post-partum women in the Western world, for relevant subgroups and assessed experienced bother in relation to UI.

Methods: Observational studies, published between January 1998 and March 2020, and reporting on prevalence and incidence between 6 weeks and 1 year post-partum were included, regardless of type of UI or setting. We used a random effects model with subgroup analyses for post-partum period, parity, and subtype of UI.

Results: The mean (weighted) prevalence based on 24 included studies, containing a total of 35.064 women, was 31.0%. After an initial drop in prevalence at 3 months post-partum, prevalence rises up to nearly the same level as in the third trimester of pregnancy at 1 year post-partum (32%). Stress UI (54%) is the most prevalent type. UI prevalence is equal amongst primi- and multiparous women. Experienced bother of UI is heterogeneously assessed and reported to be mild to moderate.

Conclusions: UI post-partum is highly prevalent in women in the Western world. After an initial drop it rises again at 1 year post-partum. Experienced bother is mild to moderate.

INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine.[1] The main subtypes of UI are stress (S)UI, urgency (U)UI, and mixed (M)UI. SUI is leaking urine when coughing or sneezing.[1] SUI is more common in younger women.[2] Pregnancy and vaginal delivery are well-documented risk factors for developing UI.[3-5] 73% of women with UI 3 months post-partum still report UI at 6 years post-partum.[6] In general, UI prevalence and incidence rise with ageing.[7] Women often experience UI as embarrassing and humiliating, resulting in loss in quality of life.[8] UI also causes considerable socio-economic costs.[9,10]

The prevalence and incidence of UI in the post-partum period are widely studied. However, these prevalence and/or incidence figures vary greatly throughout published reports, depending on local setting, case definitions applied, recruited population (period post-partum and parity), and study methodology.[11,12] A systematic review on the prevalence of post-partum UI and the relation to the mode of delivery was published in 2010.[13] At that time, studies hardly reported on bother. In 2017 the International Consultation on Incontinence (ICI) recommended that prevalence numbers should be accompanied by the experienced bother[14], as there are indications that the prevalence of bothersome UI is lower than the crude UI prevalence.[14] As women with bothersome UI tend to seek more help[15], health professionals, policy makers and researchers need reliable prevalence numbers to specify the health problem UI causes and to help set priorities and assist in planning the management of UI.

Therefore, the primary aim of this systematic review and meta-analysis was to examine the pooled overall prevalence and incidence of UI between 6 weeks and 1 year post-partum in the general population of the Western world, specified for relevant subcategories (period post-partum, parity, type of UI, frequency and amount). A secondary aim was to provide an overview of the assessment methods and outcomes for bother in relation to UI as used in included studies.

METHODS

The MOOSE statement for reporting systematic reviews and meta-analyses was followed.[16] The research protocol was published in the PROSPERO database (registration number CRD42018111991).

Search strategy

We performed a systematic review and meta-analysis of observational studies (cross-sectional and cohort studies) reporting on the prevalence and incidence of UI after delivery and experienced bother. We searched the electronic databases of PubMed, EMBASE and CINAHL. All included articles were reference checked. Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources were screened independently by two reviewers. Full text of potentially eligible studies were retrieved and independently assessed for eligibility by two review team members. Any disagreement on eligibility was resolved through discussion with a third reviewer.

We used the following search terms to search all databases: postpartum, post-partum, post partum, peripartum, peri-partum, peri partum, primiparous, multiparous, multigrav*, multipar*, urinary incontinence, urine loss, leaking urine, incontinence, prevalence, incidence, epidemiology, frequency, bothersomeness, bother*, quality of life, hindrance. In the Appendix the complete search strategy for PubMed is provided. This search string was adapted for use in the other databases.

Eligibility criteria

Observational studies published between January 1, 1998 and March 1, 2020 in Dutch, English, German and French were included. All studies examining prevalence and/or incidence of UI from 6 weeks to 12 months post-partum among adult primi- and multiparous women in the Western world, regardless of type of UI and setting were of interest. Six weeks post-partum was chosen to ensure a large proportion of the sample to have recovered physiologically from the delivery. Outcomes of interest were prevalence and/or incidence of (bothersome) UI. Exclusion criteria were: articles not available in full or not reporting an overall UI prevalence and/or incidence of any frequency, studies examining only twin pregnancies and studies originating from non-Western countries. The latter criteria were chosen for the purpose of homogeneity in population characteristics. When articles did not report a prevalence figure or response rate, an attempt was made for estimation from the information provided. Throughout this article we use the term bother (in relation to UI) as umbrella term for related constructs (impact on daily life or quality of life (QOL)).

Study selection

Titles and/or abstracts of studies retrieved using the search strategy and those from additional sources were screened independently by two reviewers (HM and EB) to identify studies that potentially meet the inclusion criteria outlined above. The full text of these potentially eligible studies were retrieved and independently assessed for eligibility by these two reviewers. Any disagreement on eligibility was resolved through discussion with a third reviewer (BB). All the included articles were reference checked.

Data extraction and risk of bias

Information on each study was extracted in a standardised data extraction form, based on the Cochrane Public Health Data Extraction and Assessment template.[17] To assess the risk of bias, the Joanna Briggs critical appraisal tool for studies reporting prevalence data was used.[18,19] The checklist consists of nine questions, with the response options yes, no, unclear or not applicable. Overall risk of study bias was rated as low (defined as 8-9 criteria answered as 'yes'), moderate (4-7 criteria answered as 'yes') or high risk (≤3 criteria answered as 'yes'). The response option not applicable (occasionally scored in criteria 5) was considered to be a 'yes'. Two reviewers (HM, EB) extracted data independently. Inconsistencies were identified and resolved through discussion including a third author (BB) if necessary.

Characteristics regarding measurement instruments for bother were extracted in a separate standardised extraction form. The form contains items like measurement instrument, related construct and measurement results.

Summary measures, statistical analyses and heterogeneity

We used a random effects model to pool the inverse variance (IV) weighted prevalence of UI in individuals to avoid undue influence on the summary estimate from smaller and less precise studies or studies with a very small prevalence. Pooled prevalence and incidence values were reported with 95% confidence intervals (CI). The degree of heterogeneity was determined by the I^2 statistic, with $I^2 > 75\%$ labelled as high heterogeneity.[20]

Prevalence was studied by subgroup [post-partum period (6 weeks, 3, 6, 9 and 12 months), type and frequency of UI, and parity (primi- and multiparous)] as this might explain why studies show varying prevalence figures. ,. Studies reporting on a post-partum period other than the five established periods are classified in the closest post-partum period. Moreover, studies reporting a period prevalence (e.g. 9-12 months post-partum) are classified in the upper range of the period prevalence (i.e. 12 months), as most women will most likely report on their current status, which is less prone to recall bias. Incidence is reported in two periods: from delivery up to and including 3 months post-partum and from 3 to 12 months post-partum and for primi- and multiparous women. STATA Statistical Software, release 15, was used for analysis.

In order to determine the overall experienced bother in relation to UI across included studies, the measurement results of the different measurement instruments for bother were converted -where possible- to a (standardized) 0 to 100 scale, with 0 indicating no bother and 100 indicating extremely bothered. We classified 1 to 20 as no to mild bother, 20 to 40 as mild to moderate bother, 40 to 60 as moderate to severe, 60 to 80 as severe to very severe, and 80 to 100 as extremely severe bother. We used the following conversion method for the ICIQ-UI SF (range 0-21): Converted score=observed original score * 4.76 (the value 4.76 is derived from 100 (upper limit converted score) / 21 (upper limit original score). Likewise, question 3 from the ICIQ-UI SF (range 0-10) is calculated as follows: converted score=observed original score * 10.

RESULTS

Study selection

Among the 1063 papers initially identified, 31 met the eligibility criteria (Figure 1), resulting in a total of 38.209 participants. All included studies were observational and published between 1998 and March 1, 2020. Studies were excluded based on inadequate study design, study population, non-Western countries, outcome, follow-up or language. 29 studies reported on prevalence and/or incidence figures and two studies only reported on incidence figures.

Risk of bias

The risk of bias for each study is shown in Table 1. High, moderate and low risk of bias was considered to be present in 1, 26 and 4 studies respectively. Risk-of-bias items with the lowest ratings were 8 and 9, and risk-of-bias items with the highest ratings were 1 and 3.

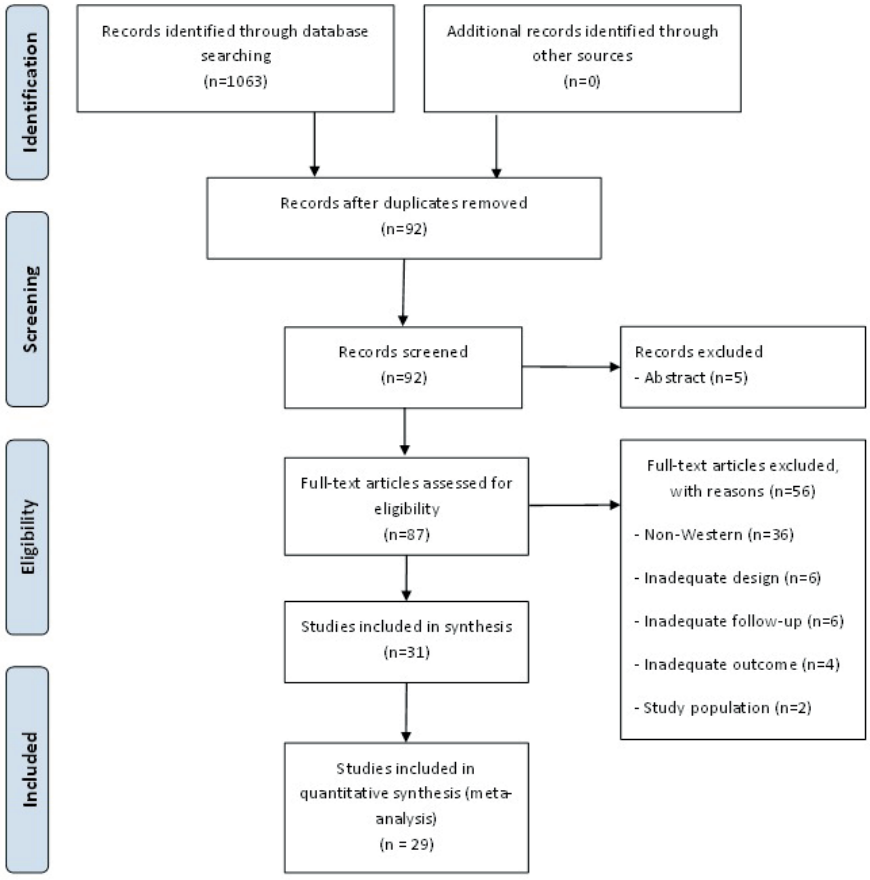

Figure 1 Study flow diagram

Table 1 Characteristics and outcomes of included studies post-partum

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Arrue et al. 2010[21]	Spain	Primipara No UI prior to pregnancy Excluded: Multiple pregnancy Gestational age <37 wks Neurological disorders Surgery and urogynaecological malformations - Delivery by CS	Urinary leakage on effort (SUI) according ICS terminology	6 months	Interview ISI ICIQ-UI-SF	30.9 (18-43)	Primipara	330 (83.3)	6 months	By type: [Incidence (from a terme): SUI: 20 out of 227 (8.8)	SUI: 50 (15.1) MUI: 10 (3.0) UUI: unknown	3,7,8
Baydock et al. 2009[22]	Canada	Singleton vaginal delivery Excluded: UI prior to pregnancy Drug/alcohol abuse UI due to medical, cognitive or mobility impairment	Urinary leakage ≥1 every 2 weeks	4 months	Telephone interview 19 item questionnaire	29 (17-43)	Median: 1 (0-8)	632	4 months	181 (28.6)	By type: SUI: 145 (23.0) UUI: 77 (12.0) MUI: unknown	4,6,7,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Borello-France et al. 2006[23]	USA	Primiparous women who delivered by cesarean section or vaginally with or without anal sphincter tear. Excluded: - IBD - Self-reported prepregnancy anorectal surgery, and neurological conditions predisposing to urinary or fecal incontinence.	A response of "sometimes" or "often" to any of the MESA questions.	6 weeks & 6 months	Telephone interview MESA	Sphinter tear: 27.6±6.0 Vaginal control: 25.8±5.7 Cesarean control: 30.2±6.6	Primipara	6 weeks: 837 (91.0) 6 months: 759 (82.0)	6 weeks & 6 months	6 weeks: 282 (33.7) 6 months: 237 (31.2)	By type: 6 weeks: SUI: 128 (45.4) UUI: 37 (13.1) MUI: 117 (41.5) 6 months: SUI: 121 (51.1) UUI: 25 (10.5) MUI: 91 (38.4)	2

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Boyles et al. 2009[24]	USA	Eligible women were identified through Oregon state birth certificates. Excluded: Women having abortions, stillbirths, or adoptions, out of state residents, and women for whom identifiers were missing.	Leakage of urine	3-6 months	Postal self-developed survey	27.7 (5.8)	Primipara	5599	4.4 months (range 3–6)	955 (17.1) [Incidence: 554 (10.0)		2,6,8,9
Brown et al. 1998[25]	Australia	All women who gave birth in a two-week period in except those who had a stillbirth or known neonatal death.	UI not specified	6-7 months	Postal survey	29.4 (15-47)	Primi- & multipara	1366 (62.5)	6-7 months	142 (10.) By parity: - Primiparous: 53 (10.4) - Multiparous: 89 (10.9)	-	6,8

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Brown et al. 2015[26]	Australia	Adult nulliparous women	Leakage of urine at least once per month	3,6,9,12 months	ISI 3,6,12 months: postal survey 9 months: telephone interview		Primipara	1507	3,6,9,12 months	-3 months: 416/1415 (29.3) -6 months: 281/1388 (20.2) -9 months: 370/1318 (28.1) -12 months: 356/1348 (26.4) -Any UI: 680/1449 (46.9)		4,5,6,9
Burgio et al. 2003[5]	USA	Convenience sample, obstetric delivery	Have you ever experienced any difficulty controlling urination? Have you ever had any accidental loss of urine, even a small amount? Have you ever wet yourself?	2-3 days, 6 weeks, 3,6,12 months	2-3 days: face-to-face interview 6 weeks, 3,6,12 months: telephone interview	28.6 (14-42)	Mean: 1.9, median: 2.0 (1-6) Primipara: 41.5%	523 (on 2/3 days)	6 weeks, 3,6,12 months	6 weeks: 56/493 (11.4) 3 months: 45/483 (9.3) 6 months: 47/447 (10.5) 12 months: 51/385 (13.3)		2,6,7,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Chaliha et al. 1999[27]	UK	Nulliparous women, English-speaking, and had singleton pregnancies in the third trimester. Excluded: - UTI - History of urinary tract abnormality, recurrent urinary tract infection, history of anorectal surgery or trauma, and active anorectal infection	SUI: loss of urine on physical effort or coughing. UUI: loss of urine associated with a strong desire to void.	3 months	Structured questionnaire: interviewed in person or by telephone	29 (17–46)	Primipara	549	3 months	80 (14.6)	SUI: 68 (85.0) UUI: 12 (15.0)	6,7,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Cooklin et al. 2015[12]	Australia	Nulliparous, adult pregnant women (singleton, ≥ 36 weeks' gestation), reporting in pregnancy the intention to breastfeed their infants for at least 8 weeks. Excluded: - Medical conditions prohibitive to breastfeeding; breast reduction surgery; dermatitis on nipple in pregnancy; or requiring services of psychiatrists or social workers during pregnancy.	UI not specified	8 weeks	Telephone interview (week 8 postpartum).	32.6 (4.1; 19–44)	Primipara	222 (73.0)	8 weeks	26 (11.7)		2,3,6,7,8
Dolan et al. 2004[28]	UK	Primigravidae between 34 and 40 weeks of gestation	Any UI within last 3 months	3 months	Postal self-developed UI questionnaire and KHQ	26 (5.3)	Primipara	362 (73.7)	3 months	47 (13.0)	SUI: 14 (29.8) UUI: 3 (6.4) MUI: 21 (44.7) Missing: 9 (19.1)	6,7,8

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Durnea 2014[11]	Ireland	Nulliparous in their first ongoing pregnancy and having a singleton foetus with a gestational age <15 weeks. Excluded: preexisting risk factors for pregnancy complications.	ICS definitions for urinary dysfunction	1 year	Australian pelvic floor questionnaire	30.5 (4.2)	Primipara	872 (58.8)	1 year	465 (53.9) [Incidence: 294 (34.1)	SUI: 204 (43.9) UUI: 72 (15.5) MUI: 189 (40.6) Incidence: SUI: 111 (37.8) UUI: 36 (12.2) MUI: 147 (50.0)	8,9
Farrell 2001[29]	Canada	Nullipara No medical illnesses Excluded: urinary tract abonormalities or pelvic surgery medication that alters urinary tract function	Do you accidentally lose urine from your bladder	6 weeks, 6 months	Written self-developed questionnaire	Median 28 (15-48)	Primipara	6 weeks: 559 (94.3) 6 months: 484 (81.6)	6 weeks, 6 months	6 weeks 148/559 (26.5) 6 months: 125/484 (25.8) [Incidence: 6 wks: 107/489 (21.9) 6 mo: 89/424 (21.0)		6,8

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Gartland et al. 2015[30]	Australia	≤24 weeks of gestation Nulliparous, ≥18 year No previous live births or stillbirths at ≥20 weeks of gestation	Leaking urine at least once a month	3,6,9,12 months	Postal questionnaire: 3,6,12 months Computer-assisted telephone Interviews: 9 months	31.7 (SD 4.6; 19–47).	Primipara	1011 (response rate estimate 28-31%)	0-3,4-6,7-9,10-12 months	0-3 months: 297/1004 (29.6) 4-6 months: 201/992 (20.3) 7-9 monhts: 282/957 (29.5) 10-12 monhts: 218/876 (24.9) Period prevalence 0-12 months: 472 (46.7)	0-3 months: SUI: 122 (41.1) UUI: 27 (9.1) MUI: 148 (49.8) 4-6 months: SUI: 114 (56.7) UUI: 26 (12.9) MUI: 61 (30.3) 7-9 monhts: SUI: 160 (56.7) UUI: 55 (19.5) MUI: 67 (23.8) 10-12 monhts: SUI: 104 (47.7) UUI: 33 (15.1) MUI: 81 (37.2)	2,5,8,9
Glazener et al. 2006[31]	Scotland/ UK/New Zealand	Primipara Excluded: twin pregnancy	Do you ever lose any urine when you don't mean to?	3 months	Postal self-developed questionnaire	26.7 (5.3)	Primipara	3405 (76.0)	3 months	989 (29.0)	SUI: 459 (46.4) UUI: 221 (22.3) MUI/other: 309 (31.2)	8
Hansen et al. 2012[32]	Denmark	Primipara ≥18 yrs	Any urinary leakage	1 year	ICIQ-UI-SF Interference daily life	28.2 (4.8)	Primipara	799 (49.8)	9-12 months	234 (29.3)	SUI: 126 (53.8) UUI: 67 (28.6) MUI: 41 (17.5)	5,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Hatem et al. 2005[33]	France	Primipara	Score ≥2 on the FPSUND tool	6 monhts	Self-administered questionnaire: FPSUND tool	27.2 (4.8)	1: 1136 (88.0) ≥2: 155 (12.0)	1291 (52.0)	171 ± 12 days	382 (29.6)	SUI: 162 (43.0) UUI: 23 (6.0) MUI: 51 (13.0) Unspecified UI: 146 (38.0)	8,9
Huebner et al. 2010[34]	Germany	Primipara Singleton pregnancy Cephalic presentation Vaginal delivery ≥38 weeks gestation	Do you leak urine involuntarily or does urge lead to UI?	6 weeks & 2 months	Self-developed questionnaire	28.1 (4.7)	Primipara	411 (67.4)	6 weeks & 2 months	6 weeks: 117 (28.5) 2 months: 39 (9.5)		6,7,8
Johannessen et al. 2018[35]	Norway	Primipara Healthy infant	Complaint of involuntary loss of urine	12 months	ICIQ-UI SF	UI alone: 29.8 (4.6; 18, 42)	Primipara	976 (65.6)	12 months	382 (39.1)		8
Mannion et al. 2015[36]	Canada	Women who delivered singletons	Since your baby's birth have you experienced UI (unintentional loss of urine?)	12 months	Self-developed questionnaire	31.5 (4.4)	Primipara: 681 (43.3) Multipara: 747 (47.5) Missing: 146 (9.3)	1574	0-12 months	773 (49.1)		2,4,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Martin-Martin et al. 2014[37]	Spain	Women with singleton pregnancy Excluded: UI before pregnancy	UI not specified	3 and 6 months	Modified ICIQ-UI-SF (by telephone)	31 (5.1)	0: 224 (58.8) ≥1: 160 (41.9)	413 (82.6) No previous UI: 381 (76.2)	3 and 6 months	3 months: 43 (11.3) 6 months: 29 (7.6) [Incidence 3 months: 13 (30.0)	3 months: SUI: 25 (57.5) UUI/MUI/ unclassified: unclear 6 months: SUI predominated	4,7,8
Mason et al. 1999[38]	UK	Nulli- and multiparous women, regardless of type of delivery	SUI: do you leak urine during physical activity or exertion, for example, whilst coughing, laughing, lifting heavy objects, climbing stairs, during sex etc?'	8-10 weeks	Self-developed questionnaire	Range: 16-45	Primi- and multiparous	572 (64.0)	8 weeks	179 (31.3) [Incidence: 45 (7.9)	SUI	4,8

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Mørkved et al. 1999[39]	Norway	All women who delivered at hospital	ICS definition and 'Do you leak urine at any time: never, seldom, weekly or daily?'	8 weeks	Structured interview 8 wks post-partum	28 (19-40)	$\bar{x}$: 1.8 (1-5)	144 (72.0)	8 weeks	Self-report: 54 (38.0) Pad test: 28 (19.0) By parity: 1: 21 (38.9) 2: 19 (35.2) 3: 11 (20.4) ≥4: 3 (5.6)		3,8
Pregazzi et al. 2012[40]	Italy	Excluded: Urethra and/or bladder surgery Lower urinary tract disorders UTI during pregnancy	SUI: UI on physical effort, UUI= UI associated with a strong desire to void.	3 months	Face-to-face interviews	19-44	Primipara: 379 (70.7) Multipara: 158 (29.3)	537	3 months	84 (15.6)	SUI: 43 (51.2) UUI: 21 (25.0) MUI: 20 (23.8)	4,8,9
Quiboeuf et al. 2015[41]	France	Singleton pregnancy Excluded: Women expected to move away from region Prepregnancy DM	'Have you had involuntary urinary leakages?'	4 months	-Self-administered postal questionnaire -BFLUTS (type UI) -Sandvik score (severity)	29 (18-44)	Primipara: 493 (30.0) Multipara: 1150 (70.0)	1643 (87.0)	4 months	340 (20.7)		4,8

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Raza-Khan et al. 2006[42]	USA	All pregnant women (3rd trimester) Excluded: History of preexisting DM Active cardiac disease excl. mitral valve prolapse Neurological disease Urinary tract surgery Congenital genito-urinary abnormalities	Any MESA answer of 'sometimes' or 'often'	6-8 weeks	- Self-completion written method MESA Hunskaar Severity Index	28 (17-41)	0: 37 (32.7) 1: 47 (41.6) 2: 18 (15.9) 3: 10 (8.8) 4: 1 (0.9)	113 (51.6)	Mean: 6.5 weeks Median: 6.3 (SD 1.6)	50 (44.2) [Incidence: 5 (4.4)	SUI: 24 (48.0) UUI: 3 (6.0) MUI: 23 (46.0)	3,8,9
Rikard-Bell et al. 2014[43]	Australia	Primipara Non-instrumental delivery Excluded: Death of baby during labour or post-partum period	UI not specified	≥ 6 months	Postal questionnaire PFDI-20-SF PISQ-12	By group: Intact perineum: 23.4 (16-41) Episiotomy: 24.8 (16-38) Spontaneous tear: 24.4 (15-40)	Primipara	196 (25.6)	≥ 6 months	123 (63.0)	SUI: 62 (50.0)	3,4,5,6,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Schytt et al. 2004[44]	Sweden	Singleton pregnancy Excluded: women not responding to all 3 questionnaires	UI: Any involuntary loss of urine during the last week SUI: 'Have you experienced involuntary loss of urine during physical exertion (for example sneezing or jumping) during the last week?'	12 months	Postal questionnaire	29.5 (median 29.0, SD 4.6)	Primipara: 1051 (44.0) Multipara: 1339 (56.0)	2390 (53.0)	12 months	12 months: SUI: 518 (21.7)	-	2,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Solans-Domènech et al. 2010[45]	Spain	Healthy nulliparous pregnant women Excluded: UI before pregnancy Neurological disease Cognitive disorders Urological pathology (non infectious) Abortion Impaired mobility Previous urogynaecologic surgery Current treatment with drugs (benzodiazepines, diuretics)	Confirmative answer on ISI (amount/ frequency)	7 weeks	Self-administered during visit ICIQ-UI-SF ISI Effect on dailyliving: VAS (0-10)		Primipara	950 (84.2)	7 weeks	155 (16.3) [Incidence: 49 (9.0)	SUI: 85 (54.8) UUI: 46 (29.7) MUI: 14 (9.0) Other: 10 (5.8)	4

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Thomason et al. 2007[46]	USA	Primipara Excluded: Genital anomalies Diabetes with risk of UTI Prior urinary tract infection/surgery Pregnant Delivered by CS UI before pregnancy	Have you involuntarily lost or leaked any amount of urine?	6-9 months	Self-constructed questionnaire	Primiparae continent: 29.7 Primipara incontinent: 29.8	Primipara	121 (75.6)	6 months	52/107 (48.6) [Incidence: 2/47 (4.3)	-	3,6,8
Torrisi 2002[47]	Italy	Nullipara Excluded: Previous pelvic surgery History of recurrent urinary tract infections, women with known malformations of their urinary tract, pre-conceptional hypertension, diabetes, connective tissue disorders, or neurological or cardiological diseases	A score of at least 3 at the ICIQ-SF	3 months	- ICIQ-SF - King's Health Questionnaire	29.8 (5.6)	Primipara	744 (70.9)	3 months	161 (21.6)	SUI: 61.0 UUI: 15.5 MUI: 12.4 Not reported: 11.1	7,8,9

Authors/ year	Country	Sample	Case definition UI	Timing measure-ment(s)	Questionnaire validation	Mean age (y) (SD; range) [a]	Parity (Number of children: n (%)	Sample size (response rate[b] (%))	Post-partum period	UI prevalence n (%) [Incidence: n (%), period]	Type of UI n (%)	Risk of bias items [c]
Wesnes et al. 2007[48]	Norway	Primipara Singleton pregnancy Continent before and during pregnancy Excluded: Not completed questionnaire 1, 3 or 4	During coughing/ laughing/ sneezing, when running/ jumping or if they had leakage accompanied by a strong urge to void	6 months	Postal questionnaire	27.9 (4.2)	Primipara	7561	6 months	[Incidence: 1562 (21.0],	SUI: 651 (41.7) UUI: 471 (30.2) MUI: 440 (28.2)	8,9

[a] Unless otherwise stated.
[b] Response rate is based on follow-up assessment in post-partum period (not initial cohort during pregnancy)
[c] Each number represents areas where risk of bias exists (based on the Joanna Briggs critical appraisal tool [18]. 1= Was the sample frame appropriate to address the target population?, 2= Were study participants sampled in an appropriate way?, 3= Was the sample size adequate?, 4= Were the study subjects and the setting described in detail?, 5= Was the data analysis conducted with sufficient coverage of the identified sample?, 6= Were valid methods used for the identification of the condition? , 7= Was the condition measured in a standard, reliable way for all participants?, 8= Was there appropriate statistical analysis?, 9= Was the response rate adequate, and if not, was the low response rate managed appropriately?

Incidence defined as new onset UI after delivery.

UI=urinary incontinence, IUGA=International Urogynecological Association; ICS=International Continence Society; SUI= stress urinary incontinence, UUI= urgency urinary incontinence, MUI= mixed urinary incontinence , ICIQ-UI-SF= International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form, IBD= inflammatory bowel disease (ulcerative colitis or Crohn's disease), wks= weeks, POP=pelvic organ prolapse, IIQ-7= Incontinence Impact Questionnaire, UDI-6= urogenital distress inventory, DM= diabetes mellitus, y= years, clin= clinical, Obst= obstetric, UTI= urinary tract infection, inf=infection, QoL= quality of life, I-QoL= incontinence quality of life, PFDI-20= pelvic floor distress inventory, ISI= Incontinence severity index, QUID= Questionnaire for urinary diagnosis, 3-IQ= 3 incontinence questionnaire, mths= months, PFDI= Pelvic Floor Distress Inventory, KHQ= Kings Health Questionnaire, sec= second, trim= trimester, MESA= Medical, Epidemiological, and Social Aspects of Aging Questionnaire, BFLUTS= Bristol Female Lower Urinary Tract Symptom questionnaire; BFLUTS=British Female Low Urinary Track Symptoms, ST= short-term, LT=long term

Study characteristics

The studies originated from Europe (n=17), North-America (n=8), and Australia (n=5). One study was mixed Europe/Australia. The majority of women were included from a (tertiary) hospital (n=26). The remaining studies included women from the community, primary health care service or health care insurance service. 19 studies only reported on primiparous women. Twelve studies used validated questionnaires to determine the presence of UI and 19 studies used self-constructed, non-validated questionnaires. Table 1 summarizes the study characteristics of included studies.

Nine studies reported on (measurement instruments for) bother. Table 2 provides an overview of the measurement instruments as used in the included studies, with the original and the converted (0-100 scale) measurement results. Five different measurement instruments for bother were used, of which the ICIQ-UI SF was most frequently used.[21,32,47,49] One study only reported the results of the ICIQ-UI SF as categories[50] and two studies did not report total scores.[51,52] One measurement instrument was self-constructed and non-validated.[53]

Synthesis of results

Overall prevalence

24 out of 31 studies contributed to the calculation of the overall prevalence of post-partum UI, involving a total of 35.064 women. The weighted mean of UI prevalence among post-partum women (6 weeks to 12 months) was 31.0% (CI 95% 26.0-36.0%; I^2: 99.0%), regardless of parity or type of UI (Figure 2). The lowest prevalence of UI found in the included studies was 10%.[54] and the highest prevalence 63%.[55] Prevalence figures for studies with low (n=3), moderate (n=20 studies) and high risk of bias (n=1), were 28% (95% CI 17.0-39.0), 29% (95% CI 24.0-35.0) and 63%, respectively (Table 1).

