Statistical Analysis Plan

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NHMRC 1134477

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The structure of this SAP follows the guidance of Gamble C et al, Guidance for the Content of Statistical Analysis Plans. JAMA 2017: 318;23

LIST OF ABBREVIATIONS

Best Practice	BP
Data Safety Monitoring Committee	DSMC
Domestic Violence and Abuse	DVA
Domestic Violence identification	DV
Domestic Violence Referral	DVREF
Domestic Violence Safety Plan	DVSP
Electronic Medical Record	EMR
Family Violence	FV
General Practitioner	GP
Incidence Rate Ratio	IRR
Interquartile Range	IQR
Latent Class Linear Mixed Model	LCMM
Medical Director	MD
North-West	NW
Relative Risk Ratios	RRR
Royal Australian College of General Practitioners	RACGP
Socio-Economic Indexes For Areas	SEIFA
South Asian	SA
South-East	SE
Standard Deviation	SD

CONTENTS

1 ADMINISTRATIVE INFORMATION

1.1 TRIAL IDENTIFIERS

- **Published protocol:** HARMONY: A pragmatic cluster randomised controlled trial of a culturally competent systems intervention to prevent and reduce domestic violence among migrant and refugee families in general practice: study protocol **BMJ Open 2021: 11e046431 doi 10.1136/**
- **Trial Registration**: ANZCTR- ACTRN12618001845224p
- **Trial funding**: NHMRC 1134477: Partnerships in Health Fund, Commonwealth of Australia Department of Social Services, Victorian government Department of Multicultural Affairs and Social Inclusion.

1.2 SAP REVISION HISTORY

Version	Date	Changes made to document	Authors
1.0 (draft)	03/02/2021	Populated known information	Felicity Young
2.0	26/10/2021	Updating all details, variable definitions variable coding and analysis	Angela Taft and Felicity Young
3.0	30/11/2021	Additional analysis and editing/checking details	Xia Li and Angela Taft
4.0	7/4/2022	Final additions following April 2022 Steering Committee agreement	Angela Taft

1.3 CONTRIBUTORS TO THE STATISTICAL ANALYSIS PLAN

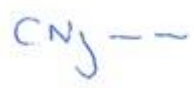
1.3.1 ROLES AND RESPONSIBILITIES

Names and ORCID	Affiliation	Role on study	SAP contribution
Angela Taft ORCID 0000-0002-6350-843X	La Trobe University	Chief investigator	Overall broad structure, coordination and content
Felicity Young ORCID 0000-0001-7369-6502	La Trobe University	Research Manager	Detail of implementation and some data description
Xia Li	La Trobe University	Associate Investigator	Statistical methods
Cattram Nguyen ORCID 0000-0002-0599-8645	Murdoch Children's Research Institution	Associate Investigator	Oversight of statistical analysis

Warwick Strangward	HABIC, Melbourne University	GRHANITE Data Project Manager	Detail of data abstraction

1.3.2 APPROVALS

The undersigned have reviewed this plan and approve it as final. They find it to be consistent with the requirements of the protocol as it applies to their respective areas. They also find it to be compliant with ICH-E9 principles and, in particular, confirm that this analysis plan was developed in a completely blinded manner (i.e. without knowledge of the effect of the intervention(s) being assessed).

Angela Taft		May 12 2022
Xia Li		May 19 2022
Cattram Nguyen		May 19 2022
Felicity Young		May 20 2022

2 INTRODUCTION

Domestic violence and abuse (DVA) is prevalent, harmful and more dangerous among diaspora communities because of the difficulty accessing DVA services, language and migration difficulties. Consequently, migrant/refugee women are common among primary care populations, but evidence for culturally competent DVA primary care practice is negligible. This pragmatic cluster randomised controlled trial aims to increase DVA identification and referral (primary outcomes) threefold and safety planning (secondary outcome) among women attending intervention versus comparison primary care clinics. Additionally, the study plans to improve recording of DVA, ethnicity, and conduct process and economic evaluations.

2.1 STUDY OBJECTIVES

2.1.1 PRIMARY OBJECTIVE

Specifically, HARMONY aims **primarily** to evaluate whether the HARMONY intervention can:

- Increase (a) GP identification and (b) referral of DVA among all women aged 18+ in intervention versus comparison clinics.

This will be measured (a) by extracting routine GP data on identification and referrals from both arms and comparing intervention and comparison rates, and (b) compared for accuracy with referrals received by InTouch Multicultural Centre for Family Violence in both arms. We will also examine the identification and referral rates among South Asian women.

2.1.2 SECONDARY OBJECTIVES

HARMONY's **secondary** aims are to:

- Increase GP safety planning for DVA among women aged 18+ in intervention compared to usual care clinics.

