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MRC Jointly Funded Initiatives
Full
PROPOSAL

Document Status: With Owner
MRC Reference:

MRC/NIHR/DfID/Wellcome Global Health Trials Call 9 – Development February 2019

Organisation where the Grant would be held

Organisation	The University of Manchester	Research Organisation Reference:	FuSION 9573
Division or Department	School of Health Sciences		

Project Title [up to 150 chars]

Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention

Start Date and Duration

a. Proposed start date	07 January 2020	b. Duration of the grant (months)	24

Applicants

Role	Name	Organisation	Division or Department	How many hours a week will the investigator work on the project?
Principal Investigator	Dr Laoise Jean Renwick	The University of Manchester	School of Health Sciences	5.62
Co-Investigator	Professor Budi Anna Keliat	University of Indonesia	Center for Health Research	3.75
Co-Investigator	Dr Helen Brooks	University of Liverpool	Institute of Psychology Health & Society	3.75
Co-Investigator	Dr Penny Bee	The University of Manchester	School of Health Sciences	1.88
Co-Investigator	Professor Karina Lovell	The University of Manchester	School of Health Sciences	1.88
Co-Investigator	Dr Herni Susanti	University of Indonesia	UNLISTED	5.62
Co-Investigator	Mr Timothy Bradshaw	The University of Manchester	School of Health Sciences	0.75

Objectives

List the main objectives of the proposed research in order of priority

The aim of this study is to adapt and refine an evidence-based family intervention for relatives and carers of people with schizophrenia in Java, Indonesia. Schizophrenia presents a major public health problem in this region. Large treatment gaps are a key contributor; the majority for whom treatment would be of benefit, do not receive any and consequently, much of the care people with schizophrenia receive is delivered by their families. In low-resource settings, family interventions are one of only three types of interventions recommended for schizophrenia by the World Bank's third edition of disease priorities. Family interventions for psychosis (FIp) have strong evidence for their efficacy in high-income countries. FIp significantly reduce relapse, re-hospitalization, increase adherence to medication regimes, enhance patient functioning and improve family environments.

We propose to use an existing intervention that is currently approved for widespread use in the NHS (according to National Institute for Clinical Excellence Guidelines) and adapt and refine the intervention to produce a culturally relevant psychosocial intervention. FIp require adaptation to different cultural contexts allowing cultural beliefs, explanatory models of illness and contextual socio-economic issues to be incorporated into the content and delivery of such interventions. This enhances acceptability, increases engagement and can enhance the efficacy of the intervention. We will explore stakeholder priorities for the intervention using an empirically-derived heuristic framework for cultural adaptation of psychosocial therapies and gain consensus from stakeholders on the components, format and delivery of this evidence-based intervention.

Our objectives are:

1. Explore preferences and priorities for delivering family interventions for relatives and carers of people with schizophrenia in Java, Indonesia
2. Synthesise findings from stakeholder interviews with an existing evidence-based intervention
3. Gain consensus on the components, format and delivery of the intervention
4. Identify the training needs of healthcare workers for delivering the intervention
5. Produce a manual to support delivery of the culturally-adapted intervention
6. Explore wider factors that may hinder or facilitate the adoption, reach and effectiveness of the intervention for delivery
7. Train healthcare professionals to deliver the intervention in primary care settings
8. Assess the feasibility of testing the intervention in a full trial and explore the acceptability of the intervention to a wide group of stakeholders

We will produce a manual to support delivery of a co-produced, culturally-relevant intervention and assess the training needs of community workers to promote scalability for a future trial to reduce the risk of relapse in schizophrenia. Using the Medical Research Council framework for complex interventions we will conduct this study in three phases. Following adaptation and refinement of the intervention, we will produce a manual to guide intervention implementation, develop training resources, train healthcare professionals to deliver the intervention and explore the acceptability of this intervention to a wide group of stakeholders. We will assess the feasibility of taking the intervention to full trial considering key aspects including recruitment, willingness of participants to be randomised, retention in the trial, intervention fidelity and completeness of outcome assessment. We will explore participants and healthcare workers views of receiving and delivering the intervention and wider implementation issues from key informants to ascertain factors affecting reach and scalability of the intervention for a future trial. The key objective is to assess the feasibility of testing this intervention in a randomised, single blind trial to determine the effectiveness of a culturally adapted version of FIp versus standard care in a primary care setting.

Summary

Describe the research in simple terms in a way that could be publicised to a general audience. If awarded, this will be made publicly available and applicants are responsible for ensuring that the content is suitable for publication.

Mental illnesses comprise the single largest source of health-related economic burden worldwide. Schizophrenia is among the most disabling conditions in these low-resource settings and 90% of those who need treatment do not receive it. Consequently, much of the burden of care is transferred to families who have few resources to support them in caring for their loved one. Often, carers lack knowledge and expertise about how to manage and having caring responsibilities

In high-resource settings family interventions (FIp) are provided as a 'talking therapy' for relatives and carers. These types of interventions focus on helping families to cope with illness, learn how to communicate, solve problems and set goals for treatment. Families also find these interventions supportive and reassuring which helps with their own coping and emotions. These interventions are known to be highly effective but they may not translate directly from one culture to another because there are differences in the way people view mental illnesses, how they see and communicate with each other and how treatment is organised.

The aim of this study is to see whether we will be able to tailor an intervention we know is effective in the UK to the needs of people living in Indonesia. To do this, we will ask people in groups what they think of the intervention, about their experiences with getting help and how schizophrenia has affected their lives. We will ask them how they would like to receive the intervention in the future, what aspects are important to include, what type of therapist they would prefer and how and when they would like to receive the intervention. We will then gather a panel of experts to make a final decision about the intervention and ask them what kind of resources they think would help to train people. We will develop a manual to help people who deliver the intervention to deliver these interventions well and we will prepare teaching resources so that in the future, they can teach others to deliver the intervention.

The final part of this work is to train people to deliver the intervention in a primary care setting. A large trial of this intervention would use lots of valuable resources to complete and would not be a good use of resources if we don't know that we can complete the trial. For example, we might not be able to recruit people so before we get to that stage we will do a small trial and see if all the pieces work together, we can recruit everyone we need and collect all the information we need. We also need to make sure that healthcare professionals delivering the intervention can do this with the manual as it is described. We will then need to check with the people who receive the intervention that they like it, whether we could change parts to make it better and whether people delivering it also like it. At the same time, we will be thinking about how this will work in primary care, we will be having conversations with the right people who will use or be affected by our new intervention and we will tell them about what we are doing.

Technical Summary

Describe the research in a manner suitable for a specialist reader. If awarded, this content will be made publicly available and applicants are responsible for ensuring that the content is suitable for publication.

Schizophrenia is among the most disabling conditions in low resource settings and 90% of those who need treatment do not receive it. Consequently, much of the burden of care is transferred to families who often lack knowledge and expertise, support and experience significant impacts on their quality of life.

Family interventions (FIp) are routine psychosocial interventions in high-income settings and have a robust evidence base for their efficacy in reducing relapse, improving functioning and family environment. The aim of this research is to adapt and refine an existing, effective intervention for relatives and carers of people with schizophrenia and test whether it is feasible to conduct a full trial of this intervention and assess acceptability. This study comprises three phases:

In Phase 1 we will conduct stakeholder consultation groups to obtain stakeholder preferences and priorities for content, format and delivery of FIp. We will then explore key informants views on wider implementation within primary care settings to ascertain factors that will assist and hinder intervention implementation during feasibility testing.

In Phase 2, we will convene stakeholder workshops to gain consensus on the intervention components, delivery format and identify the training needs of healthcare professionals. We will present the expert consensus panel with a synthesis of evidence from existing reviews and phase 1 findings and using modified nominal group techniques, we will gain consensus on intervention content, format and delivery. We will develop a manual to support delivery of the intervention and training resources to support sustainable implementation.

In Phase 3, we will evaluate the feasibility and acceptability of delivering culturally-adapted FIp to reduce relapse in people with schizophrenia.

Our aim is to provide evidence to support the process of testing a culturally-adapted intervention in a full trial.

Academic Beneficiaries

Describe who will benefit from the research

Strengthening Research Partnerships

Through conducting this research, we will continue to strengthen existing research partnerships. Previously, Renwick and Brooks were awarded an ESRC Impact Acceleration Award and HEFCE Newton Award to further cultivate collaborative partnerships within Indonesia and develop a research proposal for competitive funding from which this proposal was developed. Renwick (PI), Susanti, Keliat, Lovell, Brooks and Bee have recently been awarded a Research England GCRF award to enhance collaborations and capacity to develop scalable digital interventions for improving access to depression interventions throughout Indonesia. This latter collaborative venture is scheduled to take place in Summer 2019 which will provide an opportunity to build on existing networks and develop new partnerships as we convene and deliver trans-disciplinary workshops with clinical and academic colleagues from Indonesia here in Manchester. We will use this opportunity to showcase this research project and engage users of research to aid raising awareness, gather support from key stakeholders and seek to apply knowledge generated in a collaborative way. We will also use this opportunity to discuss our research, ensure it is relevant and contribute to a continuous process of consultation and dialogue to enhance and grow existing and new partnerships.

Research Capacity and Mentorship

Through our existing collaboration, we have partnered to develop research programmes combining people with different types and ranges of skills from user-involved research to early career researchers and senior expert researchers within and between the UK and Indonesia. This has provided opportunities for learning at different levels. We have supervised and mentored collaborative groups of UK and Indonesian researchers to enhance research capacity delivering a master level, validated research training package that emphasises excellence in participatory and implementation research. Lovell and Bee have led a NIHR PGfAR developing a NICE-endorsed research training programme for mental health service-users and carers (RP-PG-1210-12007) and this has been adapted in an MRC HSRI (PI Brooks) grant which was delivered successfully in Indonesia. This course will be further refined and delivered at the outset of the project comprising training for researchers, advisors and stakeholders extending capacity. We will recruit doctoral and masters prepared researchers to researcher positions in this study and provide a clear pathway to develop a researcher co-investigator role (as per MRC guidance) for a full trial following this study. We will support senior and early career researchers, research students at UI and user-researchers to attend the research training to further enhance research capacity. Additionally, Co-PIs Renwick and Susanti will obtain regular monthly supervision from experienced academic researchers, Lovell and Keliat, in order to enhance capacity for researchers who are earlier in their careers to undertake high-quality research efficiently.

Academic Knowledge Development

Developing the theory and methodology to culturally adapt existing, effective, psychosocial interventions to the Indonesian context will be of wider interest to academics in pan-Asian countries interested in refining and testing other evidence-based interventions. We will engage with researchers through nursing research networks, national and international conferences targeting healthcare personnel, policy makers and academics in mental health. We will publish our qualitative findings in Indonesian journals and we will publish the findings from our feasibility study in the International Journal of Mental Health Systems which is a widely read journal focusing on the emerging discipline of global mental health that includes methodological advances considered to shape the field providing opportunities to share examples of best practice.

Communications Plan

Please outline your plans for engagement, communication and dissemination about your research and its outcomes with the research community and, where appropriate, with potentially interested wider audiences

Communications Plan
We recognise that public engagement is an integral part of MRC research and as a research team, we have a strong background in mobilising knowledge for implementation and effective healthcare delivery which we will demonstrate also through this project.
Patient and Public Involvement
We recognise that patient and public involvement requires a reciprocal process of communicating the needs of the project with the needs of the stakeholder for whom the outputs will be of most interest. Involvement from PPI groups has already shaped the development of this proposal and began with a request from PPI stakeholders to assist in providing an evidence base for an intervention for carers in whom they had recognise a great need for support and assistance. Our discussions with these groups have helped us to refine our research objectives and identify optimal methods for recruitment and data collection and the processes of the study.
We will continue to work with our PPI advisors to ensure that our communications are clear and concise and take account of the cultural needs and preferences of relevant audiences. Detailed study information will be available in multiple media formats for a variety of settings and we will utilise local community workers (cadres) to engage with communities. We will co-opt specialised community cadre's within each district centre to assist recruiting individuals who are experiencing psychosis and their families. The cadres are volunteers that engage with the local community to provide public health interventions and are also members of that community strategically selected by primary care professionals for their ability to leverage community influence. In order to allow participants to define the situations they experience in their own terms and allowing for low levels of mental health literacy and literacy in general, we will co-produce case studies with community cadres in each district to aid identification of psychosis among community members and recruitment to the study.
We will also use a wider range of media including academic, patient and professional summary briefings, engagement events, online communications (e.g. webinars) and mainstream and social media as described in our pathways to impact document to engage with wider audiences. We will also develop a written publication strategy to coordinate team efforts, publishing in high-impact journals and those with high readership levels in low resource settings.