Subcategories post-partum period, type of UI and parity

Figure 3 summarizes the mean UI prevalence at 6 weeks, 3, 6, 9, and 12 months post-partum. From an initial drop in prevalence between 6 weeks (24.0%, 95%-CI: 17.0-32.0%) and 3 months post-partum (21.0%, 95%-CI: 17.0-25.0%), prevalence numbers gradually rise to 32.0% at 12 months post-partum (95%-CI: 23.0-41.0%).

Table 2 Measurement of bother and result

Measurement instrument	Background information on measurement instrument	Study	Original measurement result (mean)	Period post-partum	(Converted) measurement results (0-100)
ICIQ-UI SF (0-21)	To assess symptoms of UI and impact on QoL. (4 questions, question 4 is on moment of UI and is not within the calculation of the total).	[21]	8.2 for SUI	6 months	39.0
			10.0 for MUI	6 months	47.6
		[32]	5.9	1 year	28.1
		[35]	5.1	1 year	24.3
		[47]	6.0	3 months	28.6
		[50]	Results reported in categories. No total score.		
ICIQ-UI SF Question 3 (QoL) (0-10)	Question 3 of the ICIQ-UI SF is on the interference in daily life of UI.	[70]	4.1	3 months	41.0
			4.5	6 months	45.0
I-QOL	Quality of life in persons with UI. 3 subscales: 1. Avoidance and limiting behaviour, 2. Psychosocial impact, 3. Social embarrassment (22 questions)	[51]	No exact scores reported		
KHQ		[52]	No total score reported		
Self-constructed questionnaire		[53]	No total score reported		

ICIQ-UI SF= International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form, QoL= quality of life, I-QoL= incontinence quality of life, KHQ= Kings Health Questionnaire, SUI= stress urinary incontinence, MUI= mixed urinary incontinence

The prevalence of UI post-partum is equal amongst primi- and multiparous women, 31%.[11,12,32,35,46,47,52,56-62] and 30% [25,42,51,53,63-68], respectively. Based on 9 studies, SUI accounts for 54%, UUI and MUI for 26% and 16% of cases respectively, whereas 4% was unexplained UI.[32,42,47,52,58,60-62,66]

Subcategories frequency and amount of UI

Seven out of 31 studies reported on frequency of UI. The most used frequency categories (n=3), were: less than once a week, less than daily, more than or equal once per week, more than or equal daily leakage. A frequency of less than once a week was most frequently reported (50%-66.3%).[31,58,65] Two studies reported frequency of UI as: less than once per month, a few times a month, a few times a week, every day and/or night.[42,50] One study reported as: occasionally, once per week, several times per week, daily [38] and one study reported the ICIQ-UI SF question on frequency.[32]

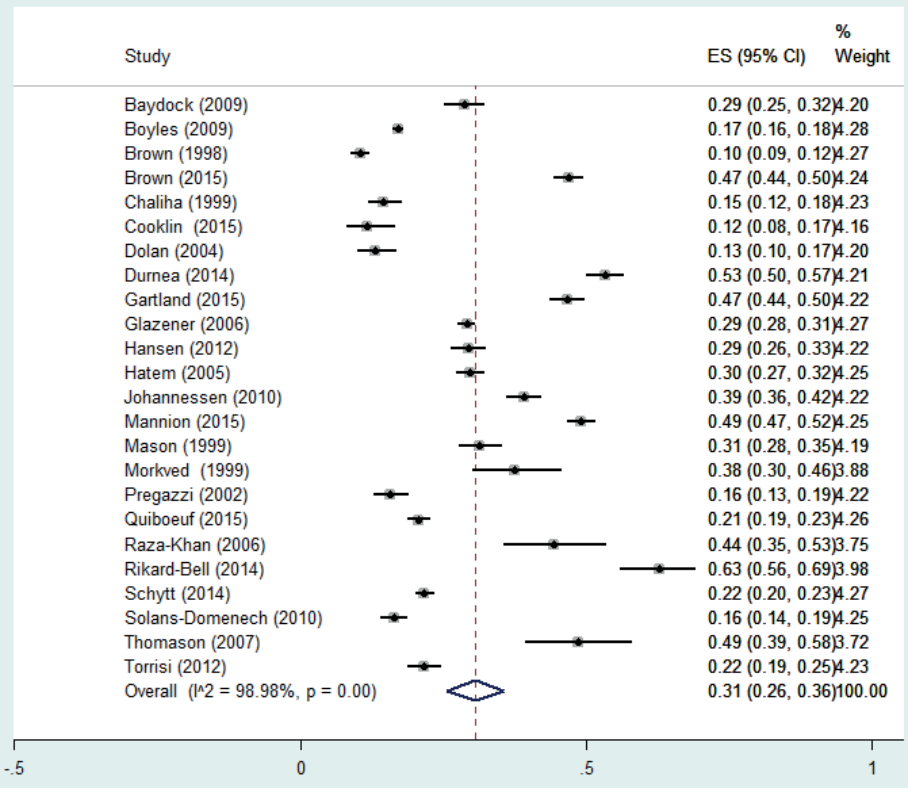

Figure 2 Pooled prevalence of UI post-partum stratified according to trimester wherever possible

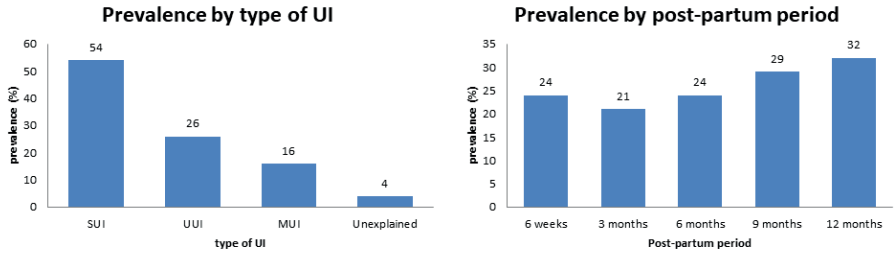

Figure 3 Prevalence of UI by type and period

Four studies reported on the amount of urine loss.[32,42,50,69] One study used the ICIQ-UI SF to assess this parameter (none, small, moderate, large amount).[32] One study reported separately the ICIQ-UI SF items 'amount', showing that the majority of UI cases lose a small amount (85.3%).[32] Other descriptions of amount of urine lost used were: drops, small splashes, and more.[42,50] Drops were most frequently reported in 71.6% of cases.[50] The remaining study reported amount as drop or two, pad or clothing damp, pad or clothing soaked.[69]

Bother

Nine studies reported on impact on daily life or quality of life [21,32,35,47,50-53,70], which was heterogeneously assessed. The ICIQ-UI SF total score was used most frequently (n-=5). Martin-Martin *et al*. reported the impact on daily life (0-10) based on the ICIQ-UI SF.[70] Other questionnaires used once to assess impact on daily life were: Incontinence Quality of life (I-QOL)[51], King's Health Questionnaire (KHQ)[52] and a self-constructed non validated questionnaire.[53] The overall bother of UI post-partum, on a 0 to 100 scale, ranges between 24.3 and 47.6, consistent with mild to moderate bother. At 3 months post-partum, degree of bother ranged between 28.6 and 41.0, at 6 months post-partum between 39.0 and 45.0 and at 12 months post-partum between 24.3 and 28.1 (Table 2).

Case definition

The majority of studies (n=11) used 'any leakage' as a case definition.[31,32,35,46,52,53,67,69,71-73] Eight studies used the ICS definition which was not mentioned as such in some cases.[11,21,38,58,65,66,68,74] Six studies did not specify a case definition for UI[12,25,47,61,70,75], five used a frequency[42,50,57,59,63], and one study used the Clinical classification of urinary incontinence (FPSUND).[51]

Incidence

Ten studies have examined incidence of UI post-partum (Table 1).[11,21,42,46,64,70-72,74] Five studies reported incidence up to and including three months[42,50,64,70,72] and six reported from three until 12 months.[11,21,46,71,72,74] One study reported for both periods.[72] The incidence of UI in primiparous and multiparous women up and until three months was 9.0 -21.9% and 4.4 -30.0%, respectively. Incidence up to 1 year was 4.3 -34.1% in primiparous women.

DISCUSSION

The aim of this systematic review and meta-analysis was to summarize the pooled prevalence and incidence of UI between 6 weeks and 12 months post-partum, to provide an overview of assessment methods for bother in relation to UI, and to assess the degree of bother post-partum. The results show an overall mean prevalence rate of UI up to 1 year post-partum of 31%, with a range of 10% to 63%. The prevalence of 10% was reported in a study on maternal health using a generic questionnaire including only one question on UI[25] in contrast to the other studies using health problem specific questionnaire. This might have influenced the tendency for women to report UI.[76]

The prevalence numbers in the first year post-partum rise from 24% at 6 weeks to 32% at 12 months post-partum after an initial drop between 6 weeks and 3 months. A recently published systematic review and meta-analysis on the prevalence of UI during pregnancy reported a prevalence of UI of 34% in the third trimester.[77] The drop in UI prevalence early post-partum compared to the 3rd trimester of pregnancy might be explained by the natural recovery of the levator ani muscle which occurs mainly up to 4 to 6 months post-partum.[78,79] The rise in prevalence from 3 to 12 months post-partum might be due to return to daily activities, such as return to work and starting with sports, with an associated increase in physical activity level and as a consequence loading of the continence system.[80,81] The prevalence of UI between primi- and multiparous women was nearly equal (31% and 30%). This is in line with the EPINCONT study on 27.900 women, which reported that the first delivery is the largest risk factor for UI, more specifically SUI and MUI, post-partum.[82]

Thom *et al*.[83] published a systematic review with 33 studies on the prevalence of post-partum urinary incontinence. The overall prevalence reported by Thom *et*

al. between 2 and 13 weeks post-partum was 33.3%. As only one included study covered the period of 14 to 52 weeks post-partum, an overall prevalence number could not be calculated.[13] 33.3% is a higher prevalence than the 24% at 6 weeks and 21% at 3 months reported in this study. This might be due to the fact that Thom *et al*. did not report a weighted prevalence.

When interpreting the prevalence numbers at different time points post-partum it is important to keep in mind that UI might be a dynamic phenomenon. This means that a woman's continence status can change both ways over a period of time.[67]

The incidence numbers between 6 weeks up to 3 months and 3 months up to 12 months and amongst primi- and multiparous women varied. The low incidence number of 4.3% in the short term might be explained by the fact that this study reported on SUI or MUI incidence only.[46] Although the study of Thomason et al. claim to report the incidence of total UI, only women who reported UI with a positive (cough) stress test were included. Women who were able to contract their pelvic floor muscles properly and timely during an in advance known rise in abdominal pressure might therefore be considered continent. However, these women might be incontinent during an unexpected rise in abdominal pressure. Also the small sample (n=121) in this study may explain the low incidence number. If the overall incidence of the up to 3 months post-partum is compared with the up to 12 months post-partum group the incidence numbers show a small rise in the latter, 4.3 - 30.0% and 4.4 - 34.1%, respectively. The rise in incidence is following the pattern of the rise in prevalence of UI between 3 and 12 months post-partum.

Most included studies showed a moderate risk of bias, which influences the possibility to differentiate on prevalence between groups regarding risk of methodological quality. The mean prevalence of UI reported by studies with low and moderate risk of bias did not differ. However, the one high risk study reported the highest prevalence of 63%.[61] Because a weighted prevalence number was calculated, this high risk study with only 196 participants and low response rate of 25.6% hardly influences the overall prevalence of UI.

The ICI recommends reporting prevalence numbers along with a measure of experienced bother.[14] Only nine out of 31 studies (approximately 30%) reported bother in relation to UI with a variety of measurement instruments which shows that combined assessment is not yet common practice.[21,32,35,47,51-53,62,70] Eight studies used high quality measurement instruments of which the ICIQ-UI SF [21,32,35,47,62] was

used most frequently. In an attempt to provide an overall assessment of degree of experienced bother in relation to UI, we (arbitrarily) chose to standardize the measurement results of different bother scales to a 0 to a 100 scale. The 0 to 100 scale can be regarded as a visual analogue scale (VAS). The VAS is a valid and reproducible method to quantify the impact of UI on QoL [84], although no studies are known that report on cut-off scores for QoL specifically in post-partum women with UI. Boonstra *et al.* compared the VAS with a measure that assesses the impact on functioning in patients with pain and identified three classes: class 1, mild interference (score 1-34), class 2, moderate interference (score 35 – 64), and class 3, severe interference with daily life (score 65 – 100).[85] Based on these classes, this systematic review revealed that women experience their post-partum UI as mild to moderate (range 24.3-47.6). Based on two studies, the results show a trend that bother of UI reduces at 12 months post-partum.[32,35] Women report for instance that UI becomes less of a problem because they get used to it and that they find practical ways to cope, by using party-liners and avoiding certain activities.[64]

Nevertheless, over half of the women with UI post-partum think that it will improve by itself in time and only 25% of women with post-partum UI actually seek help.[86] However, 73% of women with UI 3 months post-partum still report UI at 6 years post-partum.[6] Reliable information on UI prevalence is thus essential to estimate healthcare burden, allocation of health care resources and research planning.

Strengths and limitations

The strength of this systematic review and meta-analysis is the large number of included studies, which resulted in the availability of prevalence and incidence numbers for different subpopulations (parity, post-partum period, type of UI) and for different purposes (health care providers, research planning, and policy makers). This is the first review to report the prevalence and incidence over the first 12 months post-partum and bother in relation to post-partum UI.

The limitations of this study are, firstly, the presence of substantial clinical heterogeneity of the studies. Clinical heterogeneity may be due to differences in: case definition (any UI or different frequencies of UI in a certain period of time), population (primiparous and -multiparous) or periods researched. Secondly, the considerable statistical heterogeneity of the studies resulting in large CI's. Thirdly, as the Joanna Briggs critical appraisal tool does not recommend cut-off points for

high, moderate of low risk of bias, we arbitrarily chose the cut-off points reported in this systematic review to explore possible differences in prevalence numbers if stratified for risk of bias. However, we did not include or exclude studies based on risk of bias.

CONCLUSION

After an initial drop in prevalence of UI at 3 months post-partum (21%), at 1 year post-partum, prevalence rises again to 31%. UI prevalence does not differ between primi- and multiparous women. Bother of UI is heterogeneously assessed and is reported as mild to moderate.

Search strategy for PubMed

Appendix:

((((((((((‘urinary incontinence’[MeSH Terms]) OR urinary incontinence title/abstract) OR ‘urine loss’[Title/Abstract]) OR ‘pelvic floor disorders’[MeSH Terms]) OR ‘pelvic floor disorders’[Title/Abstract]) OR ‘pelvic floor dysfunctions’[Title/Abstract])) OR incontinence[Title/Abstract])) OR ‘leaking urine’[Title/Abstract])) AND ((((((((pregnancy[MeSH Terms]) OR pregnancy[Title/Abstract]) OR pregn[Title/Abstract])) OR (((((((((postpartum[Title/Abstract]) OR post-partum[Title/Abstract]) OR post partum[Title/Abstract]) OR postpartum[Title/Abstract]) OR post-partum[Title/Abstract])) OR peripartum[Title/Abstract]) OR peri-partum[Title/Abstract]) OR peri partum[Title/Abstract])) AND ((((nulliparous[Title/Abstract]) OR primiparous[Title/Abstract]) OR primigrav*[Title/Abstract]) OR primipara[Title/Abstract])))))) AND ((((((((((((((((((((((((prevalence[MeSH Terms]) OR prevalence[Title/Abstract])))) OR epidemiology[MeSH Terms])) OR epidemiology[Title/Abstract]) OR quality of life[MeSH Terms]) OR ‘quality of life’[Title/Abstract]) OR bother*[Title/Abstract]) OR bothersomeness[Title/Abstract]))

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CHAPTER 4

LONG-TERM EFFECTS OF MOTHERFIT GROUP THERAPY IN PRE- (MOTHERFIT1) AND POST-PARTUM WOMEN (MOTHERFIT2) WITH STRESS URINARY INCONTINENCE COMPARED TO CARE-AS-USUAL; STUDY PROTOCOL OF TWO MULTI-CENTRED RANDOMISED CONTROLLED TRIALS

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ABSTRACT

Background: Stress urinary incontinence (SUI) is highly prevalent during pregnancy and after delivery. It is often associated with a failing pelvic floor, sphincteric and/or supportive system. Pelvic floor muscle training (PFMT) peri-partum has been proven effective for up to one year post-partum, however long-term effects are unknown. Group PFMT given by a physiotherapist is proven equally effective as individual therapy. Motherfit is a group PFMT therapy with an emphasis on pelvic floor exercises, adherence and general fitness. Care-as-usual (CAU), if guideline driven, should as first treatment option consist of PFMT. Cost-effective strategies are of relevance, given the rise of health care costs. Motherfit group therapy has the potential to be cost-effective in women with urinary incontinence. Therefore, the objectives of the two current studies are: (1) to investigate whether intensive, supervised pre-partum (MOTHERFIT1) or post-partum (MOTHERFIT2) pelvic floor muscle group therapy reduces 18 months post-partum severity of SUI compared to CAU and (2) whether MOTHERFIT1 OR MOTHERFIT 2 is more (cost-)effective compared to CAU.

Methods: Two multi-centred randomised controlled trials (MOTHERFIT1, n=150, MOTHERFIT2, n=90) will be performed. Participants will be recruited by their midwife or gynaecologist during their routine check. Participants with SUI will receive either motherfit group therapy or CAU. Motherfit group therapy consists of eight group sessions of 60 minutes each, instructed and supervised by a registered pelvic physiotherapist. Motherfit group therapy includes instructions on pelvic floor anatomy and how to contract, relax and train the pelvic floor muscles correctly and is combined with general physical exercises. Adherence during and after motherfit will be stimulated by reinforcement techniques and a m(obile)App. The primary outcome measure is the absence of self-reported SUI based on the severity sum score of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) at 18 months post-partum. Secondary outcomes evaluate quality of life, subjective improvement and health care costs.

Discussion: The motherfit studies are, to our knowledge, the first studies that evaluate both long-term results and health care costs compared to CAU in pregnant and post-partum women with SUI. In case motherfit shows to be (cost-) effective, implementation in peri-partum care should be considered.

BACKGROUND

Urinary incontinence (UI) affects 13-40% of women during their life.[1-4] Pregnancy and childbirth are the most important provocative factors for UI during lifetime.[5]

Stress urinary incontinence (SUI), defined as any involuntary leakage of urine on effort or exertion, or on sneezing or coughing, is the most prevalent type of UI during pregnancy.[6] SUI can be the result of a failing pelvic floor, sphincteric and/or supportive system.[7] The prevalence of SUI rises from approximately 9% in the first trimester of pregnancy to 32% in the second and 38% in the third trimester.[8-10] Eight weeks after delivery the prevalence of SUI is 19%, rising to respectively 22% and 26% at six and 12 months post-partum.[8,11] Mørkved *et al*.[10] even reported a prevalence of 40% eight weeks post-partum. Many women believe that their UI will resolve by itself.[12] However, it is known that 75 to 92% of the women with SUI at three months post-partum, still have UI even after five or 12 years.[13,14] Often, UI reduces quality of life because of its negative impact on sexual relationships and daily life activities.[15,16] Despite this, 75% of women never seek help for UI because they feel embarrassed or feel that loosing urine is normal after giving birth.[12,17,18]

Pelvic floor muscle training (PFMT) aims to improve the supportive system and to achieve a timely contraction in case of expected leakage, both with voluntary (the Knack manoeuvre) and involuntary contractions.[19] Positive effects of PFMT peri-partum are proven up to one year post-partum.[20] However, it is still unknown whether long-term effects are lasting as well as whether pre- or post-partum PFMT is more effective in treating SUI compared to care-as-usual (CAU). Currently there are no guidelines on UI peri-partum for midwives and gynaecologists.[21] Therefore, CAU is known to be applied differently among health care providers and sometimes only includes prescription of incontinence materials.[22] PFMT may be provided individually or in a group. Recently, a meta-analysis on the effects of individual versus group PFMT for women with UI, both provided by a physiotherapist, showed no significant difference in results between the groups.[23] The latter is of particular interest as group therapy is less expensive when compared to individual therapy, and might therefore be a cost-effective strategy. It is known that healthcare costs are rising due to an increasing level of unhealthy lifestyle and number of people with one or more chronic diseases. For that reason, it is of relevance to focus on the evaluation of potentially cost-effective therapies.[24,25] Given the promising effects of PFMT on the short term and the potential of group therapy being a cost-effective

strategy, the Pelvic care Center Maastricht (PcCM), embedded in the Maastricht University Medical Centre (MUMC+), developed motherfit group therapy. Motherfit group therapy includes pelvic floor muscle group therapy (PFMGT) combined with general fitness exercises, provided by pelvic physiotherapists, to treat peri-partum women with SUI. Moreover, motherfit group therapy has a strong focus on self-management, as it is reported that this will promote adherence and thereby sustain longer-term effects.[26].

The primary objective of this study is to investigate whether a structured assessment and treatment program (motherfit group therapy) of intensive, supervised PFMGT, including a home maintenance program, reduces 18 months post-partum UI severity (frequency, amount, and impact) compared to CAU in adult pregnant women (MOTHERFIT1) and post-partum women with SUI (MOTHERFIT2). The secondary objective is to investigate whether motherfit group therapy is cost-effective compared to CAU in pregnant (MOTHERFIT1) and post-partum women with SUI (MOTHERFIT2) 18 months post-partum.

It is hypothesized that intensive, supervised pre-partum (study 1: MOTHERFIT1) or post-partum (study 2: MOTHERFIT2) PFMGT is more (cost-)effective compared to CAU in adult pregnant (MOTHERFIT1) or post-partum women with SUI (MOTHERFIT2).

METHODS

Study design

The study consists of two multi-centred randomised controlled trials (RCTs), namely MOTHERFIT1 and MOTHERFIT2. MOTHERFIT1 focuses on investigating PFMGT pre-partum and MOTHERFIT2 on PFMGT post-partum. Participants will be recruited in the southern part of The Netherlands from the Maastricht University Medical Center (MUMC+), Zuyderland MC (Heerlen/Sittard), Laurentius hospital (Roermond), Maxima MC (Eindhoven) and surrounding midwifery practices. Except for Maxima MC all obstetric centres are part of the Obstetric Consortium Limburg, a first, second and third line obstetric midwifery maternity care collaboration. In every region, a registered pelvic physiotherapist will provide motherfit group therapy.

Participants

Women will be included if they meet all of the following criteria: (1) ≥ 18 years, (2) UI (stress or mixed with predominant stress UI factor, according to Haylen *et al*.[6], (3) a score of > 3 on the International Consultation on Incontinence modular questionnaire- urinary incontinence- short form (ICIQ-UI SF) questionnaire[27], (4) motivated for participation in the motherfit program, (5) competent to speak and understand the Dutch language and to read and fill in forms independently, (6) mobile app (mApp) on tablet (Apple or Android) available.

Exclusion criteria are: (1) UI prior to first pregnancy, still existing during pregnancy, (2) high-risk pregnancy, resulting in a contra-indication for performing intensive pelvic floor muscle (PFM) exercises (f.i. placenta praevia, vaginal blood loss, preterm uterine contractions), (3) suffering from significant exercise limitations or co-morbidities (physical or psychological) that would restrain a woman from participation in motherfit group therapy, (4) history of chronic neurological disorders or diseases related to UI (e.g., multiple sclerosis, cerebrovascular accident, diabetes mellitus (during ≥1 year with HbA1c > 10 mmol/l)), (5) urinary tract infection (urine-sediment, urine culture), (6) history of anti-incontinence or urogynaecological surgery, (7) women who are expected to be lost to follow-up (e.g., because of a planned change of residency), (8) recent pelvic physiotherapy (< six months), (9) refusal to use a mApp.

Detailed study Plan

Patient recruitment/consent procedure

The obstetrician/gynaecologist or midwife (case manager) at each centre will be responsible for identifying eligible participants. All women will receive written and digital (www.motherfit.net) general information about the motherfit study at:

The first visit to the case manager and may be recruited from the second visit at 12 weeks or later until 27 weeks gestation (MOTHERFIT1)

Routine control at six weeks post-partum (MOTHERFIT2)

In case a woman is interested to participate, a short vaginal examination is performed to check the ability to contract the pelvic floor muscles (Table 1 and 2). The woman will receive an envelope containing: patient information, two

informed consent forms with return envelope and an information booklet on medical scientific research of the Dutch government.[28] The case manager fills in the name, telephone number and email address of the woman at a secure site (digital database), which can only be accessed by the researcher. After one week, the researcher will contact the woman by telephone and asks whether the woman has any questions regarding the study after reading the patient information. If the woman is willing to participate, she will be asked to fill in the two informed consent forms and return them to the researcher. The researcher will sign the two informed consent forms and returns one to the participant.

Table 1 Schedule of enrolment, allocation, interventions and assessments for MOTHERFIT1

	MOTHERFIT1						
	Enrolment	**Allocation**	**Inter-vention**	**Post-allocation**			
TIMEPOINT	$-t_1$ *before randomization*	t_0 *12 -26 weeks*	*Duration: 8 weeks*	t_1 *34 weeks*	t_2 *6 weeks*	t_3 *6 months*	t_4 *1 amonths*
		Pre-partum			*Post-partum*		
ENROLMENT:							
Eligibility screen	X						
Informed consent		X					
Allocation		randomized					
INTERVENTION: Motherfit group therapy			X				
ASSESSMENTS:							
Baseline characteristics		X					
Vaginal assessment		X					
ICIQ-UI-SF		X		X	X	X	X
IIQ-7		X		X	X	X	X
EQ-5D-5L		X		X	X	X	X
NVOG-q		X					
GPE				X	X	X	X
Motherfit patient satisfaction list				X (only MF group)			
MF patient cost questionnaire				X	X	X	X
Training diary				X			

t=timepoint, ICIQ-UI-SF=International Consultation on Incontinence Questionnaire Short Form, IIQ-7=Incontinence Impact Questionnaire, EQ-5D-5L=EuroQol quality of life questionnaire, NVOG-q=Nederlandse Vereniging voor Obstetrie en Gynaecologie questionnaire, GPE=Patient Global Impression of Severity

Table 2 Schedule of enrolment, allocation, interventions and assessments for MOTHERFIT2

	MOTHERFIT2					
	Enrolment	**Allocation**	**Inter-vention**	**Post-allocation**		
TIMEPOINT	$-t_1$ *before randomization*	t_0 *6 weeks*	*Duration: 8 weeks*	t_1 *4 months*	t_2 *9 months*	t_4 *18 months*
	Post-partum					
ENROLMENT:						
Eligibility screen	X					
Informed consent		X				
Allocation		randomized				
INTERVENTION: Motherfit group therapy			X			
ASSESSMENTS:						
Baseline characteristics		X				
Vaginal assessment		X				
ICIQ-UI-SF		X		X	X	X
IIQ-7		X		X	X	X
EQ-5D-5L		X		X	X	X
NVOG-q		X				
GPE				X	X	X
Motherfit patient satisfaction list				X (only MF group)		
MF patient cost questionnaire				X	X	X
Training diary				X		

t=timepoint, ICIQ-UI-SF=International Consultation on Incontinence Questionnaire Short Form, IIQ-7=Incontinence Impact Questionnaire, EQ-5D-5L=EuroQol quality of life questionnaire, NVOG-q=Nederlandse Vereniging voor Obstetrie en Gynaecologie questionnaire, GPE=Patient Global Impression of Severity

Allocation of participants

After signing informed consent, the participant will receive an email with a link to the electronic baseline questionnaires. Once the questionnaires are completed, block randomisation (block size is four) will be done by a computer-generated sequence in a 1:1 ratio on the individual patient and location level. Allocation in blocks of four is concealed and done using a central computer. Participants are either allocated to the motherfit program (intervention) or CAU (control group).

Blinding

Due to the nature of the interventions, the participants and pelvic physiotherapists cannot be blinded. During the trial the coordinating researcher is not blinded. However, once the participant has completed the questionnaires, it is not possible to make changes in the data due to locking of the questionnaires. Moreover, before the statistical analyses all participants will be appointed a new study number for which the coordinating researcher is blinded. Therefore, analyses will be done blinded for treatment allocation.

Protocol training

Case managers

Preceding the inclusion period, on site information, instruction on the standardized assessment and inclusion procedures will be provided to case managers by the researcher for one hour. Assessment follows standard procedures of the Dutch Consortium Urogynecology to assess pelvic floor signs and symptoms. Special attention will be paid to the short assessment of a correct contraction of PFMs by observation and vaginal palpation of closing and lifting of the PFMs.[29].

Pelvic physiotherapists

In The Netherlands, pelvic physiotherapy is a specialisation within the field of physiotherapy and has its own registration in order to guarantee quality.[30] Preceding the inclusion period, information, instruction and training on the standardised assessment and group therapy protocol will be provided to involved pelvic physiotherapists (PPTs) during a two-hour workshop. The PPTs receive a set of laminated A4 papers with a detailed description for each therapy session, containing: topics to discuss, PFM and homework exercises.

Interventions

Care-as-usual

In case participants with SUI are allocated to the CAU group, participating case managers give their normal advices and women make their own choices whether they want to participate in any kind of pregnancy-related course, visit to a physician or therapist.

Motherfit group therapy

All women allocated to motherfit group therapy, and unaware or unable to contract their PFMs correctly, will be referred to the PPT for individual instruction before joining the motherfit group therapy (Figure 1). Every participating region has a PPT who provides individual or group therapy. Motherfit consists of eight group therapy sessions of 60 minutes each, instructed and supervised by a registered PPT. In each group a maximum of four women are allowed to participate. Women of both studies can start when they have been randomised to motherfit group therapy. Therefore the participant's group composition may change over time. Motherfit includes instructions on pelvic floor anatomy and how to contract, relax and train the PFMs correctly and is combined with general physical exercises with a strong focus on self-management.

The PFMT protocol has been published previously by Bø *et al*.[31], and is based on the Norwegian Aerobic Fitness Model. It follows the general training principles and the recommendations concerning physical activity practice during and after pregnancy according to the American College of Obstetricians and Gynecologists and the World Health Organization (WHO)[31,32] (Table 3).

Moreover, all women receive a mApp (iPelvis)[33], an application with individualized pelvic physiotherapy exercises, and supportive video content and images. Performance and adherence to PFMT will be recorded in the participants personal training diary and is reinforced by regularly sending push notifications on the mApp. The training diary will be available for the motherfit group therapists and may be used to discuss the participants motivation to incorporate adequate PFMT and use of PFM in their daily activities. Although adverse events due to PFMT are very rare[20], adverse event forms are used to register their occurrence during the motherfit group therapy.

