Development of a registry of clinical, PROMS and PREMS for pregnant women with cardiovascular conditions

Principal Investigator UAntwerpen / UHA: Prof. E. Goossens: eva.goossens@uantwerpen.be; eva.goossens@uza.be

Principal Investigator UHGhent: Prof. Dr. Julie de Backer**:** julie.debacker@uzgent.be

Principal Investigator Ziekenhuis Aan de Stroom: Dr. Gaëlle Vermeersch gaelle.vermeersch@zas.be

Principal Investigator UHLeuven: Dr. Els Troost els.troost@uzleuven.be

Principal Investigator UHSouthamton: Dr. Linden Stocker l.stocker@soton.ac.uk

Doctoraatsstudent: Vanharen Yaël: yael.vanharen@uantwerpen.be

Contact:
Yaël Vanharen
Centre for Research and Innovation of Care
Universiteitsplein 1
2600 Wilrijk, Antwerp, Belgium

Research protocol 21/05/2024 Version 2

1. Introduction

1.1 Background

Cardiovascular disease (CVD) is the leading cause of maternal mortality during pregnancy worldwide (1). The prevalence of CVD in pregnant women increased from 6.4 to 9 per 10,000 between 2000 and 2010 (1). These increasing prevalence rates can be explained, on the one hand, by the observation that more women diagnosed with congenital heart disease are reaching adulthood and thus childbearing age, thanks to important developments in multidisciplinary cardiovascular prevention, treatment and follow-up (2). On the other hand, the average Western woman is becoming pregnant at a later age, which increases the risk of developing CVD during pregnancy and/or in the postpartum period. Finally, the prevalence of cardiovascular risk factors, such as smoking, diabetes mellitus, obesity and an increasingly sedentary lifestyle, is increasing in the general population, affecting women's risk profile for developing cardiac complications during pregnancy. These epidemiological, socio-demographic and clinical developments are driving the increasingly complex course of pregnancy in women with a cardiovascular risk profile (3).

To improve fetal, maternal and obstetric outcomes, the follow-up and management of women with CVD during pregnancy and postpartum is recommended within a multidisciplinary cardio-obstetric care programme or outpatient clinic [1-3]. However, in order to monitor these outcomes and thus assess and improve the quality of care provided by the cardio-obstetric team, guidelines call for a patient registry [2] [4]. In addition to clinical parameters indicative of obstetric, neonatal and maternal outcomes, this registry should include a set of patient-reported outcome and experience parameters (PROs and PREs) [2].

Over the past decade, several risk stratification models have been developed to reduce mortality and morbidity in this population. In parallel, registries have been developed to monitor various clinical outcomes in pregnant women with CVD. An example of such registries and risk stratification is the CARPREG (Cardiac Disease in Pregnancy Study) registry. This multi-centre Canadian registry had the first aim to record complications in pregnant women with CVD and the second aim to predict the likelihood of developing maternal cardiac complications based on the data collected [5]. Later, the ZAHARA (Zwangerschap bij Aangeboren HARtAfwijkingen) registry was also established in the Netherlands. This registry includes components of the CARPEG registry, such as cardiovascular outcomes, but also neurohumoral and uteroplacental Doppler flow changes during pregnancy. In addition, this registry focuses on pregnant women with congenital disorders and the impact of these outcomes not only on the patient but also on the

children [6]. In 2007, a general European registry was also developed, the Registry of Pregnancy And Cardiovascular disease (ROPAC) registry, which currently contains the most comprehensive dataset and is also the most widely used in Europe [7]. This ROPAC registry also further applied and validated the m-WHO risk stratification developed. However, these registries and stratification models currently focus only on the collection of a set of clinical outcomes in pregnant women with CV disease. The development of a patient-reported outcome registry is essential for the further development of high quality care and management of women with a cardiovascular risk profile and/or disease during all stages of pregnancy, based on the opinions expressed in the current set of expert-based guidelines [2, 3].

To date, the available guidelines and recommendations published by the European Society of Cardiology (ESC) and the American Heart Association (AHA) are mainly based on expert opinion with a strong emphasis on the clinical condition of the patient [2, 3]. However, there currently appears to be limited patient input into these guidelines. However, previous research has shown that the psychological impact of pregnancy and/or early parenthood is a special time in parents' lives, especially when combined with a complicated care pathway and the risk of potentially serious cardiovascular, maternal and fetal complications [8]. For example, a previous study reported that 10-20% of all mothers develop postpartum depression, but that the prevalence increases significantly when additional stressful events occur during pregnancy, such as cardiovascular stress [8]. It is therefore recommended that patients with additional aggravating risk factors, such as a cardiovascular problem, receive psychological follow-up [8]. In pregnant women with a cardiovascular risk profile, a worsening cardiovascular status may be considered a stressor. However, there is a lack of scientific understanding of the experiences and outcomes reported by patients themselves.

Patient Reported Outcome Measurements (PROMS) and Patient Reported Experience Measurements (PREMS) are proving to be important tools for measuring and monitoring patients' health status from a holistic perspective, including patients' experiences, in a wide range of current clinical trials [9]. The International Consortium for Health Outcomes Measurement (ICHOM), through consensus meetings with various stakeholders, has developed a standard set of PROMS and PREMS that can be measured in pregnant women during the peri- and postnatal period [10]. However, this ICHOM set has been developed for the general population and is not specifically targeted at pregnant women with a cardiovascular risk profile. Therefore, there is currently no relevant set of PROMS and PREMS specifically aimed at monitoring the patient

perspective in women with a cardiovascular risk profile during the antenatal, peri- and postnatal periods.

Standardised monitoring of obstetric, maternal and fetal outcomes, as well as patient-reported outcomes and experiences (PROs and PREs), is needed to ensure that future recommendations take into account the needs and requirements of pregnant women with CVDs themselves. There is also a lack of evidence on the impact of pregnancy in women with a cardiovascular profile on pregnancy outcomes. The development of a comprehensive patient registry combining clinical, maternal and fetal outcome measures, complemented by a validated set of PROs and PREs, is of paramount importance. There is also a need for scientific understanding of the relationship between these clinical outcomes and patient-reported outcome measures.

1.2 Main study objective

This study, which is part of a PhD programme, aims to establish a multi-centre patient registry of pregnant women with acquired, hereditary or congenital CVD, in which a range of obstetric, maternal and fetal outcomes, as well as PROMS and PREMS, will be collected during the perinatal and post-partum period (cf. 4th trimester). This study aims to (i) determine the impact of pregnancy through a range of maternal, obstetric and fetal/neonatal outcomes; (ii) determine the impact of pregnancy through a range of patient-reported outcomes and experiences in the perinatal and post-partum period; and (iii) explore the associations between maternal, obstetric and fetal/neonatal outcomes and PROMS/PREMS in the perinatal and post-partum period.

1.3 Research questions

1. What patient-reported outcomes are observed in pregnant women with pre-existing CVD in the perinatal and postpartum period throughout the follow-up period?
2. What is the impact of pregnancy on maternal, obstetric, fetal, neonatal and patient-reported outcomes and experiences in women with pre-existing CVD during the perinatal and postpartum period?
3. What is the relationship between recorded maternal, obstetric, fetal, neonatal and patient-reported outcomes in pregnant women with pre-existing CVD during the perinatal and post-partum period?

4. How do measured patient-reported outcomes evolve during the perinatal and postpartum period in pregnant women with pre-existing CVD?
5. What are the predictors of psychological outcomes such as mother-child bonding, anxiety and depressive symptoms and postpartum depression in women with acquired, hereditary or congenital CVD?

2. Methods

2.1 Study design

This is a prospective, multicentre, descriptive study of pregnant women with acquired, inherited or congenital CVD, recording obstetric, maternal and fetal/neonatal outcomes, as well as perinatal and postnatal patient-reported outcomes and experiences (PROs and PREs).