This will be measured by extracting routine GP data. We will also investigate the rate among migrant/refugee (specifically South Asian) women.

- Determine the cost effectiveness of the intervention relative to comparison care.
- Investigate the factors that enable practice change and sustainability.

Explore experiences a diverse sample of all clinic staff and also migrant/refugee women's experiences of intervention GP care and those in comparison GP clinics, if possible.

2.2 STUDY POPULATION

2.2.1 ELIGIBILITY CRITERIA

- Inclusion criteria: To be eligible, GP clinics must (a) have ≥1 South Asian bilingual/bicultural GPs and (b) use either of the two most common GP medical software programs in Australia (Medical Director or Best Practice) and agree to have anonymised data extraction by the GrHanite™ software program from computerised medical records.
- Exclusion criteria: clinics outside these regions, those without any South Asian GPs, and whose medical software is neither of the two most common programs.

2.2.2 RECRUITMENT

To identify eligible clinics in communities with high South Asian populations, we consulted with the Victorian State Government and South-Asian Community organisations to identify regions and postcodes with the large South-Asian population. North-West (NW) and South-East (SE) metropolitan areas were identified as the areas for recruitment.

HARMONY staff examined online website clinic data to identify GPs with SA names in relevant regions, and from the Melbourne and Monash Universities' GP research networks and Primary Health Networks.

361 Clinics were faxed or emailed letters of invitation, followed by a phone call and an in person visit to further explain the study. 24 clinics were recruited and randomised, and 5 withdrew after randomisation but before the intervention began. 19 clinics were included in the study.

3 STUDY METHODS

3.1 TRIAL DESIGN

The HARMONY Study is designed as a pragmatic (parallel group) cluster-randomised controlled trial conducted in General Practice (GP) clinics evaluating an intervention to increase rates of GP culturally competent identification, safety planning and referral of women aged 18+ experiencing domestic violence and abuse (DVA).

GP clinic staff in the intervention arm with be provided with three 90-minute culturally competent DVA training sessions, and 12-month support from a bicultural South Asian advocate educator based at a multicultural family violence service. Intervention clinic identification, safety planning and referral rates will be compared with those in the comparison arm GP clinics, which will not receive the DVA training or yearlong support from an advocate educator. Increased identification, safety planning and referral rates are expected in the intervention arm GP clinics. However, training without advocate support will be offered to comparison clinics after the 15-month data retrieval period.

3.2 RANDOMISATION AND BLINDING

Randomisation and allocation concealment

Upon recruitment of ≥10 clinics and GrHanite™ installation, a statistician (blind to assigned group) entered the list into a computer minimisation program including a random component and allocated clinics to group A or B. Recruitment continued in blocks of 4 or more. Clinics were incrementally randomised in the same way until ≤28 are randomised. Clinics were randomised stratified for: (1) size of practice - small [≤5 doctors] and large [six or more] (Full-time equivalent) and (2) SEIFA index (Australian Bureau of Statistics, 2018) for clinic postcode (1- 5 classified as 'lower' and 6 or more as 'higher) and (3) by location, where an equal number and size of clinics are assigned to the intervention (≤7 each for NW and SE) and comparison arms (≤7 each for NW and SE). Clinics were allocated and informed of their status by unblinded HARMONY research staff. The statistician considered the withdrawal and re-joining of clinics throughout the randomisation process. However, due to the impact of the Covid19 pandemic, several clinics withdrew after randomization and the clusters of intervention and comparison are unbalanced and adjustment will be made.

Blinding

HARMONY investigators and GrHanite™ staff are blinded to the randomisation outcome of clinics. HARMONY administration staff cannot be blinded to clinic status, as they are required to coordinate training in both arms of the study. Clinic staff are therefore not blinded either. Subsequent to clinic dropout, the statistician was unblinded due to the imbalance of clinics in either arm.

3.3 SAMPLE SIZE

Based on our own feasibility study and IRIS outcomes (Feder, et al., 2011), we estimate that the rate of DVA identification will be five women per 1000 female patients in the baseline arms. To detect an increase in the identification or referral rate to 20 women per 1000 with 80% power and a significance level of 5%, 873 person-years per arm is required for individual randomisation. This sample size was inflated to account for the cluster design; assuming an intra-cluster coefficient of 0.01, and a cluster size from 2000-3000 person-years per clinic (based on conservative mean size

of the GP female populations in our feasibility study). With these estimations, we require 28 clinics (allowing for a 21% drop out to 22 clusters).

These figures have been seriously affected by the Covid pandemic among our clinic areas.

The recruitment of clinics was impacted by numerous obstacles including staff changes and the outbreak of COVID-19 pandemic. The randomisation process was undertaken in stages due to rolling recruitment prior and during the pandemic.

