BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-086143
Article Type:	Protocol
Date Submitted by the Author:	06-Mar-2024
Complete List of Authors:	El-Khoury, Fabienne; Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique IPLESP,, Departement of social epidemiology Ben Ghezala, Inès; CHU Dijon, CIC 1432 (Center for Clinical Investigation); Université Bourgogne Franche-Comté Hatem, Ghada; Centre Hospitalier de Saint Denis, Service de gynécologie et obstétrique; La Maison des femmes Jaffal, Zohra; CHU Dijon, CIC 1432 (Center for Clinical Investigation) Soares, Andre; Sorbonne Universite, Département de Médecine Générale Yacini, Leila; Centre de Santé Municipal "Les Moulins" Duchesne, Sophie; Pitié-Salpêtrière University Hospital, Maison des femmes CASAVIA Service de Gynécologie Obstétrique Dommergues, Marc; Pitié-Salpêtrière University Hospital, Maison des femmes CASAVIA Service de Gynécologie Obstétrique Bretelle, Florence; Assistance Publique - Hôpitaux de Marseille Eudeline, Sara; AP-HM, Centre de santé universitaire Hoffmann, Pascale; Maison des Femmes Grenoble Alpes Masse-Navette, Claire; Centre de Santé Sexuelle de Voiron Layachi, Fanida; Maison des Femmes Reims Maurice, Odile; Centre Hospitalier Universitaire de Reims de Foucher de Careil, Tiphaine; Centre Hospitalier de Saint Denis, Service de gynécologie et obstétrique; La Maison des femmes Bardou, Marc; CHU Dijon, CIC 1432 (Center for Clinical Investigation); Université de Bourgogne UFR des Sciences de Santé de Dijon, UFR des Sciences Santé
Keywords:	MENTAL HEALTH, Psychosocial Intervention, Patient-Centered Care

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

Fabienne El-Khoury[a], Inès Ben Ghezala,[b,c] Ghada Hatem[d,e], Zohra Jaffal[b], Andre Soares[f,] Leila Yacini[g], Sophie Duchesne[h], Marc Dommergues[h], Florence Bretelle[i], Sara Eudeline[j], Pascale Hoffmann[k], Claire Masse-Navette[l], Fanida Layachi[m], Odile Maurice[n], Tiphaine de Foucher de Careil[d,e], Marc Bardou [b,c]

[a] Sorbonne Université, Institut Pierre Louis d'Epidémiologie et de Santé Publique, INSERM, IPLESP, Department of social epidemiology, 27 rue Chaligny, Paris, 75012, France

[b] CIC 1432 (Center for Clinical Investigation), CHU Dijon Bourgogne, 14 rue Gaffarel, 21000 Dijon, France

[c] Université Bourgogne Franche Comté, UFR des Sciences Santé, 7, bd Jeanne d'Arc, 21000 Dijon, France

[d] La Maison des femmes, Chemin du Moulin Basset, 93200 Saint-Denis, France

[e] Service de gynécologie et obstétrique, Centre Hospitalier de Saint Denis. 2 Rue du Dr Delafontaine, 93200 Saint-Denis, France.

[f] Sorbonne Université, Département de Médecine Générale, 27 rue Chaligny, Paris, 75012, France ; Centre Municipal et Universitaire de Santé, 94110 Arcueil, France.

[g] Centre de Santé Municipal "Les Moulins", Saint-Denis, France

[h] , Maison des femmes CASAVIA Service de Gynécologie Obstétrique, Hôpital Pitié Salpêtrière, AP-HP Sorbonne Université Paris, France

[i] Assistance Publique Hôpitaux de Marseille, Aix Marseille Université (AMU), Institut de Recherche pour le Développement (IRD) VITROME, Marseille, France

[j] Centre de santé universitaire AP-HM des Flamands, Marseille

[k] Maison des Femmes Grenoble Alpes, Grenoble, France

[l] Centre de Santé Sexuelle de Voiron, France

[m] Maison des Femmes Reims, Reims, France

[n] Centre Hospitalier Universitaire De Reims, Reims, France

Corresponding author

Marc Bardou, CIC 1432 (Center for Clinical Investigation), CHU Dijon Bourgogne, 14 rue Gaffarel, 21000 Dijon, France, marc.bardou@u-bourgogne.fr

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. Victims-survivors often face barriers in accessing specialized care, highlighting the need for a multidisciplinary response, especially in health care 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 program offers advantages over standard care in improving mental health indicators, such as PTSD.