Government and Policymaker Engagement
Through our engagement work we have networked with government and policymakers to ensure formal support for this work and that our work is informed by policy directives. We foster collaborations to ensure sustainable and impactful research and communicate primarily through face-to-face meetings and conferences, disseminating our findings and engaging policymakers in public engagement events to garner support.

Impact Summary

If awarded, this content will be made publicly available and applicants are responsible for ensuring that the content is suitable for publication.

A primary aim of our research is to build research and develop an evidence-based, testable intervention consistent with Indonesia's new mental health policy to provide a minimum standard of health for all through primary care settings. If this intervention is found to be effective, the potential social impacts are substantial in terms of improved health outcomes, wellbeing and quality of life for people with schizophrenia and their carers'. The economic impacts may also be substantial considering that a high proportion of the costs attributable to this mental illness arises from reduced productivity and lost opportunity for carers are forced to care their loved ones rather than maintaining labour force employment.
Our research is mainly exploratory so is not powered to provide evidence of effectiveness, however, there are a number of stakeholders who will directly benefit from this research in determining solutions for meeting policy directives of service provision including the wide network of over 8000 primary care centres throughout Indonesia. In the short-term, we may better understand pathways to care and issues that impact supply and demand by exploring the wider implementation issues which can inform service provision. In the medium to long term, primary care centres, of which less than 20% are

preliminary manner, whether there is capacity for delivering culturally-relevant, evidence-based interventions within primary care by utilising trial therapists who have no mental health training and some that do. There will be cross-fertilisation within faculty at UI who deliver nurse training and attempt to provide for healthcare workforce needs.

Summary of Resources Required for Project

Financial resources

Summary fund heading	Fund heading	Full economic Cost	MRC contribution	% MRC contribution
Directly Incurred	Staff	0.00	0.00	74
	Staff	0.00	0.00	80
	Travel & Subsistence	12900.00	9546.00	74
	Other Costs	0.00	0.00	74
	Sub-total	**12900.00**	**9546.00**	
Directly Allocated	Investigators	60076.72	44456.78	74
	Investigators	0.00	0.00	80
	Estates Costs	6015.00	4451.10	74
	Other Directly Allocated	0.00	0.00	74
	Sub-total	**66091.72**	**48907.88**	
Indirect Costs	Indirect Costs	37783.00	27959.42	74
Exceptions	Staff	10000.00	10000.00	100
	Travel & Subsistence	0.00	0.00	100
	Other Costs	51617.00	51617.00	100
	Sub-total	**61617.00**	**61617.00**	
	Total	**178391.72**	**148030.30**	

Summary of staff effort requested

	Months
Investigator	15.00
Researcher	0
Technician	0
Other	0
Visiting Researcher	0
Student	0
Total	15

Other Support

Details of support sought or received from any other source for this or other research in the same field.
Other support is not relevant to this application.

Classification of Proposal

(a) Grant Type

Research Grant	x								

Staff

Directly Incurred Posts

			EFFORT ON PROJECT								
Role	**Name /Post Identifier**	**Start Date**	**Period on Project (months)**	**% of Full Time**	**Scale**	**Increment Date**	**Basic Starting Salary**	**London Allowance (£)**	**Other Allowances (£)**	**Super-annuation and NI (£)**	**Total cos grant**
Co-Investigator	Professor Budi Anna Keliat*	07/01/2020	24	10	Prof scale	07/01/2020	19626	0	0	0	
Co-Investigator	Dr Herni Susanti*	07/01/2020	24	15	Prof scale	07/01/2020	19515	0	0	0	
										Total	

* The cost is an exception and therefore not subject to FEC rules.

Applicants

Role	Name	Post will outlast project (Y/N)	Contracted working week as a % of full time work	Total number of hours to be **charged** to the grant over the duration of the grant	Average number of hours per week **charged** to the grant	Rate of Salary pool/banding	Cost estima
Principal Investigator	Dr Laoise Jean Renwick	Y	100	495	5.6	65914	
Co-Investigator	Dr Helen Brooks	Y	100	330	3.8	72962	
Co-Investigator	Dr Penny Bee	Y	100	165	1.9	94377	
Co-Investigator	Professor Karina Lovell	Y	100	165	1.9	127161	
Co-Investigator	Mr Timothy Bradshaw	Y	100	66	0.8	88908	
						Total	6

Travel and Subsistence

Destination and purpose		Total £
Outside UK	2 x 3 people flights to Jakarta	4800
Outside UK	Transfers £100 per trip	200
Outside UK	Internal travel in Indonesia	400
Outside UK	2 x3 people accommodation in Indonesia	6000
Outside UK	Subsistence £50 per day	1500
	Total £	12900

Other Directly Incurred Costs

Description	Total £
4 x Research Assistants for 24 months in Indonesia	9468
Project secretary for 24 months in Indonesia	1381
4 x Trial therapists for 12 months in Indonesia	3945
Training workshop - full board meeting (20 people x 5 days) in Indonesia	8219
Training workshop - transport in Indonesia	822
Focus group phase 1 (costs for 40 participants: catering, participants travel/transport, subsistence) in Indonesia	438
Focus group phase 1 - 8 facilitators transport in Indonesia	88
Interviews phase 1 -costs for 10 participants: travel, subsistence in Indonesia	110
Interviews phase 1 - interviewer transport costs in Indonesia	110
Consensus workshop phase 2- 40 people catering, transport in Indonesia	1973
Interventions - subsistence for 30 families x 10 sessions in Indonesia	822
2- day festival in Indonesia	2000
Data collection costs - RA travel to visit families, subsistence for RAs in Indonesia	986
Regular meetings catering - 10 x 10 people in Indonesia	274
Ethics approval in Indonesia	274
Transcription costs in Indonesia	1370
Translation costs in Indonesia	1370
Office costs (photocopying, paper, printer ink etc.) in Indonesia	301
2 external hard drives (Indonesian costs)	110
4x voice recorders for RA's in Indonesia	219
2 x laptops (Indonesian costs)	2192
2 people conference fees in Canada (Indonesian costs)	1644
Conference travel - 2 people return flight Indonesia - Canada (Indonesian costs)	2740
Conference subsistence for 2 people (Indonesian costs)	822
10% overheads for Indonesia	5599
Research Advisory Group (4 meetings x 12 people) costs in Indonesia	3945
Research Advisory Group transportation costs in Indonesia	395
Total £	51617

Research Council Facilities

details of any proposed usage of national facilities
Research Council Facilities are not relevant to this application.

Human Biological Samples

Does your work involve human Biological samples: research which involves laboratory studies on human material which are specifically designed to understand or treat a disease / disorder? NB: basic biomedical research remote from application to a disease / disorder, such as the use of immortalised human cell lines in model biological systems, is excluded. No

Technology Development

Does your work involve Technology development for clinical use: development or adaptation of technologies for diagnosis or therapy, e.g. instrument development for diagnostic or surgical use; development of new techniques, such as photodynamic therapy, for clinical use. Yes

(b) Research Setting

Based on direct patient contact, indicate whether the research involves a particular medical setting such as primary care or secondary care.

Primary	x								

(c) Stem Cells

Does the research involve the use of Stem Cells or regenerative medicine?

No	x

(d) Developing Countries

Will the research involve a substantial component in developing countries? If so select those that apply.

Indonesia	x								

(ii) Keywords

schizophrenia	psychosocial
carers	intervention
relapse	family

Human Participation

Would the project involve the use of human subjects?		Yes✔	No
	If yes, would equal numbers of males and females be used?	Yes	No✔
Would the project involve the use of human tissue?		Yes	No✔
Would the project involve the use of biological samples?		Yes	No✔
Would the project involve the administration of drugs, chemical agents or vaccines to humans?		Yes	No✔
Will personal information be used?		Yes✔	No
	If yes, will the information be anonymised and unlinked?	Yes✔	No
	Or will it be anonymised and linked?	Yes	No✔
	Will the research participants be identifiable?	Yes	No✔
Please provide details of any areas of substantial or moderate severity:			

We will be obtaining the views of people with schizophrenia and their families about their preferences and priorities for receiving family interventions. We will also be including users, carers and healthcare professionals views about the components, format and delivery of the intervention while assessing the training needs of healthcare professionals to deliver the intervention. We will include up to 60 people in this phase and this will not be determined by gender. We will then recruit a further 30 people to be randomised to a feasibility study, half will receive the intervention for which we will have trained healthcare workers to deliver and all will be approached to provide baseline information, post-intervention information and we will obtain clinical information again at six months.

Our research will be undertaken in Indonesia thus we will need to obtain ethical approval from the Department of Science, Technology and Higher Education department in Jakarta before obtaining approval from the central ethics department. We will concurrently obtain approval from our host institution's ethical committees (University of Manchester).

The key ethical issues that our research raises are how to maintain the confidentiality of participants, protect their anonymity and provide information about our project such that any potential participant can understand the risks of involvement and have an opportunity to decline or consent to participate. We will follow guidelines for International Ethical Guidelines for Health-related Research Involving Humans Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO). We will obtain individual written consent for all participants and invite different participants for each successive phase to avoid engaging vulnerable groups in both action and implementation phases of the study. We will develop our participant information sheets with our RAG and we will use alternative methods of to ensure appropriate recruitment such as the use of case vignettes and storyboards such that we can account for multiple explanatory views about schizophrenia and psychotic illness. It will be made clear to all participants that

participation is voluntary and that they can withdraw from the study at any time, without any impact to their care.

There is potential for participants and/or researchers to become distressed by participants' disclosures during interviews. All potential participants will be provided with a participant information sheet written to current NRES guidelines and favourably reviewed by relevant ethics committees. They will be given time to consider participation (minimum 48 hours), and a distress protocol, approved by our RAG, will be available for use. All data will be anonymised and stored securely in line with research governance requirements as outlined in the DMP.

We will provide training in ethical conduct of research to researchers working on the study and trial therapists in the feasibility study. A detailed protocol will be approved by the relevant ethical committees and provided to researchers and our RAG. We have detailed how the study will satisfy all MRC and University of Manchester's (UoM's) requirements and guidelines on data management, sharing, security and ethics, including the UoM's Research Data Management policy. We will additionally comply with local regulations in Indonesia. Responsibility for study-wide ethical issues, adherence to the protocol, data management, security and quality assurance will be jointly shared by Dr Susanti and Dr Renwick (Co-PIs)

Animal Research

Would the project involve the use of vertebrate animals or other organisms covered by the Animals (Scientific Procedures) Act?	Yes	No✔
If yes, what would be the maximum severity of the procedures?	Mild or non-recovery	

	Severe	
Please provide details of any areas which are Moderate or Severe:		

Animal Species

Does the proposed research involve the use of non-human primates?	Yes	✔No
Does the proposed research involve the use of dogs?	Yes	✔No
Does the proposed research involve the use of cats?	Yes	✔No
Does the proposed research involve the use of equidae?	Yes	✔No

Please select any other species of animals that are to be used in the proposed research.

Fish	Sheep
Rabbit	Rat
Amphibian	Poultry
Cow	Mouse
Reptile	Guinea Pig
Pig	Other Rodent
Bird	Other Animal

Genetic and Biological Risk

Would the project involve the production and/or use of genetically modified animals?	Yes	✔	No
If yes, will the genetic modification be used as an experimental tool, e.g., to study the function of a gene in a genetically modified organism?	Yes	✔	No
And will the research involve the release of genetically modified organisms?	Yes	✔	No
And will the research be aimed at the ultimate development of commercial or industrial genetically modified products or processes?	Yes	✔	No
Would the project involve the production and/or use of genetically modified plants?	Yes	✔	No
If yes, will the genetic modification be used as an experimental tool, e.g., to study the function of a gene in a genetically modified organism?	Yes	✔	No
And will the research involve the release of genetically modified organisms?	Yes	✔	No
And will the research be aimed at the ultimate development of commercial or industrial genetically modified products or processes?	Yes	✔	No
Would the project involve the production and/or use of genetically modified microbes?	Yes	✔	No
If yes, will the genetic modification be used as an experimental tool, e.g., to study the function of a gene in a genetically modified organism?	Yes	✔	No
And will the research involve the release of genetically modified organisms?	Yes	✔	No
And will the research be aimed at the ultimate development of commercial or industrial genetically modified products or processes?	Yes	✔	No

Implications

Are there ethical implications arising from the proposed research? Yes

Provide details of what they are and how they would be addressed [up to 1000 characters]

All parties involved in this research will be bound by ethical conduct in relation to their respective institutions and in many cases due to their professional registration with nursing regulatory bodies (Nursing and Midwifery Council in the UK). Our research includes service users, carers and healthcare professionals and we have considered each of the key ethical concerns that present; confidentiality, ensuring anonymity and providing information such that participants can comprehend the consequences of involvement and decide accordingly. Participant information sheets will contain multiple methods of explaining the purpose of the research and participants will be afforded at least 48 hours to decide about their involvement. A distress protocol, co-developed and approved by our RAG and will be made available to ensure participant welfare. All data will be anonymised and stored according to MRC and institutional data management requirements to ensure confidentiality and anonymity.

