

BMJ Open Prevalence of maternal psychological disorders after immediate postpartum haemorrhage: a repeated cross-sectional study - the PSYCHE* study protocol

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ABSTRACT

Introduction The main objective of this study is to assess the prevalence of depression at 2, 6 and 12 months postpartum in women who have had an immediate postpartum haemorrhage (PPH) (blood loss ≥ 500 mL within 24 hours of delivery). The secondary objectives are to assess the prevalence of anxiety and post-traumatic stress disorder among these women and to evaluate the prevalence of psychological disorders according to the severity of the PPH.

Methods and analysis This repeated, cross-sectional, single-centre study will take place at the Clermont-Ferrand University Hospital (France). The population will comprise a cohort of women giving birth at a term ≥ 22 weeks of gestation.

For each woman with a PPH (exposed), two women without PPH (unexposed) will be included: the women who give birth immediately before and immediately after her. The PPH will be managed according to French guidelines. The principal endpoint is the prevalence of depression, measured by the Edinburgh Postnatal Depression Scale (EPDS). The intervention will consist of four surveys including various self-completed questionnaires: the first during the immediate postpartum (Post-Delivery Perceived Stress Inventory (PDPSI), Spielberger's State-Trait Anxiety Inventory (STAI)-Y-A and Y-B and Mini-International Neuropsychiatric Interview (M.I.N.I.) 5.0.0), then at 2 months (EPDS, STAI-Y-A, Generalised Anxiety Disorder (GAD-7) and Revised Impact of Event Scale (IES-R)), and finally at 6 months and 1 year postpartum (EPDS, STAI-Y-A, GAD-7, M.I.N.I. 5.0.0 and IES-R). The study will include 1542 women — 514 with PPH.

Ethics and dissemination The institutional review board (IRB) approved the study on 14 February 2017 (IRB Sud Est VI: N°AU1243).

Results will be reported in peer-reviewed journals and at scientific meetings. Findings from the study will be useful for individualising medical follow-up after childbirth, especially for woman who experienced a PPH, but also more generally in increasing birth professionals' awareness of effects of trauma. The evidence obtained might also lead to modifying practices and including this recommendation in French guidelines on PPH.

Trial registration number NCT03120208.

Strengths and limitations of this study

- The study will include a large number of women who will be followed up for 1 year (514 exposed women with postpartum haemorrhage (PPH) and 1028 non-exposed with no PPH).
- Women from both groups will complete each questionnaire at the same times relative to delivery (at inclusion, and 2, 6 and 12 months afterwards).
- The main limitation of this single-centre study based on self-administered questionnaires may be a high non-response rate, especially among the unexposed women; for this reason, we are including two unexposed women for each exposed woman.

INTRODUCTION

Background and rationale

During the postnatal period, women may develop psychological disorders that can range in severity from 'baby blues' (15% to 80% of women) to postpartum depression to puerperal psychosis.^{1–18} The prevalence of postpartum depression in the general population has been estimated to vary from 10% to 20%.^{9–16} In France, studies have reported a prevalence of 17%.^{19–20} Studies that have measured postpartum post-traumatic stress disorder (PTSD) observed a mean prevalence of 4.0% (95% CI 2.77 to 5.71) in community samples and a prevalence of 18.5% (95% CI 10.6 to 30.38) after birth for women in high-risk groups.^{21–26} The estimates of prevalence of anxiety during this period range from 8.7% to 40.4%.^{27–29}

Studies have shown that postpartum risks of onset of depression, post-traumatic stress and anxiety are higher among women whose pregnancy included obstetrical complications, compared with women with uneventful pregnancies.^{21–24 30} Other studies have shown that caesarean and operative vaginal

deliveries increase the risk of depression and post-traumatic stress.^{12 23 25 31}

A history of psychiatric disease or psychological disorders before the pregnancy is also a risk factor for both postpartum depression and post-traumatic stress disorder.^{32 33} Inversely, for women with normal deliveries, the risk of post-traumatic stress is lower when the woman feels that she was supported during the delivery by the healthcare team and her partner and that she was able to control the management of her labour.²²

Immediate postpartum haemorrhage (PPH) concerns around 3.4% of vaginal deliveries (≥ 500 mL) and 2.8% of caesareans (≥ 1000 mL) in France, where it is the leading cause of maternal death.^{34 35} According to the 2014 French guidelines, PPH is defined by blood loss ≥ 500 mL in the first 24 hours after birth, regardless of mode of delivery.³⁵ Management of severe PPH can require procedures that are medical (blood transfusion) or surgical (arterial ligation, emergency hysterectomy, etc) or involve interventional radiology.³⁵ These potential serious consequences of PPH may lead to a higher rate of psychological disorders in these women than in those without PPH. However, current French guidelines do not raise the issue of potential psychological disorders after PPH nor do they recommend their screening and their management for women with PPH.