The registry will collect these data from the first consultation in a tertiary centre up to and including 12 weeks after delivery (cf. fourth trimester). For each enrolled pregnant woman, there will be at least 4 data collection points: at least 1 data collection point during the perinatal period, depending on the date of enrolment and the current gestational age (cf. trimester 1, 2 or 3) and at least 3 data collection points during the postpartum period (cf. week 1, 6 and 12 postpartum).

2.2 Setting

The data are collected at the University Hospital Antwerp (UHA), the University Hospital Gent (UHGent), the Hospital Aan de Stroom (ZAS), the University Hospital Leuven (UHLeuven) and the University Hospital of Southampton (UHSouthampton), all tertiary hospitals with an extended outpatient clinic specialising in the care of women with CVDs in the perinatal and postpartum period. The pre-conception phase is not included, as this is difficult to impossible in practice. Many patients are not followed up until later in pregnancy because they present later to these specialised cardio-obstetric centres. Recruitment will take place in the cardiac-obstetric clinics of the participating centres, where these women will be followed up during the study period.

2.3 Selection and recruitment of the study population

Participants in this study are female patients with a current pregnancy who are being followed by a gynaecologist and/or cardiologist in the cardio-obstetrics department of one of the participating hospitals from 01.10.2023 (subject to ethics committee approval) to 01.10.2024.

The following selection criteria will be used to select study participants:

- **Inclusion criteria**
    1. Ongoing follow-up at the cardio-obstetrics/heart and women service at one of the participating centres;
    2. Pregnant women with congenital heart disease as defined by Mitchell et al, 1971[11]; and/or acquired heart disease; and/or severe pre-existing hypertension; and/or cardiac arrhythmias (with or without the presence of an internal defibrillator); and/or a history of peripartum cardiomyopathy; and/or systemic diseases with cardiac burden.
- **Exclusion**
    1. Pregnant women with pre-eclampsia/HELLP (haemolysis, elevated liver enzymes and low platelets) as a primary cardiovascular condition.

Before patients are recruited, they will be given written and verbal explanations and information about the study. The patient will then be asked if they wish to participate in the study. If so, the patient will be asked to formally confirm participation in the study by completing a written informed consent form. This form will explicitly state that data analysis and reporting of results will always be done in a pseudonymised manner to respect the privacy of the patient and their environment.

Participants will be recruited consecutively from 01/10/2023 (or as soon as ethics committee approval is obtained) to 01/10/2024 (see 4.1 'General study plan'). Recruitment will be done in consultation with the treating physician(s).

2.4 Data Collection

2.4.1 Data collection

Data are collected using the medical/electronic patient record and a set of questionnaires covering the selected PROMS and PREMS.

Once the patient has formally confirmed their participation in writing, the set of questionnaires is delivered to the patient via the Redcap software package (for UHGhent, UHLeuven, ZAS and UHSouthamton) or via UZA@home (for UHAntwerp), if the patient agrees to participate. Patients will also be offered the option of receiving the set of questionnaires on paper if they wish. The questionnaires sent out will take a maximum of 30 minutes to complete. All scales will be

collected using Redcap or the UZA@home platform. The data will then be processed using the Redcap software package and pseudonymised in the developed registry. Only coded data will be included in the analysis.

2.4.2 Data collection period

As shown in section 4.1, data collection will run concurrently with the recruitment period from October 2023 (subject to formal EC approval) to December 2025.

Figure 1 provides a visual overview of the respective data collection points for demographics and clinical outcomes. Figure 2 also provides a visual overview of the respective data collection points for the PROMS and PREMS datasets. It is important to note that the date of enrolment during the perinatal period is a highly variable element of the study, where the date of the patient's first registration at the outpatient clinic may vary between trimester 1, 2 or 3. During this perinatal period there will be at least one measurement time per participating patient. However, depending on the patient's exact enrolment date and gestational age, an attempt will be made to provide one data collection point per trimester. Ideally, however, the maximum number of measurement times (one measurement time per trimester) should be achieved, as shown in the figure.

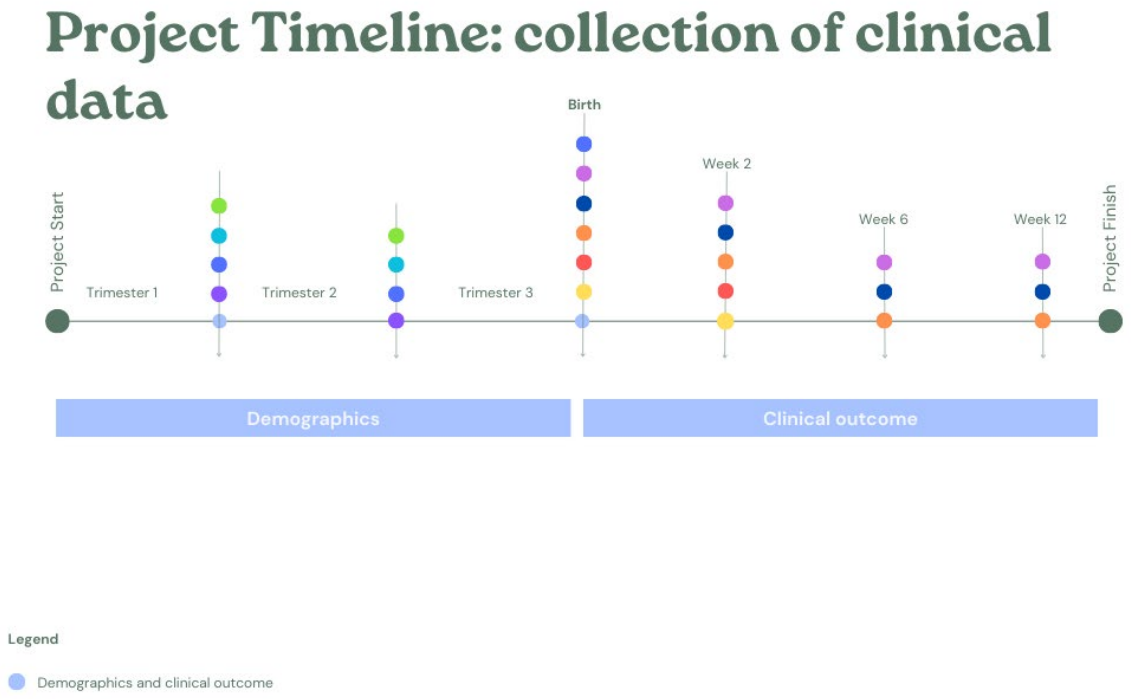


Figure 1: Data collection points for socio-demographic data and clinical outcomes.

2.5 Overview of collected variables

2.5.1 Sociodemographic and clinical characteristics

A set of socio-demographic and clinical data will be collected using the existing electronic patient record available at each participating centre. An overview of the timing of data collection for this set of clinical and sociodemographic data is shown in Figure 1.

An overview of the demographic and clinical data to be collected is given in Appendix 1 and includes the following patient data: age, sex, number of previous pregnancies, number of children, marital status, ethnicity, current smoking behaviour and highest level of education. In addition, specific data relevant to the patient's CV status are collected, such as CV diagnosis, NYHA classification [12] and m-WHO classification [13].

2.5.2 Obstetric, maternal and foetal/neonatal outcomes

The following set of obstetric, maternal and fetal/neonatal outcomes will be collected from the medical record once at 2 weeks postpartum:

- The set of **maternal and obstetric outcomes** listed in Appendix 2 of the study protocol will consist of the following variables: Maternal mortality, length of stay, haemorrhage; obstetric outcomes such as abruptio placentae, haemorrhage, emergency caesarean section, rupture of membranes (ROM); left ventricular ejection fraction, cardiomyopathy (CMP), arrhythmia, pulmonary hypertension, thromboembolic complications; hypertension, endocarditis and cardiomyopathy.