3.4 FRAMEWORK

Superiority trial and comparisons to be included are outlined below.

3.5 TIMING OF FINAL ANALYSIS AND OUTCOME ASSESSMENTS

3.5.1 TIMING OF FINAL ANALYSIS

Example, all outcomes analysed collectively

- **Baseline** analysis to be conducted by **end-May 2022**
- **3, 6, 9, 12-month** outcome assessments at intervention completion **end May to be analysed by end July**
- **15 months data** analysis delivered late August early September to check retention of outcome effects analysed by **end of October.**

3.5.2 TIME POINTS AT WHICH THE OUTCOMES ARE MEASURED INCLUDING VISIT WINDOWS

Data are extracted from clinic computers and forwarded to the statistician at 3, 6, 9, 12 and 15 months from the clinic entering the intervention period (after first training session) at intervals, following the final clinic passing that time point.

4 OUTCOMES

4.1 PRIMARY OUTCOMES

Specifically, HARMONY aims primarily to

- Increase (a) GP identification and (b) referral of DVA among all women aged 18+ in intervention versus comparison clinics.

This will be measured (a) by extracting routine GP data on identification and referrals, and (b) compared with referrals received by *InTouch* Multicultural Centre for Family Violence in both arms. We will explore the rate among migrant/refugee (especially South Asian women).

4.2 SECONDARY AIMS

HARMONY's secondary aims are to

- Increase GP safety planning for DVA among women aged 18+ in intervention compared to usual care clinics. This will be measured by extracting routine GP data. We will explore the rate among migrant/refugee (especially South Asian women)
- Determine the cost effectiveness of the intervention relative to comparison care
- Investigate the factors that enable practice change and sustainability

Primary outcomes of identification, referrals and the secondary outcome of safety planning will be extracted from routine data from 1 December 2018 to 1 December 2019 (*except for 1 clinic that had no EMR prior to 2019, and will be for 20 December 2019 to 20 December 2020*) for baseline (prior to any training and to Covid19, excluding 1), six months from each clinic's commencement date (following Session 1), 12 months (intervention completion) and 15 months following completion of each clinic's first training session to assess sustainability. Anonymised and aggregated routine data for all clinical outcomes will be collected from GP clinic medical records using the GrHanite™ software tool.

4.3 INTERVENTION

4.3.1 INTERVENTION

Clinics randomised into the HARMONY intervention arm will receive:

Clinic training with an emphasis on cultural competency. The intervention is defined as commenced following the first clinic training. Intervention staff undertake three DVA 90-minute online training sessions from a general practitioner (GP) educator and bilingual DVA advocate/educator. Following training, clinic staff and DVA affected women 18 + is supported for 12 months by the advocate/educator.

4.3.2 COMPARISON

Comparison clinics will receive half an hour of online training and reminder newsletters to better document ethnicity and DVA outcomes into routine software. They will continue to offer routine GP care for any DVA patients they see. At the end of the 12-month intervention, comparison clinics will be offered the full training program. They will not receive the specialised advocate/educator support.

5 STATISTICAL ANALYSIS

5.1 GENERAL PRINCIPLES

Statistical analysis will be conducted using an intention-to-treat analysis, adjusted for cluster, once the aggregated data have been fully extracted. See above 3.5 Timing of data analysis. Population for analysis is defined as aggregated counts of female GP patients defined as 'active' (RACGP definition – three or more visits in the past two years) aged ≥18 years on routine GP software in intervention.

❖ Summary of changes compared to the protocol or public registries

- Following the recruitment of 24 clinics and COVID-19, five dropped out, leaving an imbalance of 19 clinics. The data will be reported from the University of Melbourne GrHanite team in numbered clinics by region and not in intervention group. The practice manager will provide the statistician with aggregated numbers by group for her blinded analysis.

❖ Descriptive statistics

- All outcomes will be presented using descriptive statistics; normally distributed data by the mean and standard deviation (SD) and skewed distributions by the median and interquartile range (IQR). Binary and categorical variables will be presented using counts and percentages.

❖ Detail of statistical software that will be used for the analyses.

- RStudio will be used for all statistical analysis (RStudio Team (2019). RStudio: Integrated Development for R. RStudio, Inc., Boston, MA URL http://www.rstudio.com/)

❖ Data cleaning approach and process:

- Browsing of data tables after sorting.
- Printouts of variables not passing range checks and of records not passing consistency checks.
- Graphical exploration of distributions: box plots, histograms, and scatter plots.
- Plots of repeated measurements on the same group.
- Frequency distributions and cross-tabulations.
- Summary statistics.
- Statistical outlier detection.