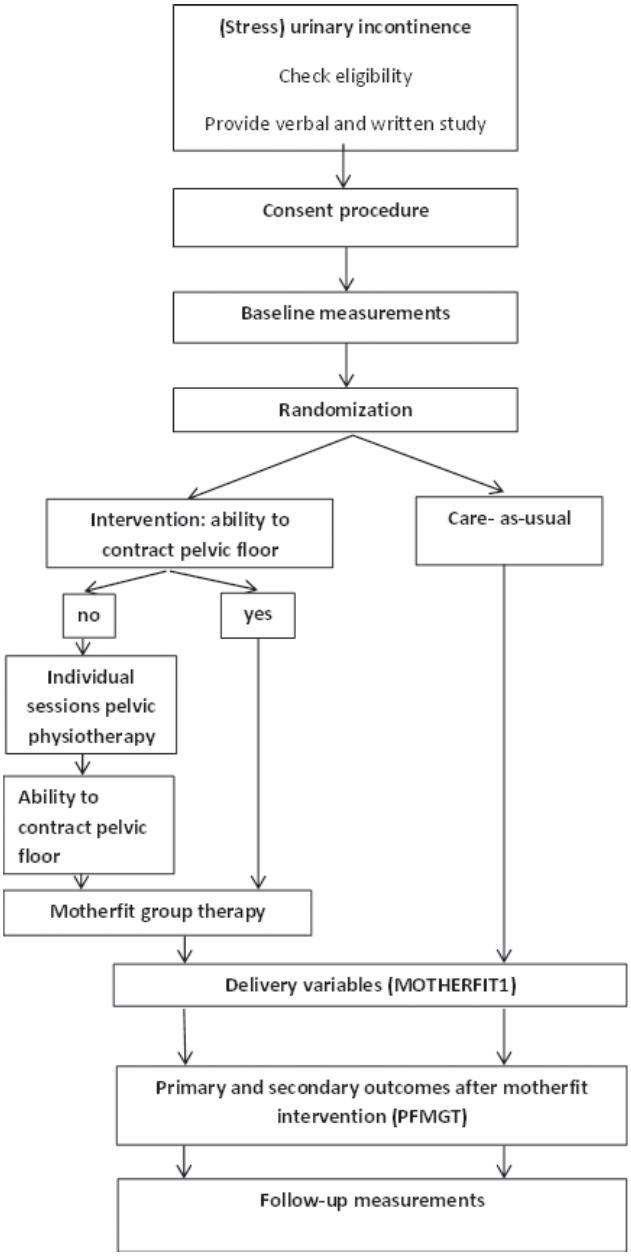

Figure 1 Study design

Table 3 Types of training provided during MOTHERFIT1 and MOTHERFIT2 with accompanying aim and exercises

Type of training	Aim	Exercise(s)
Awareness	Continue breathing during PFM contraction	Breathing and PFM exercises
Skills	Consciously timed voluntary pre-contraction	The 'Knack'- closing of vaginal hiatus and in-, up- and forward movement of the PFMs before and during increased abdominal pressure
Functional	Increase awareness to avoid unnecessary abdominal pressure and to prevent unnecessary or extreme perineal descent during daily activities	Correct pushing technique during defecation, or a PFM contraction in situations associated with a rise in abdominal pressure
Muscle strength & endurance	Build up long-lasting muscle volume, providing structural support/'stiffness', resulting in reduced perineal descent	Slow velocity Build up to 8 - 12 contractions, of 6 - 8 seconds (if possible), add 3 - 4 fast contractions on top at the end to recruit more slow twitch fibers. Start with double time rest (complete relaxation) between contractions. Three sets of exercises during the day in varying positions: lying, sitting, kneeling, standing position. Preferably daily training, but minimally 3 - 4 days a week, during at least 5 - 6 months. Maintenance muscle strength after 6 months training; 2 days a week where intensity is more important than frequency.
Muscle contraction: speed	Build up explosive strength	Fast repetitions -Build up from 10 sets of 3 quick contractions to 10 sets of 5 quick contractions, 3 times a day

PFM= pelvic floor muscle training

Data collection and outcome measures

All data (electronic case report forms and questionnaires at baseline and follow-up) of the participants and case managers will be collected in a (web-based) digital central database. Demographic variables and personal characteristics will be registered by the Nederlandse Vereniging voor Obstetrie & Gynaecologie vragenlijst (NVOG-q) at baseline for MOTHERFIT1 and MOTHERFIT2.

MOTHERFIT1: data will be collected at baseline, 34 weeks of gestation, six weeks and six and 18 months post-partum.

MOTHERFIT2: data will be collected at baseline and four, nine and 18 months post-partum.

The case manager fills in a first survey after inclusion of a participant. For MOTHERFIT1 these questions include among others expected delivery date and current medication use. Two weeks after delivery, case managers receive a second survey regarding delivery variables. For MOTHERFIT2 the case manager fills in identical surveys, except the question on expected delivery date.

Participants in the intervention group fill in a training diary and three questions regarding their general physical activity level, weekly. The pelvic physiotherapists will register attendance of the participant during the intervention period and send it by postal mail to the researcher.

Primary outcome measure

Tables 1 and 2 show the schedule of assessments for MOTHERFIT1 and MOTHERFIT2. The primary outcome measure is self-reported UI based on the severity sum score of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF). The ICIQ-UI SF is a brief (four questions) and robust measure for evaluating the frequency of symptoms and impact of UI.[34] The total score ranges from 0 (not affected) to 21 (severely affected). The ICIQ-UI SF is divided into the following four severity categories: slight (1-5), moderate (6-12), severe (13-18) and very severe (19-21).[35] The questionnaire is translated in Dutch.[36] Therapy success is defined as absence of UI or change from baseline of at least three points on the ICIQ-UI SF at 18 months post-partum.[37]

Secondary outcome measures

Patient-reported improvement: the Patient Global Impression of Severity (GPE) questionnaire assesses patients' self-reported improvement.[38] It is an accepted and reliable scale for incontinence, consisting of one question and seven response options.[39,40]

Quality of life outcomes: the Incontinence Impact Questionnaire-7 (IIQ-7) contains seven items that reliably assess the impact of UI on health-related quality of life

(QoL).[41,42] It determines UI impact on four domains: mobility, physical functioning, emotional health and embarrassment and ranges from 0 to 100.

General activity level: the trainings diary has to be filled in weekly. Next to a question regarding the number of days PFM exercises have been executed, it contains three questions regarding general activity level. The questions on general activity level are modified from the Dutch healthy exercise norm (Nederlandse Norm Gezond Bewegen). This norm is based on publications of the American College of Sports Medicine.[43]

Adherence to home training program

Only participants in the intervention group register their performance of requested pelvic floor muscle exercises, including their general physical activity, weekly, at home in the training diary. The training diary is a data entry form and if scanned, an excel file will be computer generated.

Cost-effectiveness

For the purpose of the economic evaluation, a study specific cost questionnaire has been developed. Participants' resource use ((in)direct costs related to SUI) is collected from the societal and health care perspective . Furthermore, the EuroQol instrument (EQ-5D-5L) will be administered, a validated generic health state measure [43, 44] widely used in economic evaluations. The five-level version (EQ-5D-5L) is proposed by the recently updated Dutch guideline for economic evaluations in health care [47] and consists of the EQ Visual Analogue scale and a descriptive system. The descriptive system comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension can be rated at 5 levels: no problems, slight problems, moderate problems, severe problems and extreme problems.

Process evaluation

A study specific questionnaire has been developed to evaluate patient satisfaction of motherfit group therapy (part 1, ten items) and satisfaction with the use of the mApp (part 2, seven items). Questions on motherfit group therapy were f.i. on whether the participant liked training in a group and if there were enough opportunities to ask the motherfit group therapist questions. Questions regarding

satisfaction of the mApp were f.i. on ease of use and whether participants would continue using the mApp after the intervention period. Each item ranges from 1 (strongly disagree) to 5 (strongly agree).

STATISTICAL METHODS

Sample size calculation

Assuming that the average score of the primary outcome measure (ICIQ-UI SF; range 0-21) of MOTHERFIT1 will lie at 8 and for MOTHERFIT2 at 9 (which is also the expected mean ICIQ-UI SF score at 18 months post-partum in the CAU group; in contrast, the expected mean ICIQ-UI SF score at 18 months post-partum in the experimental group is 5 (for MOTHERFIT1 and MOTHERFIT2) together with a relatively high standard deviation of 5 at baseline (because of the non-normality of the measure), participants will – with 97.5% probability – vary at baseline within the ranges of 0 to 19. The minimum acceptable score of participants to be treated is set at 3, so the range lies approximately between 3 and 19. From earlier studies[44], it became clear that the success of the PFMT exercises will be considerable and will be clinically relevant, if the gain will be higher than half the standard deviation of the baseline, presumably 3 with a somewhat smaller standard deviation of 3, because of the homogenizing effects in the experimental arm. In contrast to MOTHERFIT1 (women remain stable), in MOTHERFIT2 it is assumed that the condition of CAU participants at 18 months will worsen with an average ICIQ-UI SF score going from 9 in the baseline to 10 (SD 5).

Assuming two-sided testing, a power of 90% (beta =0.10) and a significance level of 0.95 (alpha=0.05) in each arm of the trial in MOTHERFIT1 minimally 60 and in MOTHERFIT2 minimally 35 participants will have to be included without taking into account that participants may drop out of the study during the 18 months of observations. Using a 20% drop-out, in MOTHERFIT1 each arm will need 75 participants, 150 in total, and in MOTHERFIT2 each arm will need 45 participants, 90 in total.

Statistical analysis

Analysis of the participants will be reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement.[44] Data will be analyzed according to the intention-to-treat principle. By preference, multiple imputation

techniques are used for missing values.

Descriptive analysis

Firstly, descriptive, univariate statistics will be reported. In case of metric, normally distributed variables, mean and standard deviations are presented. If not normally distributed, medians and percentiles are presented. The Shapiro-Wilk test will be used to assess normality.

Process and structure indicators will be analyzed with descriptive statistics and presented as absolute and proportion data (%) whenever the variable is categorical, or as mean (+/- standard deviation; 95% confidence intervals) or quartiles for continuous variables. A p-value <0.05 will be considered to be statistically significant. Data analysis will be carried out using SPSS version 25 (IBM. Corporation, Somers. NY, USA).

Analysis of main hypotheses

In both studies, the main hypothesis concerns differential changes in ICIQ-UI SF within time between two randomised groups of participants. (Repeated measurements) ANCOVA will be performed with baseline measurements (T0) as covariate. Transformations of original scores will be attempted, if the ICIQ-UI SF shows a non-normal distribution at T0. Randomisation groups (motherfit group therapy versus CAU) are regarded as a between factor. Next, the within-participants linear trend in time of the outcome will be calculated with the weights from the first orthogonal polynomial contrast and this is used as a dependent variable in a multiple (dummy-) regression analysis. It concerns repeated measurements from T0 to T4 (MOTHERFIT1) and T0 to T3 (MOTHERFIT2). Next to the baseline covariate measurement and the randomisation groups dummy variable, other possible confounding variables will be used in this multiple linear regression analysis of the linear trend in time of the ICIQ-UI SF.

The following potential confounding variables are considered to be used in the multiple linear regression analysis: BMI before pregnancy (>25), parity, maternal age (>35) and ability to perform a PFM contraction at baseline.

Forward selection and backward elimination techniques will be used to determine the best fit of the data to a final regression model. Testing of interactive relationships

between statistically significant effects of predictors in the final model will be done, especially if it concerns the experimental between randomisation groups factor. List wise deletion of missing cases will be used in all linear regression modelling. This may be in case of lost-to-follow-up because of a succeeding pregnancy during the follow-up period of 18 months. For the final best-fitting regression model, a residual analysis will be done on the standardized Studentized z-scores and a screening will be performed on outliers to ensure the legitimacy and validity of the use of parametric statistics in analysis by testing the normality of distribution of the linear trend in ICIQ-UI SF.

Statistical analysis on the secondary outcomes of the study, such as the IIQ-7, the GPE, and the EQ-5D-5L will be handled in the same way as the primary outcome measure ICIQ-UI SF. Process and structure indicators will be analyzed with descriptive statistics and presented quantitatively as numbers and absolute and proportion data.

ECONOMIC EVALUATION

General considerations

For both subgroups in MOTHERFIT1 and MOTHERFIT2, separate trial-based economic evaluations (EE) will be performed, but both EEs will have the same characteristics, except for the time horizon. The EE will take a societal and health care perspective, comparing motherfit group therapy with CAU. The time horizon for MOTHERFIT1 will be (about) 24 months starting from 12 weeks gestation (study inclusion) up to 18 months post-partum and for MOTHERFIT2 from approximately six weeks to 18 months post-partum. Cost-effectiveness ratios will be expressed as the societal cost per quality-adjusted life-year (QALY) (societal perspective), and the (healthcare) cost per woman in who UI is clinically relevant reduced (primary outcome; healthcare perspective). Bootstrap analysis and cost-effectiveness acceptability curves will be constructed; showing for a range of threshold values the probability that motherfit group therapy is cost-effective. Sensitivity analyses and subgroup analyses (e.g. on age categories, adherent versus non-adherent women) will be performed to test for the robustness of the results.

Cost- analysis

The cost-analysis will be performed from both a societal and health care perspective. Resource use will be measured in natural units and will be valued in monetary terms by multiplying these units by the costs per unit. If available, standardized, national cost-prices (e.g. specified by the recently updated Dutch guideline for cost research in healthcare will be used.[45] Costs are distinguished into motherfit program costs including the group sessions and home-based part and costs of the mApp (initial and replacement costs for ICT hardware and software), healthcare costs (e.g. use of incontinence materials, visits to general practitioner, gynaecologist, midwife costs, visits to pelvic physiotherapist, surgery etc.), non-healthcare costs (e.g. travel costs and productivity losses) and patient and family costs (time spent on the program, informal care costs). Data on (healthcare) resource utilization associated with SUI will be prospectively recorded during the study by the participants. Other healthcare, non-healthcare and patient and family costs will be collected by means of a standardized cost questionnaire to be filled out by patients. Costs occurring 12 months after study inclusion will be discounted at 4% according to the Dutch guidelines for economic evaluations health care.[46]

Patient outcome analysis

The outcome for the cost-utility analysis (societal perspective) is defined in terms of quality-adjusted life years (QALYs) from inclusion up to 18 months postpartum. The number of QALYs is derived by the adjustment of survival data with health-related quality of life (HRQL) HRQL will be measured with the EuroQol-5D (EQ-5D) instrument, which provides a descriptive health profile and a Dutch valuation set for obtaining utility scores EQ-5D.[47] The outcome for the cost-effectiveness analysis (healthcare perspective) is based on the proportion of women with clinically relevant reduction in UI at 18 months postpartum. Outcomes occurring 12 months following study inclusion will be discounted at 1.5% according to the Dutch guidelines for economic evaluations health care.[46]

Long-term decision analytical modelling

Next to the trial-based EE, a model-based EE will be performed, as it is expected that the economic impact of motherfit is best investigated by means of a long-term decision analytical model. First a structure and working model will be created that

will facilitate the necessary analysis to be performed throughout the project. This model will be able to incorporate the values of all input parameters (both point estimates and uncertainty). Once the structure of the model is established, four essential types of data will be required: probabilities, costs, survival and health utilities (QALYs). Short term costs and effectiveness data are readily available from the trial-based EE, whereas longer term data may require synthesis of available evidence in the literature. Estimates of the economic impact will first be made using fixed estimates of probabilities, costs, and health outcomes. Subsequently a probabilistic sensitivity analysis will be performed which will address the joint uncertainty of the model inputs. As for the trial-based cost-effectiveness analysis, cost-effectiveness acceptability curves will be constructed. As with the trial-based EE, the model-based EE will address the cost per QALY (societal perspective) and cost per UI prevented (healthcare perspective). We will express uncertainty by means of confidence intervals and by creating cost-effectiveness acceptability curves. The appropriate time horizon will be agreed upon during the study but is expected to be lifetime.

Budget Impact Analysis (BIA)

A BIA will be performed according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines.[48] The BIA addresses the financial stream of consequences related to the implementation of motherfit group therapy and thus its affordability. The budget impact will depend e.g. on patient acceptability of the program, the uptake of the program by healthcare professional and the target group, the cost-increase due to increased implementation of motherfit group therapy, and the cost-savings due to preventing or reducing UI, i.e. reduced cost-of-illness. The structure and some data input of the decision analytical model developed for the EE will be adapted for the BIA. Input parameters will be based on results of the trial, national prevalence data, unit prices and tariffs obtained in the trial-based EE, and available literature when necessary. The analyses will be performed from different perspectives, including a health care budgetary perspective and a health insurers' perspective. The model will take changes in the adoption / implementation of the program, and patient acceptability/uptake into account and will compare different scenarios as regards to the swiftness and extensiveness of the uptake. In order to test the robustness of the results, sensitivity analyses will be performed. The time horizon will be

varied from one year up to five years. No discounting will be applied.

Withdrawal of individual subjects

Subjects can leave the study at any time for any reason if they wish to do so without any consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons.

All women enrolled in the study will be followed and accounted for. Women who are unwilling or unable to commit themselves to the study plan and follow-up schedule (i.e., serious illness, during pregnancy, f.i. premature rupture of membranes, blood loss, severe high blood pressure, pre-eclampsia, movement out of the local area, etc.) may be withdrawn from the study. Women who will become pregnant again during the follow-up period of 18 months will be handled as drop-out. Upon withdrawal of a subject, immediately all documentation is available for the investigators through the electronic case report file.

DISCUSSION

The two motherfit studies are studies aim to evaluate whether motherfit group therapy is (cost)-effective 18 months post-partum for pregnant (MOTHERFIT1) and post-partum women (MOTHERFIT2) with SUI. As health care costs are rising in general, there is a need for cost-effective strategies, which is oe of the main reasons for initiating the motherfit studies. The motherfit studies are, to our knowledge, the first studies that evaluate both longer term results and healthcare costs compared to CAU in pregnant and post-partum women with SUI. The endpoint of 18 months post-partum is chosen because of the increasing possibility of a subsequent pregnancy and consequently loss to follow-up. In order to sustain long-term results, it is known that adherence is a strong predictive factor.[33] Therefore, motherfit group therapy not only focuses on PFMT, general fitness exercises and education, but also has a strong emphasis on adherence and self-management. Adherence to PFMT will be supported by a mApp.

Currently, no guidelines on urinary incontinence exist specifically for pregnant and post-partum women. In case motherfit demonstrates to be (cost-)effective, implementation of motherfit group therapy should be considered in peri-partum care and future guidelines.

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CHAPTER 5

PELVIC FLOOR MUSCLE GROUP THERAPY FOR THE TREATMENT OF URINARY INCONTINENCE DURING PREGNANCY AND POST-PARTUM: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Objectives: Pelvic Floor Muscle Group Therapy (PFMGT) is an effective treatment option in the general population. However, the effect of therapy during pregnancy and shortly thereafter is unclear. Therefore, this study investigates the effect of PFMGT in peri-partum women with UI compared to care-as-usual.

Materials and Methods: Two randomized controlled trials: study 1: pregnant women and study 2: 6 weeks post-partum women, were performed. The primary outcome was UI severity based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short form (ICIQ-UI SF). Secondary outcomes were the Global Impression of Severity (GPE) measuring patient's self-reported improvement and the Incontinence Impact Questionnaire-7 (IIQ-7), measuring UI impact. Descriptive and univariate analysis were reported and the non-parametric Mann-Whitney U test was used to compare differences between groups.

Results: Inclusion numbers could not be met, and therefore all women received individual PFMT. Study 1 showed no significant results regarding the prevalence of UI (ICIQ-UI SF), GPE and IIQ-7 at any measurement moment. As compared to baseline, study 2 showed a significant improvement for prevalence of UI and impact of UI at 4 months post-partum, however there was no significant difference between groups at other measurement moments. Significant subjective improvement was seen at 4 and 9 months post-partum, in favor of the PFMT group ($p=.02$).

Conclusion: PFMT, started after childbirth, demonstrated improved UI and quality of life with a lower number of complaints at the 4 months post-partum assessment. However, the full potential of effectiveness of PFMT could not be established due to insufficient inclusions.

INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine.[1] The reported overall prevalence of UI varies between 25 and 46.4%.[2,3] Stress urinary incontinence (SUI), the complaint of involuntary loss of urine on effort or physical exertion or on sneezing or coughing [1], is the most prevalent type among peri-partum women.[2-4] During pregnancy prevalence of UI is reported between 9 and 75%, and post-partum between 10 and 63%.[5-8] UI reduces quality of life (QoL) but nonetheless, many women tend to accept their problems because they are embarrassed, think it is normal and will diminish by itself.[8-10]

The development of UI peri-partum might be due to several reasons, including childbirth or physiological weight gain resulting in an increase of intra-abdominal pressure transmitted to the bladder and bladder neck, leading to urethral mobility and pelvic floor muscles (PFM) activity problems.[11-13] The PFMs of women with UI during pregnancy are weaker and thinner.[14] PFM training (PFMT) aims to improve the supportive system and is a first-line treatment option for UI.[15,16] As the costs for healthcare are rising, it is important to provide cost-effective therapies.[17] PFMT can be provided as individual, but also as group therapy (PFMGT). PFMGT appeared to be equally effective in the treatment of UI in women in the general or older population.[18,19] A recent Cochrane systematic review concluded that it is uncertain whether PFMT is an effective treatment option for women with UI during pregnancy and post-partum.[20] Also, information on cost-effectiveness of PFMT and long-term effects is lacking.[20]

Therefore, the primary aim of this study was to investigate whether a structured assessment and treatment program of intensive, supervised PFMGT, including a home maintenance program, reduces 18 months post-partum UI severity (frequency, amount, and impact) compared to care-as usual (CAU) in adult pregnant (study 1) and post-partum women with SUI (study 2). The secondary aim was to investigate whether PFMGT is cost-effective compared to CAU.

MATERIALS AND METHODS

Study design

In two randomized controlled multicenter trials, PFMGT (intervention group) was compared to CAU (control group). The two studies were registered as one trial in

The Netherlands National Trial Register (NTR5971). The Medical Ethics Committee (METC) of the Maastricht University Medical Center (MUMC+) has approved study 1 (METC162038) and study 2 (METC162051). The ethics boards of the participating four hospitals, Zuyderland Medical Center (two locations), Laurentius hospital and Maxima Medical Center, approved the trial, indicating also coverage for 13 local midwifery practices. The study protocol was published previously [21]

Participants

The women were recruited in the southern part of The Netherlands between 1st December 2017 and 1st August 2019 by midwives and physicians (case managers). Women were included if they met amongst others the following criteria: (1) ≥ 18 years, (2) UI (stress or mixed with predominant SUI factor, according to Haylen *et al*. [22]), and (3) a score of > 3 on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).[23] Exclusion criteria included: (1) UI prior to first pregnancy, still existing during pregnancy, (2) high-risk pregnancy, resulting in a contra-indication for performing intensive PFMT (e.g., placenta praevia, vaginal blood loss, preterm uterine contractions), (3) suffering from significant exercise limitations or co-morbidities (physical or psychological) that would restrain a woman from participation in the group therapy. A full description of in- and exclusion criteria is published elsewhere.[21]

Randomization and blinding

During a regular planned consultation with their case manager, women meeting the eligibility criteria and interested to participate, received a short vaginal examination to check the ability to contract the PFMs. The candidate participant received an email with a link to the electronic baseline questionnaire after signing the informed consent. Once the questionnaires were completed, blocked randomisation was done by a computer-generated sequence in a 1:1 ratio on patient and location level. Allocation in blocks of four was concealed and done using a central computer. Participants in the intervention group, who could not contract their PFMs correctly, were referred to a specialized (pelvic) physical therapist (PT) for individual instruction before joining PFMGT (Figure 1).

The participants, specialized PT and coordinating researcher could not be blinded. However, once the participant completed the questionnaires, they were

blocked from making alterations. Before the statistical analyses all participants were appointed a new study number for which the coordinating researcher was blinded. Therefore, analyses were done blinded for treatment allocation.

Intervention

The intervention was provided by one specialized PT in every region. In The Netherlands, pelvic PT is a specialisation within the field of physical therapy and has its own registration in order to guarantee quality.[24] The specialized PT's were instructed on the PFMGT protocol which consisted of eight once weekly PFMGT sessions of 60 minutes each. Pregnant and post-partum women could participate as soon as they were randomized in the same intervention group, with a maximum of four per group.

The intervention included instructions on pelvic floor anatomy and how to contract, relax and train the PFMs correctly in combination with general physical exercises with a strong focus on self-management. The PFMGT protocol has been published previously.[21] The women in the intervention group received a mApp (iPelvis) [25], which is an application with individualized pelvic PT exercises to reinforce adherence to and compliance with a home maintenance program.

Care-as-usual

Participants in the CAU group received regular advice from their case managers and were free to participate in any pregnancy-related course or visit a health care professional for their UI.

Measurements

Besides the measurement of the baseline characteristics in both studies the women were asked to fill in the questionnaires multiple times (Figure 1 and 2).

Primary outcome measure

The primary outcome is based on the ICIQ-UI SF. This is a validated brief (four questions) measure for evaluating the frequency, severity and impact on QoL of UI.[26] The total score ranges from 0 (not affected) to 21 (severely affected). The questionnaire is translated in Dutch.[27] Therapy success is defined as absence of

UI or change from baseline of at least three points on the ICIQ-UI SF at 18 months post-partum.[28]

Secondary outcome measures

The Patient Global Impression of Severity (GPE) questionnaire was used to assess the patients' self-reported improvement.[29] It is a reliable scale for incontinence, consisting of one question and seven response options ranging from very much improved to very much deterioration.[30,31]

The validated Incontinence Impact Questionnaire-7 (IIQ-7) was used to determine the UI impact on four domains: mobility, physical functioning, emotional health and embarrassment.[32] The total score ranges from 0 to 100, 0 meaning no impact and 100 extreme impact.

Sample size

The total sample size estimate for study 1 was 150, and study 2 was 90. These numbers are based on a significance level of 0.05, a power of 90%, and a 20% drop-out rate. Further justification has been described elsewhere.[21]

Statistical analysis

The Consolidated Standards of Reporting Trials (CONSORT) statement [33] was followed for reporting the trial. Data will be analyzed according to the intention-to-treat principle. Descriptive and univariate analysis were reported as means and standard deviations or 95% confidence intervals. The non-parametric Mann-Whitney U test was performed to compare differences between the two groups. A p-value <0.05 is considered to be statistically significant. Data analyses are carried out using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, N.Y., USA).

RESULTS

Recruitment took place between 01.06.2017 and 01.08.2019.

Participants

In study 1, 59 women were eligible for participation, of which 24 women were randomized (intervention group=11, control group=13) (Figure 1). Four participants completed the study (Figure 1). In study 2, 116 women were eligible of which 23 were randomized (intervention group=10, control group=13), 14 participants completed the study (Figure 2). Characteristics of the participants for study 1 and 2 are shown in Table 1.

Outcomes

The results are based on individual PFMT instead of PFMGT, as groups did not fill sufficiently (therefore, from this point on the term PFMT will be used). However, the original PFMGT protocol was followed. Study 1 showed no statistical significant differences between groups at any point regarding the ICIQ-UI SF total score, GPE and IIQ-7 (Table 2), although both groups showed improvements on all outcomes post-intervention.

In study 2, the intervention group improved significantly compared to the control group ($p=0.012$) at four months post-partum with regard to the ICIQ-UI SF score of ($p=0.012$) and IIQ-7 ($p=0.04$).

Moreover, the GPE of the intervention group improved significantly at T1 and T2 ($p=0.02$). T3 showed no statistical significant difference between groups (Table 2).

The mean number of days per week the participants performed PFM exercises during the eight week PFMGT was 5.9 (median 6.0) and 5.0 (median 5.3) in study 1 and 2, respectively.

Cost-effectiveness outcomes have not been calculated because both studies were underpowered.