- The set of **fetal/neonatal outcomes** listed in Appendix 3 of the protocol will consist of the following data: APGAR score, birth weight, length of stay, fetal mortality, reason for preterm birth, neonatal admission, neonatal mortality, intrauterine growth restriction (IUGR) and birth injury.

2.5.3 Patient-reported outcome and experience measures (PROMs/PREMs)

Figure 2 provides a visual representation of the data collection for the PROMS and PREMS sets. Appendix 4 provides an overview of the complete set of validated questionnaires used to measure the PROMs and PREMs.

2.5.3.1 PROMs

The possible presence of depressive symptoms is measured using the validated **Whooley** scale [14]. This questionnaire consists of two questions assessing how the patient has felt over the past month.

The **General Anxiety Disorder 7** questionnare [15] is administered to screen for the possible presence of an anxiety disorder.

Autonomy and shared decision making are assessed using **the Mothers on Autonomous Decision Making (MADM)** scale [16].

Social support is measured using the validated **Oslo-3** scale [17]. This scale consists of three short questions that assess the extent to which the patient feels socially supported.

Empowerment is assessed using the validated **Pregnancy Related Empowerment Scale (PRES)** [18]. This scale assesses empowerment using a range of attributes such as the patient's relationship with her health care providers, her involvement in decision making, and her ability to describe and apply pregnancy-related health behaviours.

The validated **'Edinburgh Postnatal Depression Scale' (EPDS)** [19] is used to assess whether the patient has symptoms of possible (postnatal) depression. It also asks about anxiety and suicidal ideation.

Finally, mother-infant bonding is assessed using the **Mother-Infant Bonding Scale (MIBS)** [20]. The validated **Postpartum Bonding Questionnaire (PBQ)** [21] is also administered at the same time to ensure that mother-child bonding has been properly assessed.

2.5.3.2 PREM

Patient satisfaction will be measured using the validated **Maternal Satisfaction with Care Questionnaire (MSQ)** developed as part of the Born in Belgium study [22].

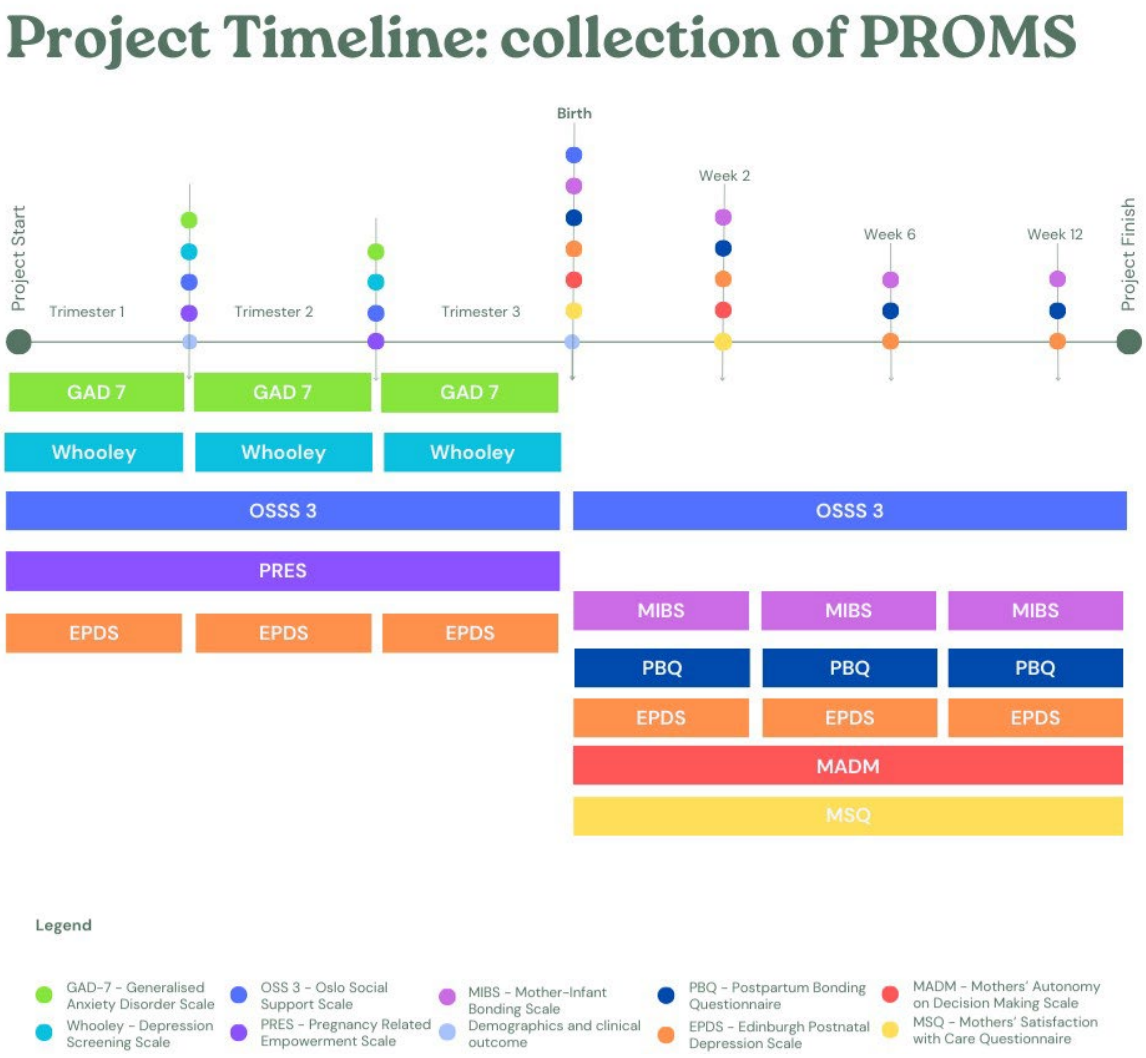


Figure 2: Data collection points for patient-reported outcomes (PROs) and patient-reported experiences (PREs).

2.6 Data analysis

Data will be analysed using SPSS version 28.0 software. Descriptive statistics will be used to describe both sample characteristics and selected outcomes.

Nominal data are compared by inferential statistics using the $\chi 2$ test or Fisher's exact test, depending on the underlying assumptions. Continuous variables are tested for normality and non-parametric tests are used where appropriate. Means and standard deviations are presented

when continuous variables are found to be normally distributed, and differences between groups are analysed using Student's t-test. For non-normally distributed continuous variables, median and interquartile range are presented and differences between groups are analysed using the Mann-Whitney U test.

Associations between different outcomes will be presented according to normality using a Pearson's R or Spearman's Rho correlation coefficient. Univariate regression analyses will also be performed to identify patient characteristics associated with adverse pregnancy outcomes, divided into three composite endpoints: obstetric outcomes, cardiac outcomes, fetal outcomes, and PROMS and PREMS. Variables univariately associated with an increased incidence of the outcomes of interest ($p<0.10$) will be included in subsequent multivariable logistic regression analyses.

The evolution of PROMS over time and the association with independent predictors of measured PROMS will be assessed using linear mixed model analysis based on at least 3 consecutive data points.

A p-value of <.05 will be considered statistically significant and tests will always be two-tailed.

3. Ethical considerations

This study will be submitted to the Ethics Committee of the University Hospital Antwerp for formal approval. All data will be pseudonymised by the principal investigator in accordance with GDPR guidelines. In order to guarantee the privacy of the study participants, all personal data collected in this study will be treated confidentially and will never be shared with third parties. Encryption of this personal data will be carried out by the principal investigator, who will also be responsible for storing it for a period of 20 years.

3.1 Disadvantages or potential risks to trial participants

There are no risks of permanent harm associated with patient participation in this study. The outcomes obtained will contribute to changing the care of these patients with the aim of improving the quality of this care and the outcomes monitored.

The questionnaires that will be administered are questionnaires used in psychology to determine the possibility of a diagnosis. For example, the EPDS measures the likelihood of (postpartum) depression, and a positive score is highly suggestive of an effective diagnosis. The GAD is used to

measure the likelihood of anxiety disorders, and the Whooley is used to screen for the risk of depression.