Method and analysis

Our pragmatic quasi-experimental study uses a non-randomized controlled cluster design. The intervention group comprises women enrolled in Maison des Femmes (MdFs) in five French cities, while the comparison group includes women receiving usual care in socio-medical structures located geographically close to MdF centers. 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 centers. The primary analysis will compare the change (difference between M6 and M0) in PTSD Checklist for DSM-V (PCL-5) scores 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 socio-professional proceedings, and healthcare utilization.

Ethics and dissemination

The study was approved by the " CPP Institutional review board on. Ref no. : 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.

Trial registration number: NCT06226818. Version Number 1- february2024

Keywords

Violence Against Women (VAW); Intimate partner violence (IPV); sexual violence;

Maison des Femmes (MdF) model ; Quasi-experimental trial; Women's health

Post-traumatic stress disorder (PTSD); Sleep disorders; Trauma-informed care

Strengths and limitations of this study

⇒ The comprehensive Maison des Femmes (MdF) model provides a holistic multidisciplinary approach, providing care for women victim of intimate partner Violence (IPV) and sexual violence.

⇒ The lack of randomization may introduce selection bias, affecting the ability to establish causality between the intervention and outcomes.

⇒ Despite the lack of randomization, this design allows for a pragmatic evaluation of the real-world effectiveness of the intervention and will facilitate future generalization.

⇒ Double-blinding is not feasible, but several measures have been taken to prevent bias.

Twitter : @fabienne_ek @lamaisondfemmes

Authors' contributions: FEK, GH, NR, TdfC and MB conceived the research intervention. MB, GH, TdfC and FEK acquired the funding. IBG and ZJ collaborated on designing the protocol, and study implementation. All authors contributed valuable remarks, helped draft and have approved the final manuscript.

Funding:

Our trial received funding from the French Hospital Clinical Research Program (*Programme hospitalier de recherche clinique*, PHRC) Award/Grant number: PREPS-22-0078. The PHRC had no role in study design, and the decision to submit the protocol for publication.

Competing interests:

The authors declare no conflicts of interest.

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.

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 behaviors 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 socio-economic boundaries. According to global estimates by the World Health Organization (WHO), approximately one in three women worldwide has experienced physical or sexual IPV or non-partner sexual violence in her lifetime.(3) An EU-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)

While VAW is common among women in different settings, a meta-analysis suggests that the prevalence of 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 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 victims-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 gynecological 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 that 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.

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 characterized 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 would lead to 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 quality of life. (18)

Many women who are victims-survivors of violence face challenges in accessing essential and specific care due to a lack of resources in healthcare centers, particularly specialized 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.

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 health care setting.(22)

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 center, founded by Dr Ghada Hatem, opened in 2016 in the Paris region - in the city of Saint-Denis. The MdF provide a holistic and integrated approach to care, streamlining the continuum of care for victims-survivors of VAW. They ensure that women victims of VAW receive multidisciplinary, coordinated and personalized care to optimize 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 socio-medical structures. We observed a 60% prevalence of PTSD among participants.(23) Notably, participants in the pilot study provided valuable insights and feedback that 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,(24) there is limited data on the effects of holistic multidisciplinary interventions in health care settings. There is also little evidence on the effect of trauma-informed interventions on women's sleep disorders.

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 specialized care improves their physical and mental health.

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

Methods

Study design and settings

Figure 1 summarizes the design of our study. It employs a pragmatic quasi-experimental approach with a non-randomized controlled cluster trial design. The intervention group consists of women enrolled in MdFs from five cities in France. The comparison group comprises of socio-medical structures such as municipal health centers (MHS) or Sexual Health Centers (or Family planning, SHC), grouped together in this article under the term "Health Centre" (HC) where women receive usual care.

To minimize bias due to sociodemographic differences, each of the five intervention centers was paired with a control center strategically located in the same area, but not in the same neighborhood, to limit the risk of contamination due to potential overlap between the two structures. Although the intervention and control centers do not provide the same services to women victims of violence, and as such a recruitment bias is possible, their proximity maximizes the likelihood of comparable socio-demographic characteristics.

The five pairs of MdF and HC are as follow: 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), 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 centers 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 standardized screening tool used in both research and clinical settings.(25)

Inclusion criteria also include the ability to understand the aims of the study, to complete the questionnaires, and give written informed consent to participate in the study. We will not include women who are: not affiliated or beneficiaries of social security (according to French regulations), subject to a protective measure, adults incapable of expressing non-opposition, and minors.