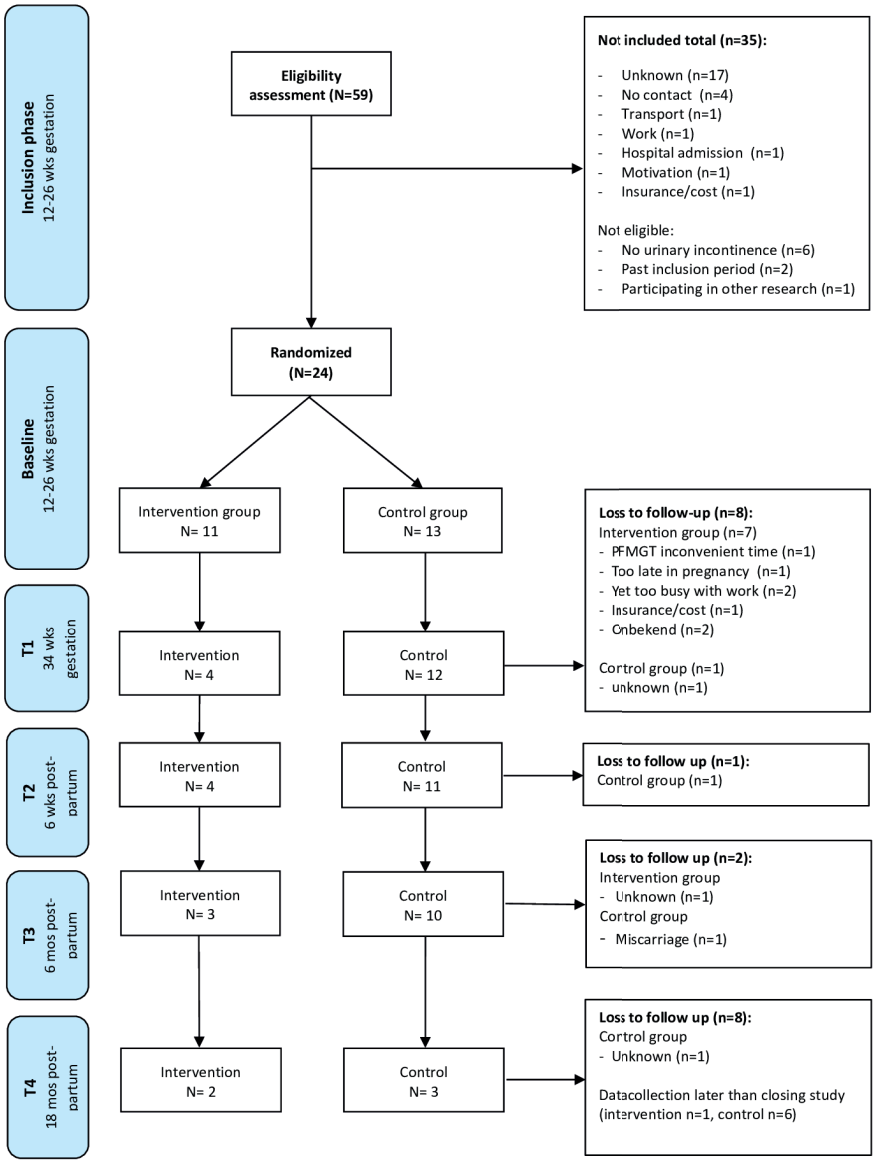

Figure 1: Flowchart study 1

T=measurement, wks=weeks, mos=months, N=number, PFMGT=pelvic floor muscle group therapy

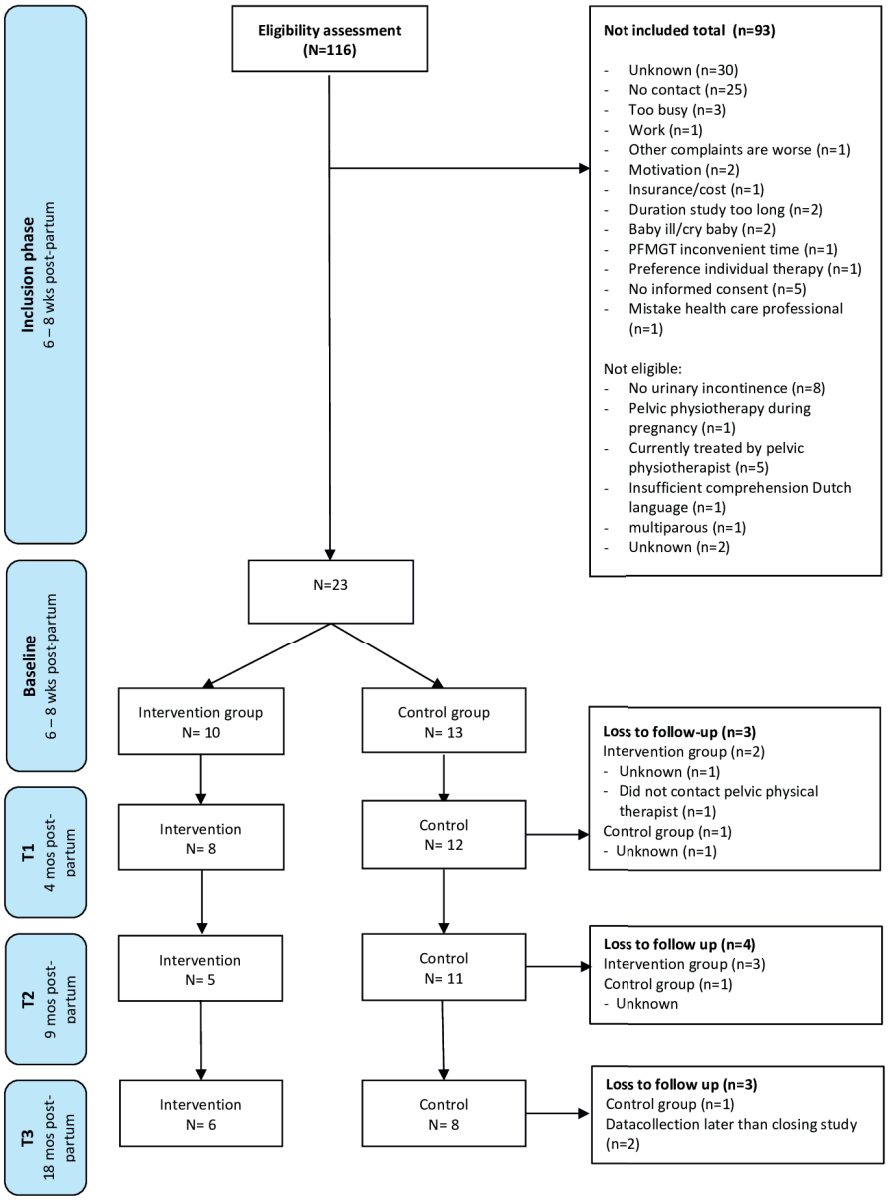

Figure 2: Flowchart study 2

T=measurement, wks=weeks, mos=months, N=number, PFMGT=pelvic floor muscle group therapy

Table 1 Participants' characteristics

		Study 1 N (%)			**Study 2 N (%)**		
		I (11)	**C (13)**	**Total (24)**	**I (10)**	**C (13)**	**Total (23)**
Age (mean, range)		32.1 (24-38)	32.9 (23-42)	32.5 (23-42)	32.3 (27-37)	30.2 (24-37)	31.0 (24-37)
Education	Secondary	4 (36.4)	4 (30.8)	8 (33.3)	3 (30.0)	5 (38.5)	8 (34.8)
	Tertiary	7 (63.6)	9 (69.2)	16 (66.7)	7 (70.0)	8 (61.5)	15 (65.2)
Parity	0	4 (36.4)	4 (30.8)	8 (33.3)	-	-	-
	1	7 (63.6)	7 (53.8)	14 (58.3)	2 (20.0)	5 (38.5)	7
	≥2	0 (0)	2 (15.4)	2 (4.2)	1 (10.0)	1 (7.7)	2
	Missing				7	7	14

N= number, I= intervention group, C= control group.

Table 2 Results ICIQ-UI SF, GPE and IIQ-7

Study 1	**Baseline 12-26 weeks gestation**			**T1**			**T2**			**T3**		
				34 weeks gestation			6 weeks post-partum			6 months post-partum		
	I (11)	C (13)	T (24)	I (4)	C (12)	T (16)	I (4)	C (11)	T (15)	I (3)	C (10)	T (13)
ICIQ-U1 SF (range 0-21)	11.2 (2.0) (8-14)	9.5 (3.2) (5-15)	10.3 (2.8) (5-15) p=.17[ø]	6.8 (2.2) (4-9)	8.6 (3.8) (4-14)	8.1 (3.5) (4-14) p=.46	6.8 (2.2) (4-9)	6.1 (3.9) (0-11)	6.3 (3.5) (0-11) p=.84	7.3 (1.5) [(6-9)	5.9 (3.8) (0-11)	6.2 (3.4) (0-11) p=.67
GPE (range 1-7)				2.3 (0.3)	3.5 (0.5)	3.2 (1.5) p=.10	2.8 (1.7)	2.6 (1.5)	2.7 (1.5) p=.89	3.3 (1.5)	2.9 (1.1)	3.0 (1.2) p=.66
IIQ-7 (range 0 - 100)	14.3 (0-57.1)	16.8 (0-57.1)	p=.84	13.1 (0-19.0)	15.9 (0-57.1)	p=.95	10.7 (0-28.5)	9.9 (0-38.1)	p=.74	7.9 (0-14.3)	4.8 (0-23.8)	, p=.40
Study 2	Baseline 6 weeks post-partum			4 months post-partum			9 months post-partum			18 months post-partum		
	I (10)	C (13)	T (23)	I (8)	C (12)	T (20)	I (5)	C (11)	T (16)	I (6)	C (8)	T (14)
ICIQ-U1 SF (range 0-21)	8.3 (1.9) (5-11)	8.6 (2.5) (6-13]	8.5 (2.2) (5-13) p=.88	5.3 (3.0) (0-11)	8.7 (2.9) (5-13)	7.2 (3.3) (0-13) p=.01*	4.2 (2.6) (1-8)	7.5 (3.8) (0-13)	6.4 (3.7) (0-13) p=0.09	4.3 (5.2) (0-13)	8.4 (3.6) (1-12)	6.6 (4.7) (0-13) p=.14
GPE (range 1-7)				2.3 (0.89)	3.3 (0.99)	2.90 (1.07) p=.02*	2.00 (0.71)	3.55 (1.21)	3.06 (1.29) p=.02*	2.0 (1.55)	3.63 (1.30)	2.93 (1.59) p=.08
IIQ-7 (range 0 - 100)	14.3 (0-38.1)	19.1 (0-57,1)	p=.90	6.0 (0-19,1)	23.0 (0-57.1)	p=.04*	13.3 (0-47.6)	20.3 (0-66.7)	p=.32	7.1 (0-33.3)	18.5 (0-47.6)	p=.09

I=intervention group, C= control group, T= total group, T1= follow-up 1, T2= follow-up 2, T3= follow-up 3, T4= follow-up 4, ICIQ-UI SF= International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form, GPE= Global perceived effect, IIQ-7= Incontinence Impact Questionnaire-7, *=significant, [ø]= between groups.

DISCUSSION

The (cost)-effectiveness of PFMT, for pregnant (study 1) and post-partum women (study 2) with SUI could not be established as planned, due to the small number of included women in both studies. As a consequence of the small numbers, all women in the intervention group received individual PFMT.

Therefore, the reported results should be interpreted with great caution and no conclusions regarding the original hypothesis can be made.

PFMT started during pregnancy showed no significant results regarding the effect on UI, impact, and self-perceived impression of severity of symptoms at any point. This is in line with a recent Cochrane systematic review, reporting no evidence of the treatment effect of PFMT on UI in late pregnancy.[20] Most likely our findings must be explained by the fact the study is underpowered. In addition, during pregnancy the continence mechanism is challenged by a multitude of factors of which some are non-modifiable. Physiological weight gain [2], and changes in the neuromuscular function of the urethral sphincter are considered examples of non-modifiable factors.[34] However, PFMT in the general female population is a proven effective intervention.[35]

PFMT post-partum revealed a positive effect directly after PFMT regarding UI, impact and self-perceived impression of severity. However, this effect was not maintained at later follow-up, except for subjective improvement. Although this study focused on adherence strategies for PFMT, the effect did not last.

We anticipated no major problems in recruiting the necessary number of participants for both studies due to a number of reasons. Firstly, the recruitment was done by case managers covering the majority of maternal care (pre- and post-partum care) in the southern part of The Netherlands, in which over 8500 babies were born in 2019.[17] Secondly, high prevalence rates of SUI during pregnancy and post-partum are reported in numerous studies [6-8] and thirdly, other studies on PFMT peri-partum in northern Europe reported high inclusion and participation rates.[36] Nonetheless, recruitment proved to be problematic.

In order to improve the number of inclusions several alterations to the eligibility criteria of the study were proposed and granted. The changes were: 1. inclusion of all women regardless of parity instead of only primigravid and primiparous women.

2. extending the inclusion period from 12 to 20 weeks up to 26 weeks of gestation. Other strategies to improve the inclusion rate were: regular presentations in the participating hospitals, visits to midwifery practices, attending clinics and regular phone conversations with midwifes and research assistants of the hospitals. Also, a monthly newsletter informing the healthcare professionals was send. Several factors might explain the disappointing inclusion numbers, which might also be useful for other researchers in the field to plan their studies or optimize their recruitment strategies. Firstly, our studies were so called 'efficiency studies' in which two different treatments are compared with regard to effect and financial costs, with the objective to discourage use of inefficient interventions.[37] Due to this design, participants were only allowed to be included by a case manager like a midwife or obstetrician, which might have influenced the disappointing inclusion numbers. In the study of Mørkved *et al*. on the effect of PFMT to prevent UI during pregnancy, all women were asked to participate through a letter which they received in combination with the invitation for their standard appointment with their case manager.[36] Secondly, a standard question on UI is lacking in electronic patient following systems in The Netherlands for case managers reporting peri-partum care. This digital reminder to ask for UI might have influenced the inclusion numbers. Thirdly, case managers involved in these studies mentioned their lack of attention as a major barrier to recruit participants together with lack of time and a difficult to implement protocol in usual clinical practice. These are well known barriers in clinical research.[38,39] Moreover, the case managers also mentioned that the standard internal assessment of the PFM in the protocol was a barrier due to lack of time. The number of drop-outs in study 1, once randomized, and in the initial inclusion phase in study 2, can be explained by known barriers for patient participation like inconvenience due to extra appointments, travel problems, costs and a preference for a specific study arm. Fourth, the sample size calculation for both studies was based on reported high UI prevalence numbers. However, the experienced bother was not taken into account. This might have resulted in an overestimation of the crude prevalence of UI, because level of experienced bother is associated with help-seeking behavior.[40]

Our result regarding PFMT post-partum may justify and therefore support the recommendation of Woodley *et al*.[20] for the development of a new RCT on this subject. However, it is advisable to recruit women through for instance (social) media because questions on UI are not standardly asked by health care professionals.[41]

Strengths of this study include that the intervention offered in both studies is protocol- and evidence based [21] and the ability to contract the PFM is checked. Women who did not know how to contract the PFM received an individual session by a specialized PT in order to learn how to contract and relax, before joining PFMT; in addition the protocol has a strong emphasis on adherence with the use of a mApp. A mApp has shown to have a beneficial effect on adherence.[42,43] The original design includes a long follow-up period and cost-effectiveness calculation.

In conclusion, PFMT, started post-partum, demonstrated statistically significant improvements in UI and QoL with a lower number of complaints at the 4 months post-partum assessment. However, the full potential of effectiveness of PFMGT could not be established due to insufficient inclusions, the latter most likely due to accepted bother from UI rather than the presence of UI itself.

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CHAPTER 6

URINARY INCONTINENCE DURING PREGNANCY: PREVALENCE, EXPERIENCE OF BOTHER, BELIEFS, AND HELP-SEEKING BEHAVIOR

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ABSTRACT

Introduction and hypothesis: Pregnancy and delivery are thought to induce urinary incontinence (UI), but its clinical impact is less known. Therefore, we investigated the prevalence of self-reported UI, level of experience of bother and beliefs, to gain a greater understanding of help-seeking behavior in adult pregnant women.

Methods: A digital survey shared on social media was used for recruitment. The survey consists of: 1. demographic variables, 2. International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), 3. ICIQ Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol), and 4. questions on beliefs and help-seeking behavior. For analysis, descriptive statistics and the independent samples t-test were used to determine differences between help- and non-help-seekers.

Results: 407 women were eligible for data analysis. The prevalence of UI rises from 55.1% in the first to 70.1% in the third trimester, with an overall prevalence of 66.8%. Nearly 43.0% of the respondents reported UI occurring once a week or less. 92.5% of women lost a small amount. 90% reported slight to moderate impact on quality of life. Only 13.1% of the respondents sought help for their UI. The main reasons for not seeking help were: minimal bother and the idea that UI would resolve by itself. Help-seeking women showed significant higher scores than non-help-seeking women regarding ICIQ-UI SF ($p<.001$), ICIQ-LUTSqol ($p=<.001$), and interference in daily life ($p<.001$).

Conclusions: During pregnancy, UI affects two out of three women, but only one in eight women sought professional help. Non-help-seeking women experience less bother.

INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine.[1] The self-reported prevalence of UI in the antenatal period is widely researched. These prevalence numbers vary greatly throughout published reports (9-63%), depending on case definitions applied, recruited population and study methodology. Pregnant women seem to differ with regard to degree of experienced bother in relation to UI.[2,3] Cautious interpretation of (high) prevalence rates is needed when case definitions used do not incorporate a measure of symptom bother as crude UI prevalence rate may overestimate the prevalence rate of significant or bothersome UI. Therefore, the International Consultation on Incontinence (ICI) recommends prevalence numbers to be accompanied by a measure of bother.[4]

For women with UI in the general population, it is known that bothersome UI, but also urgency UI (UUI), and UI severity (defined by the ICI as frequency of UI times volume of UI) are associated with help-seeking behavior.[4-6] Although pregnancy is known for its provoking effect on UI, knowledge on experience of UI bother and help-seeking behavior in this period is lacking. Furthermore, it is unclear which specific bothersome factors and beliefs are the main contributors to help-seeking behavior. Guidelines on UI in women in general recommend pelvic floor muscle training (PFMT) as a first-line treatment option.[7,8]

To inform health care providers, researchers, and policy makers it is important to have accurate prevalence rates as well as knowledge on pregnant women's beliefs and help-seeking behavior. Therefore, we aim to investigate the prevalence of self-reported UI, level of experience of bother and beliefs, to explain help-seeking behavior in pregnant women in The Netherlands.

MATERIAL AND METHODS

Study design

A cross-sectional design was used to describe the prevalence, bother, beliefs, and help-seeking behavior of pregnant women. The Medical Ethics Committee of the Maastricht University Medical Centre (MUMC+) was consulted. It was stated that ethical approval was not necessary due to the non-invasive character of the study (MECC 019-1320). Pregnant women of 18 years and older, regardless of parity and weeks of gestation, and able to fill in a digital survey were eligible to participate.

Based on an overall expected prevalence of UI of 41%, a Z statistic of 1.96 and precision of 0.05, a minimal sample size of 371 women was estimated to fill in the survey.[9] Nationwide midwifery and pelvic physiotherapy practices were amongst others asked to share a social media message (using Facebook and LinkedIn), containing brief information on the study (goal, eligibility) and a link to the patient information letter and digital survey. Before proceeding to the anonymized digital survey, eligible women signed informed consent electronically, in agreement with ethical regulations. The survey took 10 to 15 minutes to complete.

Outcome measures

The survey consisted of four parts: 1. demographic variables like age, trimester of pregnancy, educational level and parity, 2. International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)[10], 3. International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)[11], and 4. questions on beliefs and help-seeking behavior regarding UI.

The ICIQ-UI SF provides an indication of UI severity and consists of four questions. The first question assesses frequency of UI, with a score of 0 (never losing urine) to 5 (losing urine all the time). The second question describes the amount of urine loss, with four response categories ranging from 0 (no loss) to 6 (large amount). The third question assesses impact of UI on daily life, ranging from 0 (not at all) to 10 (a great deal). The total score ranges from 0 (no impact of UI on quality of life) to 21 (very severe problem). The total score is divided into four severity categories: slight (1-5), moderate (6-12), severe (13-18), and very severe (19-21).[12] A fourth question on the occurrence of symptoms of UI was used to indicate SUI or MUI.[13] A respondent was considered to have SUI when leaking urine with a cough or a sneeze and/or when physically active/exercising, but not before getting to the toilet. UUI is considered when the respondent leaks, because of irresistible need to void, before getting to the toilet. A respondent with MUI experiences both SUI and UUI.

The ICIQ-LUTSqol is a condition-specific health-related quality of life questionnaire (20 questions) adapted for use within the ICIQ structure from the King's Health Questionnaire.[11] It contains 19 questions that can be scored on life restrictions,

emotional aspects and preventive measures. It is scored on a four-point Likert scale ranging from 1 (not at all) to 4 (a lot). Three questions on relationships, sex life, and family life included additionally 'not applicable'. 'Not applicable' was considered as not affecting daily life.[14] The sum score ranges between 19 and 76. A higher score indicates a higher impact on quality of life. Every question is accompanied by a question regarding experienced bother (ranging from 0 (no bother) to 10 (extreme bother)). It is arbitrarily decided that a score of at least 5 indicates significant bother on a specific item. The 20th question is on how much urinary symptoms interfere with daily life. This is scored between 0 to 10 (similar like experienced bother). Both the ICIQ-UI SF and ICIQ-LUTSqol are rated as 'high quality' questionnaires and are recommended by the ICI.[4] The ICIQ-UI SF and the ICIQ-LUTSqol were provided in the Dutch language by the Bristol Urological Institute.[15]

All respondents at least filled in the demographic variables and ICIQ-UI SF. Answering 'never losing urine' at the frequency item of the ICIQ-UI SF indicated continence and consequently the survey was finished. When reporting UI, women completed the remaining two parts on quality of life and help-seeking behavior.

The questions on beliefs and help-seeking behavior were self-constructed. Selection of question and answer options was based on models explaining help-seeking behavior, discussion with experts in the field (epidemiologists and obstetrician/gynecologist) and modified accordingly.[16,17] Moreover, questions were reviewed by an expert for readability and comprehensiveness, followed by field testing. Ultimately, six questions were developed including four topics on health seeking behavior (actual help-seeking, reason(s) to (not) seek help, reason to seek help in the future and consulted health-care provider(s)) and two topics on beliefs (self-perceived prognosis and self-perceived best intervention to treat UI in general).

Data analysis

Data was analyzed using descriptive statistics presented as proportions (frequency and means (SD)). An independent sample t-test was conducted to compare help-seekers and non-help-seekers with regard to UI severity (ICIQ-UI-SF total score), bother (ICIQ-LUTSqol total score), and interference in daily life. A Chi-square

test was used to test relationships between categorical variables. The effect size is estimated with Cohen's *d*. Cohen's *d* presents the difference between groups (help-seekers and non-help-seekers) in standard deviation units. To interpret the strength of the effect size we follow the guidelines proposed by Cohen: .2=small, .5=medium, .8=large. An alpha of 0.05 is considered significant. Analyses were done using IBM Statistical Package for Social Sciences (SPSS) version 26.0 (New York, NY, USA).

RESULTS

In March and April 2020, 415 women filled in the survey. Eight women did not complete the survey after giving consent and were excluded from analysis. This left 407 women eligible for data analysis. The mean age was 30.4 years (SD 3.9, range 18-49), of which 146 (35.9%) were nulliparous (Table 1). The prevalence of UI rose from 55.1% (27/49) in the first trimester to 70.1% (162/231) in the third trimester.

The overall prevalence of UI was 66.8% (272/407, 95% confidence interval (CI) (62.3 – 71.3)). SUI (76.8% (209/272)) was the most frequently reported type of UI. Nulliparous women reported a significantly lower overall prevalence of 47.9% (70/146) compared with 77.4% (202/261) for (multi)parous women ($p<.001$).

Nearly 43.0% (116/271) of the respondents reported UI frequency of once a week or less and in 91.1% (247/271) of cases it was a small amount of urine per episode (Table 2). Ninety per cent of the women reported slight (33.7%, 91/270) to moderate (56.3%, 152/270) impact of UI based on the ICIQ-UI SF score, whereas the mean ICIQ-LUTSqol total score was 28.2 (SD 7.2, range 19-57). The mean interference in daily life based on ICIQ-UI SF was 3.0 (SD 2.7, range 0-10), whereas 29.9% (81/272) of women indicated a significant interference of ≥5. The ICIQ-UI SF and ICIQ-LUTSqol total scores and interference in daily life did not increase by trimester. Pregnant women experienced significant bother in relation to having UI on only 2 out of 19 questions on the ICIQ-LUTSqol, namely 'changing of wet underclothes' and 'worry because of smell'.

In total, 13.1% (35/267) of the respondents with UI sought help (Table 3). The majority of women seeking help (91%, 32/35) visited a (specialized) physiotherapist. Seven women (21.9%) reported that they initially visited the

pelvic physiotherapist for another health problem, like pelvic girdle pain. The reasons provided for not seeking help were: minimal bother (53%, 123/232), the idea that UI would improve by itself (38%, 89/232), and wanting to postpone until after the delivery (32%, 75/232). The most important reasons for seeking help in the future were: the constant use of pads (47%, 110/232), the feeling that others can smell the urine loss (33%, 77/232), and leaking/getting wet clothes (30%, 70/232). 56% (130/232) of women who did not seek help in contrast to 5.8% (2/35) of the women who did seek help for their UI, thought that their UI would completely resolve or improve a great deal in the future. Figure 1 shows the beliefs about prognosis of UI among non-help-seeking and help-seeking women as relative percentages of 100%. Of all women with UI, 71.5% (191/267), thought that the best way to treat their UI would be pelvic floor muscle exercises. Help-seeking women showed significant higher scores than non-help-seeking women regarding ICIQ-UI SF ($p<.001$), ICIQ-LUTSqol ($p<.001$), and interference in daily life ($p<.001$), with corresponding large effect sizes (ICIQ-UI SF total score: Cohen's $d= .80$, ICIQ-LUTSqol total score: Cohen's $d=.74$, and interference in daily life Cohen's $d=.76$).

Table 1 Background variables and urinary incontinence prevalence

Background variables (N=407)			**N (%)**
Age (mean, SD, range)	30.4 (3.9, 18-49)		
Education	Primary education		2 (0.5)
	Secondary education		185 (45.5)
	Tertiary education		220 (54.1)
Parity	Nulliparous		146 (35.9)
	Multiparous		261 (64.1)
Pre-partum period	Trimester 1 (1-13 weeks)		49 (12.0)
	Trimester 2 (14-26 weeks)		127 (31.2)
	Trimester 3 (27-42 weeks)		231 (56.8)
UI prevalence (by)	Overall		272 (66.8) 95% CI (62.3-71.3)
	Type	SUI	209 (76.8)
		UUI	11 (4.0)
		MUI	34 (12.5)
		Other (such as: UI during sleep or UI for no obvious reason)	18 (6.6)
	Trimester	1st (1-13 weeks)	27/49 (55.1) 95% CI (41.2-69.0)
		2nd (14-26 weeks)	83/127 (65.4) 95% CI (57.1-73.7)
		3rd (27-42 weeks)	162/231 (70.1) 95% CI (64.2-76.0)
	Parity	Nulliparous	70/146 (47.9)
		Primi-/multiparous	202/261 (77.4)

N=number, %=percentage, SD=standard deviation, CI=confidence interval, UI= urinary incontinence, SUI=stress urinary incontinence, UUI=urgency urinary incontinence, MUI=mixed urinary incontinence

Table 2 ICIQ-UI SF questionnaire results

ICIQ-UI SF		**N (%)**
ICIQ Frequency	About once a week or less often	116 (42.6)
	Two or three times a week	53 (19.6)
	About once a day	36 (13.3)
	Several times a day	63 (23.3)
	All the time	3 (1.1)
ICIQ Amount	None	4 (1.5)
	A small amount	247 (92.5)
	A moderate amount	20 (7.5)
	A large amount	0 (0.0)
ICIQ-UI SF overall interference (range 0-10)	≥5	81 (29.9)
ICIQ-UI SF total score mean (SD, range)	0-21	7.5 (3.6, 0-19)
Categories ICIQ-UI SF 2 missing	Slight (1-5)	91 (33.7)
	Moderate (6-12)	152 (56.3)
	Severe (13-18)	26 (9.6)
	Very severe (19-21)	1 (0.4)

ICIQ-UI SF= International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form, N= number, %= percentage, SD=standard deviation

Table 3 Beliefs and help-seeking behavior in relation to urinary incontinence

BELIEFS		
Prognosis UI without seeking help	**Help-seekers (N=35)**	**Non-help-seekers (N=232)**
Complete recovery	1 (2.9)	71 (30.6)
Good improvement	1 (2.9)	59 (25.4)
Some improvement	3 (8.6)	36 (15.5)
About the same	13 (37.1)	44 (19.0)
Some deterioration	7 (20.0)	13 (5.6)
Great deterioration	8 (22.9)	8 (3.4)
Worse than ever	2 (5.7)	1 (0.4)
Best way to solve UI		
Surgery	3 (8.6)	3 (1.3)
Medication	0 (0)	0 (0)
Pelvic floor muscle exercises	24 (68.6)	167 (72.0)
It will resolve by itself	0 (0)	30 (12.9)
There is no solution	0 (0)	3 (1.3)
I don't know	5 (14.3)	22 (9.5)
Other	3 (8.6)	7 (3.0)
HELP-SEEKING	**Help-seekers**	**Non-help-seekers**
Reason to seek help	**I sought help because***	**I will seek help in the future if#**
Getting wet clothes/leaking through	6 (17.1)	70 (30.2)
Need to use pad all the time	7 (20.0)	110 (47.4)
Others can smell me	0 (0)	77 (33.2)
Hindrance during sports	5 (14.3)	29 (12.5)
Hindrance during work	3 (8.6)	56 (24.1)
Hindrance playing with children	0 (0)	41 (17.7)
Hindrance during household tasks/activities	1 (2.9)	27 (11.6)
I don't know	0 (0)	28 (12.1)
Other reason(s)	13 (37.1)	30 (12.9)
Reason not to seek help		**Non-help-seekers (N=232)**
Minimal bother		123 (53.0)
It will improve by itself		89 (38.4)
Postpone until after delivery		75 (32.3)
Lack of time		8 (3.4)
No childcare		5 (2.2)
Costs		2 (0.9)
No transport		0 (0.0)
Other		22 (9.5)

N= number, UI= urinary incontinence, *= one answer possible, #= multiple answers possible

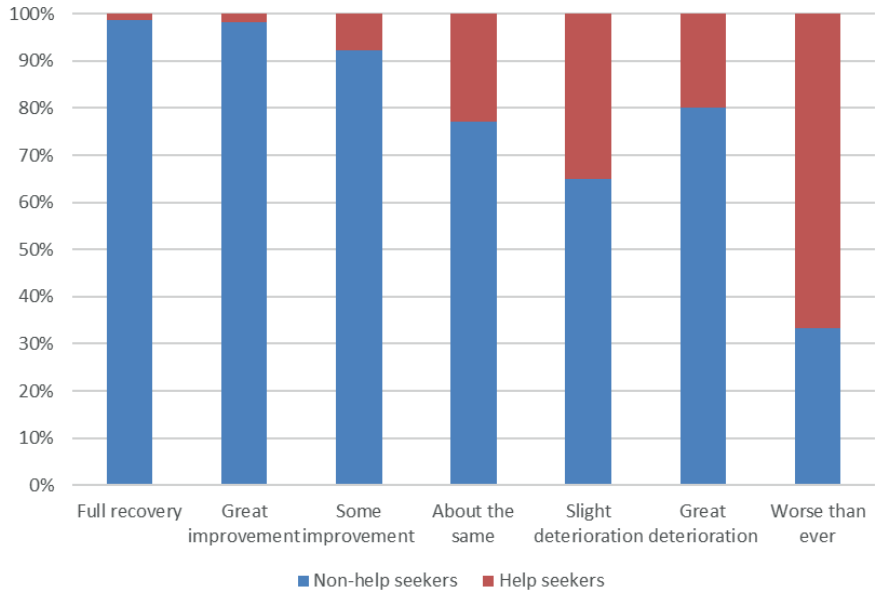

Figure 1 Beliefs about prognosis of urinary incontinence if help is not sought among non-help-seekers and help-seekers.

DISCUSSION

Principal Findings

This study showed that the crude prevalence of self-reported UI during pregnancy is high (66.8%) and rises by trimester. SUI is the most frequently reported type of UI (76.8%) with a notable difference between nulliparous (47.9%) and parous women (77.4%) in overall UI prevalence. The severity of UI is slight (33.7%) to moderate (56.3%), total bother is experienced as low and only less than one third of women indicate a significant impact in daily life. Only the presence of the factors 'changing of wet underclothes' and 'worry because of smell' were considered as a significant bother. Only 13% of respondents sought help for UI. The responders who sought help were often already seeing a (specialized) physiotherapist for other pregnancy-related problems, like pelvic girdle pain. The pelvic floor muscles are reported to play an important role in trunk stability.[18] Therefore, it is common practice for (specialized) physiotherapists to discuss any incontinence with pregnant women presenting with pelvic girdle pain. This encourages the women to mention their UI and seek help.[19] To our knowledge this is the first study reporting on the

percentage of women who actually seek help for their UI during pregnancy. However, the numbers on help-seeking might have been influenced by the fact that social media messages were sent by both midwifery and pelvic physiotherapy practices. The respondents who did not seek help stated that their UI didn't bother them a lot (53%).