Approvals

Have the following necessary approvals been given by:			
The Regional Multicentre Research Ethics Committee (MREC) or Local Research Ethics Committee (LREC)?	Yes	No✔	Not required
The Human Fertilisation and Embryology Authority?	Yes	No	Not required✔
The Home Office (in relation to personal and project licences, and certificates of designation)?	Yes	No	Not required✔
The Gene Therapy Advisory Committee?	Yes	No	Not required✔
The UK Xenotransplantation Interim Regulatory Authority?	Yes	No	Not required✔
Administration of Radioactive Substances Advisory Committee (ARSAC)?	Yes	No	Not required✔
Other bodies as appropriate? Please specify.			

Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention

1. PROJECT SUMMARY: The aim of this 24-month project is to adapt and refine an evidence-based, family intervention for relatives and carers of people with schizophrenia in Jakarta, Indonesia and evaluate the feasibility and acceptability of implementation in primary care settings. Using the Medical Research Council framework for complex interventions we will conduct a three-phase study combining stakeholder consultation and consensus workshops to produce a manual to guide intervention implementation. We will train healthcare workers to deliver the intervention and assess the feasibility and acceptability of conducting a randomised, single-blind trial of our co-produced, culturally-relevant, evidence-based intervention to reduce relapse when compared with standard care. We request total funds of £148,030 to complete this development work.

2. PROJECT TEAM: The research will be primarily conducted by researchers in Indonesia with collaboration from UK researchers providing training, supervision and mentorship to enhance research capacity. The team is multi-disciplinary comprising mental health nurses, psychiatrists, psychologists and service-users with expertise in qualitative research, mixed methods evidence appraisal and synthesis, participatory research, global mental health, complex intervention development and implementation science. Our team have collaborated previously on successful national and global mental health research. Brooks, Bee and Lovell have previously collaborated on an NIHR Grant for Applied Research to involve service-users in planning their own care (RP-PG-1210-12007 £2m). Brooks is currently leading a MRC HSRI funded project to explore civic engagement in Indonesia which delivered research capacity building activity in January 2018. Bee and Brooks with Lovell and Renwick are leading a MRC DFID NIHR funded project to develop an intervention for enhancing mental health literacy for depression with Indonesian collaborators in Java, Indonesia. Renwick, Lovell and Keliat have previously been awarded a British Council Researcher Links Award to conduct collaborative workshops and build research capacity among UK and Indonesian early career researchers [1]. We have two PIs, Renwick in the UK and Susanti in Indonesia. The project team will be supported by a Research Advisory Group (RAG) to enhance quality and relevance of the research and will comprise key influencers and beneficiaries in Indonesia; service-users, carers and advocates, healthcare professionals and primary care workers, academics and community leaders. Our FIp specialist (Dr Tim Bradshaw), will provide NICE-approved training for therapists and FIp expertise to the RAG. In his role at UoM, he has trained over 500 mental health professionals over the past 20 years using the evidence-based FIp model we will adapt and for which he was trained by the developers. KPSI is a user-led charity which runs peer support groups, education and anti-stigma activities in health services and local communities and have pledged support as our charity partners.

3. PROJECT DESCRIPTION: The study objectives are to:

I. Adapt and refine an evidence-based family intervention using stakeholder preferences in an empirically-derived heuristic framework
II. Co- produce a manual to support the delivery of the culturally-relevant, adapted intervention
III. Identify training needs for healthcare workers and train healthcare workers to deliver the intervention
IV. Evaluate the feasibility of conducting a full trial to test the effectiveness of our intervention and explore the acceptability of the intervention

Phase 1: Stakeholder Consultation *(0-6 months)* Aim: To explore key stakeholders priorities and preferences for implementing the FIp using an effective model of National Institute for Clinical Excellence (NICE) approved FIps. Methods: We will purposively sample people with schizophrenia and their caregivers, approximately 10-15 from each group, based on gender, age, geographical setting and service attendance. We will also obtain a purposive sample of approximately 10 healthcare professionals from primary care centres at district and sub-district level including non-mental health trained and mental health trained workers. We will also recruit from our charity partners (KPSI) whom have some experience of peer support and education. We will conduct a series of 4 stakeholder consultation groups comprising single participant and mixed stakeholder groups to explore attitudes and beliefs about the support needs of families, experiences of accessing services, priorities for treatment delivery, preferences for content and their views on what training should provide. Stakeholder groups will be facilitated by researchers employed at Universitas Indonesia (UI) and they will be provided training in qualitative methods, interviewing

methods, trial and data management by the wider study team. Initially, the facilitator will outline the study background, purpose of the consultation and session content and process [2, 3]. Participants will be asked sequentially; experiences of accessing and attending services, perceptions of psychological therapies, impact of illness on families and carers, suggestions to enhance the cultural validity of the intervention, preference for delivery including session duration and location, therapist preference, suggestions for resources that would support delivery and expectations for therapeutic aims and outcomes based on a heuristic framework for cultural adaptation [2]. We will identify key contributors with specialist roles (n=10) among service managers, commissioners, ministry officials and community leaders to explore the wider implications of intervention implementation and evaluate factors affecting reach, adoption and maintenance of interventions in primary care settings and the charity sector. Interviews and stakeholder groups will be transcribed verbatim and a sample will be translated into English and back-translated to verify coding frames [4]. Analysis and Synthesis: We will utilise a six-stage thematic analysis framework [5] using Nvivo software to organise text and support analysis. Interviews will be transcribed and independently coded by Indonesian researchers, the coding frame will be translated and verified among the wider research and study team. We will develop an evidence matrix combining empirical findings from this phase of study with empirical findings from existing evidence synthesis of cultural adaptation for psychosocial and mental health interventions. We will draw on two recent systematic reviews; one summarising the content and adaptation process, including moderators and mediators of effective interventions, in meta-analytic studies of culturally-adapted interventions for mental health problems [6] and another meta-analysis and review of culturally-adapted psychosocial interventions specifically for schizophrenia that provides an empirically-derived heuristic framework for cultural adaptation of psychosocial interventions [2]. The synthesis matrix will be developed by the study team tabulating findings from the existing heuristic framework by source of evidence focusing on points of commonality, divergence and representing key ideas about intervention content and delivery, barriers and facilitators to delivery and engagement and supplemented with points about adoption and implementation. The study team have significant experience synthesising evidence for research purposes to identify key intervention components [7].

Phase 2: Consensus Workshop and Manualised Intervention Co-production (6-9 months) Aim: To gain consensus on the intervention contents, delivery format and training needs for healthcare professionals. We will co-produce a manual to support delivery of a culturally-relevant FIp and resources to support a 'train the trainer's' model for sustainability. Methods: We will convene a two-day workshop using an expert consensus panel comprising individuals from key professional and stakeholder groups (n=20) and use a modified nominal group technique to gain consensus. The panel will be identified and appointed by the RAG. Briefing information comprising the rationale for the study and a review of the evidence matrix alongside a participant information sheet will be provided in advance [8]. Real-time interactive software (i.e. Mentimeter) will be used to allow participants to vote on intervention components and training resources comprising the core constructs of the intervention, content and delivery format and manual contents. Additional components and resources required to accompany training will be generated during these workshops using co-design group principles developed by the King's Fund . Small-group discussions of 4-6 participants will be facilitated by non-participant researchers focusing on areas of disagreement and clarifying each point raised for successive ranking exercises. Discussions will be recorded and transcribed to support manual refinement. Analysis: Using modified nominal group techniques we will determine the groups view on intervention components, manual resources and training needs aggregating responses producing proportional rankings for each component. A minimum defining threshold will be set for accepting items. The manual will be developed by the wider study team defining therapeutic aims and we will develop detailed procedures, patient exercise, materials and resources, good practice examples, scripts for intervention delivery and measures of processes and outcomes.

Phase 3: Feasibility Testing *(9-24 months)* Aim: To evaluate the feasibility and acceptability of delivering culturally-adapted FIp to reduce relapse in people with schizophrenia in primary care settings in Java, Indonesia. We will test the feasibility of delivering the intervention and recruiting service-users and family members and determine whether they are willing to be randomised. We will also evaluate the acceptability of the intervention and usability of the manual for healthcare workers in primary care. Methods: We will test the implementation of this intervention in primary

care centres in Bogor and Jakarta. Sites have been chosen due to strategic links with the study team and both national and international policy recommend treatment in primary care settings with mental health expertise and adjunct pharmacological treatment for schizophrenia in LMICs . We will recruit and train up to four healthcare workers (non-mental health and mental health workers) in each of two primary care centres at district level to deliver the intervention collaborating with the primary care directorate to conduct research in these sites. Over 12 months, we will recruit a convenience sample of 30 service-user and family member dyads to i) compare recruitment and retention in different settings and delivered by different health professionals, ii) assess the feasibility of collecting participant outcome measures at study entry, post-intervention and six months later, iii) assess fidelity to and usability of the intervention manual and evaluate health professionals acceptance of the intervention model and iv) assess the acceptability of the intervention to recipients.

Participants receiving treatment in primary care settings will be eligible if they have been assigned a diagnosis of schizophrenia or related diagnoses (ICD-10 F20–29/DSM-IV), are aged ≥ 18 years, have a sufficient understanding of the native language to complete outcome measures, are identified by healthcare workers as having capacity to consent and present no immediate risk to self or others. Family members must have sufficient understanding of the native language to complete outcome measures and provide consent. Recruitment leaflets and posters advertising the study will be designed in consultation with the wider study team, the RAG and enlist local community cadres to assist. Cadres are volunteers that engage with the local community to provide public health interventions and are also members of that community strategically selected by primary care professionals for their ability to leverage community influence. Family members will be recruited via service-users. Participant information sheets will be distributed in primary care settings. Quantitative data collection will comprise measures of recruitment, attendance, retention, attrition and completeness of the outcome measures at each data collection point by research assistants independent of the intervention delivery. Service-user, family member and staff outcome schedules will be devised by the RAG to include symptom severity, relapse rates and hospital episodes, social functioning, family environment and functioning, knowledge, attitudes and burden and therapeutic engagement. A checklist of items will be developed from the training manual defining core components of the intervention and a percentage of manual-specified components delivered as intended will be collated from detailed diaries recorded by researchers independent of intervention delivery. Healthcare workers delivering the intervention will keep a diary following each session to evaluate their opinions of fidelity, factors that they felt may have influenced their fidelity and their views regarding elements that were useful and those that were less useful. Qualitative interview data on participants' views of the intervention will be obtained in individual, semi-structured interviews at intervention completion. Analysis: Aggregate quantitative data will be analysed to determine intervention delivery feasibility. Descriptive statistics will be generated to assess attendance, attrition, retention and the completeness of outcome measures. Pre-specified criterion for fidelity will be used interpreting 80%–100% adherence as 'high' fidelity, 51%–79% as 'moderate' and 0%–50% as 'low' fidelity [9]. Qualitative interviews will be digitally recorded, transcribed, checked for accuracy and analysed using framework analysis [10]. Again the interviews will be verified among the wider study team. We will document our intervention according to the template for intervention description and replication (TIDieR) checklist [11].