Interventions

Intervention Group: Maison des Femmes (Mdf)

Participants in the intervention group, consulting in one the five MdFs centers, have access to a comprehensive range of customizable 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 individualized advice on social procedures and refers women to specialized facilities if their return home is at risk, 3) mental health care with a specialized 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, 4) post-trauma assessment by a forensic psychiatrist and preparation of a descriptive report, which is essential for legal proceedings, 5) legal assistance, with a specialized lawyer on site and referral to a specialized lawyer. It is also possible to receive reconstructive surgery for female genital mutilation (FGM) and to file a complaint with a police officer.

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

Comparator Group: Health Centers (HC)

In these HC, women who report being victims of VAW are informed of their right to file a complaint and are referred to specialized associative, legal, and health structures. This approach is considered the “standard of care” to health professionals by the French High Authority of Health (HAS; "Haute Autorité de Santé”).(26)

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 enrollment 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 the structure (MdF or HC) where management was initiated, in: 1) presence of sleep disorders, 2) quality of life, 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) socio-professional proceedings initiated, 7) use of health services.

Exploratory objectives. We will analyze 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 enrollment (M0) and 6-month follow-up visits (M6).

Primary outcome

1) Change in mean PCL-5 score measured using the validated French version of the Post-traumatic Stress Disorder Checklist for DSM-V (score from 0 to 80).(27)

2) 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).(28).

Secondary outcomes

1) Changes in the proportion of women with sleep disorders according to the Insomnia Severity Index (ISI),(29) and the Pittsburgh Sleep Quality Index (threshold: global PSQI score > 5).(30)

2) Changes in the mean quality of life (QoL) score the WHOQOL-BREF quality of life scale.(31)

3) Changes in the proportion of women presenting symptoms of anxiety and depression according to the Hospital Anxiety and Depression (HAD) Scale.(32)

4) Changes in the proportion of women with: low and very low self-esteem (score ≤ 31, on the Rosenberg self-esteem scale);(33) a feeling of security and well-being using five-point Likert scales.

5) Proportion of women who have initiated legal proceedings: divorce or separation, filing for legal custody of children, filing a complaint.

6) The proportion of women who have started a socio-professional procedure: looking for housing, applying for regularization and/or employment.

7) 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 specialized staff (e.g. 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. 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 standard deviation 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 centers. This questionnaire is designed to assess eligibility, specifically using the Abuse Assessment Screen (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 enrollment visit, research associates will ask participants to complete an electronic questionnaire, created with *CleanWeb* software and designed to assess primary and secondary outcomes. Additionally, socio-demographic 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 health care 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 violence against women.

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Name and contact information for the trial sponsor:

CHU Dijon Bourgogne, Centre d'Investigation Clinique INSERM 1432

14 rue Gaffarel, 21079 DIJON CEDEX

Tél : +33 3.80.29.57.53

Version Number 1, November 2023

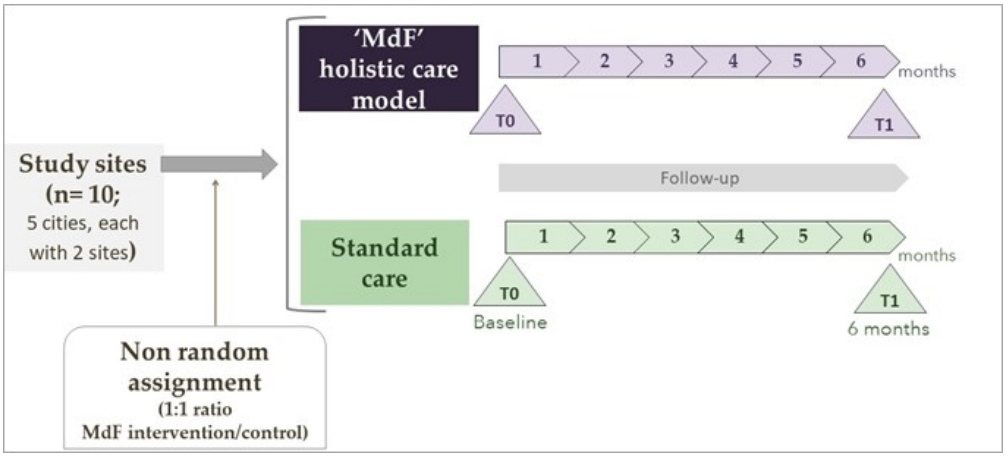
Data availability statement

Data sharing not applicable as no datasets generated and/or analyzed for this study

Acknowledgments:

We like to acknowledge all the dedicated individuals who played a pivotal role in implementing this study.