Several factors might explain why pregnant women with UI do not seek help. Firstly, nearly 40% of the respondents thought that UI would improve spontaneously after delivery. However, pregnant women might be insufficiently aware that women with UI during pregnancy have a 2 to 6 fold risk of UI post-partum, depending on severity of UI in pregnancy and period post-partum.[20] Secondly, the reported overall bother was low and impact on quality of life due to UI was not greatly affected. A higher level of bother is associated with help-seeking.[19,21] Thirdly, only 4% of the respondents had UUI and especially women with UUI are reported to have lower quality of life than women with SUI and seek more help[5]. Fourthly, 32% of the respondents wanted to wait until after the delivery to seek help. In contrast to the non-help-seekers (28.4%), most of the help-seekers (85.7%) thought that without help their UI would remain the same or deteriorate post-partum. This is consistent with Schreiber *et al*. who reported that women who are afraid that their UI would get worse are triggered to seek help.[22]

Over 70% of all respondents reported that they think that pelvic floor exercises are the best treatment option for UI. This does not mean that these women actually exercise. Burgio *et al.* found that although 84.6 % of women had heard of pelvic floor muscle exercises, only 46.7% of the women really did exercise during pregnancy.[20] Women want to be informed about pelvic floor dysfunctions preferably during pregnancy.[19,21] Antenatal classes may be a perfect opportunity to discuss pelvic floor related issues and misconceptions like the fact that UI would resolve by itself. If the importance and positive effect of PFMT are explained, women may be more willing to do their exercises.[23] Women who attend or have attended antenatal classes are more likely to practice pelvic floor muscle exercises than women who have not.[24] Another option to inform women might be with a mobile app (mApp). However, at the moment the only existing evidence-based mApp is not specifically developed for pregnant women and focusses on self-treatment and adherence of UI and not on providing information on pelvic floor dysfunctions in pregnancy.[25] Although PFMT is an effective and well-established treatment option for women with UI, the treatment effect for UI during pregnancy

is still uncertain.[26] Heterogeneity in studies due to differences in characteristics as parity, PFMT programs and control interventions may underlie the absence of robust evidence of effectiveness. Therefore, studies compensating for this heterogeneity are still needed to investigate the direct or remote effect of PFMT on UI during pregnancy.

Screening for the presence of UI and the degree of bother it causes in daily life (e.g. on activity and participation level) by health care professionals who see pregnant women is relevant to check for misconceptions and to have proper indications for subsequent interventions. However, health care professionals report not having enough time and knowledge to discuss UI.[27]

Clinical and research implications

The difference between the crude prevalence of UI and bothersome prevalence of UI during pregnancy demonstrates clearly the importance of reporting both prevalence numbers and the experience of bother in relation to UI.[4] This study reveals large effect sizes between help- and non-help-seekers regarding ICIQ-UI SF total, ICIQ-LUTSqol total scores and interference in daily life. This indicates that non-help-seeking pregnant women experience little bother, just like women in the general population.[21] This is an important factor to take into account in care planning and research as less bothered women will be not known to the healthcare system.

Strengths and limitations

Strength of this study is the large nationwide sample. Another strength is the use of high quality and recommended questionnaires to measure the prevalence and bother of UI, and impact on quality of life. To our knowledge this is the first study to use the ICIQ-LUTSqol to study bother extensively in pregnant women.

This survey has several limitations. Firstly, women in The Netherlands who do not speak Dutch could not fill in the survey. This might have influenced the outcome regarding the knowledge on the best treatment option for UI. Non-native speakers are less likely to be familiar with possible treatments e.g. pelvic floor muscle exercises.[24] Secondly, we did not ask if UI occurred before the first pregnancy or in previous pregnancies. Therefore, we do not know at what stage in their

obstetric history pregnant women experienced new onset UI. The third limitation comprises the possible risk of bias due to the accessibility of social media for recruitment. Finally, the non-response rate is not known. However, we do know that the average age and education level are comparable with another large study performed in pregnant women in The Netherlands.[28]

CONCLUSION:

UI is highly prevalent throughout pregnancy with prevalence increasing by trimester. However, the majority of women were only slightly bothered by their UI and relatively few women sought help.

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CHAPTER 7

URINARY INCONTINENCE 6 WEEKS TO 1 YEAR POST-PARTUM: PREVALENCE, EXPERIENCE OF BOTHER, BELIEFS, AND HELP-SEEKING BEHAVIOR

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ABSTRACT

Introduction and hypothesis: Post-partum, women often experience urinary incontinence (UI). However, the association between experienced UI bother and UI beliefs and help-seeking behavior is less known. Therefore, we aim to investigate the prevalence of self-reported UI, the level of experienced bother and beliefs, to explain help-seeking behavior for UI in women in the Netherlands from 6 weeks to one year post-partum.

Methods: A digital survey among post-partum women, shared on social media, was used for recruitment. The survey consists of: 1. demographic variables, 2. International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), 3. ICIQ Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol), and 4. questions on beliefs and help-seeking behavior. For analysis, descriptive statistics and the independent samples t-test were used to determine differences between help- and non-help-seekers.

Results: 415 women filled in the survey. The mean age was 30.6 years (SD 4.0, range 21-40) of which 48.2% was primiparous. The overall prevalence of UI was 57.1% (95% confidence interval (CI) (52.3 – 61.8)). Primiparous women reported a statistically significantly lower overall prevalence than multiparous women, 52.0% and 61.9% respectively (p=.043). UI was reported as bothersome in 38% of women, 25% of all women sought help. Help-seeking women showed significantly higher scores for bother, measured by the ICIQ-UI SF, than non-help seekers (p=.001).

Conclusions: More than half of all post-partum women in the Netherlands from 6 weeks to one year post childbirth experience UI (57.1%), 38% classified their UI as bothersome. In total 25% of UI women sought professional help.

INTRODUCTION

Urinary incontinence (UI) as a symptom is defined by the International Continence Society as the 'complaint of involuntary loss of urine'.[1] Prevalence numbers of UI from six weeks to one year post-partum range from 10.5 to 63.0%.[2,3] The wide range in reported prevalence might be explained by the use of different case definitions, post-partum period and study methodology. On the one hand, the International Consultation on Incontinence (ICI) has recommended to accompany prevalence numbers with experienced symptom bother, and on the other hand to measure this construct with high quality measurement instruments preferably within the International Consultation on Incontinence Questionnaire (ICIQ) structure.[4] Despite the ICI recommendations, symptom bother is often not included in prevalence studies. Moreover, a variety of measurement instruments are used for symptom bother, ranging from high quality to non-validated self-constructed questionnaires.[2,3] These factors influence reliable prevalence numbers for (bothersome) UI, which are of relevance for health care providers, policy makers, and researchers.[5] To date, knowledge on crude prevalence numbers (categorized by type of UI, post-partum period, or parity) and symptom bother measured with measurement instruments within the ICIQ structure in the post-partum period are largely lacking.

The level of bother, type and severity of UI are associated factors in help-seeking behavior in the general female population.[6] After delivery, women often believe that their UI will improve by itself.[7] Pelvic floor muscle training (PFMT) is an effective treatment option for post-partum women with UI and recommended as first treatment option in guidelines on UI.[8] However, to our knowledge it is unknown if and what kind of experiences and daily activities contribute to help-seeking and why post-partum women do not seek help. Therefore, the aim is to investigate the prevalence of self-reported UI, the level of experienced bother and beliefs, to explain help-seeking behavior in women in the Netherlands from 6 weeks to one year post-partum.

MATERIAL AND METHODS

Study design

A cross-sectional design was used to describe the prevalence, bother, believes, and help-seeking behavior of post-partum women. The Medical Ethics Committee of the Maastricht University Medical Centre (MUMC+) approved this study (number

2019-1320). All women of 18 years and older, regardless of parity and between 6 weeks and one year post-partum, who were able to fill in a digital questionnaire in the Dutch language were eligible to participate. Based on an overall prevalence of UI in women of 33%, a Z statistic of 1.96 and precision of 0.05, a minimal sample size of 340 women was estimated to fill out the survey.[9] Nationwide midwifery and physical therapy practices were amongst others asked to share a social media message (using Facebook and LinkedIn), containing brief information on the study (goal, eligibility) and a link to the patient information letter and digital survey. In this context a physical therapist is defined as a physical therapist, educated and specialized in health problems related to the pelvic floor and organs in the pelvis minor.

Before proceeding to the anonymized digital survey, eligible women signed informed consent electronically, in agreement with ethical regulations. The survey took 10 to 15 minutes to complete.

Outcome measures

The survey consists of four parts: 1. demographic variables like age, educational level and parity, 2. International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF)[10], 3. International Consultation on Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)[11] and 4. questions on beliefs and help-seeking behavior regarding UI.

The ICIQ-UI SF consists of four questions and provides an indication of UI severity. The first question is with regard to the frequency of UI, with a score of 0 (never losing urine) to 5 (losing urine all the time). The second question asks for amount of urine loss, with four response categories ranging from 0 (no loss) to 6 (large amount). The third question evaluates impact of UI on daily life, ranging from 0 (not at all) and 10 (a great deal). The total score ranges from 0 (no UI) to 21 (very severe problem). The total score is divided into four categories: slight (1-5), moderate (6-12), severe (13-18), and very severe (19-21).[12] A fourth question on the occurrence of symptoms of UI was used to indicate SUI, UUI and MUI.[13] A participant was considered to have SUI when leaking urine with a cough or a sneeze and/or when physically active/exercising, but not before getting to the toilet. UUI is considered when the respondent leaks before getting to the toilet. A respondent with MUI experiences both SUI and UUI.

The ICIQ-LUTSqol is a condition-specific health-related quality of life questionnaire (20 questions), adapted for use within the ICIQ structure from the King's Health Questionnaire.[11] It contains 19 questions that can be scored on life restrictions, emotional aspects and preventive measures. It is scored on a four-point Likert scale ranging from 1 (not at all) to 4 (a lot). Three questions on relationships, sex life, and family life include additionally 'not applicable'. 'Not applicable' was considered as not affecting daily life. The sum score ranges between 19 and 76. A higher score indicates a higher impact on quality of life. Every question is accompanied by a question regarding experienced bother (ranging from 0 (no bother) to 10 (extreme bother)). It is arbitrarily decided that a score of at least 5 indicates significant bother on a specific item. The 20th question is on how much urinary symptoms interfere with daily life, scored between 0 to 10 (like bother). Both the ICIQ-UI SF and ICIQ-LUTSqol are rated as 'high quality' questionnaires and are recommended by the ICI.[4]

All respondents at least filled in the demographic variables and ICIQ-UI SF. Answering 'never losing urine' at the frequency item of the ICQ-UI SF indicated continence and consequently the survey was finished. When reporting UI, women completed the remaining two parts on quality of life and help-seeking behavior.

The questions on beliefs and help-seeking behavior were self-constructed. Selection of question and answer options was based on models explaining help-seeking behavior, discussion with experts in the field (epidemiologists and obstetrician/gynecologist) and modified accordingly.[14] Moreover, questions were reviewed by an expert for readability and comprehensiveness, followed by field testing. Ultimately, six questions were developed including four topics on health seeking behavior (actual help-seeking, reason(s) to (not) seek help, reason to seek help in the future and consulted health-care provider(s)) and two topics on beliefs (self-perceived prognosis and self-perceived best intervention to treat UI in general).

Data analysis

Data was analyzed using descriptive statistics presented as proportions (frequency and means (SD)) and correlation was performed by Pearson's correlation coefficient. Post-partum women were categorized into three groups: 6 weeks to 3 months, 3 to 6 months and 6 to 12 months post-partum. Independent sample

t-tests were conducted to compare help-seekers and non-help seekers with regard to UI severity (ICIQ-UI SF total score), bother (ICIQ-LUTSqol total score), and interference in daily life. Chi-square tests were used to test relationships between categorical variables. One-way analysis of variance (ANOVA) was used to explore differences in experienced bother, measured with the ICIQ-UI SF scores, across the three post-partum periods. The effect size was estimated with Cohen's *d*. Cohen's *d* presents the difference between groups (help-seekers and non-help-seekers) in standard deviation units. To interpret the strength of the effect size we followed the guidelines proposed by Cohen: .2=small, .5=medium, .8=large. An alpha of 0.05 is considered statistically significant. Analyses were done using IBM Statistical Package for Social Sciences (SPSS) version 26.0 (New York, NY, USA).

RESULTS

In March 2020, 415 women filled in the survey. The mean age was 30.6 years (SD 4.0, range 21-40) of which 48.2% (200/415) was primiparous (Table 1). A total of 37.7% (157/415) followed secondary and 61.4% (255/415) tertiary education. The overall prevalence of UI was 57.1% (95% confidence interval (CI) 52.3 – 61.8). Primiparous women reported a lower overall prevalence of UI compared to multiparous women (52%, 104/200) and 61.9%, 133/215 respectively) which was statistically significant (p=.043). The prevalence of UI does not change significantly across the three post-partum periods (p=.15). However, the pattern over time shows the highest prevalence between 6 weeks and 3 months with 66.7% (50/75), almost statistically significant decreasing to 52.6% (61/116) between 3 and 6 months after which there is no significant change thereafter (56.3% (126/224), between 6 and 12 months. SUI (62.9%, 149/237) was the most frequently reported type of UI.

UI frequency of once a week or less was reported in 43.9% (104/237) and in 89.5% (212/237) of the cases it was a small amount of urine (Table 1). The impact of UI based on the ICIQ-UI SF score was reported by 29.7% (70/236) of the women as slight and by 57.6% (136/236) as moderate. There were no statistically significant differences for the ICIQ-UI SF score across the three post-partum periods (p=.06). The mean interference in daily life based on ICIQ-UI SF was 3.8 (SD 2.4, range 0-9), whereas 38% (90/237) of the respondents reported an overall interference in daily life of ≥5. The mean ICIQ-LUTSqol was 29.8 (SD 7.9, range 20-58). Respondents reported that they experienced a significant bother on three daily activities based

on the ICIQ-LUTSqol. The first is on 'physical activities', like going for a walk, run or sports. The second is regarding the 'need to change wet underclothes' and the third is about 'worrying because of smell'. Respondents with UI were least affected and bothered by the items on maintaining friendships, the effect on sleep and feeling tired. The correlation between the total score of the ICIQ-UI SF and the ICIQ-LUTSqol was high (0.74, p=.001, R^2 = 0.54).

In total, 25.7% (61/237) of the respondents sought help for their UI post-partum (Table 2). The majority of women seeking help (92%) visited a physical therapist. The reasons provided for not seeking help were: minimal bother (52.9%, 91/172) and the idea that their UI would improve in time by itself (54.1%, 93/172). The most important reasons for seeking help in the future were: the constant use of pads (45.9%, 79/172), leaking/getting wet clothes (35.5%, 61/172), the feeling that others can smell the urine loss (27.9%, 48/172) or hindrance at work (27.9%, 48/172). With regard to seeking help in the future, 32% (55/172) of women reported one and 68% (117/172) reported two or three reasons why they would seek help in the future.

Table 1 Characteristics of post-partum women, urinary incontinence prevalence, and ICIQ-UI SF questionnaire results

		Overall (n=415)	**6 weeks – 3 months (n=75)**	**3 months – 6 months (n=116)**	**6 months – 12 months (n=224)**
Age	Mean (SD, range)	30.6 (4.0, 21-40)	30.7 (4.0, 23-40)	30.1 (4.0, 21-40)	30.8 (4.0, 21-40)
Prevalence	Total	237 (57.1) 95% CI: 52.3 – 61.8	50 (66.7) 95% CI: 56.5 - 77.4	61 (52.6) 95% CI: 43.3 – 61.8	126 (56.3) 95% CI 49.3 – 63.3
	SUI	149 (62.9)	25 (50.0)	38 (62.3)	86 (68.3)
	UUI	23 (9.7)	7 (14.0)	4 (6.6)	12 (9.5)
	MUI	47 (19.8)	10 (20.0)	14 (23.0)	23 (18.3)
	Other (such as UI during sleep or UI for no obvious reason)	18 (7.6)	8 (16.0)	5 (8.2)	5 (4.0)
ICIQ-UI SF	Total score (0-21) Mean (SD, range)	8.1 (3.4, 3-17)	8.4 (3.6, 3-16)	7.4 (3.4, 3-16)	8.3 (3.4, 3-17)
Frequency	About once a week or less often	104 (43.9)	19 (38.0)	32 (52.5)	53 (42.1)
	Two or three times a week	59 (24.9)	10 (20.0)	14 (22.9)	35 (27.7)
	About once a day	31 (13.1)	12 (24.0)	5 (8.2)	14 (11.1)
	Several times a day	40 (16.9)	9 (18.0)	9 (14.8)	22 (17.5)
	All the time	3 (1.2)	0 (0)	1 (1.6)	2 (1.6)
Amount	A small amount	212 (89.5)	43 (86.0)	55 (90.2)	114 (90.5)
	A moderate amount	23 (10.1)	7 (14.0)	6 (9.8)	11 (8.7)
	A large amount	1 (0.4)	0 (0)	0 (0)	1 (0.8)
Overall Interference (range 0 – 10)	≥5	90 (38.0)	22 (44.0)	19 (31.1)	49 (38.9)
Categories (1 missing)	Slight (1-5)	70 (29.7)	16 (32.0)	21 (34.4)	33 (26.2)
	Moderate (6-12)	136 (57.6)	27 (54.0)	35 (57.4)	74 (58.7)
	Severe (13-18)	30 (12.7)	6 (12.0)	5 (8.2)	19 (15.1)
	Very severe (19-21)	0 (0)	0 (0)	0 (0)	0 (0)

N=number, %=percentage, SD=standard deviation, CI=confidence interval, UI= urinary incontinence, SUI=stress urinary incontinence, UUI=urgency urinary incontinence, MUI=mixed urinary incontinence, ICIQ-UI SF= International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form.

Table 2 Beliefs and help-seeking behavior in relation to urinary incontinence

BELIEFS		
Prognosis UI without seeking help	**Help-seekers (N=61)**	**Non-help-seekers (N=172)**
Complete recovery	2 (3.2)	38 (22.1)
Good improvement	2 (3.2)	47 (27.3)
Some improvement	12 (19.7)	34 (19.8)
About the same	17 (27.9)	41 (23.8)
Some deterioration	15 (24.6)	11 (6.4)
Great deterioration	9 (14.8)	1 (0.6)
Worse than ever	4 (6.6)	0 (0)
Best way to solve UI		
Surgery	3 (4.9)	3 (1.7)
Medication	2 (3.3)	0 (0)
Pelvic floor muscle exercises	46 (75.4)	143 (83.1)
It will resolve by itself	1 (1.6)	6 (3.5)
There is no solution	1 (1.6)	4 (2.3)
I don't know	6 (9.8)	13 (7.6)
Other	2 (3.3)	3 (1.7)
HELP-SEEKING	**Help-seekers**	**Non-help-seekers**
Reason to seek help	**I sought help because***	**I will seek help in the future if#**
Getting wet clothes/leaking through	2 (3.3)	61 (35.5)
Need to use pad all the time	11 (18.0)	79 (45.9)
Others can smell me	1 (1.6)	48 (27.9)
Hindrance during sports	12 (19.7)	27 (15.7)
Hindrance during work	4 (6.6)	48 (27.9)
Hindrance playing with children	5 (8.2)	32 (18.6)
Hindrance during household tasks/ activities	0 (0)	14 (8.1)
I don't know	24 (39.3)	25 (14.5)
Other reason(s)	0 (0)	10 (5.8)
Reason not to seek help		**Non-help-seekers (N=172)**
Minimal bother		91 (52.9)
It will improve by itself		93 (54.1)
Lack of time		25 (15.5)
No childcare		13 (7.6)
Costs		7 (4.1)
No transport		3 (1.7)
Other		28 (16.3)

N= number, *= only one response option, #= multiple response options possible.

More women, 49.4% (85/172) who did not seek help in contrast to 6.4% (4/61) of the women who did seek help for their UI, thought that their UI would completely resolve or improve a great deal in the future (p <.001). Figure 1 shows the beliefs about self-perceived prognosis of UI among non-help-seeking and help-seeking women as relative percentages of 100%. Of all women with UI, 79.7% (189/237) thought that the best way to treat their UI would be pelvic floor muscle exercises.

Help-seeking women showed significant higher scores than non-help-seeking women regarding ICIQ-UI SF (p=.001), ICIQ-LUTSqol (p<.001), and interference in daily life (p=.002), with corresponding medium effect sizes (ICIQ-UI SF total score: Cohen's *d*=0.52, ICIQ-LUTSqol total score: Cohen's *d*=0.57, and interference in daily life: Cohen's d=0.48). Parity, level of education, age, type of UI, ICIQ-UI SF Amount, and ICIQ-UI SF Frequency showed only weak correlations with help-seeking (ranging between 0.1 – 0.24).

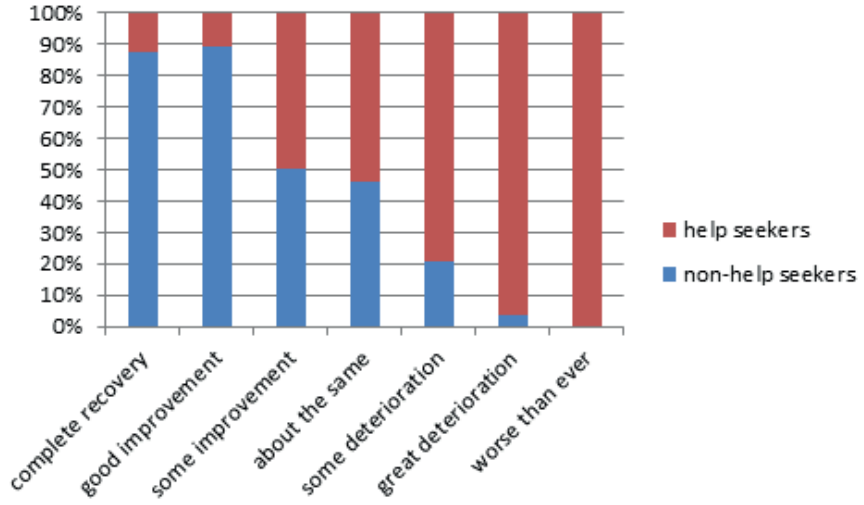

Figure 1 Beliefs about prognosis of urinary incontinence if help is not sought among non-help seekers and help seekers.

DISCUSSION

Principal findings

This study showed that the overall crude prevalence of self-reported UI post-partum is high (57.1%), with 38% experienced as bothersome UI. SUI is the most prevalent type (62.9%), followed by MUI (19.8%) and UUI (8.9%).

The high overall crude prevalence in this study is not uncommon compared to other studies.[2] The prevalence of UI in primiparous women was 52.0% rising to 61.9% in multiparous women. This is in line with other research, indicating that the first delivery is a major risk factor for UI.[15] The prevalence of UI post-partum did not change significantly in the course of the first year post-partum. Although the initial prevalence between 6 weeks and 3 months almost statistically significantly decreased at 3 to 6 months post-partum, the difference between this initial period and the second half of the year after childbirth was not statistically significant. Both Gartland *et al*. and Brown *et al.* reported a decrease of UI prevalence and thereafter an increase throughout the first year after childbirth.[16,17] The decreasing prevalence at three to six months post-partum might be explained by physiological recovery and the rise thereafter because of an increase in return to activities provoking UI, such as physical activity or work.[18]

This is one of the first studies to report the number and reasons of post-partum women to seek help for their UI.[19] In total 25.7% of post-partum women sought help for their UI, in 92% of cases they visited a physical therapist. This reflects the recommendations in the guidelines on UI for the general practitioners in The Netherlands proposing physical therapy as a first treatment option.[20] The fact that participants were recruited through social media from both midwifery and physical therapy practices this number might have been influenced. The help-seeking women reported a greater interference in daily life compared to not-help-seeking women. 46% of help-seeking women think that their UI would deteriorate when they would not seek help in contrast to 7% of non-help-seeking women ($p<.001$).This is in line with other studies in which women mentioned that they did not seek help because they were not greatly bothered by their UI and thought that it would diminish by itself in time.[7] However, up to 91% of women with SUI after their first delivery still report SUI 12 years later.[21] Although UI is not life threatening, women in the general population with UI report lower health-related quality of life

and mental well-being and 45% of women report a moderately to totally limiting effect on exercise.[22] Women with UI in this study reported significant bother of UI regarding physical activities like in the study of Monz *et al.*.[22] Women with UI during physical activities adapt by e.g. reducing the intensity and avoiding specific UI provoking activities that may impact physical fitness and mental health.[23]

Clinical and research implications

Generally, women in the Western world have a final check at six to eight weeks post-partum by a midwife or gynecologist. This recovery period might be short to judge actual pelvic floor dysfunctions.[24] On the one hand, the contractility of the pelvic floor muscles are considered to need at least 12 weeks to recuperate and at four to six months post-partum the distensibility of the hiatal area is still significantly increased during Valsalva compared to early pregnancy which can limit the physical resilience of the pelvic floor.[25] On the other hand women are in the early post-partum period also busy finding a new balance in their life and their own health may be considered less important to them at that moment.[7] With this in mind it might be more appropriate to check the mother's health regarding pelvic floor dysfunctions like UI at a later stage (three to six months post-partum). At the moment there is no validated easy assessment tool that evaluates women's well-being in a broader, more general perspective. Therefore, an evidence-based selection tool investigating and mapping women's health in general and the pelvic floor specifically, aiming to record whether and to what extent an intervention is warrant. For this purpose, a physical therapist, as an expert on both women's health and in conservative management of pelvic floor dysfunctions, may use the tool of the physical therapeutic diagnostic consultation that, given the medical diagnosis of UI, looks at the consequences of this health problem on three different levels, being the local level (impairments), personal level (disabilities) and the sociocultural level (restriction in participation.[26] Our results show that 75.4% of help seeking and 83.1% of non-help seeking women think PFMT is the best way to solve UI. This suggests that PFMT is a well-known treatment option in The Netherlands. However, this number might not reflect the knowledge of PFMT in other parts of the world as Asia and Africa. For example, 55.5% and 58% of pregnant women in Thailand and Malaysia, respectively, possessed knowledge of PFMT.[27,28]

Strengths and Limitations

The strength of this study is the large nationwide sample on post-partum women in The Netherlands. Another strength is the use of high quality, recommended questionnaires to measure the prevalence and bother of UI, and impact on quality of life. To our knowledge this is the first study to use the ICIQ-LUTSqol to study quality of life and therefor to evaluate bother extensively in post-partum women from 6 weeks to 1 year post-delivery, next to their relations with help-seeking behavior.

This survey has several limitations. Firstly, women in The Netherlands who do not speak Dutch could not fill in the survey. This might have influenced the outcome regarding the knowledge on the best treatment option for UI. Nevertheless, non-native speakers are less likely to be familiar with possible treatments e.g. PFMT.[29] Secondly, we did not ask if UI occurred before the first pregnancy or during the pregnancies. Therefore, we do not know at what stage in their obstetric history women experienced new onset UI. The third limitation comprises the possible risk of bias due to the accessibility of social media for recruitment. Though, in 2020, 75% of The Dutch population use Facebook and 38% LinkedIn.[30] Finally, the non-response rate is not known.

CONCLUSION

More than half of all post-partum women in the Netherlands from 6 weeks to one-year post childbirth experience UI (57.1%), of whom, 38% classified their UI as bothersome.. In women with UI, 25% sought help and in 92% of cases this was with a specialized (pelvic) physical therapist. Help-seeking women experience higher impact on bother than non-help seekers.

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CHAPTER 8

EXPERIENCES OF PERI-PARTUM URINARY INCONTINENCE FROM A WOMEN'S AND HEALTH CARE PERSPECTIVE: A QUALITATIVE STUDY

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Submitted

ABSTRACT

Introduction: Urinary incontinence (UI) is highly prevalent peri-partum. To gain more understanding regarding the gap between the prevalence of UI and actual help seeking behaviour of peri-partum women, this study aims to understand, 1) how peri-partum women experience UI and which factors influence these experiences and 2) the perspective of health care professionals on UI during pregnancy, and the first year after childbirth.

Method: A qualitative approach was used, using semi-structured interviews with adult pregnant and up to one year post-partum women and a focus group with health care professionals (HCP's) involved in the care of pregnant and post-partum women. Thematic analysis was used to analyse the data.

Results: Nearly all women expressed to be not, or only slightly bothered by their UI and accept it as a result of pregnancy and/or delivery. Women were surprised because they were unaware that UI could be a problem. None of the HCP's routinely asked about the presence of UI during pregnancy. At the post-natal check at 6 weeks post-partum, UI is still not a standard question for the majority of the gynecologists and registrars in contrast to the midwives.

Conclusions: Women with UI during pregnancy and the first year after childbirth were surprised but hardly bothered by their UI and accept it as part of being pregnant or as a result of the delivery. HCP's do not routinely discuss UI during pregnancy or post-partum.

INTRODUCTION

Pregnancy and delivery are well known risk factors for the development of urinary incontinence (UI) during pregnancy and post-partum.[1] The prevalence of UI, defined as the involuntary loss of urine[2] rises from 55% in the first to 70% in the third trimester.[3] In the first year post-partum, 31% of women report UI with no significant difference in prevalence numbers between 6 weeks, 6 months and 12 months post-partum.[4,5] Although the prevalence numbers of UI during pregnancy and up to one year post-partum are high, the reported corresponding experienced bother of UI appears to be low to moderate.[5-8] There are indications that the level of perceived bother influences help seeking behaviour for UI.[9] Two recently published surveys on the prevalence, experienced bother, beliefs, and help-seeking behaviour in the peri-partum period in The Netherlands, confirmed the high prevalence numbers in combination with low to moderate experienced bother.[3,10] However, these studies also showed that only 13% of pregnant women and 26% of women with UI between 6 weeks and 1 year post-partum sought help for their UI. A remarkable result is that nearly 40% of non-help seeking pregnant women and 49% of non-help seeking post-partum women believe that their UI will resolve spontaneously or improve greatly after delivery or over time.[3,10] Even though health care professionals who provide peri-partum care are knowledgeable of risk factors of pelvic floor dysfunctions like UI, it is not common practice to educate and counsel peri-partum women on UI.[11] These results demonstrate a persistent knowledge gap among women regarding natural recovery or improvement of UI and counselling by health care professionals.[12] Pregnant women are not aware of the fact that UI in pregnancy results in a two to six fold risk of UI post-partum[13] whereas up to 91% of post-partum women with UI still report UI after 12 years.[14] Existing guidelines recommend pelvic floor muscle exercises as a first line treatment option for women with UI.[15] However, only a few women actually seek help. To gain more understanding regarding the gap between the prevalence of UI and actual help seeking behaviour of peri-partum women it is important to understand the health beliefs of these women and their caretakers regarding UI, how peri-partum women experience their UI, and to acquire knowledge on subsequent health care management.

