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IROND-L: study protocol for a French prospective, quasi-experimental, multicentre trial to examine the impact of a coordinated multidisciplinary approach for women victims of violence

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ABSTRACT

Background and objectives Violence against women (VAW) is widespread and can have serious physical and mental health consequences, including post-traumatic stress disorder (PTSD) and sleep disorders. Victim-survivors often face barriers in accessing specialised care, highlighting the need for a multidisciplinary response, especially in healthcare settings. The Maison des Femmes (MdF) model provides holistic support to women experiencing VAW, including medical, psychological, social and legal support. The aim of this study is to examine whether the MdF's comprehensive intervention programme offers advantages over standard care in improving mental health indicators, such as PTSD.

Method and analysis Our pragmatic quasi-experimental study uses a non-randomised controlled cluster design. The intervention group comprises women enrolled in MdFs in five French cities, while the comparison group includes women receiving usual care in sociomedical structures located geographically close to MdF centres. Our study aims to recruit 360 women (180 per group), aged 18 years or older, who have experienced intimate partner violence or sexual violence and who seek care at the study centres. The primary analysis will compare the change in PTSD Checklist for DSM-5 (PCL-5) scores over 6 months in the two groups using multivariable linear regression with propensity score adjustment. Secondary outcomes include sleep disorders, quality of life, symptoms of anxiety and depression, self-esteem, sense of safety and well-being, initiation of legal and socioprofessional proceedings, and healthcare utilisation.

Ethics and dissemination The study was approved by the 'Comité de protection des personnes Ile de France III' (CPP Committee for the Protection of Persons Ile de France III; institutional review board on 20 December 2023; Ref no. (Numéro SI): 23.04197.000491).
The results of the study will be communicated via academic publications; easily understandable briefs for a broader public; and proactive involvement with medical institutions, journalists and advocacy groups.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The comprehensive Maison des Femmes model provides a holistic multidisciplinary approach, providing care for women victim of intimate partner violence and sexual violence.
⇒ The lack of randomisation may introduce selection bias, affecting the ability to establish causality between the intervention and outcomes.
⇒ Despite the lack of randomisation, this design allows for a pragmatic evaluation of the real-world effectiveness of the intervention and will facilitate future generalisation.
⇒ Double-blinding is not feasible, but several measures have been taken to prevent bias.

Trial registration number NCT06226818. Version Number 1- february2024.

INTRODUCTION

Violence against women (VAW) is defined by the United Nations as 'any act of gender-based violence that results in, or is likely to result in, physical, sexual or psychological harm or suffering to women, including threats of such acts, coercion or arbitrary deprivation of liberty, whether occurring in public or in private life'.[1] VAW encompasses a range of harmful behaviours that target girls and women, with common manifestations including intimate partner violence (IPV), where harm is inflicted by a current or former partner, and sexual violence, which involves non-consensual sexual acts.[2] Other common forms include physical violence, emotional or psychological abuse, and coercive control.[2]

VAW is widespread and crosses geographic, cultural and socioeconomic boundaries. According to global estimates by the WHO, approximately one in three women worldwide has experienced physical or sexual IPV or non-partner sexual violence in her lifetime.[3] A European Union–wide survey published in 2014 also found that one in three women had experienced some form of physical and/or sexual violence since the age of 15.[4] Around 8% of women in this survey reported experiencing physical and/or sexual violence in the 12 months prior to the survey interview. In France, more than 220 000 women are victims of intimate (ex)partner violence each year,[5] while rape and attempted rape are reported by around 62 000 women and sexual assault by around 553 000 women each year.[6]

One difficulty in measuring the extent of VAW is that the estimate of its prevalence depends on where the survey is conducted and the time horizon chosen. Indeed, a meta-analysis suggests that the prevalence of lifetime VAW is higher in studies recruiting women from the community (31.6%) than in those recruiting participants from clinical settings/with a clinical diagnosis (25.1% and 20.2% for help-seeking and perinatal women, respectively).[7] Interestingly, this study found that the prevalence of having experienced any IPV increased dramatically when considering lifetime (37.7%) rather than the past year (24.2%) was considered.[7]