Additionally, we like to heartfully thank all participants in the pilot study whose insights and feedback were instrumental in shaping the design of this trial. Their invaluable experiences have significantly enriched the foundation of our research.



Study design (MdF: Maison des femmes) of the French IROND-L trial

180x80mm (96 x 96 DPI)

BMJ Open

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

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-086143.R1
Article Type:	Protocol
Date Submitted by the Author:	29-Aug-2024
Complete List of Authors:	El-Khoury, Fabienne; Sorbonne Université, Institut Pierre Louis d'Épidémiologie et de Santé Publique IPLESP,, Departement of social epidemiology Ben Ghezala, Inès; CHU Dijon, CIC 1432 (Center for Clinical Investigation); Université Bourgogne Franche-Comté Hatem, Ghada; Centre Hospitalier de Saint Denis, Service de gynécologie et obstétrique; La Maison des femmes Jaffal, Zohra; CHU Dijon, CIC 1432 (Center for Clinical Investigation) Soares, Andre; Sorbonne Universite, Département de Médecine Générale Yacini, Leila; Centre de Santé Municipal "Les Moulins" Duchesne, Sophie; Pitié-Salpêtrière University Hospital, Maison des femmes CASAVIA Service de Gynécologie Obstétrique Dommergues, Marc; Pitié-Salpêtrière University Hospital, Maison des femmes CASAVIA Service de Gynécologie Obstétrique Bretelle, Florence; Assistance Publique - Hôpitaux de Marseille Eudeline, Sara; AP-HM, Centre de santé universitaire Hoffmann, Pascale; Maison des Femmes Grenoble Alpes Masse-Navette, Claire; Centre de Santé Sexuelle de Voiron Layachi, Fanida; Maison des Femmes Reims Maurice, Odile; Centre Hospitalier Universitaire de Reims de Foucher de Careil, Tiphaine; Centre Hospitalier de Saint Denis, Service de gynécologie et obstétrique; La Maison des femmes Bardou, Marc; CHU Dijon, CIC 1432 (Center for Clinical Investigation); Université de Bourgogne UFR des Sciences de Santé de Dijon, UFR des Sciences Santé
Primary Subject Heading:	Medical publishing and peer review
Secondary Subject Heading:	Patient-centred medicine, Public health, Reproductive medicine
Keywords:	MENTAL HEALTH, Psychosocial Intervention, Patient-Centered Care

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

Fabienne El-Khoury[a], Inès Ben Ghezala,[b,c] Ghada Hatem[d,e], Zohra Jaffal[b], Andre Soares[f,] Leila Yacini[g], Sophie Duchesne[h], Marc Dommergues[h], Florence Bretelle[i], Sara Eudeline[j], Pascale Hoffmann[k], Claire Masse-Navette[l], Fanida Layachi[m], Odile Maurice[n], Tiphaine de Foucher de Careil[d,e], Marc Bardou [b,c]

[a] Sorbonne Université, Institut Pierre Louis d'Epidémiologie et de Santé Publique,

INSERM, IPLESP, Department of social epidemiology, 27 rue Chaligny, Paris, 75012, France

[b] CIC 1432 (Center for Clinical Investigation), CHU Dijon Bourgogne, 14 rue Gaffarel, 21000 Dijon, France

[c] Université Bourgogne Franche Comté, UFR des Sciences Santé, 7, bd Jeanne d'Arc, 21000 Dijon, France

[d] La Maison des femmes, Chemin du Moulin Basset, 93200 Saint-Denis, France

[e] Service de gynécologie et obstétrique, Centre Hospitalier de Saint Denis. 2 Rue du Dr Delafontaine, 93200 Saint-Denis, France.

[f] Sorbonne Université, Département de Médecine Générale, 27 rue Chaligny, Paris, 75012, France ; Centre Municipal et Universitaire de Santé, 94110 Arcueil, France.