Therefore, this research aims to understand, 1) how peri-partum women experience UI and which factors influence these experiences and 2) the perspective of health care professionals on UI during pregnancy, and the first year after childbirth.

METHOD

Design, participants and procedure

A qualitative approach, using semi-structured interviews with women and a focus group with health care professionals (HCP) was used. Adult, pregnant and up to one year post-partum women who gave birth to a living baby, regardless of parity, were eligible to participate. Due to the sensitive nature of the topics, women were interviewed individually in face-to-face interviews. To promote discussion on experiences and beliefs on UI (and related bother) and how they incorporate this in the approach of their patients, HCP's involved in the care of pregnant and post-partum women like midwifes, residents and gynecologists participated in a focus group discussion.

Pregnant and post-partum women were recruited through purposive sampling. We aimed for a sample with sufficient variety regarding trimester in pregnancy and post-partum period, in order to increase transferability of the study results. Three midwifery practices in the area of Maastricht, The Netherlands, posted a social media message with general information on the study on their Facebook page. Interested women contacted the researcher by email. Subsequently, the researcher emailed the potential participant the more elaborate patient information letter and asked the woman to email a telephone number if she agreed to be contacted after a week. After a week the researcher contacted the woman to ask, if the research information was clear, if she had any questions, and if the woman was willing to participate. The HCP's were recruited by email or personally invited to participate by MS. All HCP's received an information letter well in time before the focus group. Each participant signed an informed consent form prior to participation. All included women received a €25 gift card for participating and the HCP's €100 in cash for their time. An overview of participant characteristics is displayed in Table 1.

Table 1 Participant characteristics

Participant (pregnant women)	**Age (years)**	**Education**	**Parity and gravidity (weeks pregnant)**	**General health** (0 = worst possible, 10= good)	**NRS UI**
G1	33	Tertiary	P1G2 (33)	6	7
G2	24	Secondary	P0G1 (36)	7	6
G3	30	Tertiary	P0G1 (20)	8	7
G4	38	Tertiary	P1G2 (25)	9	7
G5	36	Tertiary	P1G3 (29)	8	5
G6	37	Tertiary	P2G3 (34)	7	5
Participant (post-partum women)			**Parity (months post-partum)**		
P1	30	Secondary	P2 (6)	9	7
P2	26	Secondary	P1 (5)	2	6
P3	29	Tertiary	P2 (10)	8	8
P4	25	Secondary	P1 (8)	7	6
P5	25	Secondary	P1 (2)	8	6
P6	38	Secondary	P1 (2)	9	8
P7	25	Secondary	P1 (9)	8	7
Participant (health care professional)	**Type of health care professional**			**Hospital or privately practice**	
H1	Gynecologist			Hospital	
H2	Midwife			Private practice	
H3	Gynecologist			Hospital	
H4	Resident gynecology			Hospital	
H5	Resident gynecology			Hospital	
H6	General practitioner specialized in urogynaecology			Private	
H7	Midwife			Hospital	
H8	Midwife			Hospital	

G=pregnant/ gravida, P = post-partum, H= Health care professional, NRS= numeric rating scale, UI= urinary incontinence.

Table 2 Interview guide pregnant and post-partum women

1	What does it mean for you to have urinary incontinence?
2	How does urinary incontinence influence your daily life, relations, work, sports?
3	How would you describe bother of urinary incontinence?
4	Did your health care professional ask about urinary incontinence?
	If yes, what was the advice given?
5	What actions did you take regarding your urinary incontinence?
6	What factor is important for you to seek help?

Table 3 Interview guide focus group

1	Who wants to tell us about discussing urinary incontinence during consultation?
2	What is the reason for discussing urinary incontinence?
3	Are there reasons for not discussing urinary incontinence?
4	What advise do you give a woman with urinary incontinence?
5	Do you think women are bothered by their urinary incontinence?

The Medical Ethics Committee of the Maastricht University Medical Centre (MUMC+) was consulted. This committee declared that ethical approval was not necessary due to the non-invasive character of the study (MECC 019-1351).

Data collection

An interview guide was developed for the semi-structured face-to-face and focus group interviews, based on published literature[3,10,11,16,17] and expert opinion (Tables 2 and 3). The interviews were digitally recorded. The recordings were transferred to a safe storage place on the server of Maastricht University and subsequently deleted from the recording device. Data were de-identified by giving each participant a unique code.

Women were visited in the privacy of their home or in one case at work by a female interviewer, HM. Visits at home offer more convenience with regard to childcare and we anticipated facilitating participation. The focus group took place in a meeting room of the local hospital. The focus group interview was done by HM together with EB who took notes and assisted if necessary. The duration of the face-to-face interviews was approximately 45 minutes and the focus group discussion lasted two hours. Data collection commenced in September 2019 and was completed until saturation was reached in December 2019. Saturation was reached when no new topics emerged in the last interviews.

Data analysis

The recordings were transcribed verbatim by HM after every second interview to allow for constant comparison. If new topics arose during the face-to-face interviews alterations were made to the interview guide. NVIVO 12 pro was used for data analysis. Data were analysed thematically based on Braun and Clarke.[18] Every transcript was read thoroughly multiple times line by line and coded. The codes were reread and if necessary merged, divided, renamed and grouped in potential themes (HM). Next, mind-maps were made of the potential themes (one for the peri-partum women and one for the health care professionals) to help refine potential themes, find different levels of relationships and finally reveal the main themes. The potential themes and mind-maps were discussed and refined with EB until consensus was reached.[18] Themes were then discussed with the research team. The Standards for Reporting Qualitative Research (SRQR) were followed.[19]

Research team

The face-to-face interviews and focus group were conducted by the first author HM as part of a PhD on UI peri-partum. She has over 20 years of clinical experience in specialized physical therapy (PT). HM also performed the primary data analyses. IH (PhD) is experienced in social medicine and qualitative research. All researchers are experienced in quantitative research. EB (PhD) is an epidemiologist, PT and has experience in project management and supervision. BB (PhD) is a clinical epidemiologist, experienced in project management and has over 35 years of clinical experience in specialized PT. MS (MD, PhD) is an obstetrician.

RESULTS

In total, six pregnant and seven post-partum women were included (Table 1). The pregnant women were aged between 24 and 38 years, of which two women were primi- and four were multi-gravida. The post-partum women were aged between 25 and 38 years. Five women were primi- and two multiparous. Eight HCP's participated in the focus group discussion. The group consisted of three midwives, one working in a private practice and two in a hospital setting, two gynecologists, two residents in gynecology and a general practitioner specialized in urogynecology (Table 1).

First, the results from the peri-partum women will be discussed, followed by the results from the HCP's.

Peri-partum women

Nearly all women expressed to be not or only slightly bothered by their UI. None of the participants had visited a specialized physical therapist (PT) to treat their UI. Most women accept their UI as a result of pregnancy and/or delivery. After analysis two main themes emerged: (1) feelings and beliefs regarding UI and (2) coping and adaptive strategies.

Feelings and beliefs regarding UI

Women with UI expressed different feelings regarding their UI for example surprise but also negative and neutral feelings. Women were surprised because they were unaware that UI could be a problem in pregnancy or post-partum, that it happened to them or that it did not resolve after delivery. Some women expressed negative feelings like: shame, fear of smell or visibility of their UI for others.

> *'I expected my UI to resolve nearly completely after delivery in such a way that it would not bother me anymore.'(P5, post-partum)*

> *'I think I am a bit embarrassed. You are 25 and have UI already.' (P5, post-partum)*

Pregnant women more often than post-partum women indicated to have a neutral feeling.

> *'There are worse things you can have during pregnancy, like high blood pressure.' (G3, pre-partum)*

Most women accept their UI as an inevitable part of being pregnant or a consequence of delivery and do not experience UI as a major problem. Often pregnant women expect it to be temporary. This belief seems to originate from a variety of beliefs based on gathered information.

> *'I am 30, I have delivered a baby. That takes its toll from the body. The baby comes out vaginally. You are not left without damage.' (G1, pre-partum).*

'The midwife told me that UI is unfortunately one of the unwanted but normal issues that is part of pregnancy and delivery.' (P6, post-partum)

The feelings and beliefs the women expressed originated from different sources (see below).

Coping and adaptive strategies

Two sub-themes emerged from this theme: a) self-management and b) help-seeking.

Self-management

Different strategies were used to gather information on UI. Some women actively asked a HCP, friend or searched the internet. However, it was also mentioned that they stopped surfing the internet for information on UI because of the contradictory information found.

'I have googled UI but you read so many different things that I stopped searching, to be honest'. (P2, post-partum)

One woman expressed that she gained information by listening to others and another woman said that if she was not asked directly about UI she would not discuss it herself.

'I did not talk about it. A lot of people in my surroundings were pregnant as well. They did talk about it and I thought: 'fortunately, I am not the only one with this issue'. More women have the same problem.' (P5, post-partum)

Women with UI used different preventive and adaptive strategies for their UI. Strategies used were for instance: reducing the fluid intake, increasing micturition frequency, reducing spontaneity by for instance laughing less loud or coughing less deep, and contracting the pelvic floor muscles. The use of pads and wearing darker colour pants were also used as adaptive strategies.

'I try to squeeze down below for as far as it goes, but also prevent sneezing. What has also changed is that I go to the toilet to urinate as soon as I feel a little bit of urge.' (G3, pre-partum)

Two of the women did regular pelvic floor muscle exercises. These exercises were recommended by a general practitioner or a PT. Although most of the women indicated that they know that you can treat UI with pelvic floor muscle exercises, they did not perform them. Reasons were: questioning the effectiveness, being too busy with other and more urgent things. Moreover, issues like costs, travel distance and resistance against an internal palpation by a specialized PT were mentioned as barriers.

Help-seeking

A few women actively sought help for their UI by visiting a HCP like a general practitioner, their midwife or discussing it with the PT they were seeing for other issues.

> *'When I stopped bleeding three weeks after my delivery, I noticed that I was losing urine. I immediately made an appointment with my general practitioner.' (P2, post-partum)*

Reasons women expressed to seek help in the future were: waiting until after delivery, an increase in the amount and frequency of urine loss, occurrence at unexpected moments or an increase in negative feelings regarding their UI.

> *'I know I might lose urine when I cough or sneeze, I can live with that. I think that when I lose urine all the time I will be more bothered and then it is time to get help.' (G3, pre-partum)*

None of the participants visited a specialized PT for her UI. Pregnant women received differing advice from their HCP and also from (specialized) PT's. Frequently, pregnant women were advised to not to perform pelvic floor muscle exercises until after delivery. One woman was quite upset that a specialized PT she had visited during her first pregnancy for pelvic girdle pain advised her not to perform the exercises until after delivery in contrast to the one she is visiting in her second pregnancy who did give her exercises.

> *'When I contacted my specialized physical therapist in my first pregnancy because of my UI she told me that she could not help me. The specialized physical therapist I am visiting now (for pelvic girdle pain) thinks differently*

about that. So I am really disappointed.' (G5, pre-partum)

Health care professionals

None of the HCP's routinely asked about UI during pregnancy. At the final check at 6 weeks post-partum, UI is not a standard question for the majority of the gynecologists and registrars in contrast to the midwives. For midwives working in the hospital and in private practice, this is a more common question in their final consultation.

The focus group interview with HCP's involved in the care of peri-partum women revealed two themes: (1) lack of awareness, attention and solutions, and (2) different advices.

Lack of awareness, attention and solutions

The degree of awareness of UI during consultation varies considerably between HCP's. Different reasons were provided for less awareness. The majority of the HCP's indicated that the duration of a consultation is a big issue and that they need to prioritise.

'We have 15 minutes for the post-partum check. If a woman had a difficult childbirth there are a lot of issues that need to be discussed. UI is not considered as important in comparison.' (H4, registrar)

The HCP's discussed solutions for this problem and thought that it would benefit women if they receive an information leaflet, see a poster or information on the televisions in the waiting room. Another suggestion was to discuss UI during a regular planned appointment for all pregnant women with a specialized nurse. A midwife working in a private practice has a specialized PT in her practice and she mentioned the benefits of this collaboration. The specialized PT educated her in the importance of asking about, for instance, UI, explaining the specialized PT intervention and when to refer for consultation. Some HCP's are aware some women do not discuss issues like UI by themselves and that they need help in making it discussable.

'You need to normalize UI, tell women that it is a common problem, but that you can do something about it.' (H6, general practitioner)

The lack of a standard question on UI in the hospitals electronic patient file (EPR) as a reminder is also considered an important factor in not discussing UI, which was confirmed by a resident with experience in a hospital with a standard question on UI post-partum in the EPR.

> *'UI is not a standard question in our EPR, which is a shame. If it was a standard question it will not be forgotten to ask.' (H1, gynecologist)*

> *'I will be honest and say that it is not a question in my standard list for consultations in pregnancy. I also do not ask actively for it.' (H5, resident)*

One midwife working in a private practice has a standard question on UI in the EPR for the post-partum check. In general, the HCP's working in the hospital agreed that a question on UI in the EPR would help them in not forgetting to ask the woman. HCP's that actively ask post-partum women about UI often did this because they have been informed by a friend, colleague or because of their own experience. This specific information made that they became aware that UI is an important issue to discuss.

> *'For me taking part in sport after my own delivery was an eye-opener, because women talked a lot easier about their ailments and it felt like being among fellow sufferers.' (H5, midwife)*

> *'A friend of mine is a fitness instructor for peri-partum women, so she sees a lot of women post-partum. She said 'don't make the mistake and think that women will tell you about their UI. You really need to ask this question.' (H5, resident)*

Different advices

The second theme 'advice' revealed that HCP's give peri-partum women with UI diverse advice. Sometimes pregnant women are advised to wait and see till after delivery. Other strategies mentioned were to refer to the general practitioner, a urogynecologist or a specialized PT.

> *'I refer all peri-partum women with UI to the specialized physical therapist.' (H2, midwife)*

> *'If someone has a huge problem at 6 weeks post-partum then I know that pelvic floor muscle exercises are not going to help and I don't want to 'beat her*

around the bush' so I will send her to the urogynecologist.' (H1, gynecologist)

The discussion revealed some questions and beliefs regarding specialized PT like: how do we know that we send our patient to a properly qualified specialized PT, is there a quality register, and where do we find the location of a specialized PT? Some doubt was expressed regarding the effect of specialized PT.

> *'Specialized physical therapy is more a kind of in between solution. It can ease the problem, but not solve it.' (H1, gynecologist)*
>
> *'I have some doubts about specialized physical therapy during pregnancy for UI. On the one hand the baby has to grow and the tissue has to gain in elasticity and if I think what the specialized physical therapist wants. It is only a physiological idea.' (H5, resident)*

In conclusion, these issues suggest that HCP's are not well aware of the current guidelines on treatment of UI.

DISCUSSION

This study aimed to understand on the one hand women's experience and beliefs regarding their peri-partum UI and which factors influence these experiences, and on the other hand, learn about the perspective of HCP's on UI peri-partum. Thematic analysis was used to analyze the interviews with the women and the focus group with the HCP's.

Our results show that although some women were surprised by their UI the majority of pregnant women accepted their UI as part of being pregnant and think it will resolve after delivery. This belief is based on information women gathered in a variety of ways and is in line with other studies.[3,10] The women did not experience their UI as very bothersome and indicated that they would seek help if there was an increase in the amount and frequency of urine loss, occurrence at unexpected moments or an increase in negative feelings regarding their UI. This is in line with the results of two Dutch studies reporting on help-seeking behavior of pregnant and post-partum women.[3,10] No participant in this study had visited a specialized PT to start pelvic floor muscle exercises. Although some women asked their HCP about their UI, the majority did not. Nonetheless, several women said that they would talk about it if they were asked. Only for some an open question like 'do you

have any other issues you would like to discuss' was a trigger to discuss UI. In a study by Buurman et al. women stated that if a HCP did not ask about UI, it could not be that bad.[12] The HCP's in the focus group reported that a question on UI in pregnancy and post-partum is not standard and this could potentially mean that women are not well informed about UI.

As the women also noted that they read contradicting information and advice on the internet, the HCP could be the one to provide reliable information. The HCP's should provide women with realistic expectations regarding post-partum UI and discuss treatment options. However, the HCP's experienced the duration of the consultation as an important barrier to discuss UI as well as the lack of a standard question in the EPR. One of the reasons a standard question on UI is not in the EPR might be that in guidelines regarding pre- and postnatal care in The Netherlands, UI is hardly mentioned.[20-22] The NICE guideline on antenatal care for uncomplicated pregnancies recommends specifically to discuss pelvic floor muscle exercises, ideally at 10 weeks gestation.[23] Likewise, it is recommended to review and adapt the Dutch peri-partum guidelines, in co-creation with the involved professionals, with regard to creating awareness of UI and optional interventions such as specialized physical therapy.

According to the HCP's, women could be informed through a leaflet or on televisions/ screens in the waiting room. Other suggestions put forward were discussing UI with a specialized nurse who is already seeing the women to discuss the delivery or with a specialized PT. This is an interesting option because in that case there would also be an opportunity to provide the women with reliable information and pelvic floor muscle exercises. This will stimulate self-efficacy. Specialized PT is a first line treatment option for UI, recommended by the NICE guidelines.[15] However, especially the gynecologists and resident's showed some reservations regarding the effect of specialized PT. This is in line with the results of a Cochrane review which stated that the effect of pelvic floor muscle exercises ante- or post-natal for the treatment of UI is still uncertain.[24]. But we need to keep in mind that these results are based on (small) studies of (very) low quality. Interestingly, another Cochrane review on the effect of pelvic floor muscle exercises for women with UI in the general population concluded that pelvic floor muscle exercises can cure and improve symptoms of UI.[25] Therefore, it might be justified to consider offering peri-partum women pelvic floor muscle exercises and in the meantime executing

high quality randomized controlled trials to support evidence for this strategy. A midwife who works closely with a specialized PT in her practice mentioned the benefits of this collaboration. Also other issues like finding a properly qualified specialized PT were mentioned. This reveals that there might be a knowledge gap that needs to be addressed.

Limitations

Our study has several limitations. The focus group consisted of proportionally more HCP's who work in one hospital and not in primary perinatal care. In The Netherlands only women with high risk complicated pregnancies are monitored by a HCP in a hospital and low risk pregnancies by a midwife in primary care. As a result these consultations might have a different focus. Inclusion of women was based on self-selection and therefore women for whom discussing UI is very difficult or a taboo might not have expressed interest. All women but one had a Dutch cultural background and came from the south of The Netherlands. Fourteen percent of women living in the Netherlands have a non-western migration background[26]. This group might have different beliefs and experiences regarding peri-partum UI. Therefore the results presented in this study are not transferable to these women. Moreover, the interviewed pregnant women were mostly higher educated.[27] Nonetheless, as we interviewed until saturation was reached, we still assume that despite these shortcomings, findings are most likely generalizable to the greater majority of Dutch peri-partum women, presenting in various healthcare settings.

Conclusions

Women with UI during pregnancy and the first year after childbirth are hardly bothered by their UI and accept it as part of being pregnant or as a result of the delivery. This belief probably originates from information from a HCP, friend or the internet. Some women ask their HCP about their UI but when not asked some women do not disclose their UI. HCP's do not discuss UI on a standard basis. Discussing UI can empower women and contribute to their self-efficacy.

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CHAPTER 9

GENERAL DISCUSSION

MAIN FINDINGS

Urinary incontinence (UI) is a highly prevalent condition amongst women and often develops during pregnancy and childbirth. Despite the high reported numbers, there seems to be a mismatch between prevalence and help-seeking behavior. The main objective of this thesis was to investigate several aspects of pregnancy-related UI, including prevalence, experienced bother, anticipated course, therapeutic effect of physical therapy, and help-seeking behavior. In addition, the (cost-) effectiveness of conservative treatment of UI during pregnancy and in the post-partum period, and experiences of peri-partum UI of women and health care professionals (HCP) were of interest.

We evaluated the prevalence, incidence, and bothersomeness of UI in pregnancy (**chapter 2**) and between 6 weeks to 1 year post-partum (**chapter 3**) in two systematic reviews and meta-analyses. Based on 44 studies, with a total of 88.305 women, the mean prevalence of UI in pregnancy is 41%. The mean prevalence between 6 weeks and 1 year post-partum is 31%, based on 20 studies and 35.064 women. Stress (S) UI is the most prevalent type of UI, accounting for 63% of the cases in pregnancy and 54% of the cases post-partum. Both chapters show that the majority of studies did not combine prevalence numbers with a measure of symptom bother, as recommended by the International Consultation on Incontinence (ICI).[1] The overall reported bother during pregnancy and between 6 weeks and 1 year post-partum was mild to moderate. The next chapter (**chapter 4**) shows the design of two randomized controlled trials (RCT) on the long-term effects of pelvic floor muscle group therapy (PFMGT) compared to care-as-usual (CAU) for the treatment of UI in pregnancy and post-partum. The results of the RCTs (**chapter 5**) show no difference between groups during pregnancy regarding the prevalence and severity of UI, global perceived effect, and the impact of UI at any follow-up moment. Due to low inclusion numbers, groups did not reach the size indicated by the power calculation. As a consequence, results are based on individual pelvic floor muscle therapy (PFMT) instead of PFMGT. The results of PFMT commenced post-partum revealed a significant improvement of the prevalence and impact of UI at 4 months post-partum compared to CAU. However, at 9 and 18 months post-partum this effect was seen to decrease. Two surveys on the prevalence of UI, experienced bother and help-seeking behavior in pregnancy (**chapter 6**) and between 6 weeks and 1 year post-partum (**chapter 7**) revealed

that despite high prevalence of UI in both groups, women experienced only mild to moderate bother of UI. Amongst pregnant and post-partum women, only 16% and 25%, respectively, sought help for their UI. Women in both studies who sought help scored higher regarding bother compared to non-help-seeking women. The majority of women who did not seek help thought that their UI would resolve by itself. Moreover, a qualitative study on the experiences of peri-partum UI from a woman's and HCP perspective showed that, although women were surprised because they were unaware that UI could be a problem peri-partum, they accept their UI as a result of pregnancy and/or delivery (**chapter 8**). Moreover, none of HCPs routinely asked about the presence of UI during pregnancy. Although midwifes tend to pay attention to UI at the 6 week post-natal check, the presence of UI is not routinely asked by the majority of the gynecologists and registrars.

METHODOLOGICAL CONSIDERATIONS

UI in the peri-partum period is highly prevalent. Therefore, the aim was to perform two studies evaluating the effect of PFMGT compared to CAU for the treatment of UI in pregnancy and post-partum. The PFMGT program had a strong emphasis on promoting a healthy lifestyle ('motherfit') including pelvic floor muscle (PFM) exercises as part of it. In both studies the inclusion of participants was very slow, resulting in two underpowered studies. Therefore, the presented results need to be interpreted with caution. Due to insufficient inclusion numbers, groups did not fill and results are, as a consequence based on individual PFMT instead of PFMGT and we were unable to establish the long-term effects and cost effectiveness in our two RCTs comparing PFMGT to CAU.

Recruitment of participants

One of the most common challenges of randomized controlled trials (RCTs) is related to optimize patient recruitment.[2] The recruitment rate is influenced by both patient and investigator factors. Eligible patients may not want to participate (in general) as they may have a preference for a certain therapy and/or do not want to be randomized, they perceive the trial (information) as too complex or have difficulties completing the follow-up requirements. Investigator-related factors may be difficulties following the protocol or obtaining informed consent.[2]

As experiencing UI is a delicate subject and being in the peri-partum period is demanding, more specific reasons for recruitment problems or higher drop-out may be considered in our trials, such as: having insufficient bother in relation to UI, feeling embarrassed (in a group), strong preference for individual therapy, unfamiliarity with specialized (pelvic) physical therapy and/or group therapy (e.g. wrong idea that women need to undress), not convinced of a positive outcome, experiencing mental health issues, inconvenient time of therapy, need to arrange a babysitter, fear of losing urine during group therapy, belief that UI will resolve by itself, planning to be pregnant again soon, too many effort or impersonal contact with the investigator. Hypothetically, several reasons based on the timing of the start of PFMGT might also play a part: women being too busy finding a new balance in life, taking care of the baby and organizing going back to work as maternity leave ends standardly between 10 and 12 weeks post-partum in The Netherlands. Another factor that might be an issue is that women start with sporting activities after their post-partum check at 6 weeks and therefore might not have been aware that they have SUI, because their continence system has not been challenged yet.

The decision to participate will probably be a complex interplay between the before-mentioned factors, of which some will be modifiable and others not.[3,4]

We initially intended to include 150 primigravid and 90 primipara women. These figures were based on several sources, i.e. prevalence numbers of UI in both groups[5], number of babies born in the study area each year[6], number of participating HCPs, and previous studies with similar population characteristics and an acceptable drop-out rate.[7,8] Woldringh *et al*. studied the effect of PFMT for the treatment of UI in pregnancy in The Netherlands.[7] The women received three individual therapy sessions during pregnancy between 22 and 30 weeks of gestation, and one session at 6 weeks post-partum. During the three PFMT sessions in pregnancy, they lost 17% of the participants. Inclusion was unproblematic and the drop-out rate was within the range that was accounted for. Similarly, in the Swedish study of Ahlund *et al.*[8] on the effect of PFMT in post-partum women with UI, there was no account on inclusion problems and the drop-out rate during the trial was 18%.

To stimulate the inclusion of participants during the course of our studies, inclusion criteria were changed. First, the criterion of primigravidity and primiparity was broadened to all women regardless of parity. In the original design only primigravid

or primiparae were included because there are strong indications that the first pregnancy and vaginal delivery are the greatest risk factor for the development of pelvic floor dysfunctions like UI.[9] Kamisan Atan *et al*. more recently showed that there is no significant difference in levator ani muscle (LAM) avulsions between primi- and multipara.[10] This confirmation that consecutive vaginal deliveries do not add to the prevalence of LAM avulsion together with Altman *et al*. who reported that the number of vaginal deliveries did not affect the risk of UI, allowed the adaptation from only primigravid/para to all pregnant and post-partum women.[11] Second, the inclusion period of pregnant women was widened from up and until 20 weeks to 26 weeks of gestation as the prevalence of SUI rises substantially with gestation.[12,13]

We were unable to fully explain our disappointing inclusion numbers, because in the majority of cases the reasons for non-participation were unknown. On the one hand we do not know how many women were actually asked by their HCP to participate and how many declined at that point. On the other hand in the majority of cases considered eligible by the HCP and who consented in being approached by the researcher, it was impossible to get in contact with the women (after multiple attempts).

To get more insight into the high non-response (unlike high UI prevalence) and low inclusion rate, the research team discussed what the reasons could be as to why the studies did not run as expected in relation to reported UI prevalence.

Firstly, the way of organizing the inclusion could have played a role. In our study, the including HCPs checked eligibility of women and had to perform an internal assessment of the woman's ability to contract the pelvic floor muscles. In both Woldringhs and Ahlunds study, midwives filled in a screening list for all pregnant and post-partum women with UI, who were sent to the research institute.[7,8] Then, the researcher checked eligibility and finished the inclusion process. The fact that the midwives routinely used a screening form for all women helped in making it a habit. In our study, the workload for the HCPs was a lot higher because they were fully responsible for the inclusion process, checking eligibility, and filling in an online form. Therefore, it seems advisable to minimize responsibility or workload for the inclusion process for HCPs or integrate the eligibility check as much as possible in their regular practice. However, because our studies were efficiency studies it was not possible to make any changes in the inclusion process of the HCPs.

Secondly, with regard to intervention-related factors it is notable that there was larger number of drop-out (64%, 7/12) of pregnant women once randomized in the PFMGT group compared to the CAU group (8%, 1/13). The women dropped out for a variety of reasons like: inconvenient time of PFMGT (n=1), too busy with work (n=2), costs (n=1), and without given reason(s) (n=2). One woman was too late in her pregnancy to start PFMGT, once the informed consent procedure had been taken care off. In the post-partum study, some eligible women who decided not to participate provided the reasons during the telephone conversation with the researcher, which were: experiencing mental health issues, issues concerning the baby's health, and not being bothered enough by UI. This (limited) information tells us that the nature of reasons for non-participation in both studies are in line with known barriers for participating in RCTs which seem to be the same in pregnant and non-pregnant women.[4,8] Most of the expressed reasons are difficult to modify.

The mentioned reasons also tell us that organizational reasons prevail in the pre-partum study (above reasons related to the added value or content of PFM(G)T), and reasons for non-participation in the post-partum study are more patient-related. When reasons for non-participation differ between pre- and post-partum period, emphasis on providing information on misconceptions with regard to these issues need to be tackled.

Thirdly, the reported prevalence of UI is probably lower than expected and found in the literature.[5,14] Women experiencing UI are often unknown to the HCPs and/or underreport their UI.[15,16] This could be related to a misconception on the course of UI, acceptance of UI as a fact of life or little knowledge on the possibility to seek for effective interventions.

Fourthly, the preference for individual instead of group therapy may explain non-participation to a small extent. It appears that only a small amount of women seem to have a strong preference for individual therapy. Demain *et al.*[17] reported in a pilot study on group versus individual therapy for UI in women that 15% of women declined because they prefer individual therapy. However, in the Dutch study of Janssen *et al.*[18] only 7% of women declined because of preference for individual therapy. Another study on group versus individual therapy for the treatment of UI asked participants before randomization if they could choose whether they preferred the group therapy, individual therapy or if they had no preference.

This study showed that although 36% of women expressed a preference for individual therapy before randomization, this did not influence the attendance in both treatment groups, which was similar.[19] Next, Griffiths *et al.*[20] interviewed the women in their study who were randomized to group therapy, although they had a preference for individual therapy. These women mentioned the benefit of a group with women of the same age group or problem, like post-partum UI.[20] Next to this these women would recommend group therapy in the future.[19,20]

PFMT has proven benefit on improving UI during and after pregnancy. Apart from PFMGT being a potential (cost-) effective strategy, as it has been reported as equally effective compared to individual PFMT in women[18,19,21], another benefit is that in group therapy, women can motivate each other to do their exercises and discuss experiences and coping strategies on how to implement PFMT in daily life.[20,22,23] HCPs should therefore tailor peri-partum care. For those women who have a strong preference for individual therapy, which seems to be a minority[19], individual specialized (pelvic) physical therapy is available. Based on the evidence, group therapy seems to be accepted and feasible in the majority of peri-partum women. Studies evaluating PFMGT differ in offered group size, namely 8, 4-12, and 8-10 participants respectively.[17,18,21] The studies don't mention the reasons for the choice of the group size.