VAW has a significant impact on the health and well-being of victim-survivors, resulting in a range of physical and mental health outcomes.[8 9]

Women who experience IPV and/or sexual violence are at increased risk of suffering from a range of short-term and long-term physical health problems, including increased physical injuries, traumatic brain injury, chronic conditions and pain, headaches or migraines, and gastrointestinal and gynaecological problems.[8 10 11] Other physical consequences include sexually transmitted infections (STIs), unintended and unwanted pregnancies, and potential complications from unsafe abortions.[12]

The impact of VAW on mental health is also significant, with women presenting with depression, anxiety and post-traumatic stress disorder (PTSD) being, respectively, three, four and seven times more likely to have been exposed to lifetime domestic violence.[13]

A Canadian study published in 2023, based on a sample of 309 women who were followed for 5 years after leaving a violent partner, found that although the women's health improved significantly over time, significant levels of depression, post-traumatic stress symptoms and chronic disabling pain persisted, and there was a correlation between the severity of the violence suffered and the severity of its consequences.[14]

A Spanish study, also conducted in 2023, which surveyed women who had been victims of VAW, found depressive symptoms and anxiety in 73% and 77% of the women, respectively.[15]

The constant fear and trauma associated with living in an abusive environment can lead to a deterioration in mental well-being, affecting a woman's overall quality of life (QoL).

PTSD is a trauma-related disorder that can develop as a result of a traumatic event, such as experiencing sexual violence or other types of interpersonal violence.[16] PTSD is characterised by intrusive thoughts, nightmares and flashbacks of past traumatic events, avoidance of reminders of the traumatic experience, and arousal and reactivity symptoms (hypervigilance, anger, etc.). These disorders lead to significant social, occupational, and interpersonal impairment. People with PTSD also frequently have sleep disorders such as chronic insomnia.

Sleep disorders are also reported to contribute to the maintenance of PTSD which, in turn, exacerbates sleep disorders.[17] Sleep disorders also have deleterious health effects in the short and long term. They are associated with an increased risk of developing physical and psychological adverse outcomes such as chronic disease, depression, anxiety and reduced QoL.[18]

Many women who are victim-survivors of violence face challenges in accessing essential and specific care due to a lack of resources in healthcare centres, particularly specialised and trained health workers.[19 20] Access to care may also be hindered by fear of stigma or further episodes of violence from the perpetrator.[21] These women may also need housing, social support, as well as safety and legal protection, so a multidisciplinary response is needed. This requires coordination within the health system and between the health system and other sectors, such as the social and legal services, to provide holistic care and support.

Some interventions such as advocacy (active support by trained people) may help women victim-survivor make safety plans, deal with violence and access community resources.[22] Additionally, a range of behavioural and cognitive processing therapy –based interventions have been reported to improve mental health of victim-survivors of sexual violence experienced during adulthood.[23] The WHO recommends that care for women experiencing VAW should be multidisciplinary and comprehensive, delivered by trained health or social care providers, tailored to the woman's situation and provided within the healthcare setting.[24]

The 'Maison des Femmes' (MdF) or 'Women's House' is a French medical and social structure specifically dedicated to the care of women who are victims or survivors of violence. The first MdF centre was founded by Dr. Ghada Hatem who specialises in treating women with (female genital mutilation) FGM. It opened in 2016 in the Paris region in the city of Saint-Denis *with a high migrant population*. The MdF provides a holistic and integrated approach to care, streamlining the continuum of care for victim-survivors of VAW and adapting care to meet women's needs. They ensure that women victims of VAW receive multidisciplinary, coordinated and personalised care to optimise their care, improve their overall well-being and empower them.

We conducted a pilot study from July 2020 to June 2021, involving 67 women exposed to VAW in both MdF

and other sociomedical structures. We observed a 60% prevalence of PTSD among participants.[25] Notably, participants in the pilot study provided valuable insights and feedback, which played a crucial role in shaping the design of this subsequent trial.

