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Cohort profile: mental health and intimate partner violence amongst women from refugee background and a comparison group of Australian-born: the WATCH cohort study

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3 **Cohort profile: mental health and intimate partner violence amongst women from**
4 **refugee background and a comparison group of Australian-born: the WATCH cohort**
5 **study**
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32 **ABSTRACT**
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34 **Purpose:** The Women Aware with Their Children (WATCH) study was created because
35 prospective data is required to accurately guide prevention programmes for intimate partner
36 violence (IPV) and improve the mental health and resettlement trajectories of women from
37 refugee backgrounds in Australia.
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42 **Participants:** 1335 women (685 consecutively enrolled from refugee backgrounds and 650
43 randomly selected Australian born) recruited during pregnancy from 3 public antenatal
44 clinics in Sydney and Melbourne, Australia. The mean age was 29.7 years among women
45 from refugee backgrounds and 29.0 years among women born in the host nation. Main
46 measures include IPV, mood, panic, post-traumatic stress disorder (PTSD), disability and
47 living difficulties.
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55 **Findings to date:** Prevalence of IPV at all three time points is significantly higher for
56 refugee background women. The trend data shows that IPV rates among Australian born
57 women increased from 25.8% at Time 1 to 30.1% at Time 3, while for refugee background
58 women this rate declined from 44.4% at Time 1 to 42.6% at Time 3. Prevalence of major
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3 depressive disorder (MDD) at all three time points is higher for refugee background women.
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5 MDD among Australian born women significantly declined from 14.5% at Time 1 to 9.9% at
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7 Time 3, while for refugee background women it fluctuated, from 25.1% at Time 1 to 17.3%
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9 at Time 2 and to 19.1% at Time 3.

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12 **Plans:** We are currently examining trajectories of IPV and mental disorder across three time
13
14 points. Time 4 occurred during the COVID-19 pandemic, enabling a unique opportunity to
15
16 examine the impacts of the pandemic over time. Time 5 will start August 2021 and Time 6
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18 approximately 12 months later. The children at Time 5 will be in the early school years,
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20 providing the capacity to examine behaviour, development, and well-being of the index child.

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27 28 **STRENGTHS AND LIMITATIONS**

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32 -This is the first systematically recruited longitudinal study of women from refugee background
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34 with a comparison group of locally-born women, allowing an examination of associations
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36 between traumatic events, intimate partner violence, mental disorders, functioning and
37
38 settlement outcomes.

39 -The study has a substantial sample size, a high response and high retention rate.

40 -For assessing common mental disorders, we applied a structured diagnostic measure rather
41
42 than screening instruments, and we used the WHO measure for intimate partner violence.

43 -We used same language speaking interviewers and applied rigorous standards to ensure
44
45 measures were culturally tested and cultural accuracy.

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47 -Recruitment in public health clinics are not fully generalisable to women attending private
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49 health services or those living in low-density refugee background areas.

INTRODUCTION

The scale of the global refugee crisis is unprecedented. As a signatory to the Refugee Convention (1951), Australia and many other high-income countries including the UK and the USA have a long history of leadership in responding to international crises by admitting substantial numbers of refugees.[1] The success of refugee resettlement programs can be judged by the effectiveness of settlement policy for those admitted, indicated by health status, levels of acculturation, participation, and inclusion. It is imperative that all high income countries provide appropriate programs to assist refugees to overcome barriers to resettlement, some of the key obstacles being ongoing mental distress and exposure to stress and trauma.[1] One source of the latter that has been largely ignored is the unique experiences of women from conflict-affected backgrounds (hereon refugee women) in high-income countries. Refugee women's mental wellbeing and the problem of Intimate Partner Violence (IPV) are particularly important to consider in supporting them to settle and enjoy mental well-being in high-income countries.[2] Comprehensively defined, IPV includes physical, emotional, sexual and financial abuse by an intimate partner.[3] The World Health Organisation (WHO) estimates that the cumulative impact of IPV on morbidity and mortality exceeds the global burden of recognised public health problems.[4, 5] The stark reality is that one in six Australian women experience IPV, and between 80 and 100 women are killed every year by intimate partners.[6] Despite risk for higher IPV prevalence and the associated mental health risks, refugee women, who experience unique trauma and poverty-related factors that differentiate them from other migrants, have been largely ignored in high-income country studies of IPV [2]. Several inter-related reasons may place refugee women at risk of IPV including universal factors such as patriarchal values and economic adversity, as well as refugee-related factors such as premigration adversity, loss of social and cultural support, separation from family, and barriers to accessing and utilising educational, employment and welfare services in the new society. Refugee women face conditions of multiple jeopardy for common mental disorders (CMDs) including depression, anxiety and post-traumatic stress disorder (PTSD) because of their exposure to prior trauma in their homeland and during the process of flight; ongoing resettlement stresses; and critically, IPV in their family environment.[3] Despite this, there is dearth of systematic data examining the prevalence or impact of IPV on the mental health and functioning of refugee women either in Australia or worldwide. We set up the Women Aware with Their Children (WATCH) study because prospective data is required to provide a knowledge base to accurately guide prevention

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3 programmes for IPV, and improve the mental health and resettlement trajectories of refugee
4 women in Australia. The COVID-19 pandemic demonstrated the value of a cohort design,
5 which allows researchers to prospectively examine significant events on mental health, IPV
6 and functioning in women in high income countries, including the significant but often
7 neglected population of women from refugee background.[3]
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13 **Higher Risk for IPV and Mental Disorders**

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16 We previously confirmed a robust linear relationship between the quantum of trauma exposure
17 experienced by refugees and risk of CMDs, particularly PTSD and depression.[7] Whilst
18 refugee men are subject to traumas related to torture and imprisonment, women commonly
19 experience gendered trauma including rape, forced marriages, involuntary sterilization and
20 sexual slavery.[8-10] The effects of past trauma may be exacerbated by social and family
21 isolation during resettlement, adding to the difficulty that women face if they lack the skills,
22 knowledge or capacity to establish networks or seek assistance from support agencies.[11, 12]
23 Under these circumstances, it seems plausible that the additional trauma of ongoing IPV will
24 greatly increase the risk of onset or exacerbation of CMDs, generating compounding conditions
25 of adversity that undermine the woman's right and capacity to live in safety and achieve
26 successful resettlement. The experience-effect relationship between gender-based violence and
27 CMDs (including depression and PTSD) in women born in high income countries is now well
28 established in large cross sectional studies, with Rees and colleagues confirming this
29 association in a seminal nationally representative sample of English speaking Australian
30 women.[13] We have also shown that first exposure to IPV commonly precedes the new onset
31 of CMD in young Australian women, strengthening the argument for a causal relationship.[14]
32 Although studies are limited, IPV appears to be common in low-income, conflict-affected
33 societies that are the source of refugee flows; in addition, IPV is strongly associated with CMDs
34 in those settings.[8, 9, 15-17] Fisher et al found in rural Vietnam that experience of IPV was
35 associated with higher prevalence and severity of perinatal depression, anxiety and suicidal
36 thoughts.[16] Importantly, in a world first study in antenatal clinics in Timor-Leste, Rees and
37 colleagues found that women exposed to the dual experiences of extensive war-related trauma
38 and IPV were at 10 times greater risk of exhibiting common mental disorders.[15] Despite this,
39 no established longitudinal studies of IPV and mental illness other than the WATCH study
40 have been undertaken amongst refugees either in Australia and other high-income countries,
41 such as the USA and Canada.[11, 18] The WATCH study is one of the few rigorous studies
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3 with the capacity to define the trajectories of IPV over time, and to examine the risk factors
4 shaping adverse mental health outcomes such as depression, either in general or refugee
5 populations. Our first published paper from the WATCH baseline data reveals that women
6 identifying as refugees reported a much higher prevalence of major depressive disorder
7 symptoms and all the indicators of adversity related to that disorder. Even after risk factors
8 were accounted for, refugee status was associated with a greater risk of major depressive
9 disorder symptoms.[2]
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15 16 **COHORT DESCRIPTION**

17 18 19 **Inclusion and Exclusion Criteria**

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22 Participants were first recruited between January 2015 and March 2016. The study was
23 conducted at 3 public antenatal clinics located in refugee-dense geographic areas in Sydney
24 and Melbourne, Australia. Consecutive women were recruited from Arabic-speaking
25 countries, Sudan, and Sri Lanka (Tamil-speaking). These nations represented the largest
26 intake groups from conflict-affected regions entering Australia and other high-income
27 countries at the time of this study. By limiting the study to these language groups, we sought
28 to contain both the problems of transcultural measurement error and small cell sizes. Country
29 of origin was identified by clinic records, requests for an interpreter, or culturally
30 recognisable surnames, and country of birth data were checked against clinic appointment
31 lists. Recruitment occurred at a woman's first appointment at the clinic, which most
32 commonly occurred between 12 and 20 weeks gestation (range, 9-42 weeks). Women with
33 overt psychosis, severe medical illness, and obvious intellectual impairment were excluded.
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43 Women born in Australia attended the clinics in substantially larger numbers than those from
44 conflict-affected countries. To undertake a parallel sampling strategy over a similar time
45 frame, we applied a computer-generated selection procedure to identify a random subset of
46 women from the host country daily. Women members of the research team who spoke the
47 same language as eligible women approached them in the waiting room and, following
48 consent, conducted interviews lasting a maximum of 1 hour in private areas of the clinic, with
49 breaks for refreshments or to attend to children.
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56 57 **Public and Patient Involvement**