[g] Centre de Santé Municipal "Les Moulins", Saint-Denis, France

[h] , Maison des femmes CASAVIA Service de Gynécologie Obstétrique, Hôpital Pitié Salpêtrière, AP-HP Sorbonne Université Paris, France

[i] Assistance Publique Hôpitaux de Marseille, Aix Marseille Université (AMU), Institut de Recherche pour le Développement (IRD) VITROME, Marseille, France

[j] Centre de santé universitaire AP-HM des Flamands, Marseille

[k] Maison des Femmes Grenoble Alpes, Grenoble, France

[l] Centre de Santé Sexuelle de Voiron, France

[m] Maison des Femmes Reims, Reims, France

[n] Centre Hospitalier Universitaire De Reims, Reims, France

Corresponding author

Marc Bardou, CIC 1432 (Center for Clinical Investigation), CHU Dijon Bourgogne, 14 rue Gaffarel, 21000 Dijon, France, marc.bardou@u-bourgogne.fr

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 specialized care, highlighting the need for a multidisciplinary response, especially in health care 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 program offers advantages over standard care in improving mental health indicators, such as PTSD.

Method and analysis

Our pragmatic quasi-experimental study uses a non-randomized controlled cluster design. The intervention group comprises women enrolled in Maison des Femmes (MdFs) in five French cities, while the comparison group includes women receiving usual care in socio-medical structures located geographically close to MdF centers. 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 centers. The primary analysis will compare the change in PTSD Checklist for DSM-V (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 socio-professional proceedings, and healthcare utilization.

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 December 20th, 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.

Trial registration number: NCT06226818. Version Number 1- february2024

Keywords

Violence Against Women (VAW); Intimate partner violence (IPV); sexual violence;

Maison des Femmes (MdF) model ; Quasi-experimental trial; Women's health

Post-traumatic stress disorder (PTSD); Sleep disorders; Trauma-informed care

Strengths and limitations of this study

⇒ The comprehensive Maison des Femmes (MdF) model provides a holistic multidisciplinary approach, providing care for women victim of intimate partner Violence (IPV) and sexual violence.

⇒ The lack of randomization may introduce selection bias, affecting the ability to establish causality between the intervention and outcomes.

⇒ Despite the lack of randomization, this design allows for a pragmatic evaluation of the real-world effectiveness of the intervention and will facilitate future generalization.

⇒ Double-blinding is not feasible, but several measures have been taken to prevent bias.

Twitter : @fabienne_ek @lamaisondfemmes

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.

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 behaviors 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 socio-economic boundaries. According to global estimates by the World Health Organization (WHO), approximately one in three women worldwide has experienced physical or sexual IPV or non-partner sexual violence in her lifetime.(3) An EU-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 gynecological 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 that 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.

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 characterized 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 quality of life. (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 centers, particularly specialized 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 behavioral and Cognitive Processing Therapy (CBT) 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 health care 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 center, was founded by Dr Ghada Hatem, who specializes in treating women with FGM. It opened in 2016 in the Paris region - in the city of Saint-Denis with a high migrant population. The MdF provide 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 personalized care to optimize 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 socio-medical 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 is limited data on the effects of holistic multidisciplinary interventions in health care 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 specialized care improves their physical and mental health.

Our study therefore aims to investigate whether the MdF's comprehensive intervention program 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 summarizes the design of our study. It employs a pragmatic quasi-experimental approach with a non-randomized 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 socio-medical structures such as municipal health centers (MHS) or Sexual Health Centers (SHC, also known as Family planning), where women receive usual care. These centers were recruited through convenience sampling and grouped together in this article under the term "Health Centre" (HC).

To minimize bias due to sociodemographic differences, each of the five intervention centers was paired with a control center strategically located in the same area, but not in the same neighborhood, to limit the risk of contamination due to potential overlap between the two structures. Although the intervention and control centers do not provide the same services to women victims of violence, and as such a recruitment bias is possible, their proximity maximizes the likelihood of comparable socio-demographic characteristics.

The five pairs of MdF and HC are as follow: 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), 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 centers 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 standardized 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 give written informed consent to participate in the study. We will not include women who are not affiliated 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 the five MdFs centers, have access to a comprehensive range of customizable 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 individualized advice on social procedures and refers women to specialized facilities if their return home is at risk, 3) mental health care with a specialized 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, 4) post-trauma assessment by a forensic psychiatrist and preparation of a descriptive report, which is essential for legal proceedings, 5) legal assistance, with a specialized lawyer on site and referral to a specialized lawyer. It is also possible to receive reconstructive surgery for female genital mutilation (FGM) and to file a complaint with a police officer.