Fifthly, we hypothesized that even though timing of pregnancy-related interventions always interferes with creating balance in a period of a major life event, only when experienced bother in relation to UI is high, women are willing to do something about it.[24,25] The fact that not only the presence of UI, but especially the experienced bother in relation to UI, could be responsible (and could be underestimated as a factor) for explaining the tendency to participate, seemed very relevant to us and worthwhile to investigate.

Based on those reasons, the main focus of this thesis changed from the (cost-) effectiveness of PFMGT to learning more about other aspects of UI in pregnancy and post-partum, such as UI prevalence, experienced bother and help-seeking behavior in relation to UI.

Prevalence and incidence

We performed two systematic reviews and meta-analyses on the prevalence of UI during pregnancy and between 6 weeks and 1 year post-partum (chapters 2 and 3). To our knowledge no such study exists regarding pregnant women and for post-partum women it can only be compared with the study of Thom *et al*.[26] However, Thom *et al.* does not report incidence and experienced bother. Because reported prevalence numbers of UI during pregnancy[27,28] and between 6 weeks and 1 year post-partum[29,30] vary greatly throughout published reports, the objective was to provide more accurate prevalence numbers, by calculating the weighted prevalence based on a large number of studies.[15,31,32]

A more detailed assessment of the results of the systematic reviews reveals some remarkable observations. To begin with, the difference between the overall prevalence of 41% of UI in pregnancy and the prevalence by gestational period, which is maximal 34% in the third trimester. We hypothesize that the reported prevalence numbers might be influenced by differences in used methodology (such as used case definitions).

Next, we evaluated the wide reported range in UI between studies in relation to the calculated risk of bias. Studies with high risk of bias report higher prevalence numbers. Risk of bias was assessed with the critical appraisal checklist for systematic reviews of prevalence studies, designed by the Joanna Briggs Institute (JBI).[33] JBI is an Australian-based international research organization, which develops evidence based practice tools and resources. We have decided not to exclude studies based on risk of bias after contacting the JBI to ask their advice regarding how to report the risk of bias.[33] Although systematic reviewers can, if explained well, decide to use predetermined cut-off points, the JBI recommends presenting the results of critical appraisal for all questions via a table rather than summarizing with a score. Based on the above the authors have arbitrarily chosen cut-off points to provide an indication of the risk of bias of each study, next to presenting the critical appraisal in Table 1 of both studies. Finally, the heterogeneity in both systematic reviews was very high. Nonetheless, Borges Migliavaca *et al.*[34] showed that an $I^2 > 90\%$ in systematic reviews, including meta-analysis of prevalence studies, is very common and inevitable. Especially when there are many studies in a meta-analysis, the chi-squared test for heterogeneity has high power to detect a small amount of heterogeneity that may be clinically unimportant.[35]

In order to gain more insight into the Dutch population with regard to prevalence, experience of bother, beliefs, and help-seeking behavior we performed two digital surveys shared by midwifery and pelvic physical (PT) practices on their Facebook pages. The results of the surveys (chapter 6 and 7) report both relatively high prevalence numbers compared to the systematic reviews and meta-analyses (chapters 2 and 3). This is in line with the study of Pandya *et al.* who have recently shown that prevalence of UI reported using an online platform like Facebook is on the higher end of reported prevalence numbers.[36] This study also revealed that participating women reported a low level of experienced bother in relation to UI which is in line with our findings.[36]

To gain more knowledge on the number of women becoming incontinent, incidence is an important frequency measure.[37] Incidence rates (when possible among subgroups) provide value information on the etiology of UI with pregnancy or delivery as a (multifactorial) exposure.[38] Unfortunately, it was impossible to pool incidence numbers (that are both reliable and generalizable) in both systematic reviews due to the low number of studies reporting incidence numbers and, if reported, the wide range of case definitions used (such as any UI, UI at least once a month, type of UI (like only SUI and mixed (M) UI) and type of reporting (self-reported UI or with a cough stress test).

Experienced bother

Women with a higher level of experienced bother of UI may seek and embrace more help.[15,31,32] We have shown that prevalence numbers of UI are often not accompanied by measures of symptom bother (chapter 2 and 3) as recommended by ICI.[1]. If prevalence numbers of UI are reported with the experienced bother, this can facilitate clinical reasoning, patient selection, improve research planning and aid policy makers. On that account, we have described the experienced bother (in our systematic reviews and meta-analyses) and assessment methods as reported in the prevalence studies. We showed that it is not common practice yet to report bother in prevalence studies and that bother is heterogeneously assessed (chapter 2 and 3). Amongst measurement instruments used were the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF)[39], Incontinence Impact Questionnaire (IIQ)[40], and Incontinence Quality of Life (I-QoL).[41] These questionnaires measure bother differently. As our objective

was to report prevalence numbers with experienced bother, we encountered the issue that results of the different measurement instruments for bother could not be compared because they use different scoring options. Therefore, the total scores of the different measurement instruments for bother were converted to a (standardized) 0 to 100 scale, with 0 indicating no bother and 100 indicating extremely bothered.[42] The conversion enabled us to combine studies and thus provide the more precise results of experienced bother in relation to UI based on more women.

Most frequently used questionnaires for measuring bother (chapters 2 and 3) consist of multiple questions, which require more effort to be put in by both participants as well as HCPs. The numeric rating scale (NRS) is a valid and reliable, unidimensional, measurement instrument, widely used in pain research.[43,44] Therefore, we wanted to assess whether a single question using a NRS (0= no bother; 10= extreme bother) can be used as an alternative 'quick but complete' question to indicate bother of UI. Thus, we calculated the correlation between two questions regarding bother (chapter 6 and 7). Question 3 of the ICIQ-UI SF, i.e. 'how much does leaking urine interfere with your everyday life' (NRS 0-10) correlated with the total ICIQ-Lower Urinary Tract (LUTS)qol score. The correlation in pregnant and post-partum women was moderate to large, 0.67 ($p<0.001$) and 0.73 ($p<0.001$), respectively. This is an interesting indication that separate reporting of the result of the NRS might be sufficient to report experienced bother.

The optimal cut-off point for clinically relevant burden of symptoms differs per symptom and varies mostly between a score of 4 and 6 on a scale from 0 to 10.[45] As the cut-off point for clinically relevant bother of UI is unknown, we have decided to consider a score of ≥ 5, being in the middle of the NRS score, as the cut-off point for clinically relevant bother in our two surveys (chapter 6 and 7). To our knowledge, the NRS has not been studied with regard to validity, reliability and responsiveness in women with UI. Therefore, these clinimetric properties of the NRS for use as a measure of symptom bother of UI in studies needs to be assessed, in addition to establishing the cut-off point for clinically relevant bother of UI.

Differences in case definitions for presence of UI hamper interpretation of UI in prevalence studies. The same issue applies for definitions used for 'bother', being effect on daily activities/everyday life, interference on daily life, health-related

quality of life, severity, lifestyle changes, (perceived) impact on quality of life, distress, experienced discomfort and amount of bother (chapter 2 and 3).[46] The Dutch participants in the qualitative study (not included in manuscript, chapter 8) were asked what word they would use to described the experience of their UI. Women described their bother of UI in the Dutch language as: 'vervelend' (wearing), 'hinderlijk' (annoying) or 'ongemak' (inconvenience). These results are not published in chapter 8 because the question specifically concerned 'the Dutch' language. A more clearly defined concept of bother and the most appropriate word for it 1) needs to be addressed country-specific, because of differences in culture and language, 2) helps HCPs in their (standardized) communication with patients, 3) assists in clinical reasoning and multidisciplinary communication among HCPs, 4) facilitates interpretability and comparison of research results, and 5) facilitates reporting of research results.

Moreover, The International Continence Society (ICS) has multi-disciplinary working groups developing standardisation of terminology.[47] It is advisable to include the concept of bother for further clarification.

METHODOLOGICAL QUALITY

Our studies have been developed following the appropriate reporting guidelines. Moreover, the research protocol of the systematic reviews and meta-analyses was registered in the PROSPERO database (registration number CRD42018111991) and the MOOSE statement for reporting systematic reviews and meta-analyses was followed.[48] The design of the randomised controlled trials was published[49] and the Consolidated Standards of Reporting Trials (CONSORT) statement[50] was followed for reporting the trial. The intervention offered in both RCTs was protocol- and evidence based [49] and the ability to contract the PFM – as a pre-requisite for the intervention under study - was checked. Women who did not know how to contract the PFM received an individual session by a specialized physical therapist in order to learn how to contract and relax, before joining PFMGT. The surveys (chapters 6 and 7) consisted of high quality measurement instruments to study the prevalence and quality of life. The questions on beliefs and help-seeking behavior were self-constructed. Selection of question and answer options was based on models explaining help-seeking behavior and discussion with experts in the field (epidemiologists and obstetrician/gynecologist).[51,52] Moreover, questions were

reviewed by an expert for readability and comprehensiveness, followed by field testing. In our qualitative study, the Standards for Reporting Qualitative Research (SRQR) were followed.[53]

PERI-PARTUM URINARY INCONTINENCE

Knowledge and beliefs regarding peri-partum urinary incontinence

We observed that although UI is highly prevalent during pregnancy and up to one year post-partum, women are unaware prior to becoming pregnant that this symptom can arise and accept UI as part of being pregnant. Only few women actually seek help for their UI. This might be explained by the finding that 38% of the non-help-seeking pregnant and 54% of post-partum women believe that their UI will improve by itself (chapters 6 and 7) and that it is a normal consequence of pregnancy and delivery (chapter 8).[54-56] However, pregnant women are not or insufficiently aware that having UI in pregnancy means a 2 to 6 fold the risk of post-partum UI.[30] An average of 31% of post-partum women have UI up to one year with only small fluctuations throughout the first year after childbirth (chapter 6).[57,58] Studies have shown that 6 and 12 years post-delivery, a large number of women with post-partum UI haven't recovered (73% and 91%, respectively).[59,60] The difference between beliefs regarding the cause and recovery of UI might be due to gaps in knowledge.[61-63]

The majority of peri-partum women report that they experience mild to moderate bother by their UI (chapters 2, 3, 6 and 7).[46,54,55] Women indicated that they would seek help if there was an increase in the amount and frequency of urine loss, occurrence at unexpected moments or an increase in negative feelings regarding their UI (chapters 6 and 7). As expected, women who experience higher symptom severity and/or who are more bothered by their UI are also more likely to seek help.[31,54,55,64-66] This accounts for peri-partum women as well as older women in the general population. It is known that SUI is the dominant subtype of UI until a woman is in her 50's and mixed (M)UI gradually takes over this position.[67,68] MUI is the complaint of involuntary leakage associated with urgency(UI) and SUI.[47] Women with MUI, which occurs more unexpected than SUI, experience more bother than women with SUI alone.[69] This might explain one of the reasons that younger women seek less help for their UI than older women.[70] In addition, help-seeking also depends on beliefs, perceptions, and knowledge regarding UI and

effect of treatment options.[31,70,71] Therefore, it is important to provide peri-partum women with trustworthy information and thus increase the level of knowledge. Women need to be given Information on causes, effective solutions and where they can get help. This is essential in order to improve the quality of life of women bothered by UI.

Peri-partum care

Pre- and post-partum care is organized differently throughout the world. In The Netherlands, care for uncomplicated pregnancy and delivery is provided by a midwife in primary care. High risk pregnancies and deliveries are taken care of in secondary and third line of health care by a clinical midwife or gynecologist. The National Institute for Health and Care Excellence (NICE) guideline on pre-partum care (CG62) recommends to, ideally at the 10-week appointment, discuss PFM exercises.[72] The Dutch (multidisciplinary) standard of integral perinatal care[73], covers the period from preconception until the 6-weeks post-partum check. However, the Dutch standard of integral perinatal care, in contrast to the NICE guidelines[72], does not discuss UI and PFMT pre-partum. The Dutch standard of perinatal care describes that, post-partum, the pelvic floor is one of the topics that need to be addressed.[73] The guidelines of the Royal Dutch Organisation for Midwives (KNOV) more specifically recommends that UI, the pelvic floor, and PFM exercises as a treatment for post-partum UI are discussed post-partum.[74] If UI does not improve or gets worse, a referral to a specialized (pelvic) physical therapist is recommended.[74] However, counselling for pelvic floor dysfunctions, like UI peri-partum, is not routinely done by all HCPs. One of the main barriers is a lack of time (chapter 8).[75,76] Women wish the HCP to start the conversation and to be provided with information on UI.[61,62,77,78] Women use different strategies to get information. Some women search the internet and/or discuss their UI with friends or relatives.[15,71] This informal information usually leads to normalization and with it acceptance of UI.[25,31] Informing and educating women on UI, how women should perceive this involuntary and abnormal loss of urine, and the potential benefits of PFMT, will help to empower and motivate them to seek treatment rather than just accept it.[75] Therefore, we recommend 1) that HCPs involved in women's healthcare discuss the occurrence of UI pre- and post-partum and the beneficial effects of PFMT, 2) to add this topic to peri-partum guidelines, like the standard of

integral perinatal care, and 3) to add questions on UI and experienced bother in the electronic patient file as a reminder for the HCP.

Pelvic floor muscle therapy

Although peri-partum women are aware that PFM exercises can help to treat UI (chapters 6 and 7), this does not mean that they are actually doing them, nor that they are able to perform them effectively.[61] A barrier women expressed to start with PFM exercises was that they did not know whether or not they were contracting the PFM correctly (chapter 8). Less than 25% of women know how to contract their PFM properly, even if they think they know how to contract.[79,80] Instructing women verbally how to contract the PFM has been shown not to be effective[79], in contrast to giving digital feedback during a vaginal examination.[81] A one-time vaginal examination and instruction has been shown to be a quick and effective way to instruct a correct PFM contraction.[81] However, some peri-partum women might prefer not to have a vaginal examination. Those women should be offered other strategies to learn a proper PFM contraction like for instance; with (self) palpation on the perineum or with ultrasound.

PFMT is a proven effective treatment option for UI in the general female population.[82] In studies where peri-partum women are selected properly, well-established risk factors have been identified, UI has been diagnosed and/or women have been motivated to seek help for their health problem, PFMT studies have shown likewise positive effects. Unfortunately, many studies on PFMT for the treatment of UI during pregnancy and post-partum show varying results regarding the effect. PFMT protocols differ considerably between studies and are often not properly described.[83] The studies are also small and of low to very low quality.[83] Our study showed a positive effect of PFMT started post-partum (chapter 5). However, this effect seems to diminish in the longer term. Because of the sample size of our study, the results can only be interpreted as an indication.

There is still uncertainty as to why PFMT during pregnancy or post-partum does not show the positive effect as in the general female population. During pregnancy the continence mechanism is challenged by factors like physiological weight gain[32] and the neuromuscular function of the urethral sphincter.[84] Therefore, the question remains if PFMT would be effective for a specific group of women with UI during pregnancy, for example, primigravid women with no UI prior to pregnancy.

This was an initial inclusion criterion of our RCTs. Starting PFMT between 6 weeks and 3 months post-partum might be too early in effectiveness studies as there are indications that recovery of urethral support takes up to 6 months.[85]

Post-partum consultation

Currently, women get their final obstetric check at 6 weeks post-partum. At that time, the majority of women have not yet started with sports or their job, and as a consequence, have not yet challenged the PFM like they would in those circumstances. Thus, when a HCP at the post-partum check asks a woman if she experiences UI, this question might be answered negatively, because the symptom threshold has not yet been reached. With regard to pelvic floor dysfunctions like UI the post-partum check might be too soon and based on natural recovery of the urethral support, 6 months post-partum would be more appropriate.[85] With all this in mind it is perhaps time to reconsider peri-partum care. Women with or at risk of pelvic floor dysfunctions like UI should be given the opportunity to have a consultation with a HCP, specialized in assessing the mother's health with regard to pelvic floor dysfunctions, at approximately 6 months post-partum. A specialized (pelvic) PT would be very well suited for this task as this is an expert in pelvic health and exercise.[86] Therefore, they have the knowledge to empower women in self-management by providing information, instruction in how to perform a correct PFM contraction with a vaginal assessment and provide a PFMT program. Currently, the Dutch Society for Pelvic Physical Therapy is pilot testing a 'post-partum consultation'. Based on the results of a questionnaire on the domains of pelvic (floor) dysfunctions it is established if women need to be advised to visit a specialized PT for a post-partum consultation. Information with regard to UI can be provided through a leaflet, a website, a mobile app, and in-person. A mobile app has several advantages, like accessibility at time of preference and the option to build in interactive features. It can provide information, support PFM exercises and support adherence. Nearly all women in The Netherlands use mobile internet on their smartphone.[87] Several studies have shown the (long-term) effect of the use of a mobile app in the treatment of UI and improving adherence.[88-91] The combination of the assurance of a proper PFM contraction, information and advices of a specialized PT together with a mobile app, like the iPelvis mobile app used in our studies, might be an effective new path to improve PFM fit mothers in a post-partum consultation.

How to improve peri-partum care regarding UI

There are still a lot of women that are on the one hand unaware that UI can occur in the peri-partum period and on the other hand think this is normal and will resolve by itself. Next to this, HCPs do not standardly ask for UI during pregnancy and post-partum and therefore women might not be informed on this highly prevalent issue. In order to address these issues and improve peri-partum care regarding UI a multi-faceted approach is necessary. Several suggestions to raise awareness and educate women have been made in previous paragraphs based on the research of this thesis. In addition, other strategies on how peri-partum care can be improved further will be discussed.

First, all Dutch guidelines regarding peri-partum care should add UI as a topic to be discussed by HCPs. As a result, electronic patient files should standardly have questions on UI and experienced bother, which will remind HCPs to discuss this symptom. Second, women should be provided with or know where to find trustworthy information or help on UI. This can be facilitated by for instance their HCP (midwife, gynecologist, general practitioner, physical therapist) or a patient organization. Women prefer to be informed during pregnancy about UI.[92] Peri-partum women also like to be informed through a leaflet and/or website.[92] A leaflet regarding UI in the general public has shown that it encourages women to discuss UI, to change health behavior regarding UI, and to seek help.[93] However, peri-partum women receive a lot of information on a large number of topics and a leaflet might get lost or overseen, and therefore a trustworthy website that can be accessed where and whenever a woman wants, would be of great benefit. An example would be the website of the 'continence foundation of Australia' providing a lot of information (in multiple languages) on UI like: causes, solutions, where to get help etc. In the Netherlands the website of the patient organization 'bekkenbodem4all' provides (some) information. With the proper funding this could evolve in an attractive website where HCPs can direct their patients to and where women can find information. Third way to reach women and create awareness could be for instance during the annual continence awareness week. During this special week, a joint effort of different HCPs (midwife, gynecologist, urologist, continence nurse, and specialized physical therapist), the patient organization and women could participate in a multitude of different actions to reach the public and create awareness. One can think of: discussing UI on television and radio, but also

of editorials in magazines, newspapers etc. Fourth, if studies on the 6 month post-partum consultation by a specialized (pelvic) physical therapist show a beneficial effect, this should be offered to women with pregnancy-related UI.

Although all these suggestions will add to the improvement of peri-partum care separately, it is advisable to investigate first which strategies are necessary at different patient, HCP, and policy maker levels. Next, a planned implementation strategy for the different target groups should be developed and used as this is a key factor for success.[94]

RECOMMENDATIONS FOR FUTURE RESEARCH

As PFMGT is a potentially (cost-) effective intervention for women with pregnancy-related UI, it is still an important intervention to study. However, the RCTs described in this thesis dealt with major inclusion problems resulting in two underpowered studies. Beforehand we anticipated to have no inclusion problems based on: high prevalence numbers[5], inclusion rates in Scandinavian and Dutch studies on this topic[14,18], and the large number of HCPs involved in including participants. Therefore, before designing a future study on this topic it is important to gain more knowledge regarding acceptability, barriers and facilitators and therefore viability of PFMGT in peri-partum women.[20]

Another issue that needs to be addressed is the uncertainty as to why PFMT during pregnancy or post-partum for women with UI does not show the positive effect as in the general female population. During pregnancy new onset UI might well be explained by non-modifiable factors like anatomical and hormonal changes[95] as well as physiological weight gain.[96] However, PFMT in early pregnancy for the prevention of antenatal and post-partum UI shows a positive effect.[83] Therefore, a preventative strategy might be more appropriate and effective for pregnant women. If we could identify women at risk of becoming incontinent during pregnancy then PFMT could be offered as a preventive strategy. Post-partum, the initially positive effect of PFMT disappears which might be due to a lack of adherence. Adherence in the first year post-partum might be extra challenging because new mothers are often sleep deprived and thus fatigued.[97,98] New mothers and in particular those working experience a lack of time to get all things done.[98]

Women have expressed that a mobile app can support motivation with for instance

reminders and the first results regarding adherence are promising.[99-101] Therefore, an evidence-based mobile app, like the iPelvis mobile app we used in our studies, specifically designed for pregnant and post-partum women, can help providing information and empower women to exercise their PFM or seek help. The iPelvis app needs further validation and field testing regarding (Dutch) language, user friendliness and (cost-) effectiveness.

To accurately report the prevalence of UI based on the experienced bother we need to define the construct of 'bother' and the best way to assess bother in prevalence studies. In addition, cut-off points regarding clinical significant bother need to be established.

Peri-partum women have misconceptions regarding their UI and the natural course. This knowledge gap can influence beliefs and help-seeking behavior. It can be of interest to study whether the level of bother and help-seeking behavior changes in women who have been provided more information on UI. Women express the wish to be informed about pelvic floor dysfunctions like UI during and after pregnancy. This is not standardly described in all guidelines (midwifery and gynecology) in The Netherlands and not common practice yet. Therefore we recommend reviewing peri-partum guidelines on this topic.

To further optimize information provision regarding UI, a deeper understanding of the wishes and needs of peri-partum women is necessary. Therefore, we need to acquire more knowledge about 1) what information peri-partum women need at 2) which peri-partum period and 3) the best strategy to provide this.

The 6-weeks post-partum check might be too soon for a check on pelvic floor dysfunctions. Therefore, care for peri-partum women regarding pelvic floor dysfunctions like UI should be reviewed. A post-partum pelvic floor check at approximately 6 months might be more appropriate. A concept based on this idea (post-partum consultation) is currently being pilot tested in The Netherlands. The post-partum consultation needs to be refined based on the pilot, tested with appropriate numbers of participants conjoint with a cost-analysis.

In order to improve peri-partum care regarding UI, it is advisable to study which strategies are necessary at different levels: patient, HCP, and policy makers. Next, an implementation strategy should be developed and used as this is a key factor for success.[94]

But probably most important is to better understand what moves women to decide on starting therapy for UI or not. We hypothesize that the following issues might contribute to the decision to seek treatment in the peri-partum period. First, is the impact of the symptom indicating the underlying problem considered life-threatening or not. Second, thought is given to the consequence of watchful waiting or active treatment; does waiting make things worse? Third, does the problem raise a lot of bother? Fourth, knowledge regarding PFMT and the effectiveness of treatment. The fifth and the final consideration regards the costs in time, effort and finance for accepting and undergoing treatment. It follows that the willingness and motivation to do something about peri-partum UI and as a consequence seek help is limited, because UI is considered as not life threatening (issue 1), a large proportion (chapters 6 and 7) of non-help seeking women think their UI will resolve by itself over time (issue 2), bother of UI (issue 3) is experienced as mild to moderate (chapters 2,3,6, and 7), and although women have heard about pelvic floor muscle exercises (chapters 6 and 7) we wonder whether peri-partum women are fully aware of the benefit (issue 4) of PFMT, as UI is not standardly discussed by HCPs peri-partum (chapter 8). Finally, it is a very busy period in the life of women adapting to pregnancy, looking after a baby and returning to work (issue 5). From the perspective of UI treatment, women's decision for treatment can only improve by increasing the knowledge of the natural course of UI, as most anticipate on spontaneous recovery while this is not the case; increase knowledge about PFMT and by reducing the costs, so making the therapy as easy accessible as possible. Only when these factors are sufficiently addressed, then PFM(G)T could be studied in a novel RCT. Moreover, implementation should be facilitated in general care. Not women, but their HCPs should be aware of possible misjudgments regarding UI (in both women and professionals). They should actively transfer knowledge, but also equalize the path towards preventive PFM(G)T by reducing women's costs (and increasing the gains). This care trajectory for women should be developed multidisciplinary, including midwife, gynecologist, urologist, physical therapist, and general practitioner, all with facilitating women in mind.

CONCLUDING COMMENTS

This thesis has shown that UI is highly prevalent during pregnancy and up to one year post-partum. Women experience UI as mild to moderate bother. Only a minority of peri-partum women seek help for their UI. A substantial part of non-help seeking women think that UI is a consequence of pregnancy and delivery and will resolve by itself. Reasons women express for help-seeking in the future are an increase in the level of bother and if UI occurs when it is not expected. It is not common practice for HCPs to standardly ask for UI in the peri-partum period. Women should be better informed on UI (consequences) and management, which may promote help-seeking behavior. The long term (cost-) effectiveness of PFMGT for the treatment of UI during pregnancy and post-partum could not be established due to low inclusion numbers. As PFMGT is a potentially (cost-) effective intervention it is important to increase the knowledge regarding acceptability, barriers and facilitators and therefore viability of PFMGT in peri-partum women before designing a new study. It might be time for a change in peri-partum care by adding a 6 month post-partum consultation for women with UI. Therefore, the added value of a post-partum consultation needs to be studied because new mothers deserve to be 'motherfit'.

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CHAPTER 10

SCIENTIFIC AND SOCIETAL IMPACT

Pregnancy and delivery are the most prominent risk factors for the development of urinary incontinence (UI) in women. The results of this thesis will shed light on various aspects regarding pregnancy-related UI like prevalence, experienced bother, anticipated course, therapeutic effect of physical therapy, and help-seeking behavior as well as the experiences of peri-partum UI of women and health care professionals (HCP). The findings presented in this thesis will add to the body of knowledge of HCPs and researchers as well as policy makers. It can help researchers in for instance research planning, HCPs in their UI management and communication with peri-partum women, and provide policy makers with more details on the prevalence and incidence of peri-partum UI and their experienced bother. This chapter will highlight how the results have been and will be further disseminated, and elaborate on what the findings mean for a broad audience.

DISSEMINATION OF RESULTS DURING PHD TRAJECTORY AND PLANS FOR THE FUTURE

During the PhD trajectory the results of our studies were firstly shared in peer-reviewed scientific journals as described at the beginning of each chapter. Secondly, results were shared at multiple international conferences of the International Continence Society (ICS). The ICS members attending the meetings consist of urologists, urogynecologists, physical therapists (PT), nurses and researchers with a focus on continence and pelvic floor disorders. At ICS 2019 and 2020 the results of chapter 2 and 7 were presented. In The Netherlands the results of chapter 2 were presented at the 2019 conference of the Royal Dutch Society for Physical Therapy (KNGF).

At ICS 2021, the results of this dissertation in general, the problems we encountered with the inclusion of participants in the randomized controlled trials (RCT), and the actions taken to improve this, will be presented. In addition, I will also write a blog post and make a YouTube video on this dissertation for my social media channels. They will be posted on https://www.pelvicnewschannel.com and on YouTube (https://www.youtube.com/channel/UCZlOBILVAuESzlu0OdXjJlw). The blog will also be translated into Spanish, Portuguese and Japanese. The objective of the blog and YouTube channel is to share scientific research with colleagues with an interest in the pelvic region, especially pelvic physical therapists. By providing easily accessible short versions of studies with the implications for clinical practice

in multiple languages, colleagues who otherwise might not be aware of these studies or for whom the English language is a barrier, also have access.

SCIENTIFIC AND SOCIETAL IMPACT OF THE GENERATED KNOWLEDGE

The initial primary aim of this dissertation was to study the long-term (cost-) effect of pelvic floor muscle group therapy (PFMGT) compared to care as usual (CAU) during pregnancy and post-partum in two RCTs. However, the inclusion rate in both studies was very low, even after several facilitating changes were made to the inclusion process. The low inclusion rate in comparison to the high prevalence of UI was thoroughly discussed by all who (the research team and the HCPs) were involved in the studies. The fact that not only the presence of UI, but especially the experienced bother in relation to UI, could be responsible for explaining the tendency to participate, seemed very relevant to us and worthwhile to investigate. Therefore, the main focus of the thesis changed from the (cost-) effect of PFMGT, to learning more about other aspects of UI in pregnancy and post-partum, such as UI prevalence, experienced bother and help-seeking behavior in relation to UI. Sharing our inclusion strategies and encountered problems and subsequent actions taken with researchers will help planning future research in this field.

Prevalence and bother

As reported prevalence numbers of pregnancy related UI vary greatly between studies, one of our aims was to provide more accurate prevalence numbers. The International Consultation on Incontinence (ICI) recommends reporting prevalence numbers of UI with the experienced bother.[1] Therefore we also studied the experienced bother of UI. This is important information for research planning and policy makers because women with a higher level of experienced bother of UI seek more help.[2-4] Our systematic reviews on the prevalence, incidence and experienced bother of UI during pregnancy and between 6 weeks and 1 year post-partum are to our knowledge the first ones in this field. No such study exists regarding pregnant women and for post-partum women it can only be compared with the study of Thom *et al*.[5] However, Thom *et al.* only reports for women up to 3 months post-partum and does not report incidence and bother.

We showed that although the overall prevalence of UI during pregnancy and post-partum is high, 41% and 31% respectively, the experienced bother is low to moderate. It was also obvious that it is not common practice yet to report bother in prevalence studies and that bother is heterogeneously assessed (chapter 2 and 3).

Our results showed that the numeric rating scale (NRS, 0= no bother-10= extreme bother) might be an appropriate measurement instrument to quantify experienced bother of UI. The NRS is a valid and reliable, unidimensional, measurement instrument, widely used in pain research. However, to our knowledge the NRS for bother of UI has not been studied with regard to validity, reliability and responsiveness in women. A cut-off point for clinically relevant bother of UI also needs to be established. The NRS is quick to administer, easy to interpret, and very well suited to add to an electronic patient file. Therefore, the NRS has the potential to help HCPs in communicating with patients and in clinical decision making.