58 Members of the public with expertise in the key cultural, language and background of the
59 target population are involved in the design, conduct, reporting and dissemination of our
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3 research. We recruited and trained community members with the same cultural and language
4 backgrounds as the refugee populations to be employed as research assistants. Research
5 assistants are consulted on the design of interview protocols, cultural advice, publications, as
6 well as, if required, checking accuracy during the analytic and interpretation stage. We set up
7 advisory groups of people from Arabic and Tamil communities to share and check cultural
8 and well as language accuracy in the questionnaires.
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15 **Ethics and Research Personnel**

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17 The study was approved by the Southwestern Sydney Local Health District Human Research
18 and Monash Health Ethics Committees. Participants provided written informed consent and
19 were remunerated for their time. In total, 8 women field workers from appropriate language
20 backgrounds were given extensive training, consisting of 3 formal training days followed by
21 tests of competence. Training covered IPV, research methods and practice, sensitive
22 interviewing techniques, and the use of the diagnostic and World Health Organisation
23 measures. Staff received ongoing support, monitoring, and supervision throughout the study.
24 Interrater reliability tests were conducted serially to maintain standards, based on group
25 observations of videotaped interviews. We adhered strictly to World Health Organisation
26 guidelines for conducting safe and ethical IPV research. This study followed Strengthening
27 the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.
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37 Patients or the public are involved in the design, conduct, reporting and dissemination of our
38 research. We recruited and trained community members with the same cultural and language
39 backgrounds as the refugee populations to be employed as research assistants. All are
40 involved in design of interview protocols, cultural advice, publications, as well as checking
41 accuracy during the analytic and interpretation stage. We set up advisory groups of people
42 from Arabic and Tamil communities to share and check cultural and well as language
43 accuracy in the questionnaires.
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52 **HOW OFTEN HAVE PARTICIPANTS BEEN FOLLOWED UP?**

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55 It is critical to ascertain whether the trajectory of ongoing IPV experiences and heightened
56 mental disorder change as refugee women progress from a central focus on infant child-rearing
57 to the early education years when women are more likely to engage more widely socially and
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3 economically again (or for the first time) with the new society, either with or without having
4 another child. The purposely selected time-points in our cohort study also represent key
5 maternal-life stages, covering the critical period when women have greater potential to direct
6 their focus towards social participation and adaptation outside the family, including
7 engagement in education and employment.
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13 Recruitment and the baseline interview occurred at or close to the participant's first
14 appointment at the antenatal clinic which for most occurred between 12- and 20-weeks'
15 gestation between January 2015 and December 2016. First follow-up interviews (Time 2) were
16 conducted at home either in person or by telephone approximately 6 months after the birth of
17 the index child and the second follow-up survey (Time 3) was conducted at home either in
18 person or by telephone approximately 3.5 years after baseline and Time 4 was conducted 5.5
19 years after baseline. At Time 1 the response rate was 84.8% (1335 out of 1574), at Time 2
20 retention rate was 83.2% (1111 out of 1335 interviewed at Time 1), at Time 3 retention rate at
21 Time 3 was 67.8% (905 out of 1335 interviewed at Time 1) and the third follow-up survey
22 (Time 4) is currently being finalised and the data entered. We are currently planning Time 5
23 and Time 6. Time 5 will begin August 2021.
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33 **WHAT HAS BEEN MEASURED?**

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36 At baseline (Time 1) we included basic sociodemographic characteristics (e.g. age, marital
37 status, highest level of educational attainment, household composition and employment status),
38 past traumatic events (TEs), financial difficulties (e.g. paying bills and affording enough food
39 and heating), IPV, attitudes to gender equality and the use of violence against women; common
40 mental disorders including major depressive disorder (MDD), PTSD, panic disorder, grief
41 disorder, adult separation anxiety disorder (ASAD); and functional impairment as measured by
42 the World Health Organisation Disability Assessment Schedule (WHODAS).[19] Measures
43 related to IPV, CMDs (MDD, PTSD, panic disorder, grief disorder, ASAD) and functional
44 impairment has been included in all four surveys so far, and assessed for significance since the
45 previous interview (Time 1, Time 2, Time 3, Time 4). At Time 2 some basic measures related
46 to pregnancy and childbirth were added: antenatal care, smoking during pregnancy, drinking
47 alcohol during pregnancy, induced labour delivery (yes, no), analgesia provided in delivery
48 (yes, no), type of birth (natural or caesarean), baby's sex and birth weight; and postpartum
49 bonding score. At Time 3, in addition to common mental disorders for women, measures
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3 related to the index child's (aged 21 months and over) social and developmental indicators,
4 emotional and behavioral problems, and parental experiences were included. All mental health
5 measures were selected based on their previous psychometric evaluations and use across
6 cultures. Measures were subjected to rigorous assessment of cultural and linguistic accuracy in
7 the languages used.[20, 21] After standard translation and back-translation procedures were
8 performed, final refinements were made by groups of linguistic experts.
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15 **Traumatic events (TEs)**

16 We assessed lifetime exposure to traumatic events (TEs) based on the inventory used in the
17 World Mental Health Survey.[22]
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22 **Intimate partner violence**

23 Intimate partner violence was assessed using items from the World Health Organisation
24 (WHO) Violence Against Women questionnaire which enquires about physical, psychological
25 and sexual violence perpetrated by the most recent intimate partner in the past 12 months.
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31 **Gender role attitudes and beliefs**

32 Attitudes on gender role attitudes and beliefs including IPV were measured using the
33 'Attitudes Towards Gender Roles' items from the WHO Multi-Country Study on Women's
34 Health and Life Experiences Questionnaire.[23]
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40 **Common mental disorders (CMDs)**

41 We used the Mini-International Neuropsychiatric Interview (MINI) based on the Diagnostic
42 and Statistical Manual of Mental Disorders (Fourth Edition) (DSM-IV)[24] to assess current
43 MDD, PTSD, ASAD, Panic disorder, and Grief. We selected DSM-IV in preference to DSM-
44 5 because the latter had not yet been used extensively across cultures at the commencement of
45 the study.[25]
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51 **Functional impairment**

52 The World Health Organisation Disability Assessment Schedule (WHODAS 2.0, 12-item
53 version) has been extensively used across cultures to measure functional impairment. It
54 comprises six core functions/domains relating to cognition/communication, going out
55 (mobility), self-care, interpersonal interactions, life activities (work, home), and participation
56 in society (ratings for each item range from no impairment=1 to extreme impairment=5).[19]
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FINDINGS TO DATE

Participant's socio-demographic characteristics at baseline survey (Time 1)

At Time 1, 1335 pregnant women were interviewed (with response rate 84.8%; 1335 out of 1574), including 650 women born in Australia (48.7%) and 685 from conflict-affected countries, referred to as refugee background women in this paper (51.3%). The mean age for women born in Australia was 29.0 ($SD= 5.5$) years; for women from conflict-affected countries, it was 29.7 ($SD= 5.4$) years (Table 1). As expected, at Time 1 the socio-demographic characteristics for women born in Australia were significantly different than women born in conflict affected countries (Table 1). Among women born in Australia, 58.1% were employed at Time 1 and this rate was only 28.9% for women born in conflict affected countries. A greater proportion of women who migrated from conflict affected countries reported experiencing three or more finance-related stressors (16.4%) and this rate was 6.3% for Australian born women (Table1).

Intimate partner violence at Time 1, Time 2 and Time 3

Results in Table 2 indicate that the prevalence of IPV at all three time points were significantly higher for refugee background women as compared to women born in Australia. The trend data (Time 1, Time 2, Time 3) shows that IPV rates among Australian born women increased from 25.8% at Time 1 to 30.1% at Time 3, while for refugee background women this rate declined from 44.4% at Time 1 to 42.6% at Time 3.

Gender role attitudes

Associations between socio-demographic characteristics and gender role attitudes and beliefs with IPV were examined from two time points using bivariate and multiple logistic regression analyses (this paper is currently under review).

Common mental disorders at Time 1, Time 2 and Time 3

Prevalence of MDD at all three time points was significantly higher for refugee background women as compared to women born in Australia. The trend data (Time 1, Time 2, Time 3) shows that prevalence of MDD among Australian born women significantly declined from 14.5% at Time 1 to 9.9% at Time 3, while for refugee background women this rate fluctuated,

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3 initially significantly declined from 25.1% at Time 1 to 17.3% at Time 2 and then increased
4 to 19.1% at Time 3 (Table 2). The first paper published from the WATCH data reports the
5 analysis of data from baseline, when women were recruited during pregnancy.[2] We aimed to
6 examine prevalence and to identify which risk factors are associated with major depressive
7 disorder in women from conflict-affected backgrounds resettling in a high-income country.
8 This was an important focus because the evidence suggests that refugee women may have
9 higher risk for depressive disorders, and pregnancy may also increase the risk of depression
10 among women refugees. We found that women identifying as refugees reported a much higher
11 prevalence of major depressive disorder symptoms and all the indicators of adversity related to
12 that disorder. Even after risk factors were accounted for, refugee status was associated with
13 risk of major depressive disorder symptoms. Assessing whether women attending an antenatal
14 clinic self-identify as refugees may offer an important indicator of risk of major depressive
15 disorder symptoms and a range of associated psychosocial adversities.