Few published studies have examined the psychological impact of immediate PPH.^{36–38} One study interviewed women by telephone,³⁷ and two others sent women self-administered questionnaires by email at both 2 and 4 months postpartum, with individual telephone reminders if they failed to respond.^{35–38} These studies present methodological problems including the use of questionnaires that have not been validated in English or in French,^{36 37} the retrospective nature of the studies³⁷ and the large number of women lost to follow-up, information bias (women not all interviewed at the same intervals after delivery), recall bias, small sample size, failure to adjust for antenatal risk factors known to affect postpartum depression, PTSD or anxiety.^{36–38} One study included only women with vascular embolisation,³⁷ while another multicentre study considered only women who had lost >1500 mL blood or had a haemoglobin concentration of 7 g/dL or a drop in the haemoglobin concentration of 4 g/dL or more in postpartum,³⁸ that is, only women with severe PPH, rather than all PPH. The studies were also limited to a shorter postpartum period (4 months for Thompson *et al*).^{36–38} Clinicians with relevant expertise recommend that these assessments also be performed at 6 months and 1 year.^{9 10}

Objectives

The main objective of our study is to assess the prevalence of depression at 2, 6 and 12 months postpartum among women with an immediate PPH.

Secondary objectives are to assess, at the same intervals, the prevalence (and severity) of anxiety and PTSD, as well as the prevalence (and severity) of depression according

to the severity of the haemorrhage (mild-moderate PPH: 500 mL to <1000 mL, compared with severe PPH, defined as ≥ 1000 mL) and according to the specific types of 'second-line' medical management (transfusion, vascular embolisation, etc). The trends in the prevalence of depression over the three study periods will be analysed.

METHODS AND ANALYSIS

Status of ongoing study

This protocol is Version 9, as modified on 27 July 2016. The study began in April 2017 after it received all authorisations necessary under French law. The recruitment period should be ended before December 2019. See the trial registration data for all registration details (table 1). This PSYCHE protocol has followed published guidelines for cross-sectional studies (STROBE 2007-V4 Checklist).

Study design

This repeated, cross-sectional, descriptive and aetiological study will take place within a cohort of women giving birth, comparing each woman with a PPH (exposed) to two women without PPH (unexposed).

Setting

This is a single-centre study, performed at the University Hospital Centre in Clermont-Ferrand, France.

Participants

Women are eligible for inclusion regardless of parity and mode of delivery (vaginal or caesarean) if they give birth at a term ≥ 22 weeks' gestation or, if the term is unknown, to a fetus with a birth weight ≥ 500 g, and they are covered by the French health insurance fund (CNAMTS). Women will be excluded if they are younger than 18 years, do not understand French, refuse to participate or do not give birth at the Clermont-Ferrand University Hospital Centre Maternity Unit but are instead secondarily transferred postpartum. This term corresponds to the definition of viability according to both WHO and the French Clinical Practice Guidelines. We chose not to exclude the women with very preterm births so that our sample would be as representative as possible of the general population of women giving birth in French hospitals. Moreover, in light of the overall number of women in our study (1542 women will be included), these women should account for a small minority of the cases.

The exposed women will be those with an immediate PPH (defined as a blood loss ≥ 500 mL during the 24 hours after birth) after a vaginal or caesarean delivery. The non-exposed women will be those without an immediate PPH.

Patient and public involvement

No patients or public members were involved in the development of the research question, the study design or recruitment or outcome measures. The questionnaires were pilot tested among women in advance. We ensured the clarity and acceptability (filling time) of the