4. IMPORTANCE OF THE RESEARCH: Mental illnesses comprise the single largest source of health-related economic burden globally [12] and low-and middle income countries (LMIC) are disproportionately affected. Schizophrenia, the most common psychotic illness, is among the ten most disabling conditions worldwide. It is a complex illness, most will experience marked disability [13] and population growth and ageing is causing this burden to increase [14]. Schizophrenia is a relapsing illness so providing lifelong care is commonly required yet up to 90% of people in LMICs remain undetected, do not receive a formal diagnosis or any treatment giving rise to a significant treatment gap [15]. Consequently, much of the burden of care for people with schizophrenia lies with families and communities without adequate, skills, knowledge or resources to implement care.

Effective packages of care for schizophrenia comprise both pharmacological treatments and psychosocial interventions [16]. It is broadly considered that in LMICs, a narrower group of interventions will be feasible due to lack of finance and infrastructure, population density and under-developed social welfare systems [17]. FIps have exceptionally robust evidence for their

efficacy in high resource settings and have an emerging evidence base in LMICs [18]. Providing these interventions can reduce relapse, improve the family environment and therapeutic alliances with healthcare workers [19]. The World Bank's recently published third edition of global disease priorities (DCP3) includes FIps as one of only three potentially cost-effective interventions for people with schizophrenia and recommend these interventions should be prioritised in LMICs [20].
FIps are theoretically advanced in terms of identifying context-specific needs and the key intervention features that address these. FIps offer therapeutic elements to enhance family skills and knowledge, communication skills training, enhancing skills in problem-solving and goal setting. These are underpinned by theoretical frameworks such as cognitive models [21], cognitive-behavioural theories [3] and are framed by collaborative partnerships to enhance supportive therapeutic relationships. FIps do require adaptation to different cultural contexts allowing cultural beliefs, explanatory models of illness and contextual socio-economic issues to be incorporated into the content and delivery of such interventions [2]. Indeed, when effective interventions are successfully adapted, people are more likely to engage with psychiatric help offered increasing acceptability. Interventions within specific cultural groups delivered in their native language are twice as efficacious as those delivered without adaptation and cultural adaptation enhances interventions efficacy for treating schizophrenia, the degree of adaptation closely correlated with the degree of efficacy [2].
In Indonesia, there is an estimated 2.6 million people with schizophrenia, approximately 60,000 of whom are currently in shackles *(pasung),* restrained in sheds, cages or wooden blocks. Prevailing explanatory models of mental illness favour supernatural theories over biomedical explanations but often families lack knowledge of treatment availability and approaches to recovery to manage crises and support social functioning. The United Nations Sustainable Development Goals (SDG) have for the first time focused on reducing the burden of mental illness scaling up prevention and treatment strategies. Coupled with the World Health Organisations focus on task-shifting to increase capacity for intervention delivery and integration between primary and secondary mental health services [22], there is a need to develop FIps that are evidence-based, can be delivered by non-specialist professionals and are scalable. National policy reflects this shift as Indonesia aims to deliver mental health services for all through primary care closing the significant treatment gap. Our charity partners at Komunitas Peduli Scikizofreni Indonesia (KPSI) provide carer support presently in grassroots efforts to meet the needs of people with psychosis. Support is informally delivered through drop-ins, through social media and through a rolling psychoeducation programme provided once-monthly. PPI from our charity partners at KPSI indicates that this provision needs a robust theoretical, empirical underpinning that is influenced by the needs and preferences of recipients to ensure it is relevant and acceptable but also that the intervention delivered is effective.

5. RESEARCH IMPACT: This study will generate new knowledge that will advance our understanding of psychosocial intervention delivery for people with schizophrenia and their families. We will inform the conduct of a feasibility trial of a newly adapted, evidence-based intervention and ascertain whether a trial could be successfully conducted. Simultaneously, we will build research capacity, raise awareness of mental health and human rights issues and mobilise communities to improve the availability and access to services for people with schizophrenia and their families.

6. ETHICS: As advised by MRC Guidelines for Management of Global Health Trials, we will adhere to international ethical principles and seek independent ethical review in both Indonesia and the UK before commencing the study. In Indonesia, ethical approval will be sought from the Department of Science, Technology and Higher Education Review Committee, subsequently from Universitas Indonesia and University of Manchester and as such all policies will be adhered to.

7. FINANCIAL INFORMATION:

Organisation name	total project costs (gbp)	Total cost requested from this scheme (gbp)
University of Manchester	91404.32	67639.19
University of Liverpool	25370.4	18774.11
Universitas Indonesia	61617	61617

8. PROPOSAL HISTORY: This proposal has not been submitted to DFID, NIHR, MRC, Wellcome or any other funding organisation previously.

References

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3. Barrowclough, C. and N. Tarrier, *Families of schizophrenic patients : cognitive behavioural intervention*. 1992, London: Chapman & Hall.
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6. Rathod, S., et al., *The current status of culturally adapted mental health interventions: a practice-focused review of meta-analyses.* Neuropsychiatr Dis Treat, 2018. **14**: p. 165-178.
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15. World Health Organisation, *Mental Health Atlas 2017*. 2017: Geneva.
16. de Jesus Mari, J., et al., *Packages of Care for Schizophrenia in Low- and Middle-Income Countries.* PLoS Medicine, 2009. **6**(10): p. e1000165.
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JUSTIFICATION OF COSTS: Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention

This 24-month study for which we are requesting £148,030, will comprise three phases and be conducted in two sites (Jakarta and Bogor) within Java, Indonesia.

Phase 1 will comprise up to 4 stakeholder consultation groups (n=40) and 10 key informant interviews to explore priorities and preferences for intervention content and delivery and explore wider implementation issues
Phase 2 will comprise consensus workshops over two days for stakeholders (n=20) to ascertain consensus on the components of the intervention, synthesis of the findings to develop a manual and assess training needs to inform training resources for healthcare professionals
Phase 3 will comprise feasibility testing and we will train healthcare professionals (n=4) to deliver these interventions and recruit a sample of service-users and carers to our intervention and test the acceptability of the intervention and the methods of testing the intervention in two primary care settings.

Staff – directly incurred posts: Data collection and analysis will be undertaken by Indonesian researchers under the supervision and guidance of the Indonesia and UK co-investigators to comply with local guidelines and policy.

Phase 1 – Stakeholder Consultation – This will be led by LR and HS in collaboration with HB, BK, PB and KL. Ethical submission, data collection and management will be led by HS and BK. Training in research methodology will be provided by HB, PB, LR and KL with HS and BK.
Data will be collected by Indonesian researchers (n=2 per site). Ongoing supervision of data coding and content development to be provided by HB, PB, KL and LR.

Phase 2 – Consensus Workshops – This will be led by LR and HS in collaboration with HB, KL and BK. Synthesis and co-production of the intervention will be led by LR with HS, BK and KL, workshop facilitation will be provided by BK and KL with support from HS and LR.

Phase 3 – Feasibility Testing – This will be led by LR and HS. Intervention training will be provided by TB with LR, and HS. Methodology training will be provided by LR, HS, TB and BK with support from the wider team remotely. Ethical submission to be led by HS and BK. Data collection will be provided by Indonesian researchers at three time points (n=4 researchers). The intervention will be delivered by trial therapists (n=2) and ongoing supervision will be provided by LR, KL, HB and PB. Data collection will be overseen by HS and BK and analysis will be overseen by LR, PB, KL and HB.

The figure includes the costs for preparatory work (ethical submission, national approvals), translation and transcription costs (study proposal, questionnaire, and interview data, stakeholder data), PPI payments for study participants involved in the study (e.g. attending events and participating consensus workshops and advisory functions), administrative costs for Indonesia researchers and consumables (administrator time, digitally encrypted recorders and phone costs for researchers when lone working), training workshops for Indonesian researchers, and the costs associated with the preparation of reports for funders and dissemination of study findings (as detailed in the communications plan). Transport and hospitality are costed also for research-related events and impact events (e.g. two-day festival).

Staff – directly allocated posts: This relates to UK PI and CI time spent on the project. PI Renwick is costed in at 0.15FTE. HB is costed at 0.10FTE and KL, LR and PB are funded at 0.05FTE. We have allocated funding for three visits to Indonesia. The first will involve the

study launch, initial meeting of the research advisory group, research training methodology (validated 4-day research methods course to build capacity to a sufficient level so that they can lead the delivery of the research project) and forward planning meetings. The second will involve consensus workshop facilitation, support with synthesis and co-production of the intervention and development of the manual and training resources and planning for phase 3. The last trip will comprise the launch of the feasibility study and delivery of the intervention training.
The co-investigators will provide ongoing mentorship and supervision of the study researchers and mentorship will be provided within the team. We will coincide trips to Indonesia with meetings of the RAG to ensure consistent communication and establish quarterly coinvestigator meetings to manage project processes, outputs and deliverables. Co-investigators and PIs will also contribute to analysis, preparation of reports for funders, dissemination of study findings through manuscript development and presentations and manage impact activities.

Travel and subsistence: Travel and subsistence costs relate to three trips to Indonesia by UK Investigators:

1. 6-day visit to Indonesia for two UK investigators at the beginning of the study. This trip will allow research training delivery, familiarising and initiating study procedures and assigning roles and responsibilities, meetings between co-investigators to manage ongoing impact activities.

2. 6-day visit to Indonesia for two UK investigators in month 6 of the project to co-facilitate the synthesis and production of consensus workshop outputs and manual development with production of resources for training the trainers. Analysis and discussion of outputs from phase 1 to support ongoing development and impact activities.

3. 6-day visit in month 8 of the project to provide training in the intervention and research training for the final phase of the project. Research advisory meetings, forward planning and supervision and mentorship planning during the feasibility aspect

Co-investigator meetings will be conducted by Skype where possible given the distance between researchers.

Other Directly incurred costs: These costs relate to:
PPI payments to project partner (KPSI) plus any advisory group members outside of this organisation for their involvement in all stages in the study.
Costs associated with the initial training provided to researchers in Indonesia and the advisory group.
Back translation of a proportion of transcripts by an independent translator for validity purposes.
Costs associated with the production of manuals and training materials.
The figure includes the costs for preparatory work (ethical submission, national approvals), translation and transcription costs (study proposal, questionnaire, and interview data, stakeholder data), PPI payments for study participants involved in the study (e.g. attending events and participating consensus workshops and advisory functions), administrative costs for Indonesia researchers and consumables (administrator time, digitally encrypted recorders and phone costs for researchers when lone working), training workshops for Indonesian researchers, and the costs associated with the preparation of reports for funders and dissemination of study findings (as detailed in the communications plan). Transport and hospitality are costed also for research-related events and impact events (e.g. two-day festival).

CURRICULUM VITAE

Name: Budi Anna Keliat

Employment and Education history

I am currently working as Professor of mental health nursing at Faculty of Nursing, Universitas Indonesia in Jakarta and have been employed here since 1990. As a lecturer, I have primary responsibility in the areas of teaching, research and community service. I teach across all undergraduate and postgraduate programmes including specialist clinical and doctoral programmes. I supervise post-graduate research projects and conduct research in helping to describe, define and deliver psychosocial interventions for people with schizophrenia. I also maintain professional practice as mental health nurse. Indonesia is a place of natural disaster and since some of the more fatal humanitarian crises have hit we have been looking to develop mental health and psychosocial support models of working. Since the tsunami in Aceh in 2004, we have developed community mental health nursing models for the first time in Aceh. This has been successfully received and we are now replicating to deliver in all provinces of Indonesia. Based on this work, I was awarded **"Outstanding Achievement in field of Mental Health Care"** in 2015 from the Swiss Foundation Collaboration with World Health Organisation Centre, Geneva.

Employment History

1974 – 1975	Nurse Practitioner Medical Surgical Ward at Dr. Cipto Mangunkusumo Hospital, Jakarta
1975 – 1990	Mental Health Nurse at Bogor Psychiatric-Mental Hospital
1989 – 1990	RN in Concord Hospital, Sydney, Australia
1990 – Now	Lecturer and now Professor at Department of Mental Health Nursing, Faculty of Nursing Universitas Indonesia
2013 - 2016	Adjunct Professor at the School of Nursing, Faculty of Health Sciences of The University of Ottawa (Forensic Nursing: disaster, confinement/pasung and prison)

Educational background

1970 – 1974	Academy of Nursing Ministry of Health republic of Indonesia, Jakarta.
1985 – 1988	Bachelor of Nursing Universitas Indonesia, Jakarta
1988 – 1990	Master of Nursing: School of Nursing, Sydney University, Australia
1988 – 1990	Registered Nurse New South Wales, Sydney Australia
1998 – 2003	Doctor of Public Health: Faculty of Public Health University of Indonesia. Dissertation Title: "***Empowering clients and families in caring for clients with schizophrenia with violent behavior".***

Dr Helen Brooks – Curriculum Vitae **January 2019**

1. Name: Dr Helen Brooks (nee Cording)

2. Title: Senior Lecturer

3. Research summary: I am a health services researcher with a strong and sustained track record in high quality research contributions in the field of chronic illness, with a dual focus on the role of social networks and the implementation of programmes designed to improve health experiences incorporating patient and public involvement (h=index: 18, i10-index: 21).