❖ Data definitions/derivations:

- **Patient age** -with respect to patients under 18;
  - GrHanite will not extract any data for any patient that is under 18
  - GrHanite will not reference any data for any identified patient that occurred when they were under 18
  - In effect, any event (e.g., visit) or information (e.g., diagnoses) that took place or was disclosed whilst a person is less than 18 will be ignored.
  -
- **South-Asian patients** will be identified via 2 criteria. A patient must meet at least 1 of the criteria to be classified South-Asian.
  1. A patient has a surname classified as South-Asian from a list of over 7,000 verified South-Asian surnames collated by the research team.
  2. A patient's ethnicity and/or country of birth is denoted by the research team as

South-Asian in the medical software (BP or MD), see below.

- Medicare Card

  Certain visas (international students, overseas visitors, and temporary visa holders) are not eligible for Medicare. Responses in this column will appear as 'Y' or 'N'.

- Pension Card and Health Concession Card

Rules for pension and health card allocation in medical software:

- **BP**
  - If a patient is coded as having a Pensioner concession Card, then they will be marked as 'Y' for Pension and 'N' for Health concession card
  - If a patient is coded as having a Health Care Card, then they will be marked as 'N' for Pension and 'Y' for Health concession card
  - If a patient is coded as having a Commonwealth Senior's Health Card, then they will be marked as 'N' for Pension and 'Y' for Health concession card
- **MD**
  - If the patient has a populated Pension number field, and coded with the Pension Status field as "None" then they will be marked as 'Y' for Pension and 'N' for Health concession card
  - If the patient has a populated Pension number field, and coded with the Pension Status field as "Pension/HCC" then they will be marked as 'Y' for Pension and 'Y' for Health concession card
  - If the patient has NO populated Pension number field, and coded with the Pension Status field as "None" then they will be marked as 'N' for Pension and 'N' for Health concession card
  - If the patient has NO populated Pension number field, and coded with the Pension Status field as "Pension/HCC" then they will be marked as 'N' for Pension and 'Y' for Health concession card

- Private Health Card

  A private health care card is optional to record in the medical software. Will appear as 'Y' or 'N'.

5.1.1 METHOD FOR VALIDATING THE RESULTS

The creation of the aggregated tables is a multi-step process.

Firstly, GrHanite, created a table of all individual patients, with a separate field calculated for each and every piece of information that is relevant and required for the aggregated table build.

The XML cycles through and calculates the appropriate values for each field for each patient.

The next step is to build the aggregate table by summing the different count fields by the combination of the different parameters (Time Period, Year of birth, Medicare, Pension, Private Healthcare, South-Asian status). Test cases were developed using the EMR.

The testing follows the above two steps - patients are firstly traced from the EMR to our patient table checking the EMR data against each field/flag in the patient detail table. We then test the aggregation of the patient table to the aggregated tables.

5.2 PATIENT CHARACTERISTICS AND BASELINE COMPARISONS

Variables for clinic characteristics and patient demographics

Variable	Definition
Clinic code	Unique identifier for each clinic
Clinic Staff	Number of clinic staff
GPs	Number of GPs
Clinic Software	Identifies if the clinics is using Best Practice or Medical Director software
Extraction date	Date in which the data was extracted
Time Point Description	Text description of the time point at which the data has been retrieved e.g. End of Baseline
Time Point Date	Numerical time point at which the data has been retrieved e.g. 1/12/2019
Year of birth	Patients year of birth
SEIFA code	SEIFA index associated with patient's post-code. Decile 1 is the most disadvantaged relative to the other deciles, 10 being the least disadvantaged. SEIFA codes will be re-classified into three categories -low (1-3)/medium (4-7) /high (8-10)
Has Medicare	Patient has a Medicare card. Y = Yes; N = No
Has Pension	Patient has a Pension card. Y = Yes; N = No
Has Health fund	Patient has a Private Health Fund card. Y = Yes; N = No
Has Health Concession	Patient has a Health Concession card. Y = Yes; N = No
South Asian flag	Patient is recorded as South-Asian based on their surname from study list and/or data recorded country of birth and/or ethnicity
Gender	Patient's gender. F = Female; M = Male, I = Indeterminate
Count of Patients	Total patients, male, female and indeterminant that are classified as 'active' with the above variable.