Table 1 Trial registration data for the PSYCHE study

Data category	Information
Primary registry and trial identifying number	ClinicalTrials.gov NCT 03120208
Date of registration in primary registry	27 April 2017
Secondary identifying numbers	AU 1243, 2016-A00092-49, 160 123B-22
Source of monetary or material support	The Clermont-Ferrand University Hospital (AOI 2015)
Primary sponsor	Délégation de la Recherche Clinique, Centre Hospitalier Universitaire de Clermont-Ferrand
Secondary sponsor(s)	NA
Contact for public queries	m_julien@chu-clermontferrand.fr
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Public title	Prevalence of psychological disorders after immediate postpartum haemorrhage: the PSYCHE study protocol
Scientific title	Prevalence of psychological disorders after immediate postpartum haemorrhage: the PSYCHE study protocol
Countries of recruitment	France
Health condition(s) or problem(s) studied	Postpartum, psychological disorders
Intervention(s)	Exposed group: woman with a PPH Unexposed group: women without PPH Ages eligible for study: ≥18 years Sexes eligible for study: Female Accepts healthy volunteers: Yes
Key inclusion and exclusion criteria	Inclusion criteria: <ul style="list-style-type: none"> ▶ Woman who gave birth at a term ≥22 weeks of gestation or, if the term is unknown, to a fetus with a birth weight ≥500 g, ▶ regardless of the type of delivery (vaginal or caesarean), ▶ regardless of parity and fetal presentation, ▶ and regardless of type of pregnancy (singleton or multiple). Patient affiliated with French CNAMTS (salaried worker) health insurance. Exclusion criteria: <ul style="list-style-type: none"> ▶ Woman who gave birth before 22 weeks of gestation (<22 weeks) (or if unavailable, with a birth weight <500 g), ▶ Woman who does not understand French, ▶ who refuses to participate (did not sign consent). ▶ Minor (<18 years old). ▶ Patient who gave birth outside this UHC and was transferred here secondarily in the postpartum.
Study type	Repeated, cross-sectional, descriptive and etiological study
Date of first enrolment	April 2017
Target sample size	1542
Recruitment status	Currently recruiting
Primary outcome(s)	The prevalence of depression at 2 months, 6 months and 1 year postpartum in women who had an immediate postpartum haemorrhage.
Key secondary outcomes	The prevalence of depression, anxiety and post-traumatic stress according to the severity of the haemorrhage (mild-moderate PPH: 500 mL to <1000 mL, compared with severe PPH, defined as ≥1000 mL) and according to the specific 'second-line' medical management (transfusion, vascular embolisation, etc). The severity of depression and anxiety will be compared between women with mild-to-moderate PPH and those with severe PPH, and the severity of depression among women with a PPH requiring a second-order medical intervention.

PPH, postpartum haemorrhage; UHC, University Hospital Center.

questionnaires by administering it to 10 women. This pretest showed no difficulties in understanding and no adaptations were therefore required. The results of this trial will be disseminated by publication in international peer-reviewed scientific journals and by presentations at international and domestic conferences. If the trial results warrant changes in the standard treatment

of immediate postpartum haemorrhage, this trial will assist the implementation of a new standard of care in our maternity unit to improve systematic screening of women with psychological needs and ensure they receive adequate management of any psychological problems after delivery and after discharge. It might also provide evidence to influence the standard of care

and guidelines for PPH management, in France and elsewhere.

Variables

For our primary outcome, the prevalence of depression, we will use the Edinburgh Postnatal Depression Scale (EPDS) to detect and quantify depressive symptoms in the postpartum period (with a discrimination threshold ≥ 11),³⁹ together with the Mini-International Neuropsychiatric Interview (M.I.N.I.) 5.0.0, which studies the principal Axis 1 psychiatric disorders of Diagnostic and Statistical Manual of Mental Disorders, Fourth edition (DSM-IV) (American Psychiatric Association), including depression.⁴⁰

The study will also use Spielberger's State-Trait Anxiety Inventory (STAI-Y), which enables the evaluation of anxiety as a personality trait (form Y-B, discrimination threshold ≥ 48) and anxiety as an emotional state linked to a particular event (form Y-A, discrimination threshold ≥ 46)^{41 42}; the Generalised Anxiety Disorder (GAD-7 scale, with seven items and a discrimination threshold ≥ 10), which enables screening for generalised anxiety and the measurement of its severity^{43–45} and the Revised Impact of Event Scale (IES-R) (with a discrimination threshold ≥ 30), created by Weiss and Marmar (1997)⁴⁶ to assess the presence of traumatic stress linked to violent events. IES-R is able to differentiate subjects with acute stress from those with post-traumatic stress.^{47 48} The stress perceived by women at delivery in the immediate postpartum period will be assessed by the post-delivery perceived stress inventory (PDPSI).^{44 47 49} Other relevant individual, social and medical covariables, especially useful as confounding and especially prognostic factors for the study, will be extracted from the electronic medical file. These include history of depression, anxiolytic treatment before delivery, psychological or psychiatric care before, during and after delivery, type of delivery, gestational age at birth and the child's status at birth, etc. The women's family situation will be known from their individual medical files, so that we will be able to adjust our results according to parity and the number of children already in the home.