4. Employment history:

2019 - present	Senior Lecturer - Permanent	University of Liverpool
2017-2018	Lecturer	University of Liverpool
2015-2017	Research Fellow	University of Manchester
2009-2012	Research Associate	University of Manchester
2008-2009	Research Associate	University of Central Lancashire
2007-2008	Research Assistant	University of Central Lancashire
2006-2007	Grants Officer	Big Lottery Fund
2004-2006	Senior Research Assistant	Northumbria University
2001-2004	Research Assistant	Northumbria University

5. Qualifications:
2018 Certificate in Professional Studies in Learning and Teaching in Higher Education: Distinction.
2013 PhD. University of Manchester.
2006 MRes (merit) Social Science and Health. University of Newcastle upon Tyne
2000 BSc (hons) Psychology. 2:1. University of Newcastle upon Tyne.

6. Grant Income

Funding body	Title	PI	Amount
ODA Seed Fund	Investigating the feasibility of developing a self-help tool for psychosis sufferers in Central America	Lyons	£8,800
Wellcome Trust	Maximising the potential for future large-scale global mental health research in Indonesia: A community engagement project	Brooks	£9,800 12 months. Start Date: 1/8/18.
MRC/DFID/NIHR	**I**mproving **M**ental Health Literacy Among Young **Pe**ople aged 12-15 years in Java, Indonesia: Co-development and Feasibility **T**esting of a Culturally-appropriate, **Us**er-centred Resource (**IMPeTUs**).	Brooks/ Bee	£346,571 30 months Start Date: 01/06/18
NIHR PGfAR	Enhancing the quality of psychological interventions delivered by telephone (EQUITy). **PPI LEAD**	Bee	£2,296,276, 66 months Start date: 04/02/18
NIIHR HTA	De-escalation techniques and	Price	£520,112.84

	the use of restrictive interventions in adult mental health units (EDITION).		30 months Start date 01/01/18
MRC Health Systems Research Initiative	Exploring the potential of civic engagement to strengthen mental health systems in Indonesia (IGNITE).	Brooks/ James	£125,678 Start date: 1/11/17
ESRC Global Challenger Research Fund	PPI visit and proposal development.	Brooks/ Renwick	£5,000
NSPCC	Exploring the social networks of children with parents with severe mental illness	Bee	£45,000
ESRC IAA Global Health Award	Cultivating newly formed collaborative partnerships in Indonesia with leading mental health clinicians and academics	Brooks/ Renwick	£9,600
New Mind Network	APPLEmh: Adaptive Planning and raPid LEarning in mental health	Fox/ Brooks	£15,000
MRC Proximity to Discovery Fund	Developing a specification for an interactive, user-friendly mental health care plan.	Brooks	£6,712
Manchester Mental Health and Social Care Trust	Understanding collaborative antipsychotic prescribing in mental health services.	Lovell	£18,629
NIHR	The Collaboration for Leadership in Applied Health Research and Care (CLAHRC) – BRIGHT trial	Blakeman	£234,545
NIHR CLAHR	VOCALS	Morris	£118,500

7. Current research students

1. Khadijah Bakur (PhD). The Role of Religion and Spirituality in the experience of patients with Long QT syndromes.
2. Imogen Nevard (PhD) Understanding social networks in children of parents with severe mental illness.
3. Xiao Xiao Hou (PhD). Music in Eldercare: Improving the wellbeing and quality of life of dementia patients and their caregivers.
4. Lisa Powney. (DClin). Empathy and personal distress: A thematic analysis of the lived experience of adults with autism spectrum disorder.
5. Dawn Knowles. (DClin Recovery in bipolar disorder: A qualitative study exploring the views of mental health professionals

8. Public engagement

- Winner of NIHR Let's Get Digital Competition (animation category) for a video exploring carer involvement in mental health care planning (https://www.nihr.ac.uk/news-and- events/support-our-campaigns/video.htm).
- Winner of the 2015 CRN award for public engagement and the MHRN award for exemplary carer involvement for the NIHR CLAHRC-GM Community Mental Health Festival, engaging over 500 stakeholders living or working with Mental Illness across the North West.

Professor Karina Lovell

Position: Professor of Mental Health and Director of Research
ORCID ID https://orcid.org/0000-0001-8821-895X

Universities Attended and Awards

1978 – 1984 Registered Mental Nurse (1980), St. Crispin Hospital, Northampton
1984 – 1986 Post Registration Certificate in Nursing, ENB650 (Nursing in Adult Behavioural Psychotherapy - 1986) Maudsley Hospital, London
1986 – 1990 BA (Hons) Social Sciences (1st Class), Middlesex Polytechnic (P/T), London
1991 – 1992 Post Graduate Diploma in Education (Nursing, Midwifery and Health Visiting) Royal College of Nursing (1992), London
1990 – 1992 MSc: Sociology of Health and Illness, Southbank University (P/T), London
1992 Certificate in Cognitive Therapy, Institute of Psychiatry, London
1993 – 1997 PhD: 'Outcome of Exposure Therapy and of Cognitive Restructuring in Post-Traumatic Stress Disorder', University of London (P/T), London

Previous employment and appointments held

2002 - 2005 Senior Lecturer in Nursing, University of Manchester

1998 – 2002 Lecturer in Nursing, University of Manchester

1996 – 1997 Practice Development Nurse/CBT, The Bethlem and Maudsley NHS Trust, London

1992 – 1996 Research Nurse/Honorary Lecturer, Institute of Psychiatry, London

1991 – 1992 Student Tutor, Royal College of Nursing, London

1988 – 1991 Tutor to ENB650 (Adult Behavioural Psychotherapy) and clinical manager of the Psychological Treatment Unit, The Maudsley Hospital, London

1986 – 1988 Clinical Nurse Specialist (Behavioural Psychotherapy), The Maudsley Hospital, London

1986 – 1986 Nurse Behaviour Therapist, St George's Hospital, London

Current grants

2018

Research England GCRF Developing Scalable Digital Interventions for Improving Access to Depression Interventions throughout Indonesia Renwick, Bee, Brooks, Lovell 2019 **£47,883**

MRC Global Health Improving Mental Health Literacy Among Young People aged 12-15 years in Java, Indonesia: Co-development and Feasibility Testing of a Culturally-appropriate, User-centred Resource (IMPeTUs) 2018 **£349,950**

NIHR Programme Grant Multi-morbidity in Older Adults with Sub-threshold Depression Study (MODS) Ekers, Gilbody, Lovell 2018 **£2322868.00**

NIHR HTA De-escalation techniques and the use of restrictive interventions in adult mental health units (CI Price, Lovell, Bee, Callaghan, Brooks et al) 2018 **£520,112.84**

NIHR Programme Grant Enhancing the quality of psychological interventions delivered by telephone (EQUITy) CI Bee, Bower, Lovell, Brooks 2018 **£2,524,745,**

NIHR Programme Grant Improving access to psychological therapy on acute mental health wards. Berry, Haddock, Lovell, Bucci, Edge 2017 **£2,000000**

MRC Exploring the potential of civic engagement to strengthen mental health systems in Indonesia. Brooks, James, Lovell, Rose, Colucci Irmansyah, Keliat2017 **£126,677.75**

NIHR HTA INterventions for Complex Traumatic Events (INCiTE) Coventry, Churchill, Gilbody, Lovell, Barbui, Meader, McMillan, Wright, Temple 2017 **£187,000.00**

NIHR NIHR Global Health Research Group on Stillbirth Prevention and Management in Sub-Saharan Africa. Lavender T, Heazell A, Bedwell C, Mills T, Smyth R, Green M, Victor S, Lovell K2017 **£1,990,018.00**

NIHR NIHR Senior Investigator Award 2016-2021 **£75,000**

ARUK Fibromyalgia Optimal Management for patients with axial Spondyloarthiritis (FOMAxS) Macfarlane, Sengupta, Lovell, NcNamee, Cook, Mease, Haywood, Martin, Lee2017 **£184,561.20**

British Council Newton Fund Enhancing early psychosis care: transforming the nursing workforce through innovation in evidence based practice Yung, Lovell, Irmansyah and Renwick 2017 **£40,000.00**

Salford CCG Innovation Fund Implementing low-cost individually tailored cognitive therapy (CBT) for patients with Musculoskeletal Pain in Salford. Lovell (PI), Jones, Wilson, Boaden, McEvoy, Derbyshire, Spence. 2016 Matched funding from CLAHRC **£79,003.85**

NIHR HTA A non inferiority randomised controlled trial comparing the clinical and cost effectiveness of single session treatment with multi-session CBT in children with specific phobias. Wright, Teare, Marshall, Bee, McMillan, Lovell, Breckman, Davis, Cooper, Gega, Gilbody, Shehzad, Hargate, Biggs 2016 **£1,408,823.00**

NIHR HS&DR Enhancing the credibility, usefulness and relevance of patient experience data in services for people with long-term physical and mental health conditions using digital data capture and improved analysis of narrative data. Sanders, Bower, Lovell, Lewis, Ainsworth, Dixon, Kontopantelis, Boaden, Cahoon, Hodgson, Sinclair, Lewis, Nenadic 2015 **£516,996.79**

Hamad Medical Corporation, Qatar The development of a peer support intervention to improve the mental health of unskilled migrant workers. Price, Lovell, Pedley, Gray 2015 **£196,248**

AR UK Lessening the Impact of Fatigue: Therapies for Inflammatory Rheumatic Diseases. Basu, McNamee, Dures, Emsley, Gray, Paul, Lovell, Martin, Auld, Hewlett, Wearden, MacFarlane, Norrie, Reid, Siebert & White 2016 **£ 736,687.09**

HS&DR NOTEPAD: Non-Traditional providers to support the management of Elderly People with Anxiety and Depression: a feasibility study. Chew-Graham, Bower, Bartam, Ray, Beech, Lovell, Waheed, Ashmore, Gilbody, Burroughs, Bullock, Hay, Parker, Hughs, 2015 **£292,874.80**

NIHR HTA Pragmatic Randomised controlled trial of a trauma-focused guided self-help Programme versus Individual Trauma-Focused Cognitive Behavioural Therapy for post-traumatic stress disorder (RAPIDTFCBT) Bisson, Brookes-Howell, Kelson, Kitchiner, Lewis, Lovell, Roberts, McEwan, McNamara, Phillips, Seriki, Heke, Bligh, Jones, Pittard-Davies, Lewis, Ehlers & Cosgrove 2015 **£1,135,332.88**

Dr Laoise Renwick

Job Title: Lecturer in Mental Health Nursing

Research Summary: The first paper that I published in 2008 has contributed to national guidance for clinical practice in early intervention in psychosis (NICE CG178 Psychosis and Schizophrenia for adults). Since then I have contributed substantially to the international research effort in determining the antecedents and consequences of delays in accessing care for people with first-episode psychosis. I primarily conduct health services research and focus on areas both related to inpatient acute care (aggression and violence) and enhancing interventions for psychosocial outcomes (functional outcomes, quality of life). I have been translating these skills to address mental health issues in the global health agenda in the past three years.