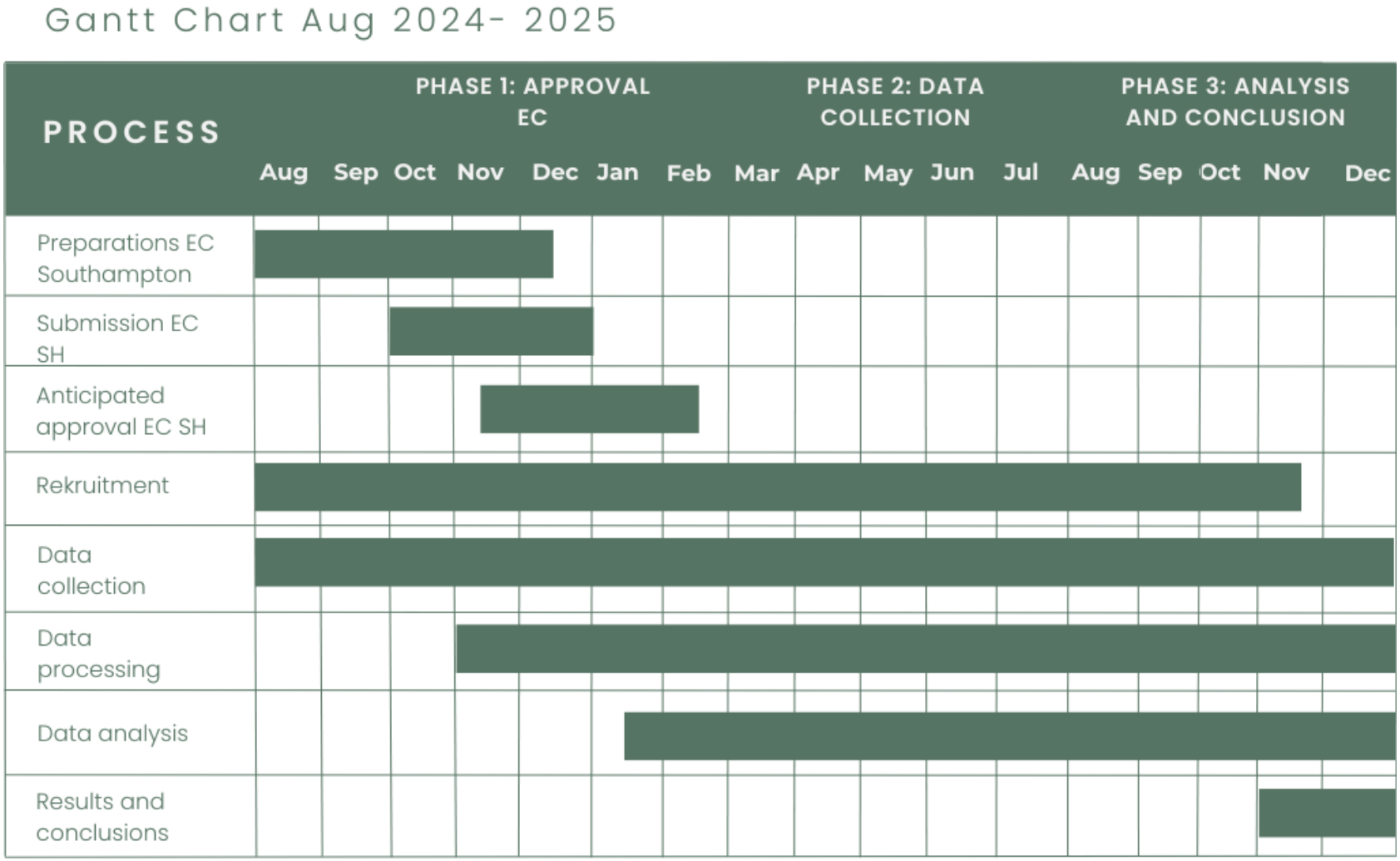
Patients may respond positively to these questionnaires. If this is the case, it is important that the patient receives psychological support or follow-up. In the case of positive responses, the researcher will contact the departmental psychologists to discuss, in consultation with the treatment team, the possibility of further psychological support for these women. At the UZ Ghent, these counsellors will then contact the patient by telephone and conduct a diagnostic interview with the patient. If a diagnosis is made, the patient will be given the contact details of a specialist counsellor/psychiatrist. If this is not possible, referrals are made to external centres with a fixed referral within a specific centre that specialises in psychological care in the perinatal and postpartum period, such as the 'centre Draag-kracht'.

3.2 Consent

Formal consent to conduct this study has already been given by the Chief of Cardiology at both UHA, UHGent, ZNA, UHLeuven and UHSouthampton. The doctors involved in the cardiology and gynaecology consultations at the specialist hospitals have been informed about the study and have already given their formal consent for the study to take place. However, the investigator will need to be available at all times, to answer questions about the study.

4. Timing

4.1 General study plan



5. References

1. Egidy Assenza G, Dimopoulos K, Budts W, Donti A, Economy KE, Gargiulo GD, et al. Management of acute cardiovascular complications in pregnancy. European Heart Journal. 2021;42(41):4224-40.

2. Regitz-Zagrosek V, Roos-Hesselink JW, Bauersachs J, Blomström-Lundqvist C, Cífková R, De Bonis M, et al. 2018 ESC Guidelines for the management of cardiovascular diseases during pregnancy: The Task Force for the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC). European Heart Journal. 2018;39(34):3165-241.

3. Mehta LS, Warnes CA, Bradley E, Burton T, Economy K, Mehran R, et al. Cardiovascular Considerations in Caring for Pregnant Patients: A Scientific Statement From the American Heart Association. Circulation. 2020;141(23):e884-e903.

4. Gnanaraj JP, Anne Princy S, Anju S, Anita S, Cecily Mary M, Gnanavelu G, et al. Pregnancy outcomes in women with heart disease: the Madras Medical College Pregnancy And Cardiac (M-PAC) Registry from India. European Heart Journal. 2023;44(17):1530-40.

5. Silversides CK, Grewal J, Mason J, Sermer M, Kiess M, Rychel V, et al. Pregnancy Outcomes in Women With Heart Disease: The CARPREG II Study. J Am Coll Cardiol. 2018;71(21):2419-30.

6. Drenthen W, Boersma E, Balci A, Moons P, Roos-Hesselink JW, Mulder BJM, et al. Predictors of pregnancy complications in women with congenital heart disease. European Heart Journal. 2010;31(17):2124-32.

7. Greutmann M, Silversides CK. The ROPAC registry: a multicentre collaboration on pregnancy outcomes in women with heart disease. European Heart Journal. 2012;34(9):634-5.

8. O'Hara MW, Wisner KL. Perinatal mental illness: definition, description and aetiology. Best Pract Res Clin Obstet Gynaecol. 2014;28(1):3-12.

9. Anker SD, Agewall S, Borggrefe M, Calvert M, Jaime Caro J, Cowie MR, et al. The importance of patient-reported outcomes: a call for their comprehensive integration in cardiovascular clinical trials. Eur Heart J. 2014;35(30):2001-9.

10. Nijagal MA, Wissig S, Stowell C, Olson E, Amer-Wahlin I, Bonsel G, et al. Standardized outcome measures for pregnancy and childbirth, an ICHOM proposal. BMC Health Serv Res. 2018;18(1):953.