Blood loss will be estimated quantitatively with a collector bag for vaginal deliveries and by the aspiration and weighing of blood in used supplies for caesareans, as usual in our maternity unit. The PPH will be managed according to the most recent national guidelines, issued in December 2014.³⁵

Data sources/measurement

The study will use scales validated in the general population and in French for the measurement of psychological status (figure 1).^{39–49} The intervention will consist of surveys conducted by self-administered questionnaires in the immediate postpartum and at 2, 6 and 12 months postpartum (figure 1). Completion of each questionnaire takes approximately 20 min, and the women will have only four questionnaires, distributed over a full year. The women are clearly informed of this timing at inclusion

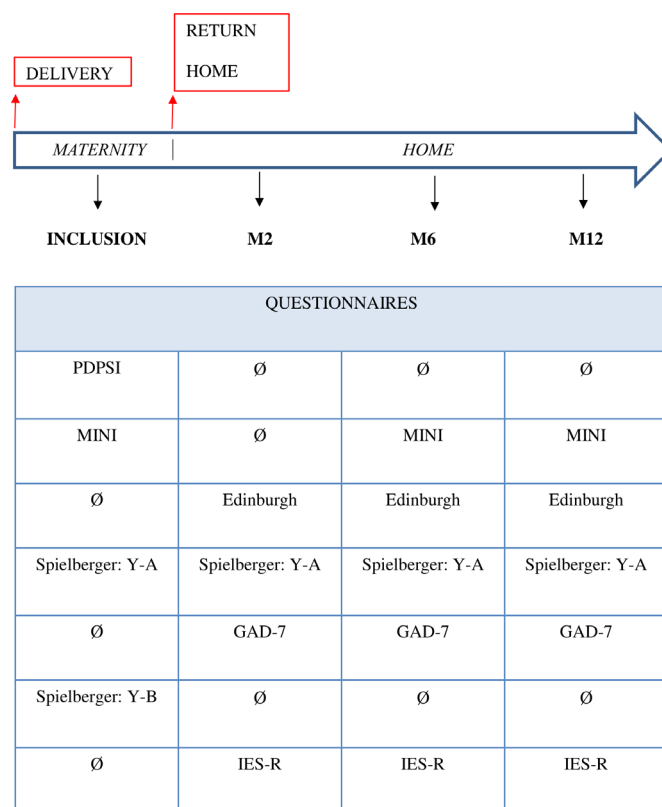


Figure 1 Schedule of enrolment, interventions and assessments of women for the PSYCHE study. GAD, Generalised Anxiety Disorder; IES-R, Revised Impact of Event Scale; M, month; MINI, Mini-International Neuropsychiatric Interview; PDPSI, post-delivery perceived stress inventory.

and can refuse to participate if it seems too difficult to them. These are multiple-choice questionnaires and accessible and quick to complete, since they require no writing. They can all be completed directly online and can be stopped and continued later, at a more convenient moment. We have attempted to facilitate as much as possible for the completion of the questionnaires.

For each woman with a PPH (exposed), the study will include two women without PPH (unexposed): the eligible women who gave birth immediately before and immediately after her. If one of these two unexposed women refuses to participate, another woman immediately just before or after them will be included.

Information and inclusion will take place in the immediate postpartum period at the Clermont-Ferrand University Hospital Centre, France. An investigator (midwife or obstetrician) will inform eligible women about the study. This investigator will provide them with a written information sheet and obtain their written consent before their discharge. The women of the cohort will complete each questionnaire at the same interval after their date of delivery (immediate postpartum, and 2, 6 and 12 months afterwards). They will receive an email asking them to complete the questionnaires, including a participation number and an internet link to the self-administered online questionnaires. Should the questionnaire identify

a woman in need of immediate psychological care, that is, find any test score above the thresholds listed above, she will be immediately contacted by phone by the research midwife and encouraged to consult a competent professional (psychologist, psychiatrist, etc) at our hospital who is aware of this research protocol and willing to see these women.