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Prevalence of PTSD and panic disorder was found to be comparatively higher among women
born in Australia and over the years the rates fluctuated in both groups of women. As compared
to refugee background women, prevalence of grief disorder was found to be lower in Australian
born women; and for both groups of women the rates were stable across three time points. One-
fifth of the women in both groups met the Adult Separation Anxiety Disorder (ASAD)
threshold criteria and over the years the rates fluctuated in both groups of women (Table 2).
Functional impairment scores were found to be almost same in both groups of women with the
mean score for women born in Australia declining from 16.6 ($SD=6.0$) at Time 1 to 13.9
($SD=4.8$) at Time 3, and for refugee background women from 16.7 ($SD=6.1$) at Time 1 to 14.7
at Time 3 ($SD=5.6$).

Pregnancy and childbirth measures at Time 2 and Time 3

About two thirds of the women in both groups (Australian born: 64.6%, Refugee background:
68.1%) reported that in addition to the index child (born in between Time 1 and Time 2 survey)
they had one or more children (Table 3). The rate of smoking and drinking alcohol during
pregnancy was significantly higher for women born in Australia. More than a quarter of
Australian-born women had a caesarean birth (27.4%) and this rate was higher (30.6%) for
refugee background women. Among the Australian born women, 40.7% required induced
labour delivery and this rate was 30.5% for refugee background women. Low birth weight
(birth weight <2500 gram) among indexed babies born to Australian born mother (8.5%) was

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3 higher when compared to refugee background women (6.3%). The mean postpartum bonding
4 score was found to be almost same for both groups of women (Table 3).
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8 **Child behaviour and parental stress experience at Time 3**

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10 The mean score indicating compromised social and emotional development at Time 3 for the
11 index child (aged 21-32 months) born to refugee background women was significantly higher
12 than for the Australian born women's index children (Table 3). The mean parental stress score
13 for refugee background women was also found to be significantly higher than Australian born
14 women.
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20 **Time 4 and COVID-19**

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22 Time 4 is novel in that it occurred during COVID-19, allowing a natural study of the impact of
23 the pandemic on women's mental health and IPV prevalence. We have also included specific
24 COVID-19 related questions of related hardship and stress. We can examine, for the first time
25 in a study of this kind, a comparison of the impact of COVID-19 on women from refugee
26 backgrounds and women born in Australia. This analysis is current.
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32 **STRENGTHS AND LIMITATIONS**

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35 The main strength of our study is that, to our knowledge, it is the first systematically recruited
36 longitudinal study of women from refugee background with a comparison group of locally-
37 born women, allowing an examination of associations between traumatic events, IPV, mental
38 disorders, functioning and settlement outcomes. Other strengths include a substantial sample
39 size and a high response and high retention rate. For assessing common mental disorder, we
40 applied a structured diagnostic measure rather than screening instruments and we used the
41 WHO measure for IPV, allowing for global comparisons to be made. We used same language
42 speaking interviewers and applied rigorous standards to ensure measures were culturally tested.
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50 Our deliberate strategy to focus on public health clinics where women from conflict-affected
51 countries concentrate may mean that the findings are not fully generalisable to women
52 attending private health services or those living in low-density refugee background areas.
53 Retrospective distortions, gaps in memory, and reluctance to divulge sensitive information (e.g.
54 related to IPV) are acknowledged possibilities that may lead to inaccuracies in reporting of past
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3 events. It is difficult to determine whether these influences led to the overreporting or
4 underreporting of adversities.
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7 **COLLABORATIONS AND FURTHER DETAILS**

10 Interested scholars and others may contact the study team (Susan Rees, Zachary Steel or Jane
11 Fisher) if they wish to receive more information or have a proposal for collaboration. We are
12 interested in extending partnerships, particularly in preparing for future waves of data
13 collection and secondary data analysis.
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19 **Conflict of interest:** None declared.
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23 GNT1164736
24
25

26 **Contributorship Statement:** SR, MM, JF, ZS, NN, BM, FH, YK, BK made substantial
27 contributions to the initial study conception and study design. SR, MM, JF, ZS, NN, BM, FH,
28 YK, BK made substantial contributions to the design and content of the study protocol, to the
29 initial drafting of this manuscript and the critical revision of the submitted manuscript; and
30 have approved the final article for submission. MM, SR, BM were involved in data analysis
31 and interpretation. SR, JF, ZS, NN, BM, FH, YK, BK are responsible for recruitment and
32 monitoring of study participants. SR, JF, ZS have responsibility for overseeing the study as it
33 progresses and for provision of guidance to research staff.
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Table 1 Socio-demographic characteristics for women born in Australia (host nation women) and women from conflict-affected countries (refugee background women) at baseline (Time 1).

Sociodemographic Characteristics	Australian women: No. (%)	^a All Conflict- country women: No. (%)
All	650 (100.0)	685 (100.0)
Age group		
<25	153 (23.5)	122 (17.8)
25-34	381 (58.6)	423 (61.8)
35 and above	116 (17.8)	140 (20.4)
<i>Mean age (standard deviation)</i>	<i>29.0 (5.5)</i>	<i>29.7 (5.4)</i>
Highest level of educational attainment		
No post school qualification	286 (44.0)	350 (51.1)
Diploma and vocational education	171 (26.3)	122 (17.8)
University degree	193 (29.7)	213 (31.1)
<i>Chi-square test: p values</i>		
Marital status		
Married/Domestic partnership	566 (87.1)	649 (94.7)
Separated/Divorced/Others	84 (12.9)	36 (5.3)
Family composition of household		
One parent family with dependent children/others	65 (10.0)	49 (7.1)
Couple family without/with dependent children/others	494 (76.0)	556 (81.2)
Multiple family without/with dependent children	91 (14.0)	80 (11.7)
Housing status		
Owner without a mortgage	39 (6.0)	30 (4.4)
Owner with a mortgage	252 (38.8)	212 (30.9)
Renter	241 (37.1)	367 (53.6)
Boarder and others	118 (18.2)	76 (11.1)
Employment status		
Employed	383 (58.1)	198 (28.9)
Unemployed and others	267 (41.1)	487 (71.1)
General traumatic events (TEs) counts ^b		
None	344 (52.9)	336 (49.1)
One TE	182 (28.0)	212 (30.9)
Two to three TEs	103 (15.8)	112 (16.4)
Four or more TEs	21 (3.2)	25 (3.6)
<i>Mean TEs (standard deviation)</i>	<i>0.8 (1.2)</i>	<i>0.9 (1.1)</i>
Number of finance related stress/difficulties ^c		
None	498 (76.6)	427 (62.3)
One to two	111 (17.1)	146 (21.3)
Three or more	41 (6.3)	112 (16.4)

^a Country of birth for refugee background women No. (%): Iraq 260 (38.0%); Lebanon 125 (18.2%); Sudan 66 (9.6%); Syria 30 (4.4%); Egypt 29 (4.2%); Afghan 13 (1.9%); Sri Lanka 71 (10.9%); India, Pakistan and others 91 (13.3%).

^b General TE counts included 13 items: (1) Were you ever kidnapped or held captive?; (2) Were you ever involved in a life-threatening automobile accident?; (3) Did you ever have any other life-threatening accident, including on your job?; (4) Did you ever have a life-threatening illness?; (5) As a child, were you ever badly beaten up by your parents or the people who raised you?; (6) Were you ever mugged, held up, or threatened with a weapon?; (7) Did someone very close to you ever die unexpectedly; for example, they were killed in an accident, murdered, committed suicide, or had a fatal heart attack at a young age?; (8) Did you ever have a son or daughter who had a life-threatening illness or injury?; (9) Did anyone very close to you ever have an extremely traumatic experience, like being kidnapped, tortured or raped?; (10) Did you ever do something that accidentally led to the serious injury or death of another person?; (11) Did you ever on purpose either seriously injure, torture, or kill another person?; (12) Did you ever experience any other extremely traumatic or life-threatening event that I haven't asked about yet?; (13) Did you ever have a traumatic event that you didn't report because you didn't want to talk about it? (each item coded yes=1, no=0).

^c Number of ongoing finance related stressors included following seven items: (1) Could not pay electricity/gas/telephone bills on time; (2) Could not pay for car registration/insurance on time; (3) Pawned or sold something; (4) Went without meals; (5) Unable to heat my home; (6) Sought assistance from welfare/community organisations; and (7) Sought financial help from friends or family (each item coded yes=1, no=0). A summary financial stress count was generated by adding all endorsed items (score ranges from 0 to 7).

Table 2 Prevalence of intimate partner violence (IPV) and common mental health disorders for women born in Australia (host nation women) and women from conflict-affected countries (refugee background women) at baseline (Time 1) indices for Australian born and refugee background women at Baseline survey (Time 1) and two follow-up surveys (Time 2, Time 3).