Variables for outcome data

Variable	Definition
Clinic code	Unique identifier for each clinic
Clinic Software	Identifies if the clinics is using Best Practice or Medical Director software
Extraction date	Date in which the data was extracted
Time Point Description	Text description of the time point at which the data has been retrieved e.g., End of Baseline
Time Point Date	Numerical time point at which the data has been retrieved e.g. 1/12/2019
Year of birth	Patient's year of birth
South Asian flag	If a person is denoted as South-Asian based on their surname and/or country of birth and/or ethnicity
Count of unique DV-related patients	A patient is classified with DV if at any point in time during Baseline (2018-19) or intervention period (after first training), (but NOT the interim) period: (1) There is a DV-related text in either the BP VISIT.VISITNOTES or VISITREASON.REASON fields. In this case the 'VisitDate' is the date to be used to determine the earliest DV-related date for the patient, or (2) There is a DV-related text in either the BP PASTHISTORY.ITEMTEXT or PASTHISTORY.DETAILS fields. In this case the 'RECORDCREATEDDATE' is the date to be used to determine the earliest DV-related date for the patient. A patient who does not have any visit during these periods will not be included. A patient who ONLY had non-DV-related visits during these periods will still be included IF they are classified with DV. A patient will be included if they had any visit during these periods, and they are classified as DV-related due to a current or previous visit or diagnosis at any time since the commencement of the baseline period. We will use the Created Date for Diagnoses/Past History. The terms (and combination of terms) to be used for the selection criteria are those in Groups 1-6 (See Appendix 2 for terms.
*Count of visits with DV text	Aggregate visits recorded indicating DV appointment. E.g., Domestic violence victim
*Count of visits with Safety Plan	Visit recorded that indicates a safety plan appointment. E.g., Safety Plan. This variable cannot be triggered without a DV text variable.
*Count of visits with Referral	Visit recorded that indicates a referral to a DV service. E.g., Safe Steps. This variable cannot be triggered without a DV text variable.
**Count of visits	Aggregated count with DV in visit record

with DV	
**Count of visits with DVSP	DVSP recorded in visits record
**Count of visits with DVREF	DVREF recorded in visits record
Count of non-DV related visits	This count will only include visits since the first DV-related visit or diagnosis for that patient.
Count of patients with between 1-5 visits	Count of patients who had this count range of visits for any reason during the baseline and intervention periods.
Count of patients with between 6-10 visits	Count of patients who had this count range of visits for any reason during these periods
Count of patients with over 10 visits	Count of patients who had this count range of visits for any reason during these periods
SEIFA code 1-3	SEIFA index associated with patient's post-code. Decile 1 is the most disadvantaged relative to other deciles
SEIFA code 4-7	Middle range of SEIFA codes – medium
SEIFA code 8-10	The least disadvantaged codes - High.
Has Medicare	Indication if patient has a Medicare card. Y = Yes; N = No
Has Pension	Indication if patient has a Pension card. Y = Yes; N = No
Has Health fund	Indication if patient has a Private Health Fund card. Y = Yes; N = No
Has Health Conc	Indication if patient has a Health Concession card. Y = Yes; N = No
Gender	Patient's gender. F = Female; M = Male, I = Indeterminate
Count of Patients	Total patients, male, female and indeterminant that are classified as 'active' with the above variable.

* Text provided to GrHanite of word combinations to flag. A Safety Plan will override a DV text and a Referral will override a Safety Plan/ DV text in an appointment. E.g. 'Domestic violence, safety plan' will appear under safety plan. Eg2. 'Safety plan, CASA referral' will appear as a Referral to a DV service. (See Appendix 2).

** The mutually exclusive terms (DV, DVSP, DVREF) will only appear in the intervention period outcome data. DV will be overridden by DVSP, and DV and DVSP will be overridden by DVREF. E.g. DV, DVSP will appear in DVSP only. Eg2. DVSP, DVREF will appear as a DVREF only. (See Appendix 2).

5.3 MULTIPLICITY ADJUSTMENT

Evaluation of the primary and secondary outcomes will be analysed independently, and no multiplicity adjustments will be made for these.

6 ANALYSIS OF OUTCOMES

6.1 OUTCOME DEFINITIONS

6.1.1 PRIMARY OUTCOME

- Recorded **identification** of DVA among active (RACGP definition – three or more visits in the past two years) female patients aged ≥18 years on routine GP software in intervention (I) clinics compared with comparison (C) clinics. The denominator for this outcome and the one below will be the number of all active female patients ≥18 years in the same time period.
- Number of **referrals** of all affected active female patients 18 ≥recorded on routine GP software compared with comparison clinics
- **Count of referrals of women recorded as received by InTouch** from intervention clinics versus comparison clinics will also be compared

6.1.2 SECONDARY OUTCOMES

- **Recorded safety planning** of all affected active female patients by GPs in intervention clinics compared with comparison clinics among active female patients ≥18 experiencing DVA.
- **Economic evaluation** will estimate cost-effectiveness and cost utility. Cost-effectiveness will be computed from a provider perspective (cost of the intervention per case of DVA identified, and the cost per woman referred to a DVA advocate). Data on the number of consultations, length and type of consultation will be imputed through extraction via the GrHanite™ tool. Following the approach taken in the economic evaluation of IRIS, we will then extend the cost-effectiveness analysis to report a cost-utility analysis. This will require a Markov model, estimating longer term impacts of the intervention on both service use and health outcomes. Probabilistic sensitivity analysis will be used to explore the impact of uncertainty on the results. These costs will predominantly be collected using our own study-specific forms.

