



PRISM: designing a community-randomised trial to reduce depression and improve maternal physical health after birth

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PRISM

- An integrated program of **primary care** and **community** based strategies designed to improve maternal emotional and physical health following childbirth by mobilising communities in support of **mothers**
- First conceived 1993/4
- Launched 16 June 1998



PRISM beginnings... much earlier

- Victorian Ministerial Review of Birthing Services 1988-90
- Little known about maternal depression
 - *No population-based prevalence studies*
- Almost nothing known about mothers' physical health problems
- Not possible to design a sensible intervention to improve maternal health



Questions in need of answers

- How common are depression & physical health problems in recent mothers?
- How do women experience the first year of motherhood?
- What factors contribute to depression and other health problems?
- What help do women seek?
- What assists in recovery?



Program of research initiated

- First population-based survey of recent mothers in 1989, repeated in 1994 & 2000
- Several interview studies, including with immigrant women
- To inform development of an appropriate intervention to improve maternal health outcomes



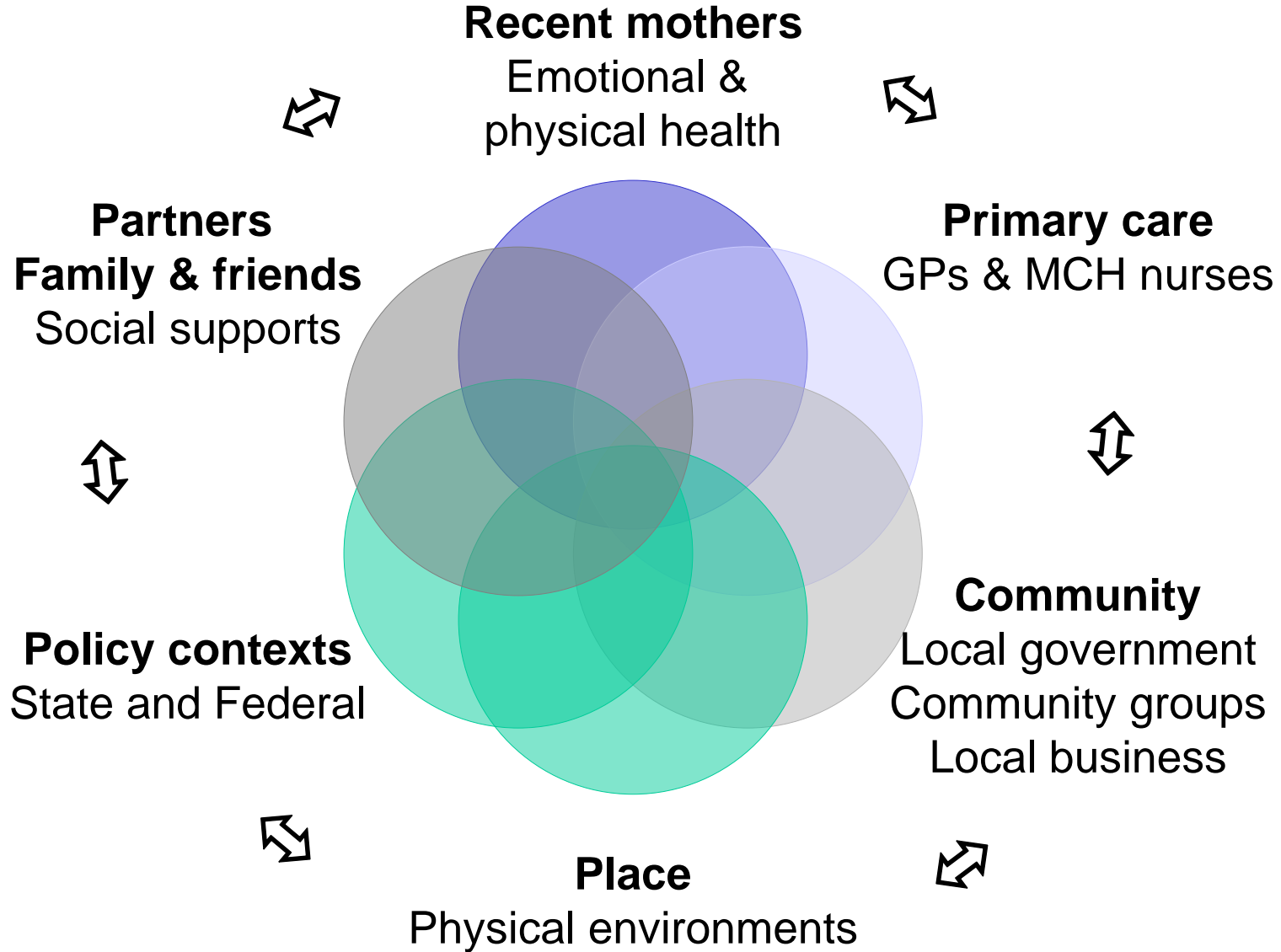
PRISM: Rationale

- Evidence of significant maternal physical and emotional ill-health
 - 1 in 6 mothers (14-17%) experience depression
 - 94% have one or more physical health problems
 - Physical ill-health contributes to depression
 - Women experience difficulties finding someone to talk to
 - Few women actively seek help from health professionals
 - Women who *do* find someone who listens with empathy describe this as very helpful
 - Isolation, lack of support and few opportunities for time out from infant care all impact on wellbeing
 - RCT evidence for benefits of ‘active listening’ for mothers identified as depressed