Intimate partner violence (IPV) and common mental health disorders	Women born in Australia			Refugee background women		
	Time 1 (n=650)	Time 2 (n=528)	Time 3 (n=435)	Time 1 (n=685)	Time 2 (n=583)	Time 3 (n=470)
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Intimate partner violence (IPV): Yes	168 (25.8)	143 (27.1)	131 (30.1)	304 (44.4)	256 (43.9)	200 (42.6)
Major Depressive Disorder :Yes	94 (14.5)	63 (11.9)	43 (9.9)	172 (25.1)	101 (17.3)	90 (19.1)
Post-traumatic Stress disorder (PTSD):Yes	39 (6.0)	43 (8.1)	33 (7.6)	37 (5.4)	24 (4.1)	37 (7.9)
Panic Disorder : Yes	47 (7.2)	51 (9.7)	52 (12.0)	26 (3.8)	20 (3.4)	15 (3.2)
Grief disorder :Yes	21 (3.2)	16 (3.0)	14 (3.2)	40 (5.8)	26 (4.5)	23 (4.9)
Adult Separation Anxiety Disorder: Yes	127 (19.5)	107 (20.3)	86 (19.8)	170 (24.8)	111 (19.0)	103 (21.9)
<i>WHODAS disability score: Mean (SD)</i>	<i>16.6 (6.0)</i>	<i>13.9 (4.3)</i>	<i>13.9(4.8)</i>	<i>16.7 (6.1)</i>	<i>14.5(5.2)</i>	<i>14.7 (5.6)</i>

Table 3 Woman and Index child's characteristics at first follow-up survey (Time 2), social emotional score for babies (aged 21-32 months) and parental stress experience at 2nd follow-up survey (Time 3).

Woman and index child's characteristics at Time 2	Australian Born (n=528)	Refugee background (n=583)
Does woman have any other Children: Yes	340 (64.6)	397 (68.1)
Smoked during pregnancy: Yes	84 (15.9)	24 (4.1)
Drink alcohol during pregnancy: Yes	52 (10.1)	7 (1.3)
Induced Labor Delivery: Yes	214 (40.7)	177 (30.5)
Analgesia provided in delivery (pain relief/epidural)?: Yes	333 (65.3)	315 (56.4)
Type of birth		
Natural	382 (72.6)	404 (69.4)
Caesarean	144 (27.4)	178 (30.6)
Total	526	582
Caesarean section planned: Yes	70 (49.6)	91 (51.1)
Baby's sex		
Male	252 (47.9)	300 (51.5)
Female	274 (52.1)	283 (48.5)
Birth weight (in gram)		
Under 2000 gram	16(3.1)	12 (2.1)
2000 to 2499 gram	28 (5.4)	24 (4.2)
2500 gram and above	476 (91.5)	538 (93.7)
Total	520	574
<i>Mean birth weight in gram (standard deviation)</i>	<i>3300 (600)</i>	<i>3200 (600)</i>
<i>Postpartum Bonding score: Mean (standard deviation)</i>	<i>28.6 (6.2)</i>	<i>28.8(6.3)</i>
Index child's development score; and parental stress at Time 3	Australian Born (n=435)	Refugee background (n=470)
<i>Ages and Stages Social Emotional score (21- 32 months) : Mean (SD)</i>	<i>29.3 (20.0)</i>	<i>35.2 (24.5)</i>
<i>Parental Stress total score: Mean (SD)</i>	<i>62.4 (7.1)</i>	<i>64.5 (6.9)</i>

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STROBE Statement—Checklist of items included in the WATCH *cohort study*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	

1	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
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9	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
10				
11	Discussion			
12				
13	Key results	18	Summarise key results with reference to study objectives	
14	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
15				
16	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
17				
18				
19	Generalisability	21	Discuss the generalisability (external validity) of the study results	
20				
21	Other information			
22	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	
23				
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26 *Give information separately for exposed and unexposed groups.

27
28 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
29 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
30 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
31 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
32 available at <http://www.strobe-statement.org>.
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BMJ Open

Cohort profile: mental health and intimate partner violence amongst women from refugee background and a comparison group of Australian-born: the WATCH cohort study

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health
Keywords:	PUBLIC HEALTH, MENTAL HEALTH, Adult psychiatry < PSYCHIATRY

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3 **Cohort profile: mental health and intimate partner violence amongst women from**
4 **refugee background and a comparison group of Australian-born: the WATCH cohort**
5 **study**
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9 Susan Rees,^{1*} Mohammed Mohsin,^{1,2} Batool Moussa,¹ Jane Fisher,³ Zachary Steel,¹ Nawal
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32 **ABSTRACT**
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34 **Purpose:** The Women Aware with Their Children (WATCH) study was created because
35 prospective data is required to accurately guide prevention programmes for intimate partner
36 violence (IPV) and improve the mental health and resettlement trajectories of women from
37 refugee backgrounds in Australia.
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42 **Participants:** 1335 women (685 consecutively enrolled from refugee backgrounds and 650
43 randomly selected Australian born) recruited during pregnancy from 3 public antenatal
44 clinics in Sydney and Melbourne, Australia. The mean age was 29.7 years among women
45 from refugee backgrounds and 29.0 years among women born in the host nation. Main
46 measures include IPV, mood, panic, post-traumatic stress disorder (PTSD), disability and
47 living difficulties.
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55 **Findings to date:** Prevalence of IPV at all three time points is significantly higher for
56 refugee background women. The trend data shows that IPV rates among Australian born
57 women increased from 25.8% at Time 1 to 30.1% at Time 3, while for refugee background
58 women this rate declined from 44.4% at Time 1 to 42.6% at Time 3. Prevalence of major
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3 depressive disorder (MDD) at all three time points is higher for refugee background women.
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5 MDD among Australian born women significantly declined from 14.5% at Time 1 to 9.9% at
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7 Time 3, while for refugee background women it fluctuated, from 25.1% at Time 1 to 17.3%
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9 at Time 2 and to 19.1% at Time 3.

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11 **Plans:** We are currently examining trajectories of IPV and mental disorder across three time
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13 points. Time 4 occurred during the COVID-19 pandemic, enabling a unique opportunity to
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15 examine the impacts of the pandemic over time. Time 5 started in August 2021 and Time 6
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17 will be approximately 12 months later. The children at Time 5 will be in the early school
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19 years, providing the capacity to examine behaviour, development, and well-being of the
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21 index child.

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24 Funded by National Health and Medical Research Council, Australia GNT1086774,
25
26 GNT1164736

27 28 29 30 **STRENGTHS AND LIMITATIONS**

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33 -This is the first systematically recruited longitudinal study of women from refugee background
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35 with a comparison group of locally-born women, allowing an examination of associations
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37 between traumatic events, intimate partner violence, mental disorders, functioning and
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39 settlement outcomes.

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41 -The study has a substantial sample size, a high response and high retention rate.

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43 -For assessing common mental disorders, we applied a structured diagnostic measure rather
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45 than screening instruments, and we used the WHO measure for intimate partner violence.

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47 -We used same language speaking interviewers and applied rigorous standards to ensure
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49 measures were culturally tested and cultural accuracy.

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51 -Recruitment in public health clinics are not fully generalisable to women attending private
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53 health services or those living in low-density refugee background areas.
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INTRODUCTION

The scale of the global refugee crisis is unprecedented. As a signatory to the Refugee Convention (1951), Australia and many other high-income countries including the UK and the USA have a long history of leadership in responding to international crises by admitting substantial numbers of refugees.[1] The success of refugee resettlement programs can be judged by the effectiveness of settlement policy for those admitted, indicated by health status, levels of acculturation, participation, and inclusion. It is imperative that all high income countries provide appropriate programs to assist refugees to overcome barriers to resettlement, some of the key obstacles being ongoing mental distress and exposure to stress and trauma.[1] One source of the latter that has been largely ignored is the unique experiences of women from conflict-affected backgrounds (hereon refugee women) in high-income countries. Refugee women's mental wellbeing and the problem of Intimate Partner Violence (IPV) are particularly important to consider in supporting them to settle and enjoy mental well-being in high-income countries.[2] Comprehensively defined, IPV includes physical, emotional, sexual and financial abuse by an intimate partner.[3] The World Health Organisation (WHO) estimates that the cumulative impact of IPV on morbidity and mortality exceeds the global burden of recognised public health problems.[4, 5] The stark reality is that one in six Australian women experience IPV, and between 80 and 100 women are killed every year by intimate partners.[6] Despite risk for higher IPV prevalence and the associated mental health risks, refugee women, who experience unique trauma and poverty-related factors that differentiate them from other migrants, have been largely ignored in high-income country studies of IPV [2]. Several inter-related reasons may place refugee women at risk of IPV including universal factors such as patriarchal values and economic adversity, as well as refugee-related factors such as premigration adversity, loss of social and cultural support, separation from family, and barriers to accessing and utilising educational, employment and welfare services in the new society. Refugee women face conditions of multiple jeopardy for common mental disorders (CMDs) including depression, anxiety and post-traumatic stress disorder (PTSD) because of their exposure to prior trauma in their homeland and during the process of flight; ongoing resettlement stresses; and critically, IPV in their family environment.[3] Despite this, there is dearth of systematic data examining the prevalence or impact of IPV on the mental health and functioning of refugee women either in Australia or worldwide. We set up the Women Aware with Their Children (WATCH) study because prospective data is required to provide a knowledge base to accurately guide prevention