Although some interventions for women victims of violence have shown positive effects on women's mental health,[26] there are limited data on the effects of holistic multidisciplinary interventions in healthcare settings. Current literature indicates a significant gap in evidence on the effect of trauma-informed interventions on women's sleep disorders.[27]

In order to improve care for women victims of violence around the world, there is a need for robust data demonstrating that specific, tailored and specialised care improves their physical and mental health.

Our study therefore aims to investigate whether the MdF's comprehensive intervention programme has advantages over standard care, particularly in improving health indicators such as PTSD and sleep disturbance in women victim-survivors of VAW.

METHODS

Patient and public involvement

The insights and feedback gathered from participants in the pilot trial played a crucial role in refining and improving the design of the IROND-L trial.

Study design and settings

Figure 1 summarises the design of our study. It employs a pragmatic quasi-experimental approach with a non-randomised controlled cluster trial design. The intervention group consists of women enrolled in MdFs from five cities in France. The comparison group comprises women recruited in sociomedical structures such as municipal health centres or sexual health centres (also known as family planning), where women receive usual care. These centres were recruited through convenience sampling and grouped together in this article under the term 'health centres' (HC).

To minimise bias due to sociodemographic differences, each of the five intervention centres was paired with a control centre strategically located in the same area, but not in the same neighbourhood, to limit the risk of contamination due to potential overlap between the two structures. Although the intervention and control centres do not provide the same services to women victims of violence, and as such a recruitment bias is possible, their proximity maximises the likelihood of comparable sociodemographic characteristics.

The five pairs of MdF and HC are as follows: Mdf and HC of Saint-Denis (Seine Saint Denis), MdF of Paris (Pitié Salpêtrière) and HC of Arcueil (Val de Marne), Mdf and HC of Reims (Marne), MdF and University HC of Marseille (Bouches du Rhône), and MdF of Grenoble and HC of Voiron (Isère).

The pragmatic quasi-experimental approach was chosen to compare two existing models of care where random assignment was not possible. It is the women themselves who decide where their first consultation takes place, regardless of the factors influencing their decision.

Eligibility criteria

Our study will include adult women aged 18 years or older who are victims of VAW. Women will be included if they attend one of the participating centres for any reason and either spontaneously report being exposed to violence or are identified through systematic screening for VAW.

We will determine exposure to violence by assessing positive responses to at least one question on a modified 4-item version of the Abuse Assessment Screen (AAS), which is a standardised screening tool used in both research and clinical settings.[28]

Inclusion criteria also include the ability to understand the aims of the study, to complete the questionnaires, and to give written informed consent to participate in the study. We will not include women who are not affiliated

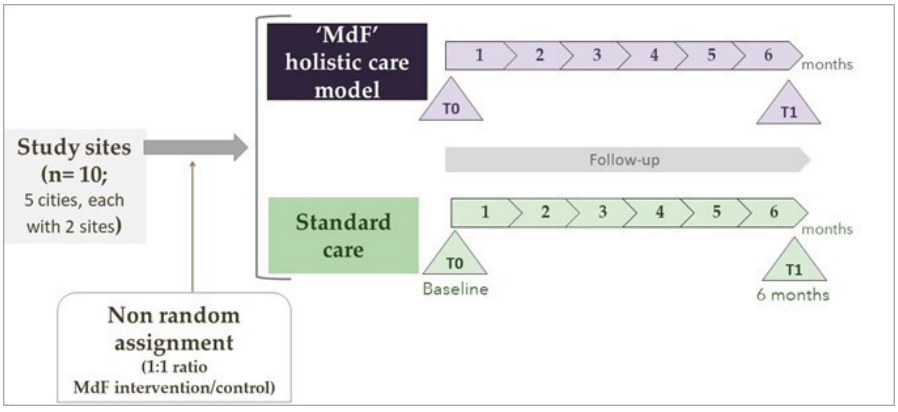

Figure 1 Study design for the French IROND-L trial, a quasi-experimental, multicentre trial to examine the impact of a coordinated multidisciplinary approach for women victims of violence. Non-randomised assignment of participants across 10 sites compares the Maison des Femmes (MdF) holistic care model and standard care over 6 months, with assessments at baseline (T0) and at study completion (T1).

or beneficiaries of social security (as required by French regulations), subject under legal protection (curatorship, guardianship), adults incapable of expressing non-opposition and minors.