6.1.3 TERTIARY/EXPLORATORY OUTCOMES

As an addition to the published protocol, we plan to analyse trends in primary and secondary outcomes across the 3, 6, 9, 12 and 15-month time points to see if there is a specific time point at which time point the intervention was most beneficial. This would be helpful for policy makers should the intervention be effective. This will be Figure 2. Refer to Section 6.5.5 for details.

6.2 HARMS

6.2.1 SAFETY OUTCOMES

GP clinics have been surveyed monthly to request any information about harms to clinic staff or patients. Any reported data will be presented to the DSMC, however none have been reported to date.

6.3 DATA SETS TO BE ANALYSED

As this is a cluster RCT, data relating to each GP clinic patient population, both demographic characteristics and primary and secondary outcome measures, will be aggregated for each clinic. This is to conform with the ethics requirements and the protocol. This will be an ITT patient population, so all clinics and patients will be analysed according to arm, whether or not they have

received all the intervention as randomised.

Both the clinic datasets and the patient population datasets will be analysed.

6.4 COMPLIANCE TO STUDY INTERVENTION(S)

The research team requested that 75% of GP undertake the training in order to ensure this was a 'whole-of-clinic' intervention. Administrative staff were invited to partake in some training and practice nurses and other health providers in the clinics were able to complete the training. Records of training attendance by GPs, other clinicians and administrative staff were kept.

We will report proportions in each category and number of sessions attended. We will also report how many of these clinics had a clinical staff member who volunteered to be a clinic champion / key contact person for the advocate educator.

Comparison clinics were asked to complete a brief 20-30 minute 'documenting and recoding' session with a member of the research team. These sessions were recorded and sent to staff unable to attend. These sessions were for all staff.

Dummy table: Clinic details of staff are taken from when the clinic was recruited. We will report where personnel changes have occurred during the pandemic.

Clinical role	Group A (n %)	Group B (n %)	Total
Total GPs, n			
GPs who received training*, n (%)			
Total Clinical staff (includes GPs, Nurses, other allied health, n			
Clinical staff who received training* (includes GPs, Nurses, other allied health), n (%)			
Total Admin staff, n			
Admin staff who received training*, n (%)			

* Training includes the attendance of 1 or more culturally competent family violence intervention staff sessions or for comparison clinic staff the recording and documenting session.

During the COVID-19 hiatus, all clinics received 4 e-newsletters to keep them engaged in the study.

When the study recommenced (28 September 2020), the intervention clinics received an e-newsletters with updates on training availability and relevant news items. This also included reminders on how to record DV patients. Between 28 September 2020-25 October 2021, the intervention clinics received **8** e-newsletters. The comparison clinics also receive different HARMONY e-newsletters, with reminders about training to record and document DV, and later reminders about how to record DV. Between 28 September 2020-25 October 2021 the comparison clinics received **6** e-newsletters.

Adverse events data for either staff or patients are collected from both intervention and comparison clinics. Intervention clinics are receiving requests for information throughout their intervention period and comparison clinics will receive a request for information at the end of

their 12-months.

The advocate educator is keeping a detailed record of correspondence with clinics, including phone calls, emails, zoom meetings and in-person visits. Out-reach at a minimum will be monthly to organise a clinic visit. However, Covid-19 has greatly impacted the ability for in-person visits and the advocate educator will aim to continue to contact clinics regularly noting the demand on GPs as well administrative staff during the pandemic.

Clinic champions were sought from all intervention clinics. This concept had varying success, mainly due to the covid-19 pandemic. 4 clinics had a designated clinic champion, 1 had a GP that was in regular contact with the Advocate educator and 5 were unresponsive to the concept.