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3 programmes for IPV, and improve the mental health and resettlement trajectories of refugee
4 women in Australia. The COVID-19 pandemic demonstrated the value of a cohort design,
5 which allows researchers to prospectively examine significant events on mental health, IPV
6 and functioning in women in high income countries, including the significant but often
7 neglected population of women from refugee background.[3]
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13 **Higher Risk for IPV and Mental Disorders**

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16 We previously confirmed a robust linear relationship between the quantum of trauma exposure
17 experienced by refugees and risk of CMDs, particularly PTSD and depression.[7] Whilst
18 refugee men are subject to traumas related to torture and imprisonment, women commonly
19 experience gendered trauma including rape, forced marriages, involuntary sterilization and
20 sexual slavery.[8-10] The effects of past trauma may be exacerbated by social and family
21 isolation during resettlement, adding to the difficulty that women face if they lack the skills,
22 knowledge or capacity to establish networks or seek assistance from support agencies.[11, 12]
23 Under these circumstances, it seems plausible that the additional trauma of ongoing IPV will
24 greatly increase the risk of onset or exacerbation of CMDs, generating compounding conditions
25 of adversity that undermine the woman's right and capacity to live in safety and achieve
26 successful resettlement. The experience-effect relationship between gender-based violence and
27 CMDs (including depression and PTSD) in women born in high income countries is now well
28 established in large cross sectional studies, with Rees and colleagues confirming this
29 association in a seminal nationally representative sample of English speaking Australian
30 women.[13] We have also shown that first exposure to IPV commonly precedes the new onset
31 of CMD in young Australian women, strengthening the argument for a causal relationship.[14]
32 Although studies are limited, IPV appears to be common in low-income, conflict-affected
33 societies that are the source of refugee flows; in addition, IPV is strongly associated with CMDs
34 in those settings.[8, 9, 15-17] Fisher et al found in rural Vietnam that experience of IPV was
35 associated with higher prevalence and severity of perinatal depression, anxiety and suicidal
36 thoughts.[16] Importantly, in a world first study in antenatal clinics in Timor-Leste, Rees and
37 colleagues found that women exposed to the dual experiences of extensive war-related trauma
38 and IPV were at 10 times greater risk of exhibiting common mental disorders.[15] Despite this,
39 no established longitudinal studies of IPV and mental illness other than the WATCH study
40 have been undertaken amongst refugees either in Australia and other high-income countries,
41 such as the USA and Canada.[11, 18] The WATCH study is one of the few rigorous studies
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3 with the capacity to define the trajectories of IPV over time, and to examine the risk factors
4 shaping adverse mental health outcomes such as depression, either in general or refugee
5 populations. Our first published paper from the WATCH baseline data reveals that women
6 identifying as refugees reported a much higher prevalence of major depressive disorder
7 symptoms and all the indicators of adversity related to that disorder. Even after risk factors
8 were accounted for, refugee status was associated with a greater risk of major depressive
9 disorder symptoms.[2]
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16 **COHORT DESCRIPTION**

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19 Participants and recruitment. Participants were first recruited between January 2015 and
20 March 2016. The study was conducted at 3 public antenatal clinics located in refugee-dense
21 geographic areas in Sydney and Melbourne, Australia. Consecutive women were recruited
22 from all Arabic-speaking countries, Sudan (all regions), and Sri Lanka (Tamil-speaking).
23 These nations represented the largest intake groups from conflict-affected regions entering
24 Australia and other high-income countries at the time of this study. By limiting the study to
25 these language groups, we sought to contain both the problems of transcultural measurement
26 error and small cell sizes. Country of origin was identified by clinic records, requests for an
27 interpreter, or culturally recognisable surnames, and country of birth data were checked
28 against clinic appointment lists. We refer to our cohort as people from refugee background,
29 however theoretically not all people who arrive from conflict-affected countries enter
30 formally as 'refugees' on Humanitarian Visas. Our inclusion criteria were informed by
31 knowledge that most people in those selected backgrounds (all Arabic-speaking countries,
32 Sudan, and Sri Lanka- Tamil-speaking) would have come from a conflict-affected country,
33 the extent to which is examined when we analyse our data. In some analysis we have tested
34 whether self-identifying as a refugee indicated a higher risk for mental disorder. We found
35 that women who identified as refugees from within our broader conflict-affected country
36 cohort indeed experienced higher prevalence of mood disorder, even after all other risk
37 factors were accounted for [2].
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53 One of the main objectives of this longitudinal project was to explore the prevalence and risk
54 factors of intimate partner violence (IPV) amongst Australian born and refugee background
55 women. Prior to the baseline survey (due to lack of data about prevalence of IPV among
56 Australian born and refugee background women in Australia and lack of information about
57 variability in the proportion of IPV) we assumed maximum variability as 0.50. Furthermore,
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3 considering a desired 95% confidence level and $\pm 5\%$ precision, with 90% power we
4 estimated that a sample of 385 women will be required for each group of women. It is to also
5 be noted that this longitudinal project was anticipated to extend to six waves of assessments
6 covering a period of 6 years or more. Dropout or loss of follow-up is a common problem in
7 longitudinal cohort studies – in order to achieve sufficient sample size ($n=385$) by the 6th
8 wave of assessment – considering 10.0% drop out rate between the two waves of data
9 collection – we estimated a sample size of 620 at the baseline survey would be required for
10 each group of women. This will ultimately allow us to achieve an estimated required sample
11 size of 385 at the 6th wave of assessment for each group of women respectively. This paper
12 refers to wave 1, wave 2 and wave 3 data; at wave 1, a total of 650 Australian born and 685
13 refugee background women were interviewed; and at wave 3, a total of 435 Australian born,
14 and 470 for refugee background women were interviewed; and the achieved sample sizes
15 (larger than 385 for both group) was sufficient for any advanced level statistical analysis
16 (refer to Figure 1)

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18 Recruitment occurred at a woman's first appointment at the clinic, which most commonly
19 occurred between 12 and 20 weeks gestation. Women with overt psychosis, severe medical
20 illness, and obvious intellectual impairment were excluded.

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22 Women born in Australia attended the clinics in substantially larger numbers than those from
23 conflict-affected countries. To undertake a parallel sampling strategy over a similar time
24 frame, we applied a computer-generated selection procedure to identify a random subset of
25 women from the host country daily. The randomised procedure was based on a kish grid,
26 with the primary number being determined by the total of attendees listed to attend the clinic
27 on each day (each arrival being allocated a number). Women members of the research team
28 who spoke the same language as eligible women approached them in the waiting room and,
29 following consent, conducted interviews lasting a maximum of one hour in private areas of
30 the clinic, with breaks for refreshments or to attend to children. Interviews with women from
31 Sudan were able to be conducted in either Dinka, English or Arabic.

32 33 34 **Public and Participants Involvement**

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36 Members of the public with expertise in the key cultural, language and background of the
37 target population are involved in the design, conduct, reporting and dissemination of our
38 research. We recruited and trained community members with the same cultural and language
39 backgrounds as the refugee populations to be employed as research assistants. Research
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3 assistants are consulted on the design of interview protocols, cultural advice, publications, as
4 well as, if required, checking accuracy during the analytic and interpretation stage. We set up
5 advisory groups of people from Arabic and Tamil communities to share and check cultural
6 and well as language accuracy in the questionnaires. The advisory groups consisted of
7 respected experts representing each culture. The experts were recommended to us by our
8 research assistants. The groups met and discussed the quality of the translation. They worked
9 through each interview question and debated and discussed it until agreement was reached on
10 the most accurate translation, taking into account linguistic, ethnic and cultural
11 interpretations. The Chief Investigator led the group discussion to ensure that the intended
12 meaning of the question or item was maintained. The groups identified and corrected
13 anything that was considered incomprehensible, unacceptable, incomplete or extraneous [19].
14 Our advice from Sudanese advisors was that agreement on the correct language in Dinka or
15 other ethnic Sudanese languages would be difficult to achieve because of the relative
16 complexity and nuance in the English questionnaire. The advice, therefore, was that person
17 interviewing in Sudanese (only one for consistency) would need to ensure uniformity with
18 her application of the interpretation from the English hard copy into Sudanese, and also when
19 translating the participant response back to score on the English version. It was also common
20 for Sudanese participants to be interviewed using the Arabic or English version, which was
21 checked by our Sudanese expert for cultural accuracy.
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37 **Ethics and Research Personnel**