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

Comparison Group: Health Centers (HC)

In these HC, women who report being victims of VAW are informed of their right to file a complaint and are referred to specialized associative, legal, and health structures. This approach is considered the “standard of care” to health professionals by the French High Authority of Health (HAS; "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 enrollment 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 the structure (MdF or HC) where management was initiated, in: 1) presence of sleep disorders, 2) quality of life, 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) socio-professional proceedings initiated, 7) use of health services.

Exploratory objectives. We will analyze 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 enrollment (M0) and 6-month follow-up visits (M6).

Primary outcome

Change in mean PCL-5 score measured using the validated French version of the Post-traumatic Stress Disorder Checklist for DSM-V (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 (ISI),(32) and the Pittsburgh Sleep Quality Index (threshold: global PSQI score > 5).(33)

3) Changes in the mean quality of life (QoL) score the WHOQOL-BREF quality of life scale.(34)

4) Changes in the proportion of women presenting symptoms of anxiety and depression according to the Hospital Anxiety and Depression (HAD) 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 five-point Likert scales.

6) Proportion of women who have initiated legal proceedings: divorce or separation, filing for legal custody of children, filing a complaint.

7) The proportion of women who have started a socio-professional procedure: looking for housing, applying for regularization 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 specialized staff (e.g. 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. 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 standard deviation 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 centers. This questionnaire is designed to assess eligibility, specifically using the Abuse Assessment Screen (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 enrollment visit, research associates will ask participants to complete an electronic questionnaire, created with *CleanWeb* software and designed to assess primary and secondary outcomes. Additionally, socio-demographic 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 health care 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 violence against women.

Authors' contributions:

FEK, GH, TdfC and MB conceived the research intervention. MB, GH, TdfC and FEK acquired the funding. IBG and ZF collaborated on designing the protocol, and study implementation. AS, CM-N, FB, FL, LY, MD, 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.

Funding:

Our trial received funding from the French Health Ministry under the Research programme on the performance of the healthcare system (*Programme de recherche sur la performance du système des soins* – PREPS) Award/Grant number: PREPS-22-0078. The PHRC had no role in study design, and the decision to submit the protocol for publication.

Competing interests:

The authors declare no conflicts of interest.

Data availability statement

Data sharing not applicable as no datasets generated and/or analyzed for this study

Acknowledgments:

We like to acknowledge all the dedicated individuals who played a pivotal role in implementing this study.

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Name and contact information for the trial sponsor:

CHU Dijon Bourgogne, Centre d'Investigation Clinique INSERM 1432

14 rue Gaffarel, 21079 DIJON CEDEX

Tél : +33 3.80.29.57.53

Version Number 1, November 2023

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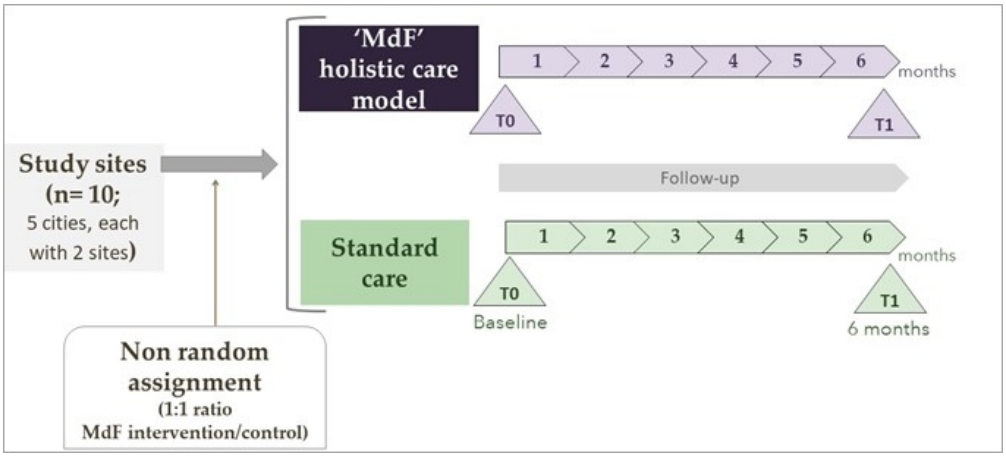
Figure legend:

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



Study design (MdF: Maison des femmes) of the French IROND-L trial

180x80mm (96 x 96 DPI)