6.5 ANALYSIS OF THE PRIMARY OUTCOME/S

6.5.1 TIMING OF ANALYSIS

To be conducted using an ITT analysis. Analysis of the primary outcomes will be undertaken for the following time points:

1. **At Baseline** a twelve-month period prior to the intervention. All clinics except for A12's baseline period are 1/12/2018 to 1/12/2019. A12's baseline period is 20/12/2019 to 20/12/2020 due to not having prior electronic records.
2. **Twelve-months** after the first training date for the clinic and the end point of the intervention
3. **15 months**, three months after the clinic finishes the twelve-month intervention period to assess retention of intervention lessons
4. The **denominators for the analysis** (i.e. number of RACGP active female patients per clinic) are also extracted over the same period.
5. Poisson regression will be used to compare the intervention and comparison arms, with the number of documented identifications and referrals within the twelve-month intervention period for every cluster as the independent variables. The same will be undertaken for safety planning. The Poisson regression models with random effects will include the number of active women ≥18 per clinic as the exposure variable and GP clinic as the random effect to take account of clustering. Models will adjust for any randomisation imbalance in key factors or confounders at baseline.
6. Sub-group analysis with South Asian populations will be performed using aggregated data of the South Asian population per clinic, calculated from an algorithm using a database of over 7000 South Asian names and patient recorded ethnicity or country of birth. This sub-group analysis for estimated proportions of South Asian women will not be generalisable or accurate, as we have not powered the study for SA status and identification methods are not rigorous. We will analyse 15-month outcome data to test sustainability of the training.

6.5.2 PRIMARY ANALYSIS

Step 1:
All outcomes and related variables in the analysis will be presented using descriptive statistics; normally distributed data by the mean and standard deviation (SD) and skewed distributions by the median and interquartile range (IQR). Binary and categorical variables will be presented using

counts and percentages. RStudio will be used for all statistical analysis. The descriptive statistics will provide the information based on the overall dataset, and separately for each of the two arms. The subsections below will describe analyses in addition to the descriptive statistics.

Step 2:
Before the analysing the clinic and patient data, we will describe their proportionate distributions to compare the two arm groups on categorical variables. Comparisons will be carried out firstly to explore the difference between two different arms for the key factors or confounders.

Step 3:
The denominators for the analysis (i.e. number of active female patients per clinic) are also extracted over the same period. Poisson (or Negative Binomial in the case of over-dispersion) regression mixed effect models will be used to compare the intervention and comparison arms, with the number of documented identifications and referrals within the twelve-month intervention period for every cluster as the independent variables. Different GP Clinics will be considered as random effects, different arms as fixed effects. Baseline variables that are not balanced across groups will be included as covariates. Models will also adjust for any randomisation imbalance in key factors or confounders. Incidence Rate Ratios (IRR) measuring the effect of the independent variables on the dependent variable will be reported and together with their 95% confidence intervals and p values.

6.5.3 ADJUSTED ANALYSES

Analysis will be adjusted for:

- Baseline differences
- Region
- Size of clinic
- SEIFA index

6.5.4 SUBGROUP ANALYSES

We will conduct limited sub-group analysis for the proportion of South Asian patients identified in each group. Our hypothesis is that intervention clinics should identify and refer more South Asian patients. This analysis will not be generalisable, but it will be important for the study to test the difference between arms.

A comparable table for the one above will be included but we will adjust for SA clinicians in either group.

6.5.5 SECONDARY ANALYSIS

Changing patterns over time will be plotted and explored for the aggregated number of documented identifications and referrals, moreover, to identify subgroups of distinct trajectories over time. Latent class linear mixed model (LCMM) will also be used which takes into account the expected heterogeneity among the trajectories. Once the different groups of trajectories arere found, multinomial logistic regression models will then be fitted where the probability of belonging to each class depended on explanatory variable (variables used to aggregated). Results will be reported in terms of estimated relative risk ratios (RRR), i.e., ratios of the relative probability of being in a given class over the probability of being in the reference class.

6.6 ANALYSIS OF SECONDARY OUTCOMES

6.6.1 SECONDARY OUTCOME 1: SAFETY PLANNING

- Increase GP safety planning for DVA among women aged 18+ in intervention compared to usual care clinics. This will be measured by extracting routine GP data. We will explore the rate among migrant/refugee (especially South Asian women).
  The same analysis methods as used in the primary outcome will be undertaken for safety planning.

6.6.2 SECONDARY OUTCOME 2: ECONOMIC EVALUATION

- Determine the cost effectiveness of the intervention relative to comparison care.

Markov model-based cost-effectiveness analysis will be used to determine the cost effectiveness of the intervention. We will construct a Markov model to estimate lifetime quality-adjusted life-years (QALYs) and costs from a national health service and a societal perspective. Markov modelling is a technique for estimating the costs and outcomes in a hypothetical cohort of women over time. We will simulate a cohort of 10 000 representative women with and without the HARMONY programme and used the differences between the two simulations to calculate the incremental costs and outcomes associated with HARMONY. We report our findings in terms of costs, QALYs and incremental costs per QALY gained. To construct the Markov model, we will define a set of mutually exclusive and exhaustive states experienced by women in relation to DV. The model then simulated the hypothetical cohort of women moving between the states, using a matrix of transition probabilities reflecting the likelihood of moving from each state to every other state within each discrete time period.