Bias

To avoid coercion and reduce selection bias, the investigator who will be asking women to participate will not be involved in her direct care. To limit information bias, the patients will complete each questionnaire at the same intervals after delivery (immediate postpartum, 2, 6 and 12 months). The self-administered questionnaires (all validated in French) will be used under the same conditions in which they were validated. Because it is important to take women's anxious personality traits (trait anxiety) before delivery into account, STAI form Y-B will be completed at inclusion.

Study size

For a power of 90%, with a two-sided alpha of 5% and two unexposed subjects for each exposed subject, and according to the Australian study by Thompson *et al* (2011),³⁸ which found a depression rate of 10% in unexposed and 16% in exposed women at 4 months postpartum, this study requires 1028 women in the unexposed group, with no haemorrhage, and 514 women in exposed group with a haemorrhage. We have chosen this ratio because we think that we are likely to have a substantial rate of loss to follow-up among the unexposed women. A total of 1542 women must therefore be included.

Statistical methods

Quantitative variables will be expressed by their means \pm SD or by categorical variables, as appropriate.

The participation and refusal rates will be calculated at each survey point, together with the prevalence of the psychological states studied. Some women will be lost to follow-up at the month 6 and month 12 surveys. These women will be included in the crude descriptive analyses, and population lost to follow-up will be compared with the study population to look for possible differences in the principal characteristics studied. We plan to perform an interim analysis to assess the need to adjust the study calendar. This interim analysis will be performed after half of the planned subjects have been included.

The statistical methods used for the crude analyses will be a descriptive analysis of the sample with a comparison of the characteristics of the exposed and unexposed groups. The χ^2 test (or Fisher's exact test when appropriate) will be used to compare the qualitative variables and Student's t-test (or a Mann-Whitney test) for the quantitative variables.

Prevalence rates and their 95% CIs will be calculated at 2, 6 and 12 months. The course of the prevalence rates (and their 95% CI) of depression, anxiety and PTSD at

these points will be compared within each of the three survey periods by a matched χ^2 (or McNemar) test.

A multivariate analysis (logistic regression) will be conducted to take into account confounding factors as well as clinically relevant prognostic factors (for example, history of depression, gestational age at birth, mode of delivery, etc) for depression at each survey time point (at 2 months, 6 months and 1 year). The results will be expressed as adjusted ORs. At the end of the study, another multivariate analysis (generalised linear mixed model) will be performed to study the trends in the prevalence of depression over the three study periods. The missing data will be treated as missing and excluded from the analyses.

ETHICS AND DISSEMINATION

Protocol amendments

Any modifications to the protocol must be characterised as substantial or minor. Substantial modifications must be approved *de novo* by the institutional review board.

Consent

The women will be informed completely and fairly of the objectives and constraints of the study, of any possible risks, of their right to refuse to participate and of their right to withdraw their consent and end their participation at any time. All of this information will be included on the information and consent form provided to the woman. The investigator shall collect each woman's free and informed consent in writing.

Confidentiality

In compliance with French regulations, persons with direct access to the data will take all precautions necessary to ensure the confidentiality of the data concerning women participating in this study. Moreover, the storage of data collected for this study must comply with French guidelines issued by the competent agency (CNIL: National Data Protection Authority—<http://www.cnil.fr>).

The study documents shall be archived on the premises of the PEPRADE research team until the end of their practical utility and then stored in the sponsor's central archives for 15 years. The Clermont-Ferrand University Hospital Centre is the sponsor of this study.

Access to data

At the conclusion of the research, the data collected about the participants will be anonymised before the statistical analysis. Access to the anonymised data will be limited to the two principal investigators.

Dissemination policy

The data will be divulged only after the joint accord of the principal investigator and the sponsor. The results will be the subject of scientific communications and publications. The authorship eligibility will follow the Recommendations for the Conduct, Reporting, Editing and

Publication of Scholarly Work in Medical Journals, 2015 (<http://www.icmje.org>).

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Contributors MP and FV designed the study, wrote the study protocol and obtained the funding for the study. MP is the coordinator-investigator and FV the methodologist and supervisor of MP, a PhD student. All the authors (MP, AL, IDC, PML and FV) wrote and approved the final manuscript.

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Competing interests None declared.

Ethics approval The PSYCHE study protocol (V.9, 2016) was approved by the institutional review board (IRB) on 14 February 2017 (IRB Sud Est VI: N°AU1243), and by the ANSM (National Agency for the Drug and Medical Product Safety) on 03 February 2016 (ID RCB: 2016-A00092-49).

Provenance and peer review Not commissioned; externally peer reviewed.

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