We observed a great variety of words used to describe 'bother' of UI in our studies (chapter 2 and 3). A more clearly defined concept of bother could help in the assessment, standardisation of communication and reporting of study results. The International Continence Society (ICS) has multi-disciplinary working groups developing standardisation of terminology.[6] We advise to include the concept of bother for further clarification. When we asked Dutch women with pregnancy-related UI what word they would use for their experience of UI, several words were suggested and none of them was the word the research team thought beforehand was the most appropriate. This shows the importance of studying the 'best' word to discuss bother, country-specific because of differences in language and culture. Knowing the word that resonates the best with women regarding bother of UI can help HCPs in their communication with patients and with other HCPs (multidisciplinary). In addition, it can facilitate the interpretability and comparison of research results. Moreover, it is useful when information is developed regarding UI in women

Help-seeking behavior

Women in our studies indicated that they would seek help if there was an increase in the amount and frequency of urine loss, occurrence at unexpected moments or an increase in negative feelings regarding their UI (chapter 6 and 7). Only a small number of peri-partum women actually sought help for their UI. Reasons for not

seeking help were often based on the belief that UI would resolve by itself and that it is a normal consequence of pregnancy and delivery. This misconception is important knowledge for HCPs, as they can provide peri-partum women with trustworthy information. Information on causes, solutions and where they can get help when they need it. To further optimize information provision regarding UI, a deeper understanding of the wishes and needs of peri-partum women is necessary. Therefore, we need to acquire more knowledge about 1) what information peri-partum women need at 2) which peri-partum period and 3) the best strategy to provide this.

Good information sites are available. Examples are 'the pelvic floor' by HCPs of the University of Antwerp, Belgium at https://www.thepelvicfloor.be/ (in Dutch), and 'pelvic floor first' from the Continence Foundation of Australia at (http://www.pelvicfloorfirst.org.au/ (English).

Pelvic floor muscle therapy

Based on the promising effects of pelvic floor muscle therapy (PFMT), described in the first version of the Cochrane systematic review on 'pelvic floor muscle training for prevention and treatment of UI and fecal incontinence in antenatal and postnatal women', we planned our two RCTs.[7] They were designed following the recommendations of the CONSORT statement to ensure high quality. The latest update of this Cochrane review reports that there is still uncertainty regarding the treatment effect of PFMT provided in the pre- or post-partum period.[8] However, we have to keep in mind that these results are based on a small number of studies of (very) low quality. Current peri-partum multi-disciplinary guidelines recommend PFMT for post-partum UI.[9-11]

Unfortunately, our studies on the long-term effect of PFMT compared to care-as-usual were underpowered and results therefore need to be interpreted with caution. Our study showed a positive effect of PFMT started post-partum (chapter 5). However, this effect seems to diminish longer term. There is still uncertainty as to why PFMT during pregnancy or post-partum does not show the positive effect as in the general female population. The question remains if PFMT would be effective for a specific group of women with UI during pregnancy, for example, primigravid women with no UI prior to pregnancy. Starting PFMT between 6 weeks and 3 months post-partum might be too early in effectiveness studies. Based on

the current evidence we recommend offering women with UI after delivery PFMT as a treatment option. Therefore, we suggest changes in the current peri-partum care as will be discussed next.

Peri-partum care

Dutch guidelines regarding pre-partum care incorporate no discussion of or recommendations for pelvic floor dysfunctions like UI and for the post-partum period recommendations vary.[10,12] There may be a difference between the need of peri-partum women and the HCP regarding this topic. Therefore, more attention and uniformity regarding this topic in peri-partum guidelines is warranted.

We suggest it is time for a change in post-partum care. Currently, women get their final obstetric check at 6 weeks post-partum. But at that time, women have not yet (fully) started with sports and/or their job and as a consequence the symptom threshold, for pelvic floor dysfunctions like UI, might not have been reached yet. A check at 6 months after delivery for women at risk for pelvic floor dysfunctions might be more appropriate. A specialized (pelvic) PT would be very well suited for this task as this is an expert in pelvic health and exercise.[13] They have the knowledge to empower women in self-management by providing information, instruct a proper pelvic floor muscle contraction with a vaginal assessment and give a pelvic floor muscle training program. In The Netherlands, the Dutch Society for Pelvic Physical therapy has developed and pilot tested a concept called the 'post-partum consultation'. Based on the pilot study the concept needs further refinement and needs to be studied with appropriate numbers of participants conjoint with a cost-analysis. A post-partum consultation has the potential to be a valuable extension of current peri-partum care, for women with or at risk of UI, and empower women to seek help and become 'motherfit'.

Education

The pelvic floor muscles and pelvic floor dysfunctions are hardly discussed in the curricula of physical therapists in The Netherlands, although pelvic floor dysfunctions are very prevalent. Basic knowledge of the pelvic floor, dysfunctions and the relation with the moving body should therefore be part of the curriculum. This also raises interest and awareness for the specialization of pelvic physical

therapist. In the curricula for HCPs involved in peri-partum care like the gynecologist, midwife or specialized pelvic physical therapist it is important to emphasize the importance of asking a woman specifically about UI together with the experienced bother. In addition, HCPs should learn how to assess experienced bother and know where women can find trustworthy information and get good quality care to remain or become 'motherfit'.

HCPs in training can contribute to the body of knowledge regarding research questions on peri-partum UI. If existing research questions are specifically adapted for students, taking into account the amount of time students have for a (graduation) project (sub-questions), this could be a win-win situation on all accounts. For this purpose, good contacts between (or within departments of) research institutions, educational institutions, HCP courses, but also with professional associations is a prerequisite. At the moment, contacts exist between various stakeholders with regard to research questions for specialized pelvic physical therapy in training, though informally. Collaboration could be more effective if this would be formalized.

CONCLUSION

The initial primary aim of this dissertation to study the long-term (cost-) effect of pelvic floor muscle group therapy (PFMGT) compared to care as usual (CAU) during pregnancy and post-partum did not succeed due to very low inclusion rates. However by sharing our inclusion strategies and encountered problems and subsequent actions taken with researchers will help planning future research in this field. To reveal possible reasons of the disappointing inclusion numbers other aspects of UI in pregnancy and post-partum such as UI prevalence, experienced bother and help-seeking behavior in relation to UI were studied. We showed that although the overall prevalence of UI during pregnancy and post-partum is high, the experienced bother is low to moderate and few women seek help. It was also evident that prevalence studies do not report the accompanying bother standardly and that bother is heterogeneously assessed. UI is not a standard question for the majority of HCPs in peri-partum care. More attention and uniformity regarding UI in peri-partum guidelines is warranted.

As a consequence of the hurdles we had to take, the key factors in medical decision

making for patients with UI had to be reviewed. That lead to profound insight in the most important variables that are almost unnoticedly weighed by those offered care or execute RCTs. From our experiences and observations we learned that we should better understand and systematically weigh what factors women drive to decide on starting therapy. We hypothesized on five issues that might contribute to deciding to seek help: 1) the impact of the symptom indicating the underlying problem is considered life-threatening or not, 2) the consequence of expectant management as compared to active treatment, 3) experienced bother, 4) knowledge regarding PFM(G)T, and 5) the costs in time, effort and finance for accepting and undergoing treatment. Holding a clear view on all these factors might be incredibly helpful on designing future studies and care trajectories and weighing the necessity to implement them upfront.

The results have been and will be shared in various ways to reach as many researchers, HCPs and the general public. Our results can help researchers with research planning, HCPs regarding communication with patients, and policy makers can use our results in calculating future health care cost.

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SUMMARY

The main objective of this thesis was to gain more knowledge on pregnancy-related urinary incontinence (UI) including prevalence, experienced bother, anticipated course, therapeutic effect of physical therapy and help-seeking behavior. In addition, the (cost-)effectiveness of conservative treatment of UI during pregnancy and in the post-partum period, and experiences of peri-partum UI of women and health care professionals (HCPs) were of interest.

Chapter 1 discusses the background and subsequent research questions of this thesis. UI is a very common symptom in women. Pregnancy and delivery are well known risk factors for developing UI, of which stress (S) UI is the most common type of pregnancy-related UI. UI often has a negative impact on quality of life and reduces participation in sports and other activities. Pelvic floor muscle therapy (PFMT) is an accepted and effective treatment option for women with UI. PFMT may be provided individually or in a group. Group PFM(G)T seems to be equally effective as individual PFMT. The latter is of particular interest as group therapy is less expensive when compared to individual therapy, and might therefore be a cost-effective strategy. Reported prevalence and incidence figures of UI in pregnancy and post-partum show a wide range and it is advised to report prevalence figures with a measure of symptom bother. There are indications that the level of perceived bother influences help-seeking behavior for UI. The lifetime risk of surgery for SUI is high and therefore (cost-)effective strategies are warranted. The reported studies in this thesis contribute to the body of knowledge of (HCPs) concerning the beliefs of peri-partum women regarding UI. This may support the development and dissemination of adequate information (strategies). Moreover, accurate prevalence numbers, knowledge about experienced bother in relation to peri-partum UI and help-seeking behavior, provide relevant information on the extent and impact of UI in this population, which may help HCPs optimizing their clinical reasoning and guide researchers and policy makers in policy making**.**

Chapter 2 and 3 discusses the findings of two systematic reviews and meta-analyses on the prevalence, incidence, and bothersomeness of UI during pregnancy (chapter 2) and between 6 weeks and 1 year post-partum (chapter 3). Based on 44 studies (chapter 2), involving a total of 88.305 women, the weighted average of UI prevalence among pregnant women was 41.0%. SUI was the most

common type of UI, accounting for 63% of cases. The overall prevalence for UI rises by trimester, 9%, 19%, and 34%, respectively. Of those experiencing UI, 40% of women have monthly UI, 33% have weekly UI, and 26% have daily UI. Bother was heterogeneously assessed. The overall bother of UI during pregnancy, on a 0 to 100 scale, ranges between 9.5 and 34.1, consistent with mild to moderate bother, whereas the experienced bother is higher in the 3rd trimester. Few studies have examined incidence of UI during pregnancy.

The mean weighted prevalence of UI between 6 weeks and 1 year post-partum (chapter 3) is 31.0%, based on 24 studies with a total of 35.064 women. At 6 weeks post-partum, 24% of women have UI, at 3 months 21%, and then gradually rising to 32% at 1 year post-partum. Primi- and multiparous women did not differ with regard to prevalence of UI. The most common type of UI was SUI with 54% of cases. Bother was heterogeneously assessed. The overall bother of UI post-partum, on a 0 to 100 scale, ranges between 24.3 and 47.6, consistent with mild to moderate bother. The incidence of UI in primiparous and multiparous women up and until three months was 9.0 -21.9% and 4.4 -30.0%, respectively. Incidence up to 1 year was 4.3 -34.1% in primiparous women.

Chapter 4 describes the design of two multi-centre randomized controlled trials (RCTs). The RCTs aimed to study the long-term effect of PFMGT (Motherfit) compared to care-as-usual in pre- (study 1) and post-partum (study 2) women with SUI. Eligible women were amongst others ≥18 years of age, had SUI or mixed (M)UI (SUI dominant). Women were recruited by their midwife or gynaecologist during their routine check-up. Inclusion period during pregnancy was between 12 and 26 weeks of gestation (study 1) and at the final 6-week post-partum check-up (study 2). Motherfit group therapy consisted of eight group sessions of 60 minutes each, instructed and supervised by a registered pelvic physical therapist. Motherfit group therapy included instructions on pelvic floor anatomy and how to contract, relax and train the pelvic floor muscles correctly and was combined with general physical exercises. Adherence during and after motherfit was stimulated with reinforcement techniques and a m(obile)App. The primary outcome measure was the absence of self-reported UI based on the severity sum score of the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) at 18 months post-partum. Secondary outcomes evaluated quality of life, subjective improvement and health care costs.

Chapter 5 presents the results of the two RCTs. In both RCTs, inclusion numbers could not be met, and therefore all women received individual PFMT instead of PFMGT. Study 1 showed no significant results regarding the prevalence of UI (based on the ICIQ-UI SF), subjective improvement and quality of life at any measurement moment. As compared to baseline, study 2 showed a significant improvement for prevalence of UI and impact of UI at 4 months post-partum, however no significant difference existed between groups at other follow-up moments. Significant subjective improvement was seen at 4 and 9 months post-partum, in favor of the PFMT group (p=.02). The full potential of (cost-) effectiveness of PFMT could not be established due to insufficient inclusions. To increase our knowledge on experienced bother in relation toUI and help-seeking behavior, as well as which specific bothersome factors and beliefs are the main contributors to help-seeking behavior in the peri-partum period, two digital surveys were performed in The Netherlands.

Chapter 6 describes the results regarding prevalence, experience of bother, beliefs, and help-seeking behavior of pregnant women. The prevalence of UI rises from 55.1% in the first to 70.1% in the third trimester, with an overall prevalence of 66.8%. SUI was the most frequently reported type of UI. Nearly 43.0% of the respondents reported UI occurring once a week or less. 92.5% of women lost a small amount. 90% reported slight to moderate impact on quality of life. Only 13.1% of the respondents sought help for their UI. The main reasons for not seeking help were minimal bother and the idea that UI would resolve by itself. The most important reasons for seeking help in the future were: the constant use of pads, the feeling that others would smell the urine loss, and leaking/getting wet clothes. Help-seeking women showed significant higher scores than non-help-seeking women regarding bother and interference in daily life.

Chapter 7 describes the results regarding prevalence, experience of bother, beliefs, and help-seeking behavior of women between 6 weeks and 1 year post-partum. The overall prevalence of UI was 57.1% and did not change significantly across the post-partum period. SUI was the most frequently reported type of UI (62.9%). Primiparous women reported a statistically significantly lower overall prevalence than multiparous women, 52.0% and 61.9% respectively (p=.043). UI frequency of once a week or less was reported in 43.9% whereas in 89.5% of the cases it was a small amount of urine. UI was reported as bothersome in 38% of women, 25% of all women with UI sought help. Help-seeking women showed significantly higher scores for experienced bother, than non-help seekers (p=.001).

The most important reasons for seeking help in the future were: the constant use of pads, leaking/getting wet clothes, the feeling that others would smell the urine loss or hindrance at work. In order to gain more understanding regarding the gap between the prevalence of UI and actual help-seeking behavior for UI of peri-partum women, it is important to understand the health beliefs of these women and their HCPs regarding UI, how peri-partum women experience their UI, and to acquire knowledge on subsequent health care management.

Chapter 8 discusses the results of a qualitative study on this topic. Adult pregnant and up to one year post-partum women were interviewed and a focus group with HCPs involved in the care of pregnant and post-partum women was performed. Nearly all women expressed to be not, or only slightly bothered by their UI and accept it as a result of pregnancy and/or delivery. Women were surprised because they were unaware that UI could be a problem peri-partum. None of the HCPs routinely asked about the presence of UI during pregnancy. At the post-natal check at 6 weeks post-partum, UI is still not a standard question for the majority of the gynecologists and registrars in contrast to the midwives.

Chapter 9, the general discussion, presents an overview of the main findings of the studies presented in this thesis. Methodological strengths and weaknesses are discussed as well as implications for clinical practice and future research. Overall, we can conclude that peri-partum UI is a common symptom, which is underestimated by women and HCPs. To be motherfit, presence and burden of UI should receive more attention from relevant HCPs; women should be better informed on UI (consequences) and management, which may promote help-seeking behavior.

Finally, in **chapter 10**, the scientific and societal impact of this thesis is discussed. The results of our studies, have been and will be in the future, disseminated in peer-reviewed journals and presented at various conferences and on social media in order to reach as many researchers, HCPs, and the general public as possible. Our results can help researchers with research planning, HCPs regarding management of UI and communication with patients, and policy makers can use our results in estimating disease burden and future health care cost for UI. Last but not least, if HCPs adapt their management and communication regarding UI, based on the results of our studies, it will help and empower peri-partum women to become 'motherfit'.

SAMENVATTING

Het hoofddoel van dit proefschrift was het verkrijgen van meer kennis over zwangerschapsgerelateerde incontinentie voor urine (UI) waaronder de prevalentie, ervaren hinder, verwachtte beloop, therapeutisch effect van fysiotherapie en hulpzoekgedrag. Daarnaast waren ook de (kosten)effectiviteit van conservatieve behandeling van UI tijdens de zwangerschap en in de post-partum periode en de ervaringen van vrouwen en zorgprofessionals van belang.

Hoofdstuk 1 bespreekt de achtergrond en vervolgens de onderzoeksvragen van dit proefschrift. UI is een veelvoorkomend symptoom bij vrouwen. De zwangerschap en bevalling zijn bekende risicofactoren voor het ontstaan van UI. Stress (S)UI is het meest voorkomende type van zwangerschapsgerelateerd UI. UI heeft vaak een negatieve impact op de kwaliteit van leven en belemmerd de deelname aan sport en andere activiteiten. Bekkenbodemoefeningen (PFMT) zijn een geaccepteerde en effectieve behandeloptie voor vrouwen met UI. PFMT kan zowel individueel als in een groep worden gegeven. Groep PFM(G)T lijkt even effectief te zijn als individuele PFMT. Dat laatste is in het bijzonder interessant omdat de kosten voor groepstherapie lager zijn in vergelijking met individuele therapie en het daarom mogelijk een kosteneffectieve strategie is. De gerapporteerde prevalentie en incidentie cijfers van UI in de zwangerschap en post-partum laten een grote spreiding zien en het wordt geadviseerd om prevalentie cijfers te rapporteren met de mate van ervaren hinder van UI. Er zijn aanwijzingen dat de mate van ervaren hinder hulpzoekgedrag voor UI beïnvloedt. De kans op een operatie voor SUI is groot en daarom zijn (kosten)effectieve strategieën belangrijk. De studies in dit proefschrift dragen bij aan de body of knowledge van zorgprofessionals (HCP) met betrekking tot de overtuigingen die peri-partum vrouwen hebben met betrekking tot UI. Dit kan de ontwikkeling en verspreiding van goede informatie (strategieën) ondersteunen. Bovendien kunnen accurate prevalentie cijfers, kennis over ervaren hinder met betrekking tot peri-partum UI en hulpzoekgedrag relevante informatie verschaffen over de mate en impact van UI in deze populatie. Dit kan HCPs helpen hun klinisch redeneren te optimaliseren en onderzoekers en beleidsmakers hun toekomstige plannen op te baseren.

Hoofdstuk 2 en 3 bespreken de resultaten van twee systematische reviews en meta-analyses over de prevalentie, incidentie en ervaren hinder van UI tijdens de

zwangerschap (hoofdstuk 2) en tussen 6 weken en 1 jaar post-partum (hoofdstuk 3). Gebaseerd op 44 studies (hoofdstuk 2) en in totaal 88.305 vrouwen, is de gewogen gemiddelde prevalentie van UI onder zwangere vrouwen 41.0%. SUI was het meest voorkomende type UI, verantwoordelijk voor 63% van de gevallen. De totale prevalentie voor UI stijgt per trimester respectievelijk 9%, 19% en 34%. Van degene die UI ervaren, heeft 40% van de vrouwen maandelijks UI, 33% wekelijks UI en 26% dagelijks UI. De ervaren hinder werd heterogeen gemeten. De totaal ervaren hinder van UI tijdens de zwangerschap gemeten op een 0 tot 100 schaal, varieert tussen de 9.5 en 34.1 wat overeenkomt met een mild tot matige ervaren hinder. De ervaren hinder van UI in het derde trimester is hoger. Weinig studies hebben de incidentie van UI tijdens de zwangerschap onderzocht. De gemiddelde gewogen prevalentie van UI tussen 6 weken en 1 jaar post-partum (hoofdstuk 3) is 31%, gebaseerd op 24 studies met in totaal 35.064 vrouwen. Op 6 weken post-partum hebben 24% van de vrouwen UI, op 3 maanden 21% om vervolgens geleidelijk te stijgen tot 32%, 1 jaar post-partum. Er was geen verschil in prevalentie van UI tussen primi- en multipara. Het meest voorkomende type UI was SUI in 54% van de gevallen. Ervaren hinder werd heterogeen gemeten. De totale ervaren hinder van UI post-partum, op een schaal van 0 tot 100 varieert tussen de 24.3 en 47.6 overeenkomstig met een mild tot matig ervaren hinder. De incidentie van UI in primi en multipara tot en met 3 maanden post-partum was respectievelijk 9.0 – 21.9% en 4.4 – 30%. De incidentie tot 1 jaar was 4.3 – 34.1% in primipara.

Hoofdstuk 4 beschrijft het design van twee multicenter gerandomiseerde gecontroleerde studies (RCTs). De RCTs hadden tot doel om het lange termijn effect van PFMGT (Motherfit) te vergelijken met standaard zorg in pre- (studie 1) en post-partum (studie 2) vrouwen met SUI. Om deel te mogen nemen moest vrouwen onder andere ≥18 jaar zijn, SUI of gemengd (M)UI (dominant SUI) hebben. Vrouwen werden geworven door hun verloskundige of gynaecoloog gedurende de standaard controle. In studie 1 werden vrouwen tussen de 12 en 26 weken zwangerschap en in studie 2 tijdens de nacontrole, 6 weken post-partum, geïncludeerd. De motherfit groepstherapie bestond uit 8 groepstherapie behandelingen van ieder 60 minuten die werden gegeven door een geregistreerd bekkenfysiotherapeut. De motherfit groepstherapie bestond uit uitleg over de anatomie van de bekkenbodem en hoe de bekkenbodem moet worden aan- en ontspannen en correct moet worden getraind in combinatie met oefeningen voor

de algemene fitheid. Therapietrouw tijdens en na motherfit werd gestimuleerd door therapietrouw versterkende technieken en een app. De primaire uitkomstmaat was de afwezigheid van subjectief ervaren UI gebaseerd op de ernst gebaseerd op de International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) op 18 maanden post-partum. De secondaire uitkomstmaten onderzochten de kwaliteit van leven, de subjectief ervaren verbetering en de kosten voor de gezondheidszorg.

Hoofdstuk 5 rapporteert de resultaten van twee RCTs. In beide RCTs werden de inclusie aantallen niet gehaald en daarom hebben alle vrouwen individuele PFMT in plaats van PFMGT gekregen. Studie 1 toonde geen significant resultaat aan betreffende de prevalentie van UI (gebaseerd op de ICIQ-UI SF), de subjectieve verbetering en de kwaliteit van leven op enig meetmoment. Studie 2 toonde een significante verbetering aan voor de prevalentie en impact van UI op 4 maanden post-partum in vergelijking met de nulmeting Er was echter geen significant verschil tussen de groepen op andere meetmomenten. Op 4 en 9 maanden post-partum was een significante subjectieve verbetering te zien in voordeel van de PFMT groep (p=.02). De mogelijke (kosten)effectiviteit van PFMT kon niet worden vastgesteld als gevolg van onvoldoende inclusies. Om onze kennis te vergroten over de ervaren hinder van UI, hulpzoekgedrag en welke specifieke factoren en overtuigingen het meeste bijdragen aan hulpzoekgedrag in de peri-partum periode werden twee digitale vragenlijstonderzoeken gedaan in Nederland.

Hoofdstuk 6 beschrijft de resultaten betreffende de zwangere vrouwen. De prevalentie van UI stijgt van 55.1% in het eerste tot 70.1% in het derde trimester met een gemiddelde prevalentie van 66.8%. SUI was de meest gerapporteerde vorm van UI. Bijna 43% van de respondenten ervaarden eens per week of minder UI. 92.5% van de vrouwen verloren een kleine hoeveelheid urine. 90% gaf een lichte tot matige invloed aan op de kwaliteit van leven. Slechts 13.1% van de respondenten heeft hulp gezocht voor hun UI. De hoofdredenen om geen hulp te zoeken waren het ervaren van minimale hinder en het idee dat het UI vanzelf over zou gaan. De belangrijkste redenen om in de toekomst hulp te zoeken waren het continue gebruik van opvangmateriaal, het gevoel dat anderen urine kunnen ruiken en het doorlekken en krijgen van natte kleding. Vrouwen die hulp gezocht hadden scoorden significant hoger dan niet hulp zoekende vrouwen met betrekking tot ervaren hinder en inbreuk op het dagelijks leven.

Hoofdstuk 7 beschrijft de resultaten met betrekking tot de prevalentie, ervaren hinder, overtuigingen en hulpzoekgedrag van vrouwen tussen de 6 weken en 1 jaar post-partum. De gemiddelde prevalentie van UI was 57.1% en dit veranderde niet significant gedurende de post-partum periode. SUI was met 62.9% het meest gerapporteerde type UI. Vrouwen die voor het eerst waren bevallen gaven in vergelijking met vrouwen die meerdere keren bevallen waren een lagere prevalentie aan, respectievelijk 52.0% en 61.9% (p=.43). In 43.9% van de gevallen hadden vrouwen eens per week of minder vaak UI en in 89.5% van de gevallen was dit een kleine hoeveelheid. UI werd door 38% van de vrouwen als hinderlijk ervaren en 25% van alle vrouwen heeft hulp gezocht. Vrouwen die hulp gezocht hebben scoorden significant hoger op ervaren hinder dan de vrouwen die geen hulp gezocht hebben (p=.001). De belangrijkste redenen om in de toekomst hulp te zoeken waren het continue gebruik van opvangmateriaal, doorlekken en krijgen van natte kleding, het gevoel dat anderen urine kunnen ruiken en hinder tijdens het werk. Om meer inzicht te krijgen in het verschil tussenprevalentie van UI en het daadwerkelijke hulpzoekgedrag voor UI van peri-partum vrouwen. is het belangrijk om de overtuigingen met betrekking tot gezondheid van deze vrouwen en hun zorgprofessionals te begrijpen met betrekking tot UI. Kennis over hoe peri-partum vrouwen hun UI ervaren en om inzicht te krijgen in het hierop volgend gezondheidsmanagement.

Hoofdstuk 8 beschrijft de resultaten van een kwalitatieve studie over dit onderwerp. Volwassen zwangere en tot 1 jaar post-partum vrouwen werden geïnterviewd en een focusgroep werd gehouden met zorgprofessionals die betrokken zijn bij de zorg van zwangere en post-partum vrouwen. Bijna alle vrouwen gaven aan niet of slechts een klein beetje hinder te ervaren van hun UI en zij accepteren het als gevolg van de zwangerschap en/of bevalling. Vrouwen waren verbaasd omdat ze zich niet bewust waren dat UI een probleem kon zijn in de peri-partum periode. Geen van de zorgprofessionals vroeg standaard naar UI tijdens de zwangerschap. Bij de 6 weken post-partum nacontrole was een vraag over UI nog steeds niet een standaard vraag voor de meerderheid van gynaecologen en arts-assistenten in tegenstelling tot de verloskundigen.

Hoofstuk 9, de algemene discussie, laat een overzicht zien van de belangrijkste resultaten van de studies die in dit proefschrift worden beschreven. De methodologische sterke en zwakke punten worden besproken net als de

gevolgen voor de klinische praktijk en toekomstig onderzoek. In het algemeen kunnen we concluderen dat peri-partum UI een veel voorkomend symptoom is, dat wordt onderschat door vrouwen en zorgprofessionals. Om motherfit te zijn moet de aanwezigheid en de ervaren hinder van UI meer aandacht krijgen van de betrokken zorgprofessionals, moeten vrouwen beter geïnformeerd worden over (de consequenties) UI en wat er aan gedaan kan worden. Dit kan mogelijk hulpzoekgedrag bevorderen.

Tot slot wordt in **hoofdstuk 10** de wetenschappelijke en maatschappelijke impact van dit proefschrift besproken. De resultaten van onze studies zijn en zullen in de toekomst worden gedeeld in peer-reviewed journals en worden gepresenteerd op verschillende congressen en via sociale media met als doel om zoveel mogelijk onderzoekers, zorgprofessionals en de bevolking te bereiken. Onze resultaten kunnen onderzoekers helpen bij het plannen van onderzoeken, zorgprofessionals helpen in hun aandacht voor UI en de communicatie met patiënten en beleidsmakers kunnen onze resultaten gebruiken bij het schatten van de ziektelast en toekomstig zorgkosten met betrekking tot UI. Tot slot, als zorgprofessionals hun management en communicatie met betrekking tot UI, gebaseerd op de resultaten van onze studies aanpassen zal dit peri-partum vrouwen helpen en in staat stellen om 'motherfit' te worden.

DANKWOORD

“It is not the mountain we conquer but ourselves”
(*Sir Edmund Hillary)*

Promoveren wil ik vergelijken met de beklimming van een berg, een hele hoge berg. De weg naar de top is lang, zowel fysiek als mentaal zwaar en vol met uitdagingen die overwonnen moeten worden. Een goed team ter ondersteuning van de bergbeklimmer is daarbij onontbeerlijk en van onschatbare waarde. Voor het proefschrift dat voor u ligt (mijn beklimming) had ik een fantastisch team. Graag wil ik hen hier persoonlijk bedanken.

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CURRICULUM VITAE

Heidi Moossdorff-Steinhauser was born on November 5th, 1968 in Dordrecht, The Netherlands. After completing secondary education (Scholengemeenschap Noordendijk, Dordrecht) she went to Australia for a year. Once back in The Netherlands she studied physical therapy at Hogeschool West-Brabant and graduated in 1994. From 1999 onwards she specialized in pelvic physical therapy. Once the specialized register for pelvic physical therapists was initiated in 2005 she obtained her registration. Because of her interest in scientific research, she studied clinical health sciences (part-time) at Utrecht University and graduated in 2011.

In 2015, she started as a researcher at the urology department of Maastricht University Medical Center (MUMC+) in combination with first line patient care. In December 2016, she commenced as a PhD student at the Department of Epidemiology of the Faculty of Health, Medicine and Life Sciences (FHML) of Maastricht University, on the research project that led to this thesis: pregnancy-related urinary incontinence, does it bother. At the moment, Heidi is a senior lecturer at Avans+ for the pelvic physical therapy education.

From 2011 to 2016, Heidi was a board member of the Dutch Society for Pelvic Physical therapy (science and education). Besides this, she was a Faculty board member as a representative of the scientific staff of FHML (Faculty of Health, Medicine and Life sciences), of Maastricht University, between 2017 and 2019 and from 2015 to date she is a member of the ethics committee of the International Continence Society (ICS). In October of 2021 Heidi will join the physiotherapy committee of ICS.

Heidi has co-authored the Dutch proficiency profile of the pelvic physical therapist. In order to raise awareness for pelvic floor dysfunctions, she published many non-peer reviewed articles for colleagues and the general public. In addition she has a blog and YouTube channel for professionals with an interest in the pelvic region since 2019 (https://www.pelvicnewschannel.com) in which she discusses recently published studies on a variety of topics on the pelvic region.

LIST OF PUBLICATIONS

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