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39 The study was approved by the South Western Sydney Local Health District Human
40 Research and Monash Health Ethics Committees. Participants provided written informed
41 consent and were remunerated for their time. In total, 8 women field workers from
42 appropriate language backgrounds were given extensive training, consisting of 3 formal
43 training days followed by tests of competence. Training covered IPV, research methods and
44 practice, sensitive interviewing techniques, and the use of the diagnostic and World Health
45 Organisation measures. Staff received ongoing support, monitoring, and supervision
46 throughout the study. Interrater reliability tests were conducted serially to maintain standards,
47 based on group observations of videotaped interviews. We adhered strictly to World Health
48 Organisation guidelines for conducting safe and ethical IPV research. This study followed
49 Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting
50 guidelines[20]
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3 Patients or the public are involved in the design, conduct, reporting and dissemination of our
4 research. We recruited and trained community members with the same cultural and language
5 backgrounds as the refugee populations to be employed as research assistants. All are
6 involved in design of interview protocols, cultural advice, publications, as well as checking
7 accuracy during the analytic and interpretation stage. We set up advisory groups of people
8 from Arabic and Tamil communities to share and check cultural and well as language
9 accuracy in the questionnaires.
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18 **HOW OFTEN HAVE PARTICIPANTS BEEN FOLLOWED UP?**

21 It is critical to ascertain whether the trajectory of ongoing IPV experiences and heightened
22 mental disorder change as refugee women progress from a central focus on infant child-rearing
23 to the early education years when women are more likely to engage more widely socially and
24 economically again (or for the first time) with the new society, either with or without having
25 another child. The purposely selected time-points in our cohort study also represent key
26 maternal-life stages, covering the critical period when women have greater potential to direct
27 their focus towards social participation and adaptation outside the family, including
28 engagement in education and employment.
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36 Recruitment and the baseline interview occurred at or close to the participant's first
37 appointment at the antenatal clinic which for most occurred between 12- and 20-weeks'
38 gestation between January 2015 and December 2016. First follow-up interviews (Time 2) were
39 conducted at home either in person or by telephone approximately 6 months after the birth of
40 the index child and the second follow-up survey (Time 3) was conducted at home either in
41 person or by telephone approximately 3.5 years after baseline and Time 4 was conducted 5.5
42 years after baseline. At Time 1 the response rate was 84.8% (1335 out of 1574), at Time 2
43 retention rate was 83.2% (1111 out of 1335 interviewed at Time 1), at Time 3 retention rate at
44 Time 3 was 67.8% (905 out of 1335 interviewed at Time 1) and the third follow-up survey
45 (Time 4) is currently being finalised and the data entered. We are currently planning Time 5
46 and Time 6. Time 5 will begin August 2021.
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56 **WHAT HAS BEEN MEASURED?**

At baseline (Time 1) we included basic sociodemographic characteristics (e.g. age, marital status, highest level of educational attainment, household composition and employment status), past traumatic events (TEs), financial difficulties (e.g. paying bills and affording enough food and heating), IPV, attitudes to gender equality and the use of violence against women; common mental disorders including major depressive disorder (MDD), PTSD, panic disorder, grief disorder, adult separation anxiety disorder (ASAD); and functional impairment as measured by the World Health Organisation Disability Assessment Schedule (WHODAS).[21] Measures related to IPV, CMDs (MDD, PTSD, panic disorder, grief disorder, ASAD) and functional impairment has been included in all four surveys so far, and assessed for significance since the previous interview (Time 1, Time 2, Time 3, Time 4). At Time 2 some basic measures related to pregnancy and childbirth were added: antenatal care, smoking during pregnancy, drinking alcohol during pregnancy, induced labour delivery (yes, no), analgesia provided in delivery (yes, no), type of birth (vaginal or caesarean), baby's sex and birth weight; and postpartum bonding score. At Time 3, in addition to common mental disorders for women, measures related to the index child's (aged 21 months and over) social and developmental indicators, emotional and behavioral problems, and parental experiences were included. All mental health measures were selected based on their previous psychometric evaluations and use across cultures. Measures were subjected to rigorous assessment of cultural and linguistic accuracy in the languages used.[22, 23] After standard translation and back-translation procedures were performed, final refinements were made by groups of linguistic experts (refer section above on public and participant involvement).

Traumatic events (TEs)

We assessed lifetime exposure to traumatic events (TEs) based on the inventory used in the World Mental Health Survey.[24]

Intimate partner violence

Intimate partner violence was assessed using items from the World Health Organisation (WHO) Violence Against Women questionnaire which enquires about physical, psychological and sexual violence perpetrated by the most recent intimate partner in the past 12 months. [25]

Gender role attitudes and beliefs

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3 Attitudes on gender role attitudes and beliefs including IPV were measured using the
4 'Attitudes Towards Gender Roles' items from the WHO Multi-Country Study on Women's
5 Health and Life Experiences Questionnaire.[26]
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10 **Common mental disorders (CMDs)**

11 We used the Mini-International Neuropsychiatric Interview (MINI) based on the Diagnostic
12 and Statistical Manual of Mental Disorders (Fourth Edition) (DSM-IV)[27] to assess current
13 MDD, PTSD, ASAD, Panic disorder, and Grief. We selected DSM-IV in preference to DSM-
14 5 because the latter had not yet been used extensively across cultures at the commencement of
15 the study.[28]
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22 **Functional impairment**

23 The World Health Organisation Disability Assessment Schedule (WHODAS 2.0, 12-item
24 version) has been extensively used across cultures to measure functional impairment. It
25 comprises six core functions/domains relating to cognition/communication, going out
26 (mobility), self-care, interpersonal interactions, life activities (work, home), and participation
27 in society (ratings for each item range from no impairment=1 to extreme impairment=5).[21]
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34 **FINDINGS TO DATE**

35 **Participant's socio-demographic characteristics at baseline survey (Time 1)**

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38 At Time 1, 1335 pregnant women were interviewed (with response rate 84.8%; 1335 out of
39 1574), including 650 women born in Australia (48.7%) and 685 from conflict-affected
40 countries, referred to as refugee background women in this paper (51.3%). The mean age for
41 women born in Australia was 29.0 ($SD= 5.5$) years; for women from conflict-affected
42 countries, it was 29.7 ($SD= 5.4$) years (Table 1). As expected, at Time 1 the socio-demographic
43 characteristics for women born in Australia were significantly different than women born in
44 conflict affected countries (Table 1). More than half (54.2%) of the refugee background women
45 arrived in 2010 or earlier, a third (33.4%) arrived in between 2011 and 2014, and the remaining
46 women 12.4% arrived in 2015 or later. Among women born in Australia, 58.1% were employed
47 at Time 1 and this rate was only 28.9% for women born in conflict affected countries. A greater
48 proportion of women who migrated from conflict affected countries reported experiencing
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three or more finance-related stressors (16.4%) and this rate was 6.3% for Australian born women (Table1).

Intimate partner violence at Time 1, Time 2 and Time 3

Results in Table 2 indicate that the prevalence of IPV at all three time points were significantly higher for refugee background women as compared to women born in Australia. The trend data (Time 1, Time 2, Time 3) shows that IPV rates among Australian born women increased from 25.8% at Time 1 to 30.1% at Time 3, while for refugee background women this rate declined from 44.4% at Time 1 to 42.6% at Time 3.

Gender role attitudes

Associations between socio-demographic characteristics and gender role attitudes and beliefs with IPV were examined from two time points using bivariate and multiple logistic regression analyses (this paper is recently published).[29]

Common mental disorders at Time 1, Time 2 and Time 3

Prevalence of MDD at all three time points was significantly higher for refugee background women as compared to women born in Australia. The trend data (Time 1, Time 2, Time 3) shows that prevalence of MDD among Australian born women significantly declined from 14.5% at Time 1 to 9.9% at Time 3, while for refugee background women this rate fluctuated, initially significantly declined from 25.1% at Time 1 to 17.3% at Time 2 and then increased to 19.1% at Time 3 (Table 2). The first paper published from the WATCH data reports the analysis of data from baseline, when women were recruited during pregnancy.[2] We aimed to examine prevalence and to identify which risk factors are associated with major depressive disorder in women from conflict-affected backgrounds resettling in a high-income country. This was an important focus because the evidence suggests that refugee women may have higher risk for depressive disorders, and pregnancy may also increase the risk of depression among women refugees. We found that women identifying as refugees reported a much higher prevalence of major depressive disorder symptoms and all the indicators of adversity related to that disorder. Even after risk factors were accounted for, refugee status was associated with risk of major depressive disorder symptoms. Assessing whether women attending an antenatal clinic self-identify as refugees may offer an important indicator of risk of major depressive disorder symptoms and a range of associated psychosocial adversities.