Universities Attended and Awards

PhD: University College Dublin, 2012

Bachelor of Nursing: Dublin City University, 2007

Diploma in Higher Education: Registered Mental Health Nursing: Anglia Ruskin University, 2001

Qualifications/training (other)

University of Manchester, (2017) New Academic Programme

Royal College of Physicians, Ireland (2013) Quality Improvement Trainee Programme

Douglas Research Institute/McGill University, Canada (2010) Professional Internship

Professional qualifications

Registered Nurse (Mental Health - Part 3), June 2001

Previous employment and appointments held

2013-2014 Post-doctoral Researcher, Institute of Psychiatry, Psychology and Neuroscience, Kings College London

2008-2012 HRB Research Fellow, DETECT Early Psychosis Service, Dublin

2006-2013 Clinical Nurse Specialist (Psychosis), DETECT Early Psychosis Service, Dublin

2005-2006 Community Mental Health Nurse, Cluain Mhuire Service, Dublin

2001-2005 Staff Nurse, Addictions, Eating Disorders & Acute Day Hospital, Dublin

Editorial and Scientific Duties

Chair, 24th International Mental Health Nursing Conference 2018 (Royal College of Nursing)

Editorial Board Member, Journal of Psychiatric and Mental Health Nursing

Grants Awarded

2018	**L. Renwick, P. Bee, H. Brooks, K. Lovell** *Developing Scalable Digital Interventions for Improving Access to Depression Interventions throughout Indonesia*	Research England GCRF	**£47,883**
2017	**P. Bee, H. Brooks, K. Lovell, L. Renwick** *Improving Mental Health Literacy Among Young People aged 12-15 years in Indonesia: IMPeTUs*	MRC/DFID/NIHR	**£349,950**
2017	**L. Renwick & H. Brooks** *Scoping global challenges research fund*	Newton HEFCE	**£5,000**

	opportunities		
2016	**L. Renwick & H. Brooks** *Cultivating newly formed collaborative partnerships in Indonesia with leading mental health clinicians and academics*	ESRC Impact Acceleration Award	**£9,600**
2016	**A. Yung, K. Lovell & L. Renwick** *Enhancing early psychosis care: transforming the nursing workforce through innovation in evidence based practice*	British Council Researcher Links	**£29,060**
2016	**L. Renwick** *Developing priority setting partnerships for early intervention in psychosis*	Burdett Trust for Nursing	**£7,350**
2013	**L. Renwick & S. Hill** *Computer assisted patient assessment*	Nursing & Midwifery Planning Development Unit	**€17,668**
2013	**L. Renwick** *Quality of life in first-episode psychosis*	Bloomberg Emerging Nurse Scholar Forum Bursary	**$1,500**
2008	**L Renwick** *Quality of life in first-episode psychosis*	Health Research Board, Career Development Awards	**€232,910**

Current Research Students

Aziza al Sawafi (PhD) Psychosocial family interventions for relatives of people living with schizophrenia in the Oman

Chiu-yi Lin (PhD) Service-user perspectives of shared decision making in secondary mental health care in Taiwan

Public Engagement

Research Priorities for Psychosis: I have instigated and lead a national project engaging with service-users, carers and healthcare professionals to find out the important issues facing the people that use and deliver services. This project provides researchers and funders (NIHR) with information about what needs to be researched, potentially making future research meaningful and relevant.

http://www.vip.bmh.manchester.ac.uk/

Engagement in Indonesia: Through collaborating with colleagues in Indonesia (National Centre for Mental Health, Bogor and Universitas Indonesia) I have conducted public engagement activities and knowledge sharing between partners in Indonesia.

http://nursing.ui.ac.id/peran-perawat-dalam-menangani-klien-psikosis/

http://yankes.kemkes.go.id/read-metamorfosis-bkmm-menjadi-rumah-sakit-khusus-mata-pada-sertijab-kepala-bkmm-cikampek-792.html

Professor Penny Elizabeth Bee (nee Clarke)

EMPLOYMENT HISTORY:

Present appointment: Professor (Applied Mental Health Research).
School of Health Sciences, University of Manchester.

Previous Appointments:

08/15-05/18	Reader (Mental Health Services	University of Manchester
08/12-08/15	Research) Senior Lecturer (Health Services Research)	University of Manchester
08/08-08/12	Lecturer (Health Services Research)	University of Manchester
03/07-07/08	Research Fellow	University of Manchester
03/02-03/07	Research Associate	University of Manchester
03/05-09/05	Research Associate (NIHR-funded)	University of Manchester
03/02-02/05	Research Associate	University of Manchester
09/97-11/01	Postdoctoral Research Scholar	Loughborough University

Maternity Leave 1: 06/04-12/04; Maternity Leave 2: 03/07-09/07

EDUCATION:

1997-2001	PhD Psychology	Loughborough University
1994-1997	BSc Hons. (1st Class), Human Biology	Loughborough University

RESEARCH CONTRIBUTIONS:

Award	Funding Details	Amount & Responsibili
NIHR HS&DR	Services to support early intervention and self-care for children and young people referred to Children and Young People's Mental Health services	£643 000, 36 months, Start date: 01/10/18 Co-applicant
NIHR PGfAR	Enhancing the quality of psychological interventions delivered by telephone (EQUITy) (CI Bee)	£ 2,524,745, 60 months Start date: 04/02/18, Chief Investigator
MRC/NIHR/DFID	Improving Mental Health Literacy Among Young People aged 12-15 years in Indonesia: IMPeTUs (CI Bee)	£330,000, 30 months Start date: 01/04/18 Chief Investigator
NIHR HTA	De-escalation techniques and the use of restrictive interventions in adult mental health units (CI Price)	£520,112.84, 30 months Start date 01/01/18 Qualitative lead
Wellcome Trust Strategic Support	Development and evaluation of an interactive performance to raise awareness and understanding of Young Carers (CI Bee)	£4700, 6 months, Start date 01/07/16 Chief Investigator
NIHR HTA	A non-inferiority RCT comparing the clinical & cost-effectiveness of one session treatment with multi-session CBT in	1,371,954.00, 48 months Stat date 01/01/16 Qualitative lead

	children with phobias (CI Wright)	
NIHR HTA	Multicentre RCT of a group psychosocial intervention for postnatal depression (CI Husain)	£1,964,501, 48 months Start date 01/02/16 Qualitative lead
NIHR HTA	Enhancing health related quality of life in children who live with a primary carer with serious mental illness (CI Abel)	£473,475, 36 months Start date: 01/01/16 Qualitative lead
MRC	Multi-centre RCT to evaluate the clinical and cost-effectiveness of a culturally adapted therapy (C-MAP) in patients with a history of self-harm (CI Husain)	£736,697, 36 months Start date 01/08/15 Qualitative lead
NIHR RfPB	Enhancing maternal and infant wellbeing: a feasibility study of the Baby Triple P Positive Parenting Programme for mothers with severe mental illness (CI Wittkowski)	£242,632, 36 months Start date 04/04/16 Qualitative lead
NIHR PHR	Interventions to aid return to work after long term sickness absence (CI Bower)	£266,650.80, 20mths, Start date 01/04/14 Qualitative lead
NIHR HS&DR	Rapid Evidence synthesis of Outcomes and Care Utilisation following Self-care support for children and adolescents with long term conditions. Reducing care utilisation without compromising health outcomes (CI Bee)	£158,418, 16 months; Start date 01/02/15 Chief Investigator
British Council	Transforming the nursing workforce: improving population health through evidence-based practice (CI Lovell)	£44,490, 12 months, Start date 01/11/14 Research Advisor
NIHR CLAHRC-GM	Mental Health, Patient-centred Care theme	Responsible for £555,487 against total funding of £9,998,769.
NIHR HTA	Community-based interventions for maintaining or improving quality of life in children and adolescents of parents with serious mental illness (CI Bee)	£159, 892, 18 months, Start date 01/11/10 Chief Investigator
NIHR HTA	Obsessive Compulsive Treatment Efficacy Trial (CI Lovell).	£1,942,196 48 months, Start date 01/03/11 Manchester Site Lead
NIHR Programme Development Grant	Enhancing the quality and purpose of care planning in mental health services (CI Lovell)	£95, 431, 12 months Start date 01/10/11 Systematic Review Lead

Dr Timothy John Bradshaw.

Universities Attended (all on a part time basis)

2002-2008 University of Manchester (PhD)
2011-2012 University of Bolton (PGCE)
1996-1999 University of Manchester (MPhil)
1994-1996 University of Manchester (BSc Hons)
1993-1994 University of Manchester (Diploma Professional Nursing Studies)

Academic qualifications

2008 PhD A*n evaluation of health education groups for adults with a diagnosis of schizophrenia*
2012 PGCE Education in Teaching and Learning for Professional Practice
1999 MPhil *Does structured clinical supervision during psychosocial intervention education enhance outcome for mental health nurses and the service users they work with?*
1996 BSc (Hons) Professional Nursing Studies (Upper second class)
1993 Diploma in Professional Nursing Studies (THORN Nurse Initiative in psychosocial intervention)

Present appointment

From 2015 **Programme Director -** MSC Advanced Practice Interventions in Mental Health (APIMH)-a part time post graduate programme with three pathways 1) Psychosis; 2) Dementia care and 3) Primary mental health care.
From 2016 **Reader in Mental Health Nursing**, (Teaching Focused) Division of Nursing, Midwifery and Social Work, University of Manchester

Previous appointments

2009 -2016 **Senior Lecturer-** Mental Health Nursing, (Teaching Focused) School of Nursing, Midwifery and Social Work, University of Manchester
1997–2009 **Lecturer** (Teaching Focused), School of Nursing Midwifery and Social Work, University of Manchester
1996–1997 **Lecturer / Practitioner** (I grade), Wigan and Leigh Health Services NHS Trust and the University of Manchester
1995–1996 **Community Mental Health Team Manage**r (H grade), Wigan and Leigh NHS Health Services Trust
1989–1995 **Community Psychiatric Nurse** NHS posts grade D – G
1987–1989 **Mental Health Nursing Student**, Wigan Health Authority
1986–1987 **Staff Nurse Surgical ward**, St.Helens and Knowsley Health Authority
1983–1986 **General Nursing Student**, St.Helens and Knowsley Health Authority

B. Research contributions

Although employed on a teaching focused contract I have always participated in research / scholarly activity closely aligned to the content of my substantive teaching, holistic approaches to improve the Physical and Mental wellbeing of people with Serious Mental Ill Health. In view of my expertise in this area I have recently published papers in high impact peer review journals including Lancet Psychiatry and an editorial in the British Journal of

Psychiatry. I have also been invited to co-author national guidance on smoking cessation for people with serious mental illness endorsed by four Royal Colleges and the Royal Society for Public Health http://rcpsych.ac.uk/pdf/PrimaryCareGuidanceonSmokingandMentalDisorders2014update.pdf

Grants awarded

1. SCIMITAR plus (Smoking Cessation for severe Mental Ill health Trial) – Chief Investigator Professor Simon Gilbody (University of York) - **£1.5M** HTA CET funding (application number 11/136/52). This is the largest randomised controlled trial of smoking cessation for people with serious mental ill health in the world too date. The study commenced in September 2015 and I am Principal Investigator for the Manchester site.
2. SCIMITAR (Smoking Cessation for severe Mental Ill health pilot study) - Chief Investigator Professor Simon Gilbody (University of York) - **£500K** from the Health Technology Assessment Programme to conduct the first pilot randomised controlled trial of smoking cessation people with serious mental ill health in the UK. I was Principal Investigator for the Manchester site taking over this role from the late Professor Helen Lester.