11. Mitchell SC, Korones SB, Berendes HW. Congenital heart disease in 56,109 births. Incidence and natural history. Circulation. 1971;43(3):323-32.
12. THE CLASSIFICATION OF CARDIAC DIAGNOSIS. Journal of the American Medical Association. 1921;77(18):1414-5.
13. Regitz-Zagrosek V, Blomstrom Lundqvist C, Borghi C, Cifkova R, Ferreira R, Foidart JM, et al. ESC Guidelines on the management of cardiovascular diseases during pregnancy: the Task Force on the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC). Eur Heart J. 2011;32(24):3147-97.
14. Whooley MA, Avins AL, Miranda J, Browner WS. Case-finding instruments for depression. Two questions are as good as many. J Gen Intern Med. 1997;12(7):439-45.
15. Spitzer RL, Kroenke K, Williams JB, Löwe B. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006;166(10):1092-7.
16. Vedam S, Stoll K, Martin K, Rubashkin N, Partridge S, Thordarson D, Jolicoeur G. The Mother's Autonomy in Decision Making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. PLoS One. 2017;12(2):e0171804.
17. Kocalevent RD, Berg L, Beutel ME, Hinz A, Zenger M, Härter M, et al. Social support in the general population: standardization of the Oslo social support scale (OSSS-3). BMC Psychol. 2018;6(1):31.
18. Klima CS, Vonderheid SC, Norr KF, Park CG, editors. Development of the Pregnancy-related Empowerment Scale2015.
19. Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987;150:782-6.
20. Taylor A, Atkins R, Kumar R, Adams D, Glover V. A new Mother-to-Infant Bonding Scale: links with early maternal mood. Arch Womens Ment Health. 2005;8(1):45-51.
21. Brockington IF, Fraser C, Wilson D. The Postpartum Bonding Questionnaire: a validation. Arch Womens Ment Health. 2006;9(5):233-42.
22. Stas A, Breugelmans M, Geerinck L, Spinnoy A, Van Laere S, Gucciardo L, et al. Maternal satisfaction with reduced postnatal length of stay in Brussels: evidence from the KOZI&Home program. BMC Pregnancy Childbirth. 2023;23(1):475.
23. Tien HC, Spencer F, Tremblay LN, Rizoli SB, Brenneman FD. Preventable Deaths From Hemorrhage at a Level I Canadian Trauma Center. Journal of Trauma and Acute Care Surgery. 2007;62(1):142-6.
24. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task

Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). European Heart Journal. 2021;43(7):561-632.

25. Baumgartner H, Hung J, Bermejo J, Chambers JB, Evangelista A, Griffin BP, et al. Echocardiographic assessment of valve stenosis: EAE/ASE recommendations for clinical practice. J Am Soc Echocardiogr. 2009;22(1):1-23; quiz 101-2.

6. Appendices

6.1 Appendix 1: Overview of set of socio-demographic characteristics

	Description outcome type	*Response options or data*
Socio-demographic characteristics	Date of birth	Year of birth and month (MM-YYYY)
	Date of first contact Heart Pregnancy Team (= application date)	DD - MM - YYYY
	Ethnicity	Hispanic – White, non-Hispanic – Black, non-Hispanic
	Marital status at time of delivery	Single – Cohabiting - Legal cohabitation – Married – Widowed
	Highest level of education attained	Primary - Secondary - Bachelor - Master - PhD
	Active smoker	YES – NO
Medical history	Previous cardiac intervention undergone	YES – NO If yes, type: Minimally invasive – Surgical
	Previous coronary events	YES – NO
	Diameter of aorta	… mm
	m-WHO classification (11)	I – II – II- III – III – IV
	Cardiac disease	Structural heart disease - congenital heart disease (CHD) - valve disease (VHD) - cardiomyopathy (CMP) - ischaemic heart disease (IHD) - aortic pathology (AOP) - pulmonary hypertension - arrhythmia
	Congenital heart disease based on the CONCOR classification	Tetralogy of Fallot - Coarctation Aorta - L-TGA - D-TGA - Ventricular septum defect - Atrial septum defect - Atrioventricular septum defect - Aortic valve stenosis - Transposition of the great arteries - Pulmonary valve stenosis - Atrial septum defect - Mitral valve abnormalities - Aortic valve abnormalities - Pulmonary valve abnormalities - Mitral valve stenosis - Subvalvular aortic stenosis - Fontan - Ebstein anomaly -

	Eisenmenger - Patent ductus arteriosus - Pulmonary atresia - Double outlet ventricle - Univentricular heart - other
Underlying genetic syndrome based on the ACHD AP classification.	Turner (45X) - DiGeorge(22Q11.2 deletion) - Klinefelter XXY - Noonan - Williams - Marfan - Ehler Danlos - other
Acquired cardiac disorder based on the ACHD AP classification	Arrhythmia - PHT - AHT - Aortic pathology - Valve disease - Venous/arterial stenosis
Specification documented arrhythmia	Arrhythmia requiring no treatment: Bradyarrhythmia, atrial or ventricular tachyarrhythmia not requiring anti-arrhythmic therapy, cardioversion or ablation - Arrhythmia under control with therapy: Bradyarrhythmia requiring pacemaker implantation - Atrial or ventricular tachyarrhythmia requiring anti-arrhythmic therapy, cardioversion or ablation - AF and controlled ventricular response - Patients with an ICD - Refractory arrhythmias: Atrial or ventricular tachyarrhythmia currently unresponsive to or refractory to anti-arrhythmic therapy or ablation
Cardiac support device	YES – NO If yes, type: Pacemaker – Implantable Cardioverting Device – Chronic Resynchronisation Therapy
Symptoms of heart failure on clinical examination	YES – NO
Chronic arterial hypertension defined as arterial hypertension (>140/90mmHg) prior to pregnancy or diagnosed before 20 weeks of gestation (20).	YES – NO
Pulmonary hypertension defined as right ventricular systolic pressure (RVSP) >30 mmHg at rest(21).	YES – NO
Left ventricular ejection fraction	%
Atrial fibrillation	YES – NO
Diabetes Mellitus	YES – NO
Length	… cm
Weight	… kg
NYHA Functional class(10).	I – II – III – IV

Actua drug treatment	B-Blockers	YES – NO
	ACE-inhibitors	YES – NO
	Diuretica	YES – NO
	Anti-platelet therapy	YES – NO
	DOAC	YES – NO

6.2 Appendix 2: Overview of the maternal clinical outcomes

Maternal outcome	*Description of outcome*	*Outcome measure*
Obstetric outcome	Date of delivery	DD - MM - YYYY HR-MIN
	Number of weeks, days pregnant at delivery	MM - DD
	Start of labour	DD-MM-YYYY
	Gravity Parity Mater Abortion (GPMA)	G-P-M-A
	Mode of current parity	Spontaneous - IVF
	Specify mode of delivery	Induced – Spontaneous Vaginal –Caesarian Section
	Reason for sectio	Decription (as string variable)
	Emergency sectio	YES – NO
	Location of current parity	In Hospital – Birthing house – At Home
	Maternal mortality defined as death of the patient from direct or indirect obstetric causes, more than 42 days but less than one year after termination of pregnancy (WHO).	YES – NO
	Intensive care admission	YES – NO
	Maternal admission duration postpartum	...days
	Extended admission for cardiac reason	YES – NO
	Late maternal complication within 42d post-partum	YES – NO

	Post-partum haemorrhage (22)	Major bleeding – Minor bleeding – No Vageinal delivery with blood loss >500 ml – Caesarean section with blood loss >1000 ml or transfusion needed directly after birth and up until 24 hrs postpartum
	Major bleeding for other reason (bleeding that results in a decrease in haemoglobin level of at least 1 g/dl (or 0.62 mmol/l), the need for transfusion of blood products or end-organ damage such as haemorrhagic cerebrovascular accident or retinal haemorrhage) [23].	YES – NO
	Solutio placentae	YES – NO
	Monitoring during delivery, being a 3-lead ECG.	YES – NO
	Maternal injury due to birth	YES – NO
	Premature rupture of membranes (ROM) defined as membrane rupture before onset of uterine contractions (23).	YES – NO
	Premature labour defined as spontaneous onset of labour <37 weeks' gestation (24).	YES – NO
	Breastfeeding	YES – NO
Cardiac outcome *Arrythmias*	Ventricular arrhythmia defined as three or more consecutive ventricular beats with a mean frequency greater than 100 beats per minute; however, only clinically relevant VT/VES (25).	No – Ventricular Tachycardia – Ventricular ExtraSystole
	Date onset ventricular arrythmia	DD – MM – YYYY
	Supraventricular arrhythmia that was clinically documented.	None – AFL – AF – AVNRT – AVRT Persistent – Paroxysmal
	Date onset SVT	DD – MM – YYYY
Cardiac outcome	Endocarditis	YES – NO