Interventions

Intervention group: Maison des Femmes (Mdf)

Participants in the intervention group, consulting in one of the five MdF centres, have access to a comprehensive range of customisable services tailored to meet the diverse needs of women victims of VAW.

MdF care consists of the following elements: (1) medical care with on-site consultations with a physician and/or midwife; (2) consultations (as many sessions as necessary) with a social worker who provides individualised advice on social procedures and refers women to specialised facilities if their return home is at risk; (3) mental healthcare with a specialised psychologist and psychiatrist, with at least 20 sessions over several months; (4) post-trauma assessment by a forensic psychiatrist and preparation of a report, a minimum of 20 sessions over a period of several months; (5) post-trauma assessment by a forensic psychiatrist and preparation of a descriptive report, which is essential for legal proceedings; and (6) legal assistance, with a specialised lawyer on site and referral to a specialised lawyer. It is also possible to receive reconstructive surgery for FGM and to file a complaint with a police officer.

MDFs centres also offer support groups, art workshops, self-defence courses and training for professionals.

Comparison group: health centres (HC)

In these HC, women who report being victims of VAW are informed of their right to file a complaint and are referred to specialised associative, legal and health structures. This approach is considered the 'standard of care' to health professionals by the French High Authority of Health ('Haute Autorité de Santé').[29]

Given the pragmatic nature of our study, which is designed to reflect real-world conditions, participants in both groups will be able to receive all relevant concomitant treatments and interventions during the study trial.

Objectives

All comparisons between the two groups will be made between enrolment and 6-month follow-up visits.

Primary objective. To compare changes in post-traumatic stress between the first visit and 6 months later in women victims of VAW according to whether they were treated in MdF or HC.

Secondary objectives. To compare changes, according to the structure (MdF or HC) where management was initiated, in: (1) presence of sleep disorders; (2) QoL; (3) presence of depressive and anxiety symptoms; (4) women's self-esteem and perception of autonomy, as well as their perception of their own and their children's safety and well-being; (5) legal and (6) socioprofessional proceedings initiated; and (7) use of health services.

Exploratory objectives. We will analyse the modalities of care both qualitatively, in terms of types of treatment, and quantitatively, in terms of the number and duration of interactions.

Outcomes

For primary and secondary outcomes, all comparisons between the two groups will be carried out between the enrolment (M0) and 6-month follow-up visits (M6).

Primary outcome

Change in mean PCL-5 score measured using the validated French version of the PCL-5 (score from 0 to 80).[30]

Secondary outcomes

1. Changes in the proportion (difference between M6 and M0) of women with a PCL-5 score <33 (validated threshold for the absence of overt PTSD).[31]
2. Changes in the proportion of women with sleep disorders according to the Insomnia Severity Index[32] and the Pittsburgh Sleep Quality Index (PSQI) (threshold: global PSQI score >5).[33]
3. Changes in the mean QoL score and the WHO Quality of Life Brief Version scale.[34]
4. Changes in the proportion of women presenting symptoms of anxiety and depression according to the Hospital Anxiety and Depression Scale.[35]
5. Changes in the proportion of women with: low and very low self-esteem (score ≤31, on the Rosenberg self-esteem scale)[36]; a feeling of security and well-being using 5-point Likert scales.
6. Proportion of women who have initiated legal proceedings: divorce or separation, filing for legal custody of children and filing a complaint.
7. The proportion of women who have started a socioprofessional procedure: looking for housing, applying for regularisation and/or employment.
8. The number of emergency visits and other medical and psychological care for women and their children.

Exploratory outcomes

1. Number and type of care activities provided
2. Record of care structures and navigation between them for each enrolled woman.
3. Types of specialised staff (eg, number of people trained in psychotrauma) to care for women who have experienced violence.

Participant timeline

The recruitment phase is estimated to begin in February 2024 and will end after all women from the last study site will have been followed for 6 months. At a given study site, the study may take up to 12 months to complete, depending on the efficiency of the enrolment phase.