Selected international teaching activities (* by invitation expenses paid)

Year	Institution, venue and audience (student numbers)	Topic/s
2013*	Nursing Education Association for **South Africa,** Pretoria. Senior Nurse academics (n=50)	Evaluating Complex Health Care interventions: two day workshop
2010*	EANS, PhD Summer School, University of Witten /Herdecke, **Germany**, 3rd year students (n=60)	Evaluating Complex Health Care interventions: One day workshop
2010	EANS scientific meeting, University of Lisbon, Portugal, EANS Fellows and Scholars (N=50)	Complex interventions in Mental Health
2009	EANS, scientific meeting, University of Klaipedia, **Lithuania.** EANS Fellows and Scholars (N=50)	Scholarly activity of Fellows and Scholars of EANS 2003-2007
2009*	EANS, PhD Summer School, The University of Turku, **Finland**, 2nd year students (n=60)	Undertaking research with vulnerable people: One day workshop
2005*	St.Patricks Hospital, Dublin**, Ireland** Level M Programme (n=30)	Psychosocial interventions for psychosis
2002* (October)	KwaZakhele township, Port Elizabeth, **South Africa**, Community Health Workers (n=50)	Helping people with Mental Health Problems: training the trainers one day workshop
2004* (March)	KwaZakhele township, Port Elizabeth, **South Africa**, Community Health Workers (n=25)	Helping people with Mental Health Problems: training the trainers: One day workshop
2004* (March)	KwaZakhele township, Port Elizabeth, **South Africa**, Community Health Workers (n=50)	Understanding Mental Health: Three day workshop
2002* (July)	The University of Port Elizabeth, **South Africa**, South African Mental Health Nurses (n=45)	Psychosocial interventions in Mental Health Care: Three day workshop
2002* (July)	KwaZakhele township, Port Elizabeth, **South Africa**, Community Health Workers (n=35)	Understanding mental health: Three day workshop

Dr Herni Susanti, SKp, MN, PhD

Position: Assistant Professor and Manager of Corporation and Venture

Other Roles

Head of The Center of Indonesian Service and Development of Mental Health Disaster Nursing

Vice President of Mental Health Collegium in Indonesia

Coordinator of Research Division in the Indonesian Mental Health Nurses Association

Editor of International Journal of Indonesian National Nurses Association

Coordinator of Research Division in the Association of Emergency and Disaster Nursing in Indonesia

History of Employment and Position

1998 - Now Lecturer Department of Mental Health Nursing Faculty of Nursing Universitas Indonesia

2016-2018 (January) Head of Department of Mental Health Nursing Faculty of Nursing Universitas Indonesia

2018 (February)-Now Manager of Corporation and Venture Faculty of Nursing Universitas Indonesia

Education

Bachelor of Nursing (SKp)	1998	Faculty of Nursing Universitas Indonesia
Master of Nursing Australia	2005	School of Nursing Curtin University of Technology,
PhD	2016	School of Nursing, University of Manchester, UK

Title of thesis: **Exploration of the needs of carers from hospital based-mental health services in Indonesia**

Current research projects

1. *The development of standard of nursing practice for disaster risk management impacting on heath.* Research based in Indonesia funded by *Penelitian Unggulan Perguruan Tinggi (Superior University Research grant) 2016-2018 (Team: Hamid AYS, Susanti H, Mulyono S, Chandra, YA).* ***Total Grant IDR 400.000.000*** Research based in Indonesia, collaboration with Japanese researchers
2. *Exploring the potential of civic engagement to strengthen mental health systems (IGNITE) 2018* Research based in Indonesia, funded by MRC UK, collaboration with UK researchers (university of Liverpool, University of Manchester) (Team: Brooks H, Lovell K, James K, Irmansyah, Budi AK, and Susanti H)**.** Total grant **46.117.82 poundsterling**
3. *Exploration of the need of nursing care in for drug and substance addiction* Research based in Indonesia, A grant for advanced reseracher in FON UI 2018 (team: Susanti H, Wardani IY, Fitriani, N)**. Total Grant IDR 50.000.000**
4. *Impacts of Lombok earth quake on wellbeing of vulnerable survivors* Research based in Indonesia (self-funded as volunteer in Lombok disaster)

Current Research Students

Siti Hajar H (Master) Experience of Post Traumatic Growth among teens experienced earth quake , tsunami and liquifaction in Palu, Indonesia

Eriyono (Master) Perception of disaster volunteering nurses about Post Traumatic Growth in Indonesia

Selected Research Activities

1. Mental health services in Indonesia: Challenges and Future (speaker) 2012 7th Annual mental health research conference, Manchester, UK
2. Qualitative interviews with mental health professionals In Indonesia about the needs of carers from mental health services (speaker) 2014 9th Annual Conference: Showcasing Mental Health Research across Primary and Secondary Care Services. Manchester, UK
3. What Does the Literature Suggest About What Carers Needs from Mental Health Services for Own Well Being? (speaker) 2016 Oral Presentation 1st International Nursing Scholars Congress (INSC)
4. A Policy Review Relating To Support For Carers of People With Serious Mental Illness In Indonesia (speaker) 2016 Oral Presentation 1st International Conference on Global Health (ICGH)
5. The Need of Carers From Hospital-Based Mental Health Service in Indonesia (speaker) 2016 Oral Presentation 1st International Conference on Global Health (ICGH)
6. Maternal Mental Health Disaster Affected Area: A Systematic Review (speaker) 2016 Oral Presentation. 4th WSDN Academic Conference, Jakarta
7. The application of nursing intervention by mental health nurse specialist in Indonesia (speaker) 29 September 2017 The 14th National Conference of mental health Nursing, Banjarmasin

Research Organisation

Chairperson of Organizing Committee of the 4th Academic Conference of the World Society Disaster Nursing 2016 Jakarta, Indonesia

Chairperson of Organizing Committee of the 1st INSC (International Nursing Scholar Conference) 2016 Universitas Indonesia

Chairperson of Organizing Committee of the 6st BINC (Biennial International Nursing Conference) 2017 Universitas Indonesia

Chairperson of Organizing Committee of The 2nd International Nursing Scholar Congress, Universitas Indonesia 2018 Universitas Indonesia

Vice-chair person of the 1st International conference of Indonesian National Nurses Association 2018 INNA (Indonesia)

UNIVERSITAS INDONESIA
FAKULTAS ILMU KEPERAWATAN

Gedung Fakultas Ilmu Keperawatan
Kampus UI, Depok Jawa Barat 16424
T. 62 21 788 49 120 F. 62 21 786 41 24
E. fik@ui.ac.id I www.fik.ui.ac.id

31st January 2019

Re: Support for project application 'Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention'

Dear Review Panel,

I am writing to confirm that Prof. Dr. Budi-Anna Keliat, SKp, M AppSc. and Dr. Herni Susanti, SKp, MN, PhD are both lecturers and researchers here at the Faculty of Nursing, Universitas Indonesia and to express my support for the proposed project. Prof. Keliat and Dr. Susanti have been involved in several collaborative projects with researchers at the University of Manchester and the proposed project 'Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention' was co-developed initially during meeting held at Universitas Indoensia in May 2017. These meetings were attended by the applicants herein and Dr. Laoise Renwick and Dr. Helen Brooks, co-applicants from the Universities of Manchester and Liverpool respectively. The projects primary scientific leadership will be provided by Dr. Laoise Renwick and Dr. Herni Susanti and the research will be primarily conducted in Indonesia with oversight from our Faculty.

The proposed projects build on some areas of research priority within the Faculty. Prof. Keliat and Dr. Susanti have both conducted extensive research in establishing novel models of psychosocial interventions and understanding the needs of carers of people with schizophrenia. Developing a carer intervention brings their expertise together with support from faculty collaborators at University of Manchester to advance the field within Indonesia so we wholeheartedly welcome this further collaborative project. We have excellent relationships with clinical partners and we are able to use our networks to negotiate access to research sites to ensure recruitment to research studies and confirm we have committed to delivering on the outputs of this project. We are also able to recruit stakeholders and key informants to ensure dissemination once the study is completed. We also collaborate with the research department at the Ministry of Health on other mental health-related projects.

We commit significant intellectual expertise and acknowledge the value for both the research team and our organisation in collaborating that will support building research capacity from within. The team are planning to meet in Manchester in July 2019 having been awarded a Research England GCRF award to enhance collaborations and capacity to develop scalable digital interventions for depression throughout Indonesia. This will further ensure we can build the infrastructure and capacity to maintain and sustain any emerging scientific and training needs.

I believe Prof Keliat and Dr Susanti are an excellent fit for this project and I am writing to express my full support. Please do not hesitate to contact me with further questions.

Sincerely,

Dr Agus Setiawan, BN, MN, DN
a-setiawan@ui.ac.id

KOMUNITAS PEDULI

ESIA

Alamat : Jl. Jatinegara Timur 99, RT 005/02, Balimester, Jatinegara – Jakarta Timur
Telepon : 021 – 857 9618
Email : info.kpsi@gmail.com
Facebook : Komunitas Peduli Skizofrenia Indonesia
Twitter : @kpsi_pusat
website : http://www.skizofrenia.org/

31st January 2019

Re: Support for project application 'Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention'

Dear Review Panel,

I am writing to confirm my complete support for the proposed project 'Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention'. We are Indonesia's foremost charity lobbying for better care and services for people with schizophrenia and their family members. I am the founder of this organisation which I set up mostly because I have a family member with schizophrenia and we had great difficulty obtaining evidence-based services and there were few places we could go to get accurate help and advice. Since 2012 we have been providing an informal service for communities in Jakarta who need help and advice around mental illness.

We commit substantial support to this project to recruit participants and we will be heavily involved in the research advisory committee providing specialist advice as experts by experience. The outputs of this project are of significant interest to us and aligned with our organisational goals to improve care and enhance treatment access pathways for families so we are very committed to the success of the project. We are also able to support this project with our public engagements on social media. We facilitate weekly national radio shows to talk about mental illness and we raise awareness of mental illness through our networks including Twitter and Facebook. As an example, we have Facebook followers of 39,534 people so we can reach many people in Indonesia to raise awareness about this project.

In summary, I am more than happy to commit my support to this project and the support of our organisation. If you have any further queries please get in touch.

Jakarta, 31st January 2019

Mr. Bagus Utomo

Komunitas Peduli Skizofrenia Indonesia

Pathways to Impact

Key users of the outputs of our proposed research include people with schizophrenia, their relatives and carers, healthcare professionals, service-delivery leads in primary care responsible for delivering a minimum standard of mental health care, academics and researchers of psychosocial interventions for schizophrenia and primary care health service researchers. Our outputs will be locally relevant and useful in Jakarta and Bogor and nationally and internationally, they will be more broadly of interest as we will provide empirical and theoretical knowledge for delivering psychosocial interventions for families of people with schizophrenia in primary care settings.

Stakeholder Engagement Through developing this project we have consulted widely with service-users, people with psychosis and their families, healthcare professionals, academics, policy-makers and health service managers in health service settings and charities throughout Jakarta and Bogor, Indonesia. User-led, peer support groups for people with psychosis and their families are provided by our charity partners (KPSI) but these are not evidence-based and have not been evaluated. This has been a significant driver of this project as our stakeholders have expressed a need for delivering interventions with more certain evidence for processes and outcomes and that can be scaled up for wider implementation. We will work with KPSI to identify service-user and carers to be involved in our Research Advisory Group (RAG) to ensure user voices are included in decisions about the conduct and progress of the project. We will also include healthcare professionals, research advisors from the Ministry of Health (Dr Irmansyah) and primary care service managers with whom we have engaged through the development of this project. We have demonstrable impact from our activities in Indonesia as our previous work to cultivate newly formed partnerships informed the development of Indonesia's first early psychosis clinic at the National Centre for Mental Health and we will invite our colleagues in this programme to be members of the advisory to inform the development of this intervention.
The RAG will meet four times during the course of the study to review procedural documents, questionnaire and interview schedules and advise on recruitment, retention and feasibility aspects of the study. The RAG will also advise on ways to enhance acceptability of processes and procedures. Simultaneous to this, we will recruit people with psychosis, families, healthcare professionals, academics and researchers to determine the components, format and delivery of the intervention. During these consensus groups, we will present the refined and adapted intervention, the evidence and framework supporting the intervention and develop user-informed resources to support the training needs of healthcare professionals and resources to guide a train the trainer's package of education for healthcare professionals. The RAG will meet periodically throughout the study at a cost of £4,340 gbp to include hospitality, venue hire and transport for full-day meetings. This includes participation payments for public involvement. The consensus workshops include venue hire, hospitality, transport and participant involvement payments at £1,973 for a two-day workshop. On completion of the project, we will host a two-day mixed-stakeholder dissemination festival in Java to engage a wider audience, allowing us to showcase our intervention, and encourage adoption of our programme deliverables. We will aim for wider endorsement and to strengthen the profile of our research to develop further affiliations for successive research projects. We will target policy makers, service-level decision-makers and primary care personnel throughout West Java in addition to stakeholders already supporting our research. A previous 6 day festival held in November 2018 was positively evaluated by stakeholders. We include cost of £2,000 to deliver this festival to approximately 100 people. Targeted dissemination will also include national conferences and audiences with a strong presence of policymakers and practitioners (e.g. the World Psychiatric Association, Indonesian Psychiatric Association, and Indonesian Mental Health Nurses Association). We have included conference fees of £5,206 for Indonesian and UK researchers to attend a global mental health conference to disseminate.

