Harmony Study

Memorandum of Understanding

between the Judith Lumley Centre, La Trobe University and general practices participating in the HARMONY Study

Judith Lumley Centre
(for mother, infant and family health research)

V7. 14/07/2020

Memorandum of Understanding

This is an agreement between the Judith Lumley Centre, La Trobe University and_____ (insert name of general practice), regarding participation in the HARMONY study to respond to family violence in migrant and refugee, including South Asian, communities through an intervention in general practice.

The memorandum covers the following areas:

1. HARMONY: the project
2. Roles and responsibilities of the research team and practice participants
3. Acceptance of randomisation and study processes
4. Compensation for participation
5. Funding and Ethics
6. Project timelines
7. Mechanism for communication between research team and practice participants
8. MonReN disclaimer

1. HARMONY: the project

1.1 **Overview**

HARMONY is a cluster randomised controlled study of a family violence (FV) intervention in general practices in Melbourne's NW and SE suburbs. It aims to test the feasibility and effectiveness of a program of GP training, referral and case work support to increase identification, safety planning and referral of all, but especially South Asian migrant and refugee women patients who are experiencing FV, as a strategy to promote their safety and improve wellbeing.

1.2 **Aims**

HARMONY aims to:

a) Culturally adapt and test a successful intervention in primary care currently implemented in the UK to improve identification and supportive referral of women experiencing FV.

b) Test the effectiveness of a program of training, referral and case work support for bilingual South Asian general practitioners (GPs) and their clinical colleagues, to strengthen their capacity to sensitively identify and provide culturally safe, supportive care for South Asian migrant and refugee women who are experiencing FV.

c) Evaluate the trial process through interviews conducted with GPs, other staff and women referred at the end of the trial period.

1.3 **Brief Methods**

We will use a waitlisted cluster randomised controlled study design, recruiting 28 general practices in total, and randomly allocating 14 practices (7 each in the NW and SE suburbs) to the intervention described below, with the remaining 14 practices serving as comparison, and providing standard care.

Clinicians in the intervention arm will agree to:

1. **Attend three online training specialised FV sessions,** RACGP accredited (40 points), facilitated by a GP trainer and a bilingual advocate educator based at In Touch, a multi-cultural FV agency in Melbourne. Session 1: 1-hour (all staff); Session 2: 1.5 hours (clinical only); Session 3: 1.5hours (clinical only).

   With a focus on cultural safety, clinicians will be trained to identify, and document symptoms potentially associated with FV, sensitively enquire and respond to women experiencing FV, and to confidentially refer affected women to the FV case worker. Providing clinicians with the skills, resources and support to enhance the safety of women and their children on disclosure of violence is a top priority of the training. Training will also include routinely documenting FV practice in computer software.

   Clinicians will be offered the opportunity to attend two webinars during the intervention period to discuss difficult cases, especially in the context of a pandemic.
2. **Use the skills developed through the training to identify, document, support and if appropriate, refer affected women to the FV case worker.** The advocate educator will also be available on the phone for secondary consultation with doctors.
3. **Administrative staff (e.g.: the practice manager, receptionists) in the intervention arm will attend Session 1, 1-hour online training session** on improving the safety, confidentiality and privacy of patients and of the clinic staff themselves. It will also include training to record ethnicity routinely onto computer software.

Clinicians in the comparison arm will agree to:

1. **Attend one online training session**, facilitated by the Research Team. The session will run for approximately 30-minutes and cover how to record FV patients and patient ethnicity in the medical software and the aims of the study.
2. **Administrative staff (e.g.: the practice manager, receptionists)** in the comparison arm will also need to attend this session.
3. **Undertake** the three online training sessions **12-months after** attending the comparison (30-minutes) training session.

2. Roles and Responsibilities of the Research Team and Practice Participants

2.1 **The Research Team**

2.1.1 The Research Team members are as follows:

SL #	Name	Role	Affiliation
1.	Professor Angela Taft	Chief Investigator (Lead)	Principal Research Fellow, Judith Lumley Centre, College of Science, Health and Engineering, La Trobe University
2.	Professor Kelsey Hegarty	Chief Investigator	Department of General Practice, University of Melbourne
3.	Associate Professor Jane Yelland	Chief Investigator	Murdoch Children's Research Institute
4.	Professor Danielle Mazza	Chief Investigator	Head, Department of General Practice, Monash University
5.	Professor Alan Shiell	Chief Investigator	Professor of Health Economics, Department of Public Health, La Trobe University
6.	Professor Gene Feder	Chief Investigator	Professor of Primary Care, School of Social and Community Medicine, University of Bristol
7.	Felicity Young	Research Manager	Judith Lumley Centre, College of Science, Health and Engineering, La Trobe University
8.	Molly Allen	Research Assistant	Judith Lumley Centre, College of Science, Health and Engineering, La Trobe University

2.1.2 The research team has overall responsibility for the project design, conduct of research, and analysis, writing up and dissemination of findings.

2.1.3 Angela Taft, the principal investigator, is accountable to La Trobe University for the conduct of the research within ethics requirements and as approved by the University, to the National Health and Medical Research Council and to any other contributing funding bodies.

2.1.4 GP trainers are responsible for conducting three training sessions (total of 4 hours) for all participating clinics either at the start (for intervention practices) or end (for comparison practices) of the 12-month intervention period.