General outcome		
	Pulmonary hypertension defined as right ventricular systolic pressure (RVSP) >30 mmHg at rest (21).	YES – NO
	Thromboembolic complications	Mechanische kleptrombose – veneus trombo-embolie (mineur trombo-embolische complicaties) – cerebrovasculair accident (majeur trombo-embolische complicaties)
	Aortic dissection	YES – NO
	Increase in aortic diameter	YES – NO
	Acute coronary syndrome	YES – NO
	Hypertension during pregnancy, also known as pregnancy-induced hypertension (PIH). Definition of response options: newly developed hypertension (>140/90 on two occasions) after >20 weeks' gestation; PIH criteria plus >0.3 g proteinuria in the 24-hour urine sample; pre-eclampsia with grand mal attacks; pre-eclampsia with fatal outcome (25).	Pregnancy induced hypertension – Preëclampsia - HELLP – Eclampsia
	Clinical signs of heart failure	YES – NO
	Cardiomyopathy	YES – NO
	Hospitalisation due to cardiac disease	YES – NO
	LoS Hospitalisation	DD
	Reason for hospitalisation	…
	Cardiac intervention during pregnancy	YES – NO
	If yes: which	Decription (as string variable)
Medication	NYHA Functional class	I – II – III – IV
	Start-up medication due to cardiac reason	YES – NO
	Low-molecular Weight Heparine	YES – NO
	Bèta-blockers	YES – NO
	Calcium antagonists	YES – NO
	Diuretics	YES – NO
	If diuretics, regular monitoring of amniotic fluid?	YES – NO

	Acetylsalicylic acid	YES – NO
Aortapathology	Diagnosed aortic stenosis	YES – NO
	Degree of severity [24], with moderate severity defined as a maximum transaortic gradient ≥ 36 mmHg (corresponding to a peak velocity ≥ 3 m/s) and severe AS defined as a maximum aortic gradient ≥ 64 mmHg (corresponding to a peak velocity ≥ 4 m/s). s) using the simplified Bernoulli equation.	Mild – Severe
	Bicuspid valve	YES – NO
	Aortic valveInsufficiency	YES – NO
	Coarctatio aortae	YES – NO
Mitral Valve Pathology	Diagnosed mitral valve stenosis, defined according to the recommendations of the European Association of Echocardiography and the American Society of Echocardiography for echocardiographic assessment of valve stenosis [25].	YES – NO
	Cause	Congenital – Rheumatic
	Degree of severity stenosis defined as mild MS = valve area >1.5 cm2or if area unavailable: mean gradient <6 mm Hg - Moderate MS = valve area 1.0 to 1.5 cm2or if area unavailable: mean gradient 6 to 12 mmHg - Severe MS = valve area <1.0 cm2or if area unavailable: mean gradient >12 mm Hg [25].	Mild – Moderate – Severe
	Mitral valve regurgitation (visual evaluation)	YES – NO
	Severity mitral regurgitation	I – II – III – IV
Hart failure, only when symptomatic	Onset HF developed during ZS	DD-MM-YYYY

	HF postpartum	YES – NO
	Diastolic dysfunction	YES – NO
	LVEF	…%
Ischemic disease	Acute Coronary Syndrome	YES – NO
	Coronary intervention	No – Minimal Invasive – Surgical
Pulmonary hypertension	Peak velocity tricuspid regurgitation	YES – NO
	RVSP by ultrasound + CVD	… mmHg <30 – 30 until 50 - 50 until 70 – 70 until 90 - >90 mmHg – No information available
	RV function	Normal – mildly impaired function – severely impaired function
	Right prepartum catheterisation to establish pulmonary hypertension	YES – NO
	Mean pulmonary arterial pressure (Mean PAP) invasive	… mmHg
	Pulmonary vascular resistance	YES – NO
	Etiology Pulmonary Hypertension: Group 1: Patients with PAH in case of iPAH, CHD-PAH or oPAH caused by connective tissue disease or vascular malformations. Group 2: Patients with PAH caused by left heart disease (LHD-PH) with left ventricular systolic dysfunction, valve disease or congenital/acquired left heart inflow or outflow tract obstructions or congenital cardiomyopathies (21).	Group 1 – Group 2 – Other

6.3 Appendix 3: Overview of the foetal/neonatal clinical outcomes

Foetal/neonatal outcome	Mors In Utero (MIU) or foetal mortality defined as Intentional abortion, or the removal of the foetus in the womb before 20 weeks of pregnancy; Spontaneous	YES – NO If yes, type • IA

Abortion (SA), the loss of the foetus up to and including 20 weeks of pregnancy and Intrauterine Foetal Death (IUFD) or stillbirth: loss of a baby after 20 weeks of pregnancy but before birth.	• SA • IUFD
Reason intentional abortion	(description as string variabele)
Reason Spontaneous Abortus	(description as string variabele)
Reason Intra-Uterine foetal death	(description as string variabele)
Intra-Uterine Growth Restriction (IUGR)	YES – NO
Premature Birth	YES – NO
Premature Birth Reason Prematuur	Nee/spontaneous/iatrogenic (CS or induction)
Admission to NICU	YES – NO
Neonatology admission	YES – NO
Neonate admission duration (Los)	…dagen
APGAR-score	.../10
Birth weight	… gram
Neonatal mortality: according to WHO classification mortality up to 28 days after birth	YES – NO

6.4 Appendix 4: Patient-reported outcomes and experience measures

Maternal Satisfaction with care Questionnaire

The first two statements are about care during your pregnancy. Answer with 'Yes' or 'No' and tick the corresponding circle.

		Yes	N0
1	I had already seen an independent midwife during my pregnancy for further care at home (after delivery).	0	0
2	I was aware of the length of stay in the maternity unit (after delivery) during my pregnancy.	0	0

The following statements measure your overall satisfaction with the care given during your pregnancy and during labour and delivery. Indicate to what extent you agree with each statement. Tick the appropriate circle: 'Totally disagree', 'Disagree', 'Neutral', 'Agree' or 'Totally agree'.

		Totally disagree	Disagree	Neutral	Agree	Totally agree
3	I am satisfied with the prenatal preparation/care.	0	0	0	0	0
4	I am satisfied with the care I received during labour.	0	0	0	0	0
5	I am satisfied with the care I received during labour.	0	0	0	0	0

Stas A, Breugelmans M, Geerinck L, Spinnoy A, Van Laere S, Gucciardo L, et al. Maternal satisfaction with reduced postnatal length of stay in Brussels: evidence from the KOZI&Home program. BMC Pregnancy Childbirth. 2023;23(1):475

The following statements are about satisfaction with your stay at the maternity department.