Enhancing Public Awareness The outputs of this project will be important to engage communities in our research to improve the quality of our research but also to enable the public to exercise civic participation from an informed position with greater understanding about mental health and human rights concerns in Indonesia. The development phase will produce knowledge of people's experiences accessing and attending services, the impact of illness on families and carers and how they perceive psychological therapies which will be used to contribute to wider public debates and efforts to minimise negative views of mental illness and challenge public stigma. We will actively engage with public groups through KPSI anti-stigma activities and utilise their weekly public radio slots to deliver information about our research project and our findings. Almost half of the total population of Indonesia are connected on social media (Statista, 2017) which provide extensive reach and immediacy so we can deliver our message continuously throughout the lifecycle of the project. Youtube and Facebook are the most popular social networking sites and we will utilise these platforms to connect and empower people interested in countering stigma and promoting mental health through establishing a network on Facebook and delivering a series of interviews with key study personnel uploaded to a purposely-created Youtube channel, making our research accessible to the widest audience possible. Our multimedia strategy will be delivered by researchers working on the project thus will be subsumed under researchers costs. We will keep a continuous media presence with updates on the progress of research and engage with critical debates, researchers and bloggers in our area to inform our research and garner support for future intervention adoption and implementation.

Strengthening Health Systems This study aims to evidence the feasibility of recruiting and retaining families and carers of people with schizophrenia in a psychosocial intervention to improve family environment and reduce illness severity. As there are presently no psychosocial interventions for this group and few seek assistance from primary care, successfully establishing pathways into care is essential to improve outcomes for people with schizophrenia, their families and demonstrate a degree of demand for services. This knowledge will enhance research systems in primary care where national policy in Indonesia aims to provide a Minimum Standard of Service for all. If we demonstrate the feasibility of conducting a future trial of FIp, we will co-produce resources to support training to promote sustainability. Our 'train the trainers' resource kit will comprise the intervention manual and a series of resources the facilitator will use to simultaneously teach participants how to train others.

This will be accompanied by an online resource which will include the intervention manual, a framework for cultural adaptation, procedural resources and training resources that are co-produced with participants from the development phases of the study. We will target focussed knowledge exchange activities with our key stakeholders in the Agency for Health Research and Development, Ministry of Health and our academic partners at UI including webinars and presentation at key stages (following completion of analysis tasks). We will collaboratively deliver public lectures at UL with their public lecture series to raise awareness of this research and increase impact. Some examples below which have been evaluated positively. Co-PIs and co-invesitigators will be responsible for delivery of impact activities.

http://nursing.ui.ac.id/peran-perawat-dalam-menangani-klien-psikosis/

http://yankes.kemkes.go.id/read-metamorfosis-bkmm-menjadi-rumah-sakit-khusus-mata-pada-sertijab-kepala-bkmm-cikampek-792.html

STATISTA. 2017. *Penetration of leading social networks in Indonesia as of 3rd quarter 2017. In Statista - The Statistics Portal.* [Online]. Statista-The Statistics Portal. [Accessed January 29 2019].

Publication List

1. Brooks, H., James, K., Irmansyah, I., **Keliat, B. A.,** Utomo, B., Rose, D., Colucci, E., & Lovell, K. (2018). Exploring the potential of civic engagement to strengthen mental health systems in Indonesia (IGNITE): a study protocol. International Journal of Mental Health Systems. International Journal of Health Systems 12: 49, 1-10.
2. Sukamti, N., **Keliat, B. A.,** & Mustikasari. (2018). Coping skill training and family health education against anxiety in prevention substance abuse. International Journal of Advanced Nursing Studies.7:2, 107-108.
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Dr Helen Brooks – selected relevant publications

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Prof Penny Bee, Selected publications (Peer-reviewed):

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Tim Bradshaw Publications – selected

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Harris, N., Williams, S. and Bradshaw, T. (eds) (2003) Psychosocial Interventions for People with Schizophrenia: A Practical Guide for Mental Health Workers. Palgrave Macmillan. This text book has been listed as recommended reading on many psychosocial intervention education programmes in the UK and beyond and sold over 4,000 copies in the UK and EU.

Book chapters (teaching related)

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Dr Herni Susanti -Selected Publications

My publications have been cited 87 times, h-index is 5, ORCID ID https://orcid.org/0000-0002-6033-741X

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Karina Lovell - Selected Relevant Publications

Brooks H, Lovell K, Bee P, Fraser C, Molloy C & Rogers A. Implementing an intervention designed to enhance service user involvement in mental health care planning: a qualitative process evaluation. Social Psychiatry & Psychiatric Epidemiology (2018).

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Bower P, Reeves D, Sutton M, Lovell K, Blakemore A, Hann M, Howells K, Meacock R, Munford L, Panagioti M, Parkinson B, Riste L, Sidaway M, Lau Y, Warwick-Giles L, Ainsworth J, Blakeman T, Boaden R, Buchan I, Campbell S, Coventry P, Reilly S, Sanders C, Skevington S, Waheed W & Checkland K. Improving care for older people with long-term conditions and social care needs in Salford: the CLASSIC mixed-methods study, including RCT. Health Serv Deliv Res 2018;6(31)

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Laoise Renwick Publication Summary and Selected Publications

My publications have been cited 621 times, h-index is 15, ORCID ID https://orcid.org/0000-0001-7060-4537.

L. Renwick, M. Lavelle, K. James, D. Stewart, M. Richardson, L. Bowers. 2019. **The physical and mental health of acute psychiatric ward staff, and its relationship to experience of physical violence.** International Journal of Mental Health Nursing, 28(1):268-277.

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TEMPLATE FOR A DATA MANAGEMENT PLAN

0. Proposal name

Reducing Relapse for People with Schizophrenia in Jakarta, Indonesia: Developing a culturally-relevant, evidence-based Family Intervention

1. Description of the data

1.1 Type of study This study will used mixed methods to adapt and refine an evidence-based family intervention to improve outcomes for people with schizophrenia in Indonesia. The study will determine the feasibility of taking this culturally-adapted intervention to full trial.

1.2 Types of data Quantitative questionnaires, qualitative interviews and group consensus meeting data will be obtained. Data will include audio recordings of interviews and stakeholder groups, field diaries, paper-based questionnaires, transcripts of interviews and groups, numerical data representing quantitative outcomes in both digital and non-digital formats.

1.3 Format and scale of the data To enable long-term accessibility and validity we will store copies of data in formats that are non-proprietary and open for public use. Audio recordings of interviews and stakeholder groups will be recorded on encrypted digital Dictaphones and saved in MP3 format (approximately 80 hours total). Questionnaire data will be in paper format and will be entered into a statistical programme in pseudo anonymised format. Data in paper questionnaires will be entered into the statistical package at weekly intervals and saved in excel files also for long-term preservation. Consent forms will be in print format in Word documents. Encrypted quantitative and qualitative data in digital format will be stored securely on servers at Universitas Indonesia (UI).

2. Data collection / generation

2.1 Methodologies for data collection / generation This study will be conducted in three phases in two research sites (Jakarta, Bogor). Firstly, we will obtain preferences and priorities from service-users, carers and healthcare professionals about family interventions for schizophrenia. We will include the views of key informants to understand whether there may be wider issues about implementing the intervention. Secondly, we will generate consensus on the components, format and delivery of the intervention and consult with stakeholders about training needs and ideal resources to accompany training for trainers. Thirdly, we will conduct a feasibility study to assess the feasibility and acceptability of taking the intervention to a full trial. Compliance with University of Manchester (UoM) and UI mandatory procedures for secure handling of data will be ensured. Data will be gathered on offline devices for offline working on an encrypted device and uploaded daily to the university research data storage system.

2.2 Data quality and standards Standardised operating procedures will be developed to guide the conduct of data collection to ensure consistent data collection procedures and protocols will be developed for the storage and maintenance of digital and non-digital data. Quality checks will be conducted periodically to ensure that interviews have been transcribed accurately and data have been entered correctly into statistical packages. We will develop a code-book for defining items within the instrument schedule to ensure consistent measurement and update research staff regularly. Transcriptions will be sampled to check accuracy and translations will be validated by native Bahasa speakers who also speak English. A portion of translations will be back translated for accuracy checks.

3. Data management, documentation and curation

3.1 Managing, storing and curating data.

The project will primarily use the Research Data Service at UI to store, manage and curate data. We will also utilise the UoM Research Data Management Service (RDMS) which provides managed, secure, replicated storage. The RDMS allows researchers to securely transfer digital data to UoM and can be used to store, manage and curate data to preserve this after the lifecycle of the project. With participants consent, anonymised versions of participant's

quantitative and qualitative data will be made publically accessible, only available to the research team or destroyed at the end of the project depending on individual permissions. Non-digital data e.g. consent forms and manuals generated from the research programme, will be stored in stand-alone locked cabinets held in a secure location in UI. Data will be stored in raw, processed, analysed, and final dataset format to ensure quality and will be transferred between host and sponsor university using Dropbox for Business.

3.2 Metadata standards and data documentation Metadata to aid secondary users to understand and re-use the data will be retained including contextual information about these data, definitions of variables, and units of measurement, data collection mechanisms, methodologies, analytical and procedural information, documented analyses and results. Metadata will comply with MRCs policy and guidance for researchers on data sharing https://www.mrc.ac.uk/research/policies-and-guidance-for-researchers/data-sharing

3.3 Data preservation strategy and standards All digital data formats will be retained in the UoM RDMS in line with MRC guidelines for retention of research outputs (minimum of 10 years). All data stored in the UoM RDMS will be replicated. Any personal data (e.g. consent forms) will be destroyed at project end. All investigators will adhere to the UK Data Protection Act.

4. Data security and confidentiality of potentially disclosive information

4.1 Formal information/data security standards Data will comply with the UI Information Security Policy and UoM Information Security Policy - http://documents.manchester.ac.uk/display.aspx?DocID=6525

4.2 Main risks to data security Risks to data security include theft of portable devices, data transferred in unencrypted formats, unauthorised access via computers left unprotected. Data will be securely stored in such a way that data cannot be individually identified. Participants will have an opportunity to decline from making their information open access. Personal data will be pseudo-anonymised at the earliest opportunity and study identifiers will be retained in a separate locked cupboard. Personal data shared with UoM from UI will be encrypted and transferred via Dropbox for Business using two step verification procedures. Once received, we will remove files from transfer files and they will then be stored securely and offline in an encrypted format. Data capture equipment will not be used for storage purposes and personal data obtained in this way will be transferred to secure storage daily. Formal risks assessments will be completed at project initiation and managed accordingly being incorporated into staff training, maintained as a recurring agenda item on research management team meetings and protocols for minimising risk will be emphasised in the standard operating procedures.

5. Data sharing and access

5.1 Suitability for sharing *Yes*

5.2 Discovery by potential users of the research data We will use ONESearch (a feature from Indonesia National Library and Archive) to aid discoverability in Indonesia and register with Pure to enhance visibility. We will publish data sharing information on our study website.

5.3 Governance of access Creative Commons License will be attributed CC BY 4.0. We will store these data in respective institutional repositories, on open data sources (ClinicalTrials.gov and UK Clinical Trials Gateway) to aid discoverability.

5.4 The study team's exclusive use of the data

Data will not be made available to other researchers until primary outputs are published and impact has been reached which will be within three years of generating the dataset.

5.5 Restrictions or delays to sharing, with planned actions to limit such restrictions Data will be shared in an anonymised format where participants have permitted use. Participant information sheets and consent forms will include information on plans for data sharing and enable participants to give their explicit and informed consent to such data sharing. Sensitive information will be withheld.

5.6 Regulation of responsibilities of users A stepped access procedure will be initiated

where aggregate data may be available initially followed by individual-level data that has been anonymised. Confidential data that is anonymised may not be accessed unless explicitly permitted by the participant and will be subject to data sharing restrictions.

6. Responsibilities

Responsibility for data management, data security, metadata creation and assuring quality will be the dual responsibility of the Co-PIs Dr Laoise Renwick and Dr Herni Susanti.

7. Relevant institutional, departmental or study policies on data sharing and data security

Please complete, where such policies are (i) relevant to your study, and (ii) are in the public domain, e.g. accessible through the internet.

Add any others that are relevant

Policy	**URL or Reference**
Data Management Policy & Procedures	~~http://documents.manchester.ac.uk/display.aspx?DocID=33802~~
Data Security Policy	http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=6525
Data Sharing Policy	MRC Guidelines
Institutional Information Policy	*http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=24420*
Data Protection Policy	http://documents.manchester.ac.uk/DocuInfo.aspx?DocID=14914

8. Author of this Data Management Plan (Name) and, if different to that of the Principal Investigator, their telephone & email contact details

Dr Laoise Renwick