6.6.3 SECONDARY OUTCOME 3: PROCESS EVALUATION OF CLINIC STAFF, TRAINERS AND WOMEN

Investigate the factors that enable practice change and sustainability.

As this is a qualitative process evaluation and does not require statistical analysis, these methods will not be described here, but are include in the protocol.

6.7 ANALYSIS OF SAFETY OUTCOMES

6.7.1 ADVERSE EVENTS

We have surveyed clinics monthly to request any reports of harm to clinic staff or to female patients. This will be reported by group and in narrative form if they occur.

7 REFERENCES

Australian Bureau of Statistics. (2018). Socio-Economic Indexes for Australia (SEIFA), 2016. Canberra, ACT, Australia.

Feder, G., Davies, R., Baird, K., Dunne, D., Eldridge, S., Griffiths, C., . . . Sharp, D. (2011). Identification and referral to improve safety (IRIS) of women experiencing domestic violence with a primary care training and support programme: a cluster randomised controlled trial. *Lancet*(378), 1788–95.

APPENDIX 1: PROPOSED TABLES AND FIGURES

Table 1: **Baseline characteristics (cluster summary)**

Dummy tables: Description of GP clinic characteristics and eligible female patients will be described in the following tables:

Group	No. and ethnicity of clinicians		Clinic region	Clinic Size Small [≤5 doctors] & large [six or more] (Full-time equivalent)	SEIFA index	Clinic software
Group A	**SA clinicians**	**Non-SA clinicians**	**SE or NW**	**Small or Large**	**Low, Medium or High**	**BP or MD**
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Total						
Group B	**SA clinicians**	**Non-SA clinicians**	**SE or NW**	**Small or Large**	**Low, Medium or High**	**BP or MD**
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Clinic ID						
Total						

Table 2: **Characteristics of eligible female patients (additional table for South Asian patients only vs Non-SA).**

Characteristics	Total	Group A	Group B
Age quintiles **18-25 (years, N (%)** **26-35(years, N (%)** **36-45(years, N (%)** **46-55(years, N (%)** **55+ (years, N (%)**			
SEIFA index **1 – 3 (high disadvantage, N (%)** **4 – 7 (moderate disadvantage, N (%)** **8 – 10 (low disadvantage, N (%)**			
Medicare Card **Yes/No (N (%)**			
Pension Card **Yes/No (N (%))**			
Health Care Card **Yes/No (N (%))**			
Private Health Fund **Yes/No N (%))**			
South Asian **Yes/ No N (%)**			

Table 3: **DV identified patients**

Characteristics	Group A N (%)	Group B N (%)
Total DV Patients		
Total South-Asian DV Patients		

Analysis for % DV patients over denominator of all patients, all SA DV over all SA patients.

DUMMY TABLE FOR **PRIMARY OUTCOME TABLE (this will be repeated for DV identification and referral and for safety plans, and for South Asian subgroups**

	Group A n= (%)	Group B n= (%)	IRR	95% CI
DV identified				
Region **NW** **SE**				
Clinic size **Small** **Large**				
SEIFA Indices **Low** **Medium** **High**				
Identified baseline differences				

Table 4: **Compliance to intervention**

Table 5: **Reasons for discontinuing intervention**

Table 6: **Protocol deviations**

Table 7: **Adverse events**

Figure 1: **Consort Flowchart**

Figure 2: **Longitudinal mean plot of DV identification, referral and safety planning**

APPENDIX 2: TERMS FOR DV PATIENT IDENTIFCATION

Groups 1-6, provided to GrHanite, to support identification of type of appointment during the baseline and intervention period.

Group 1: DV Text	Group 2: Safety Plan	Group 3: Referral	Group 4: DV	Group 5: DVSP	Group 6: DVREF
a combination of	*a combination of*	Police	DV (EXCEPT 'ADV' OR 'DVT' OR 'DVA')	DVSP	DVREF
spouse	Safety	crisis service	dv		
partner	Risk	refuge	d.v		
boyfriend	**AND**	safe steps			
mother-in-law	Plan	inTouch			
father-in-law	Assessment	in Touch			
brother-in-law		women's health west			
sister-in-law		berry street			
family		1800-RESEPCT			
domestic		Centre against sexual assault			
relationship		CASA			
brother		Legal centre			
sister		CLC			
AND		legal service			
violen		WLS			
abus		Legal Aid			
aggress		VLA			
assault		WIRE			
harass		Relationships Australia			
intimidat		Psych			
threat		Orange Door			
insult					
humiliat					
hit					
kick					
beat					
bash					
batter					
rape					
stab					
chok					
strangl					
coerc					
control					
force					