		Totally disagree	Disagree	Neutral	Agree	Totally agree
6	I am satisfied with my stay in the maternity ward after giving birth.	0	0	0	0	0
7	The care at this hospital could not be better.	0	0	0	0	0
8	The midwives spent enough time with me to teach me how to take care of myself.	0	0	0	0	0
9	The midwives spent enough time with me to teach me how to take care of the baby.	0	0	0	0	0
10	The midwives spent enough time with me to meet my emotional needs.	0	0	0	0	0
11	The information given by different healthcare providers about self-care and caring for my baby was similar.	0	0	0	0	0
12	All my questions about how to take care of myself were answered.	0	0	0	0	0
13	All my questions about caring for my baby were answered.	0	0	0	0	0
14	My maternity room was comfortable and suited my needs.	0	0	0	0	0
15	My room in the maternity ward was suitable for visiting family and/or friends.	0	0	0	0	0
16	I stayed in a clean and tidy environment.	0	0	0	0	0
17	Running the household was not difficult for me.	0	0	0	0	0
18	Meal preparation was not time consuming.	0	0	0	0	0
19	I had enough rest during my maternity leave.	0	0	0	0	0
20	Caregivers* respected my privacy during care. **e.g. midwife, nurse, physiotherapist*	0	0	0	0	0
21	The cleaning staff respected my privacy.	0	0	0	0	0
22	I am satisfied with the number of hospital staff* who came to my room during my maternity stay.**e.g. midwife, gynaecologist,*	0	0	0	0	0

MSQ Stas A, Breugelmans M, Geerinck L, Spinnoy A, Van Laere S, Gucciardo L, et al. Maternal satisfaction with reduced postnatal length of stay in Brussels: evidence from the KOZI&Home program. BMC Pregnancy Childbirth. 2023;23(1):475

	paediatrician, physiotherapist, cleaning lady, logistics assistant, dietician					
23	I am ready to go home and look after myself and the baby.	0	0	0	0	0

The following statements are about breast or bottle feeding. Indicate to what extent you agree with each statement and tick the corresponding circle.

		Totally disagree	Disagree	Neutral	Agree	Totally agree
24	I can tell if my baby is getting enough milk.	0	0	0	0	0
25	I can breastfeed or bottle feed successfully.	0	0	0	0	0
26	I am happy with my current breastfeeding or bottle-feeding situation.	0	0	0	0	0
27	I can breastfeed or bottle feed my baby despite his/her crying.	0	0	0	0	0
28	I can tell when my baby is finished breastfeeding or bottle feeding.	0	0	0	0	0

29	Are you breastfeeding?	☐ Yes, I breastfeed exclusively or combine breast and bottle feeding. -> go on to **question 30**
		☐ No, I have never breastfed -> go to **question 39**
		☐ No, I have stopped breastfeeding. Please fill in the reason below and then go to **question 39**

	Please enter the reason(s) why you stopped breastfeeding (multiple answers possible):	☐ Sore nipples ☐ Too exhausting ☐ My baby was losing weight ☐ Breast infection ☐ I didn't want to pump ☐ My baby would not drink ☐ I didn't have enough milk ☐ My baby was sick ☐ I underwent breast surgery ☐ Lack of support (caregivers/partner/family) ☐ I wanted to go on a diet ☐ Because of medication ☐ I wanted to smoke and/or drink alcohol ☐ I was ill ☐ Other reason, namely:.....

MSQ Stas A, Breugelmans M, Geerinck L, Spinnoy A, Van Laere S, Gucciardo L, et al. Maternal satisfaction with reduced postnatal length of stay in Brussels: evidence from the KOZI&Home program. BMC Pregnancy Childbirth. 2023;23(1):475

	To what extent do you agree with the following statements:	Totally disagree	Disagree	Neutral	Agree	Totally agree
30	I can breastfeed without supplementing formula.	0	0	0	0	0
31	I know that my baby is latching on well throughout the feeding.	0	0	0	0	0
32	I want to continue breastfeeding.	0	0	0	0	0
33	I am comfortable breastfeeding in front of my family.	0	0	0	0	0
34	I am satisfied with my breastfeeding experience.	0	0	0	0	0
35	I can cope with the fact that my breastfeeding can be time consuming.	0	0	0	0	0
36	I know when my baby has finished at one breast before I switch to the other.	0	0	0	0	0
37	I can continue to breastfeed at each feeding.	0	0	0	0	0
38	I can meet my baby's feeding needs.	0	0	0	0	0

	The last statements are about your satisfaction with breastfeeding or bottle feeding:	Totally disagree	Disagree	Neutral	Agree	Totally agree
39	I am satisfied with the support at the maternity unit for feeding my baby.	0	0	0	0	0
40	The midwives had enough time to help me feed my baby.	0	0	0	0	0
41	The information I received from different midwives about breast and/or bottle feeding was similar.	0	0	0	0	0
42	The midwives were able to answer all my questions about breast and/or bottle feeding.	0	0	0	0	0

43. This questionnaire was completed by:

- ☐ Myself
- ☐ My partner
- ☐ My family
- ☐ A translator/mediator

Mother-Infant Bonding Scale

These questions probe your thoughts and feelings towards your newborn baby. Please tick only one box that best reflects how you feel.

	VERY MUCH	A LOT	A LITTLE	NOT AT ALL
Loving	**0**	**0**	**0**	**0**
Resentful	**0**	**0**	**0**	**0**
Neutral or felt nothing	**0**	**0**	**0**	**0**
Joyful	**0**	**0**	**0**	**0**
Dislike	**0**	**0**	**0**	**0**
Protective	**0**	**0**	**0**	**0**
Disappointed	**0**	**0**	**0**	**0**
Aggressive	**0**	**0**	**0**	**0**

Date of birth of baby: Date form filled in:

Taylor A, Atkins R, Kumar R, Adams D, Glover V. A new Mother-to-Infant Bonding Scale: links with early maternal mood. Arch Womens Ment Health. 2005;8(1):45-51.

Postpartum Bonding Questionnaire

Indicate how often the following thoughts occur for you right now. There are no 'right' or 'wrong' answers. Tick the box that most closely matches how you are feeling at the moment:

		Always	Very often	Quite often	Some times	Rarely	Never
1	I feel close to my baby	0	0	0	0	0	0
2	I wish the old days when I had no baby would come back	0	0	0	0	0	0
3	I feel distant from my baby	0	0	0	0	0	0
4	I love to cuddle my baby	0	0	0	0	0	0
5	I regret having this baby	0	0	0	0	0	0
6	The baby does not seem to be mine	0	0	0	0	0	0
7	My baby winds me up	0	0	0	0	0	0
8	I love my baby to bits	0	0	0	0	0	0
9	I feel happy when my baby smiles or laughs	0	0	0	0	0	0
10	My baby irritates me	0	0	0	0	0	0
11	I enjoy playing with my baby	0	0	0	0	0	0
12	My baby cries too much	0	0	0	0	0	0
13	I feel trapped as a mother	0	0	0	0	0	0
14	I feel angry with my baby	0	0	0	0	0	0
15	I resent my baby	0	0	0	0	0	0
16	My baby is the most beautiful baby in the world	0	0	0	0	0	0
17	I wish my baby would somehow go away	0	0	0	0	0	0
18	I have done harmful things to my baby	0	0	0	0	0	0
19	My baby makes me feel anxious	0	0	0	0	0	0
20	I am afraid of my baby	0	0	0	0	0	0
21	My baby annoys me	0	0	0	0	0	0
22	I feel confident when caring for my baby	0	0	0	0	0	0
23	I feel the only solution is for someone else to look after my baby	0	0	0	0	0	0
24	I feel like hurting my baby	0	0	0	0	0	0
25	My baby is easily comforted	0	0	0	0	0	0

Brockington IF, Fraser C, Wilson D. The Postpartum Bonding Questionnaire: a validation. Arch Womens Ment Health. 2006;9(5):233-42.

Generalised Anxiety Disorder Assessment 7

Over the last 2 weeks, how often have you been bothered by any of the following problems?

		Not at all	Several days	More than half the days	Nearly every day
1	Feeling nervous, anxious or on edge	0	1	2	3
2	Not being able to stop or control worrying	0	1	2	3
3	Worrying too much about different things	0	1	2	3
4	Trouble relaxing	0	1	2	3
5	Being so restless that it is hard to sit still	0	1	2	3
6	Becoming easily annoyed or irritable	0	1	2	3
7	Feeling afraid as if something awful might happen	0	1	2	3

Brockington IF, Fraser C, Wilson D. The Postpartum Bonding Questionnaire: a validation. Arch Womens Ment Health. 2006;9(5):233-42.