2.1.5 The advocate educator will provide referral support and feedback to the clinicians in the intervention practices during the intervention period and be available for ad-hoc secondary consultations via the phone. She should become embedded in the intervention clinics and **attend at least three clinic meetings over the 12-month intervention period to provide feedback and hear any concerns**.

2.1.6 Felicity Young is responsible for project coordination, management and implementation, with support from Molly Allen.

2.2 **The practice participants**

2.2.1 In agreeing to participate in the HARMONY study, each participating practice agrees to accept the randomisation process and undertake the activities as outlined below for intervention and comparison arms

- Each participating clinic in the **intervention arm** accepts the responsibility for clinicians participating in **three sessions of specialised FV training**, the first session for 1 hour and the second and third sessions for 1.5 hours at the beginning and three months into the intervention period. **All three session should be completed in the first three months of the intervention.**
- Each participating practice in the **comparison arm** accepts the responsibility of clinicians participating in **one 30-minute session** at the beginning of the intervention period and then three sessions of specialised family violence training, after the end of the intervention period (12-months).
- The reception staff of both the intervention and comparison practices will participate in a brief training program (approximately 1-hour long for intervention, 30 minutes for comparison) on issues of safety, privacy and confidentiality in relation to addressing family violence in general practice. This training will coincide with the timing of the GP training in each study arm.

2.2.2 Each practice agrees to the querying of the medical records of participating GPs via GRHANITE, installed on a practice computer, for extracting aggregated, anonymised, de-identified data pertaining to the identification and referral of women patients who are experiencing FV. Data extracted via GRHANITE will not be used for any other research beyond the current HARMONY study.

3. Acceptance of randomisation and processes

3.1 It is crucial to the success of the project that participating practices agree to be randomised to the intervention or comparison arms of the study, and that each practice accepts the outcome of this process, whether it results in allocation to intervention or comparison status.

3.2 **The process of randomisation** will be computer generated and doctors will be informed by email. The randomisation process determines if a clinic is in the intervention arm or the comparison arm. The clinics in the intervention arm will receive the 3-training session in the first 3 months of the study. The comparison arm clinics will receive a short training at the beginning of the study (30-minutes) and will be able to receive the 3-training session at the end of the 12-month period.

3.3 **Withdrawal** from participation in HARMONY following the outcome of randomisation threatens the study design and the capacity to test whether the intervention is effective. However, should your clinic wishes to withdraw from the study, please contact Felicity Young at f.young@latrobe.edu.au or 03 9479 3539. Alternatively, you can email the study at harmony@latrobe.edu.au.

3.4 Data collected and analysed from the HARMONY study will be anonymised and presented in summary, aggregate form so as not to identify any individual patient. These outcome data will be published in scientific and research journals and presented at conferences and seminars both nationally and internationally. We will also update participating practices about the progress of the study via a newsletter, and forward results to practices after study completion or present them for discussion if desired.

4. Compensation for participation

4.1 A participating practice will receive $500 at the end of the study as reimbursement for participation.

5. Funding and Ethics

This study has been funded by an NHMRC Partnerships for Health Fund and represents funding from the NHMRC, the federal Department of Social Services and the Victorian Department of Health and Human Services and has received approval from the LTU Human Ethics Committee(UHEC 18413). If you have any complaints or concerns about your participation in the study that the researcher has not been able to answer to your satisfaction, you may contact Heidi Gaulk, the Manager Ethics, Integrity and Biosafety at researchintegrity@latrobe.edu.au or by telephone at 03 9479 1443. Please quote the UHEC application reference number.

6. Proposed project timelines

		2020						2021					
		Jan	**Mar**	**May**	**Jul**	**Sep**	**Nov**	**Jan**	**Mar**	**May**	**Jul**	**Sep**	**Nov**
1	MoU signed												
2	Informed consent administered												
3	GrHanite™ installation												
4	Randomisation of practices												
5	GP training in intervention practices												
6	Intervention period												
7	GP training in comparison practices												
8	Data analysis begins												

7. Mechanisms of communication between the research team and practices

7.1 **General**

7.1.1 The nominated contact people from the research team at La Trobe University for discussion of any project related issues are Angela Taft (9479 8809) and Felicity Young (9479 3539).

7.1.2 Each participating practice agrees to nominate their own contact person to be responsible for general communication about project related issues.

Please provide the name and contact information of the nominated person in the practice:

Name: Click or tap here to enter text.

Telephone number: Click or tap here to enter text.

Email address: Click or tap here to enter text.

7.2 **Dispute resolution**

7.2.1 Should there be a dispute about any matter relating to the project, the two parties undertake to raise any such matter in a timely manner, and to utilise this memorandum of understanding as a basis for discussion and for reaching agreement on a satisfactory resolution of the issues underlying any dispute.

8. MonReN

8.1 The practice was identified for recruitment through Monash University's Practice-Based Research Network (MonReN) a network of practices involved in education and/or research with Monash University's Department of General Practice.

8.2 Throughout the Harmony Study the practice will remain affiliated with Monash University and remain part of MonReN in all study documentation. Practice details will not be shared with the University of Melbourne or La Trobe University with the exclusion of General Practice recruiter, Jennifer Raymond and the University of Melbourne HaBIC R2 team for the sole purpose of fulfilling their obligations to the Harmony project.

Signed

Click or tap here to enter text.	Click or tap here to enter text.
(Name of Practice Owner/Practice manager) (Name of Practice) Address and contact information	Professor Angela Taft Judith Lumley Centre On behalf of La Trobe University
Date: Click or tap here to enter text.	Date: Click or tap here to enter text.