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3 Prevalence of PTSD and panic disorder was found to be comparatively higher among women
4 born in Australia and over the years the rates fluctuated in both groups of women. As compared
5 to refugee background women, prevalence of grief disorder was found to be lower in Australian
6 born women; and for both groups of women the rates were stable across three time points. One-
7 fifth of the women in both groups met the Adult Separation Anxiety Disorder (ASAD)
8 threshold criteria and over the years the rates fluctuated in both groups of women (Table 2).
9 Functional impairment scores were found to be almost same in both groups of women with the
10 mean score for women born in Australia declining from 16.6 ($SD=6.0$) at Time 1 to 13.9
11 ($SD=4.8$) at Time 3, and for refugee background women from 16.7 ($SD=6.1$) at Time 1 to 14.7
12 at Time 3 ($SD=5.6$).
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22 **Pregnancy and childbirth measures at Time 2 and Time 3**

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24 About two thirds of the women in both groups (Australian born: 64.6%, Refugee background:
25 68.1%) reported that in addition to the index child (born in between Time 1 and Time 2 survey)
26 they had one or more children (Table 3). The rate of smoking and drinking alcohol during
27 pregnancy was significantly higher for women born in Australia. More than a quarter of
28 Australian-born women had a caesarean birth (27.4%) and this rate was higher (30.6%) for
29 refugee background women. Among the Australian born women, 40.7% required induced
30 labour delivery and this rate was 30.5% for refugee background women. Low birth weight
31 (birth weight <2500 gram) among indexed babies born to Australian born mother (8.5%) was
32 higher when compared to refugee background women (6.3%). The mean postpartum bonding
33 score was found to be almost same for both groups of women (Table 3).
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43 **Child behaviour and parental stress experience at Time 3**

44 The mean score indicating compromised social and emotional development at Time 3 for the
45 index child (aged 21-32 months) born to refugee background women was significantly higher
46 than for the Australian born women's index children (Table 3). The mean parental stress score
47 for refugee background women was also found to be significantly higher than Australian born
48 women.
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55 **Time 4 and COVID-19**

56 Time 4 is novel in that it occurred during COVID-19, allowing a natural study of the impact of
57 the pandemic on women's mental health and IPV prevalence. We have also included specific
58 COVID-19 related questions of related hardship and stress. We can examine, for the first time
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3 in a study of this kind, a comparison of the impact of COVID-19 on women from refugee
4 backgrounds and women born in Australia. This analysis is current.
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8 **STRENGTHS AND LIMITATIONS**

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11 The main strength of our study is that, to our knowledge, it is the first systematically recruited
12 longitudinal study of women from refugee background with a comparison group of locally-
13 born women, allowing an examination of associations between traumatic events, IPV, mental
14 disorders, functioning and settlement outcomes. In addition, this study responds to a need in
15 larger pregnancy cohorts to be more inclusive of women born in war affected countries. Other
16 strengths include a substantial sample size and a high response and high retention rate. For
17 assessing common mental disorder, we applied a structured diagnostic measure rather than
18 screening instruments and we used the WHO measure for IPV, allowing for global comparisons
19 to be made. We used same language speaking interviewers and applied rigorous standards to
20 ensure measures were culturally tested. The MINI is a widely used diagnostic measure, and is
21 validated across cultures. One potential limitation of the MINI in the perinatal period is the
22 inclusion of somatic items that may be affected by pregnancy and lactation.
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33 Our deliberate strategy to focus on public health clinics where women from conflict-affected
34 countries concentrate may mean that the findings are not fully generalisable to women
35 attending private health services or those living in low-density refugee background areas.
36 Retrospective distortions, gaps in memory, and reluctance to divulge sensitive information (e.g.
37 related to IPV) are acknowledged possibilities that may lead to inaccuracies in reporting of past
38 events. It is difficult to determine whether these influences led to the overreporting or
39 underreporting of adversities. We cannot rule out selective attrition, for example “lack of time”,
40 the most common reason provided for drop-out, could indicate that women with greater child
41 rearing demands were less likely to remain involved in the study. Finally, recent arrivals of
42 participants from refugee background were not as strongly represented as those who arrived
43 after 2015, an observation that suggests the need for caution when generalizing our findings to
44 recent arrivals.
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55 **COLLABORATIONS AND FURTHER DETAILS**

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3 Interested scholars and others may contact the study team (Susan Rees, Zachary Steel or Jane
4 Fisher) if they wish to receive more information or have a proposal for collaboration. We are
5 interested in extending partnerships, particularly in preparing for future waves of data
6 collection and secondary data analysis.
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11 **Conflict of interest:** None declared.
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14 **Funding:** National Health and Medical Research Council, Australia GNT1086774,
15 GNT1164736
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19 Contributorship Statement: SR, JF, MY, NN, BM, FH, YK, BK made substantial
20 contributions to the initial study conception and study design. SR, MM, JF, ZS, MY, NN,
21 BM, FH, YK, BK made substantial contributions to the design and content of the study
22 protocol and the critical revision of the submitted manuscript; All authors have approved the
23 final article for submission. SR was responsible for the initial drafting of the manuscript.
24 MM, SR, BM were involved in data analysis and interpretation. SR, JF, ZS, NN, BM, FH,
25 MY, YK, BK were responsible for recruitment and monitoring of study participants. SR, JF,
26 ZS have responsibility for overseeing the study as it progresses and for provision of guidance
27 to research staff.
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Table 1 Socio-demographic characteristics for women born in Australia (host nation women) and women from conflict-affected countries (refugee background women) at baseline (Time 1).

Sociodemographic Characteristics	Australian women: No. (%)	^a All Conflict- country women: No. (%)	Australian born vs. Refugee background: p-values
All	650 (100.0)	685 (100.0)	
Age group			
<25	153 (23.5)	122 (17.8)	
25-34	381 (58.6)	423 (61.8)	
35 and above	116 (17.8)	140 (20.4)	$\chi^2=7.02$ (2); p=0.030
<i>Mean age (standard deviation)</i>	<i>29.0 (5.5)</i>	<i>29.7 (5.4)</i>	<i>0.019</i>
Highest level of educational attainment			
No post school qualification	286 (44.0)	350 (51.1)	
Diploma and vocational education	171 (26.3)	122 (17.8)	
University degree	193 (29.7)	213 (31.1)	$\chi^2=14.7$ (2); p=0.001
Marital status			
Married/Domestic partnership	566 (87.1)	649 (94.7)	p<0.001
Separated/Divorced/Others	84 (12.9)	36 (5.3)	
Family composition of household			
One parent family with dependent children/others	65 (10.0)	49 (7.1)	p=0.062
Couple family without/with dependent children/others	494 (76.0)	556 (81.2)	p=0.021
Multiple family without/with dependent children	91 (14.0)	80 (11.7)	p=0.204
Year of Arrival (for refugee background women)			
Arrived in 2015 or later		85(12.4)	
Arrived in 2011 to 2014		229 (33.4)	
Arrived in 2010 or before		371(54.2)	
Housing status			
Owner without a mortgage	39 (6.0)	30 (4.4)	p=0.180
Owner with a mortgage	252 (38.8)	212 (30.9)	p=0.003
Renter	241 (37.1)	367 (53.6)	p<0.001
Boarder and others	118 (18.2)	76 (11.1)	$\chi^2=38.93$ (3); p<0.001
Employment status			
Employed	383 (58.1)	198 (28.9)	
Unemployed and others	267 (41.1)	487 (71.1)	p<0.001
General traumatic events (TEs) counts ^b			
None	344 (52.9)	336 (49.1)	
One TE	182 (28.0)	212 (30.9)	
Two to three TEs	103 (15.8)	112 (16.4)	
Four or more TEs	21 (3.2)	25 (3.6)	$\chi^2=2.18$ (3); p=0.335
<i>Mean TEs (standard deviation)</i>	<i>0.8 (1.2)</i>	<i>0.9 (1.1)</i>	<i>p=0.112</i>
Number of finance related stress/difficulties ^c			
None	498 (76.6)	427 (62.3)	
One to two	111 (17.1)	146 (21.3)	
Three or more	41 (6.3)	112 (16.4)	$\chi^2=42.27$ (2); p<0.001

^a Country of birth for refugee background women No. (%): Iraq 260 (38.0%); Lebanon 125(18.2%); Sudan 66 (9.6%); Syria 30 (4.4%); Egypt 29 (4.2%); Afghan 13 (1.9%); Sri Lanka 71 (10.9%); India, Pakistan and others 91 (13.3%).

^b General TE counts included 13 items: (1) Were you ever kidnapped or held captive?; (2) Were you ever involved in a life-threatening automobile accident?; (3) Did you ever have any other life-threatening accident, including on your job?; (4) Did you ever have a life-threatening illness?; (5) As a child, were you ever badly beaten up by your parents or the people who raised you?; (6) Were you ever mugged, held up, or threatened with a weapon? ; (7) Did someone very close to you ever die unexpectedly; for example, they were killed in an accident, murdered, committed suicide, or had a fatal heart attack at a young age?; (8) Did you ever have a son or daughter who had a life-threatening illness or injury? ; (9) Did anyone very close to you ever have an extremely traumatic experience, like being kidnapped, tortured or raped?; (10) Did you ever do something that accidentally led to the serious injury or death of another person?; (11) Did you ever on purpose either seriously injure, torture, or kill another person?; (12) Did you ever experience any other extremely traumatic or life-threatening event that I haven't asked about yet? ; (13) Did you ever have a traumatic event that you didn't report because you didn't want to talk about it? (each item coded yes=1, no=0).

^c Number of ongoing finance related stressors included following seven items: (1) Could not pay electricity/gas/telephone bills on time; (2) Could not pay for car registration/insurance on time; (3) Pawned or sold something; (4) Went without meals; (5) Unable to heat my home; (6) Sought assistance from welfare/community organisations; and (7) Sought financial help from friends or family (each item coded yes=1, no=0). A summary financial stress count was generated by adding all endorsed items (score ranges from 0 to7).