Whooley

Indicate, by colouring the appropriate circle, whether the following things did (Yes) or did not (No) apply to you in the past month:

	Yes	No
During the past month have you often been bothered by feeling down, depressed or hopeless?	0	0
During the past month have you often been bothered by little interest or pleasure in doing things?	0	0

Whooley, M.A., Avins, A.L., Miranda, J. & Browner, W.S. (1997) *Case-finding instruments for depression. Two questions are as good as many*. J Gen Intern Med, 12(7), 439-45

Edinburgh Postnatal Depression Scale

As you are pregnant or have recently had a baby, we would like to know how you are feeling. Please check the answer that comes closest to how you have felt **IN THE PAST 7 DAYS**, not just how you feel today.

Here is an example, already completed.

I have felt happy:

☐ Yes, all the time

☒ Yes, most of the time This would mean: "I have felt happy most of the time" during the past week. ☐ No, not very often Please complete the other questions in the same way. ☐ No, not at all

In the past 7 days:

1. I have been able to laugh and see the funny side of things
   - ☐ As much as I always could
   - ☐ Not quite so much now
   - ☐ Definitely not so much now
   - ☐ Not at all

2. I have looked forward with enjoyment to things ☐ As much as I ever did
   - ☐ Rather less than I used to
   - ☐ Definitely less than I used to
   - ☐ Hardly at all

*3. I have blamed myself unnecessarily when things went wrong
   - ☐ Yes, most of the time
   - ☐ Yes, some of the time
   - ☐ Not very often
   - ☐ No, never

4. I have been anxious or worried for no good reason
   - ☐ No, not at all
   - ☐ Hardly ever
   - ☐ Yes, sometimes
   - ☐ Yes, very often

*5 I have felt scared or panicky for no very good reason
   - ☐ Yes, quite a lot
   - ☐ Yes, sometimes
   - ☐ No, not much
   - ☐ No, not at all

*6. Things have been getting on top of me
   - ☐ Yes, most of the time I haven't been able to cope at all
   - ☐ Yes, sometimes I haven't been coping as well as usual
   - ☐ No, most of the time I have coped quite well
   - ☐ No, I have been coping as well as ever

*7 I have been so unhappy that I have had difficulty sleeping
   - ☐ Yes, most of the time
   - ☐ Yes, sometimes ☐ Not very often
   - ☐ No, not at all

*8 I have felt sad or miserable
   - ☐ Yes, most of the time
   - ☐ Yes, quite often
   - ☐ Not very often ☐ No, not at all

*9 I have been so unhappy that I have been crying
   - ☐ Yes, most of the time
   - ☐ Yes, quite often
   - ☐ Only occasionally ☐ No, never

*10 The thought of harming myself has occurred to me
   - ☐ Yes, quite often
   - ☐ Sometimes
   - ☐ Hardly ever
   - ☐ Never

Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression. Development of the 10-item Edinburgh Postnatal Depression Scale. Br J Psychiatry. 1987 Jun;150:782-6. doi: 10.1192/bjp.150.6.782. PMID: 3651732.

Mothers' Autonomy on Decision Making

This part of the questionnaire focuses on the autonomy you experienced when talking to your healthcare provider during perinatal care. Perinatal concerns refers to the period beginning at the twenty-second week of pregnancy until the seventh day after birth.

To answer this questionnaire, we ask you to draw on your conversations with your doctor and/or midwife about the different care options you were offered (e.g.: antenatal tests, start of labour, relaxation during labour, medication, place of delivery, mode of delivery (vaginal or caesarean, care of newborn, feeding of newborn ...). Because in Belgium perinatal care is carried out by different healthcare providers, you have the choice to answer this questionnaire individually several times (up to a maximum of 3 times).

My answers describe my conversations or experiences with:

- ☐ My GP
- ☐ My obstetrician/gynaecologist
- ☐ My midwife

Describe your experiences of making decisions during your pregnancy, labour and/or delivery.

		Completely disagree	Strongly disagree	Somewhat disagree	Somewhat agree	Strongly agree	Completely agree
1	My GP/obstetrician/gynaecologist asked me how involved in decision making I wanted to be	0	0	0	0	0	0
2	My GP/obstetrician/gynaecologist told me that there are different options for my maternity care	0	0	0	0	0	0
3	My GP/obstetrician/gynaecologist explained the advantages and disadvantages of the maternity care options	0	0	0	0	0	0
4	My GP/obstetrician/gynaecologist helped me understand all the information	0	0	0	0	0	0
5	I was given enough time to thoroughly consider the different maternity care options	0	0	0	0	0	0

Vedam S, Stoll K, Martin K, Rubashkin N, Partridge S, Thordarson D, et al. The Mother's Autonomy in Decision Making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. PLoS One. 2017;12(2):e0171804

6	I was able to choose what I considered to be the best care options	0	0	0	0	0	0
7	My GP/obstetrician/gynaecologist respected that choice	0	0	0	0	0	0

Vedam S, Stoll K, Martin K, Rubashkin N, Partridge S, Thordarson D, et al. The Mother's Autonomy in Decision Making (MADM) scale: Patient-led development and psychometric testing of a new instrument to evaluate experience of maternity care. PLoS One. 2017;12(2):e0171804

Oslo Social Support Scale

Indicate what applies to you at this time:

1	How many people are so close to you that you can count on them if you have great personal problems?	None	1-2	3-5	5+	x
2	How much interest and concern do people show in what you do?	None	Little	Uncertain	Some	A lot
3	How easy is it to get practical help from neighbours if you should need it?	Very difficult	Difficult	Possible	Easy	Very easy

Kocalevent RD, Berg L, Beutel ME, Hinz A, Zenger M, Härter M, et al. Social support in the general population: standardization of the Oslo social support scale (OSSS-3). BMC Psychol. 2018;6(1):31

Pregnancy-Related Empowerment Scale

Please read each statement and then choose the response that best describes how you feel.
"Health care provider" refers to your midwife, doctor, or other health care provider.

1.	I can ask my health care provider about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
2.	I have enough time with my health care provider to discuss my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
3.	My health care provider listens to me.	Strongly Disagree	Disagree	Agree	Strongly Agree
4.	My health care provider respects me.	Strongly Disagree	Disagree	Agree	Strongly Agree
5.	I expect my health care provider to respect my decisions about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
6.	My health care provider respects my decision, even if it is different than her/his recommendation.	Strongly Disagree	Disagree	Agree	Strongly Agree
7.	I take responsibility for the decisions I make about my pregnancy like eating healthy food.	Strongly Disagree	Disagree	Agree	Strongly Agree

Klima CS, Vonderheid SC, Norr KF, Park CG, editors. Development of the Pregnancy-related Empowerment Scale2015.

8. I can tell when I have made a good health choice.	Strongly Disagree	Disagree	Agree	Strongly Agree
9. Since I began prenatal care, I have been making more decisions about my health.	Strongly Disagree	Disagree	Agree	Strongly Agree
10. Women need to share experiences with other women when they are pregnant.	Strongly Disagree	Disagree	Agree	Strongly Agree
11. I share my feelings and experiences with other women.	Strongly Disagree	Disagree	Agree	Strongly Agree
12. I know if I am gaining the right amount of weight during my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
13. I have a right to ask questions when I don't understand something about my pregnancy.	Strongly Disagree	Disagree	Agree	Strongly Agree
14. I am able to change things in my life that are not healthy for me.	Strongly Disagree	Disagree	Agree	Strongly Agree
15. I am doing what I can to have a healthy baby.	Strongly Disagree	Disagree	Agree	Strongly Agree
16. If something is going wrong in my pregnancy, I know who to talk to.	Strongly Disagree	Disagree	Agree	Strongly Agree

Klima CS, Vonderheid SC, Norr KF, Park CG, editors. Development of the Pregnancy-related Empowerment Scale2015.

Klima CS, Vonderheid SC, Norr KF, Park CG, editors. Development of the Pregnancy-related Empowerment Scale2015.