Sample size

Our primary outcome, the PCL-5 score, had a mean score of 37.1 (SD=16.1) in the pilot study.[25] Therefore, to achieve 80% power and a 5% (two-tailed) significance level to detect an average difference of 5.5 between the two groups, assuming the SD of the differences is 16, a minimum of 135 women per group is required.

Thus, we need to recruit 180 women per group, 360 in total, with a potential dropout rate of 25%.

Recruitment

Physicians or research assistants will administer a brief pre-inclusion questionnaire to women presenting at one of the participating centres. This questionnaire is designed to assess eligibility, specifically using the AAS tool.

Following the assessment, eligible women will be introduced to the study and provided with comprehensive information, including the nature, objectives, methodology, duration, expected benefits, limitations and foreseeable risks of the study. The investigator will present the patient with an informed consent form detailing the essential aspects of the research.

Eligible women will be given the opportunity to ask any questions they may have about the research and will be informed of their right to refuse to participate or to withdraw from the study at any time without prejudice and without having to justify their decision.

Data collection, management and monitoring

During the enrolment visit, research associates will ask participants to complete an electronic questionnaire, created with *CleanWeb* software and designed to assess primary and secondary outcomes. Additionally, sociodemographic characteristics, substance use patterns, as well as a detailed history of traumatic events and experiences of violence will be collected.

Participants will be invited to return in 6 months for a follow-up visit, or alternatively, they may provide their contact information for a follow-up questionnaire to assess primary and secondary outcomes.

Data entry will be validated in real time by dynamic coherence checks implemented during database construction. A series of queries will be conducted periodically throughout the project by a data manager in coordination with monitoring visits to ensure the coherence of all data. These queries will be repeated iteratively until an error-free database is achieved.

Data storage and archiving will be managed by the *CleanWeb* software hosted by Telemedicine Technologies through its secure internet hosting platform. A copy of the 'csv' format extraction file of the locked database will also be kept on a server at CHU Dijon Bourgogne, protected by a password managed by the data manager.

Statistical methods

For the primary analysis, we will compare the evolution of the average PCL-5 score (difference between M6 and M0) between the two groups (MdF intervention vs control) using multivariable linear regression adjusted for a propensity score. The variables included in the propensity score will be all those related to the socio-demographic, clinical characteristics and history of violence of the patients that significantly affect the likelihood of being cared for in an MdF rather than in a HC, as identified by logistic regression. Second, we will compare the evolution of the proportion (difference between M6 and M0) of women with a PCL-5 score <33 between the two groups by multivariable logistic regression adjusted for the propensity score.

In addition, each secondary outcome (change in the proportion of women with sleep disturbances, change in the mean quality of life score, change in the proportion of women with symptoms of anxiety and depression, change in the proportion of women with low and very low self-esteem and a low sense of security and well-being, change in the proportion of women initiating legal proceedings, change in the proportion of women initiating socio-professional proceedings, and change in the number of visits to emergency and other medical and psychological care for women and their children) will be compared between the two groups (MdF intervention vs control) as follows: for categorical outcomes, through a multivariable logistic regression adjusted for the propensity score, and for continuous outcomes, through a multivariable linear regression adjusted for the propensity score.

Expected impact

The findings of this study can inform policy decisions and healthcare practices, promoting the integration of holistic care strategies for women affected by violence. Ultimately, the study has the potential to strengthen the large-scale provision of services for women affected by VAW that can improve their overall well-being and mental health. This will fill a critical gap in public health initiatives to address the pervasive problem of VAW.

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Contributors FEK, GH, TdFdC and MB conceived the research intervention. MB, GH, TdFdC and FEK acquired the funding. IBG and ZJ collaborated on designing the protocol and study implementation. AS, CM-N, FB, FL, GH, LY, OM, PH, SD and SE contributed to refining the design and the research methodology and in defining study outcomes. All authors contributed valuable remarks, helped draft and have approved the final manuscript. FEK is responsible for the overall content as guarantor. We used AI solely to detect grammar mistakes, which we then reviewed and corrected manually.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

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