Table 2 Prevalence of intimate partner violence (IPV) and common mental health disorders for women born in Australia (host nation women) and women from conflict-affected countries (refugee background women) at baseline (Time 1) indices for Australian born and refugee background women at Baseline survey (Time 1) and two follow-up surveys (Time 2, Time 3).

Intimate partner violence (IPV) and common mental health disorders	Women born in Australia			Refugee background women		
	Time 1 (n=650)	Time 2 (n=528)	Time 3 (n=435)	Time 1 (n=685)	Time 2 (n=583)	Time 3 (n=470)
	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)	Number (%)
Intimate partner violence (IPV): Yes	168 (25.8)	143 (27.1)	131 (30.1)	304 (44.4)**↑	256 (43.9)**↑	200 (42.6)**↑
Major Depressive Disorder :Yes	94 (14.5)	63 (11.9)	43 (9.9)	172 (25.1)**↑	101 (17.3)*↑	90 (19.1)**↑
Post-traumatic Stress disorder (PTSD):Yes	39 (6.0)	43 (8.1)	33 (7.6)	37 (5.4)	24 (4.1)**↓	37 (7.9)
Panic Disorder : Yes	47 (7.2)	51 (9.7)	52 (12.0)	26 (3.8)**↓	20 (3.4)**↓	15 (3.2)**↓
Grief disorder :Yes	21 (3.2)	16 (3.0)	14 (3.2)	40 (5.8)*↑	26 (4.5)	23 (4.9)
Adult Separation Anxiety Disorder: Yes	127 (19.5)	107 (20.3)	86 (19.8)	170 (24.8)*↑	111 (19.0)	103 (21.9)
<i>WHODAS disability score: Mean (SD)</i>	<i>16.6 (6.0)</i>	<i>13.9 (4.3)</i>	<i>13.9(4.8)</i>	<i>16.7 (6.1)</i>	<i>14.5(5.2)*↑</i>	<i>14.7 (5.6)*↑</i>
				Australian born vs. Refugee background: p-values for respective surveys		
				T1 vs. T1	T2 vs. T2	T3. vs T3
Intimate partner violence (IPV): Yes				<0.001	<0.001	<0.001
Major Depressive Disorder :Yes				<0.001	<0.011	<0.001
Post-traumatic Stress disorder (PTSD):Yes				0.638	0.005	0.872
Panic Disorder : Yes				0.006	<0.001	<0.001
Grief disorder :Yes				0.026	0.213	0.204
Adult Separation Anxiety Disorder: Yes				0.020	0.610	0.429
<i>WHODAS disability score: Mean (SD)</i>				<i>0.762</i>	<i>0.037</i>	<i>0.021</i>

Note: (↑) indicates rates (or mean) for refugee background women are significantly higher as compared to Australian born women;
(↓) indicates rates (or mean) for refugee background women are significantly lower as compared to Australian born women;
*Indicates significant at $p < 0.05$; **Indicates significant at $p < 0.01$.

Table 3 Woman and Index child's characteristics at first follow-up survey (Time 2), social emotional score for babies (aged 21-32 months) and parental stress experience at 2nd follow-up survey (Time 3).

Woman and index child's characteristics at Time 2	Australian Born (n=528)	Refugee background (n=583)	Australian born vs. Refugee background: p-values
Does woman have any other Children: Yes	340 (64.6)	397 (68.1)	0.193
Smoked during pregnancy: Yes	84 (15.9)	24 (4.1)**↓	<0.001
Drink alcohol during pregnancy: Yes	52 (10.1)	7 (1.3)**↓	<0.001
Induced Labor Delivery: Yes	214 (40.7)	177 (30.5)**↓	<0.001
Analgesia provided in delivery (pain relief/epidural)?: Yes	333 (65.3)	315 (56.4)**↓	0.003
Type of birth			
Vaginal	382 (72.6)	404 (69.4)	0.342
Caesarean	144 (27.4)	178 (30.6)	0.226
Total	526	582	
Caesarean section planned: Yes	70 (13.3)	91 (15.6)	0.262
Baby's sex			
Male	252 (47.9)	300 (51.5)	0.215
Female	274 (52.1)	283 (48.5)	
Birth weight (in gram)			
Under 2000 gram	16(3.1)	12 (2.1)	
2000 to 2499 gram	28 (5.4)	24 (4.2)	
2500 gram and above	476 (91.5)	538 (93.7)	0.165
Total	520	574	
Mean birth weight in gram (standard deviation)	3300 (600)	3200 (600)**↓	0.006
Postpartum Bonding score: Mean (standard deviation)	28.6 (6.2)	28.8(6.3)	0.597
Index child's development score; and parental stress at Time 3	Australian Born (n=435)	Refugee background (n=470)	
<i>Ages and Stages Social Emotional score (21- 32 months) : Mean (SD)</i>	29.3 (20.0)	35.2 (24.5)**↑	<0.001
<i>Parental Stress total score: Mean (SD)</i>	62.4 (7.1)	64.5 (6.9)**↑	<0.001

Note: (↑) indicates rates (or mean) for refugee background women are significantly higher as compared to Australian born women;
(↓) indicates rates (or mean) for refugee background women are significantly lower as compared to Australian born women;
*Indicates significant at p<0.05; **Indicates significant at p<0.01.

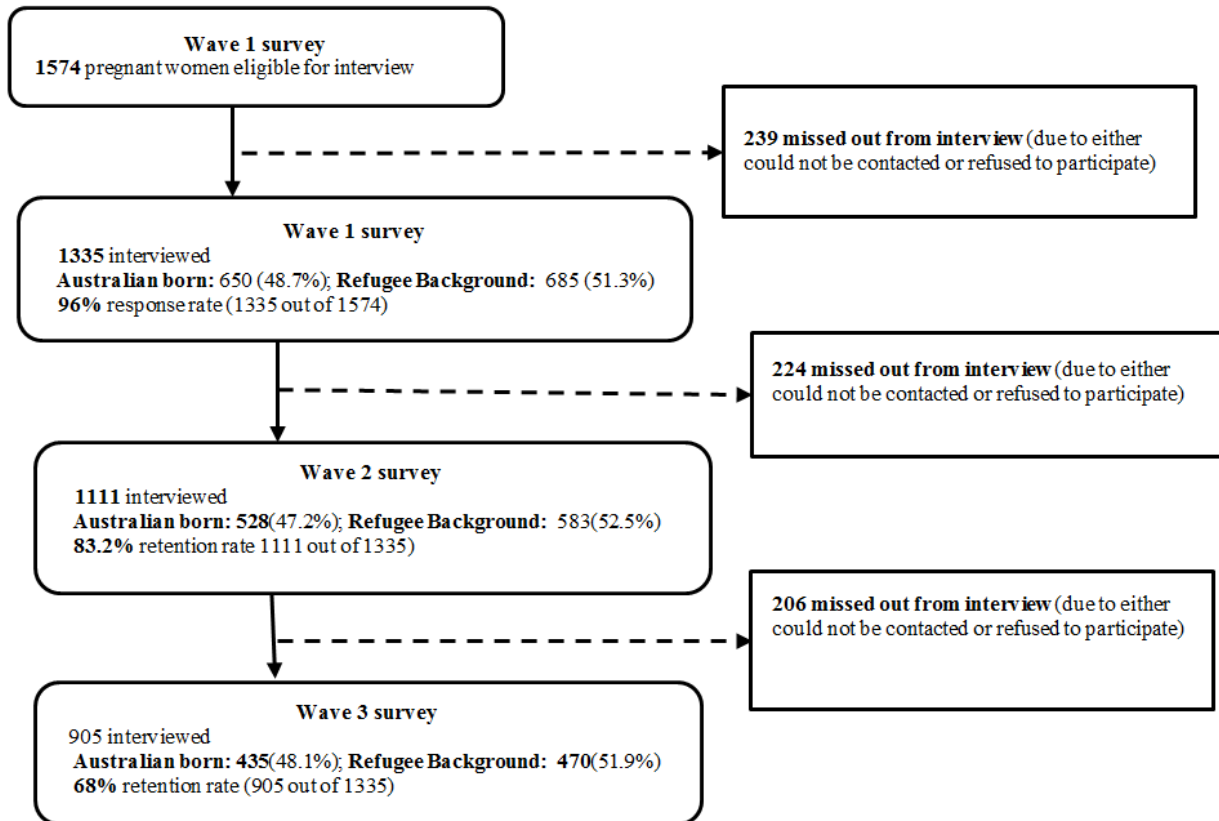
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For peer review only

Figure 1. Flowchart covering participants interviewed at Wave 1 to Wave 3 survey

STROBE Statement—Checklist of items included in the WATCH *cohort study*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	
Objectives	3	State specific objectives, including any prespecified hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	Report numbers of outcome events or summary measures over time	

1	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	
2			(b) Report category boundaries when continuous variables were categorized	
3			(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
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9	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	
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11	Discussion			
12				
13	Key results	18	Summarise key results with reference to study objectives	
14	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	
15				
16	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	
17				
18				
19	Generalisability	21	Discuss the generalisability (external validity) of the study results	
20				
21	Other information			
22	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	
23				
24				

25
26 *Give information separately for exposed and unexposed groups.

27
28 **Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and
29 published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely
30 available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at
31 <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is
32 available at <http://www.strobe-statement.org>.
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