Designing an integrated set of intervention components

- Community
 - To increase recognition & support for mothers in their local communities
- Primary health care
 - To raise awareness & responsiveness of GPs and MCH nurses to maternal health issues
- Individual women
 - Provide women with better information and opportunities for support and friendship





The thinking that informed PRISM

- Mobilising communities to provide more recognition and support for *all* mothers: a universal intervention
- Strengthening and building on existing services for mothers in local communities
- Broadening community involvement in providing support for mothers
- Implementation of strategies found effective in RCTs; recommended by women; and in accord with community development principles
- Commitment to rigorous evaluation



PRISM: Trial design

- Community (cluster) randomised trial
- 16 participating municipalities (8 metro/8 rural) randomised to intervention / comparison status
- Two year establishment/implementation phase with embedded process & impact evaluation: 1999 & 2000
- Maternal health outcome evaluation - postal survey@ 6mths and 24mths pp: 2000-2003
- Economic and ecological evaluation (Do the benefits outweigh the costs? How is PRISM experienced in communities; what are the flow-on effects?)



PRISM: Intervention design

Key minimum program elements (1)

- **Local co-ordination**
 - Full-time community development officer (CDO) for two years
 - Steering committee of local stakeholders to shape and implement the key elements and support additional strategies





Key program elements (2)

- Education programs for maternal and child health nurses and GPs

- enhance recognition and treatment of emotional and physical health problems
- promote 'listening skills' and offers to women of 'time to talk'

GPPP

E Emotional
How are YOU feeling in yourself?
How do you find being a mother?

S Social
How is your relationship going?
What interests do you have apart from caring for the baby?
Who shares the work of caring for your baby?
How much time do you get to yourself?

P Physical
Pain - perineum, back or breasts?
Haemorrhoids?
Your health - any other problems?
Sex?
Incontinence of urine or faeces?
Coughs and colds
Anaemia
Lack of energy/exhaustion?

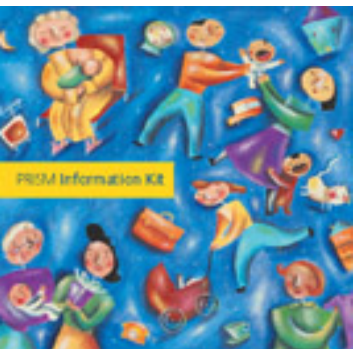
EYES
UNDIVIDED ATTENTION
HEART

EAR 聽



Key program elements (3)

- **Mothers' information kit**
 - Common experiences of early motherhood: emotional health; physical health; info for fathers
 - Locality guides: information about local services & community activities supporting mothers





Key program elements (4)

- Voucher Scheme

- incorporated in Mothers' Information Kit
- incentives for mothers to use local services or enjoy 'time out' (eg vouchers for occasional child care)
- involvement of local businesses and community agencies in support for mothers





Key program elements (5)

- **Befriending**
 - concerted local effort to increase opportunities for mothers to find and make friends
 - aiming to reduce isolation mothers so often experience by developing mutually supportive friendships
 - [*not* aiming to form groups]





Key elements

Mechanisms/messages

Hypothesised outcomes

CDO/Stg C'tees

Enabling local engagement around support for mothers

More mother-friendly & supportive communities

MCH/GP training

Health provider interest in skill development; improved responsiveness to maternal health issues

Mothers encouraged to talk about issues; feel listened to, problems addressed → better health

Mothers Information kits

Common problems acknowledged; local services profiled; time-out valued; tool for MCHNs with mothers

Women better informed, feel less alone, more able to ask for help & time-out

Voucher scheme

Chance for local businesses to express support for mothers; time-out options

Women feel supported and connected, less depressed

Befriending

More opportunities for women to make friends locally

Less isolation, more support, less depression



Then came...

MRC framework for the design and evaluation of complex interventions, *BMJ* 2000

- How useful? And...
- How did the design of PRISM measure up?



Sequential phases of developing randomised controlled trials of complex interventions

Definitive randomised controlled trial

Long term implementation

Compare a fully defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power

Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term

Exploratory trial

Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative

Modelling

Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other

Theory

Explore relevant theory to ensure best choice of intervention and Hypothesis and to predict major confounders and strategic design issues

Preclinical

Phase I

Phase II

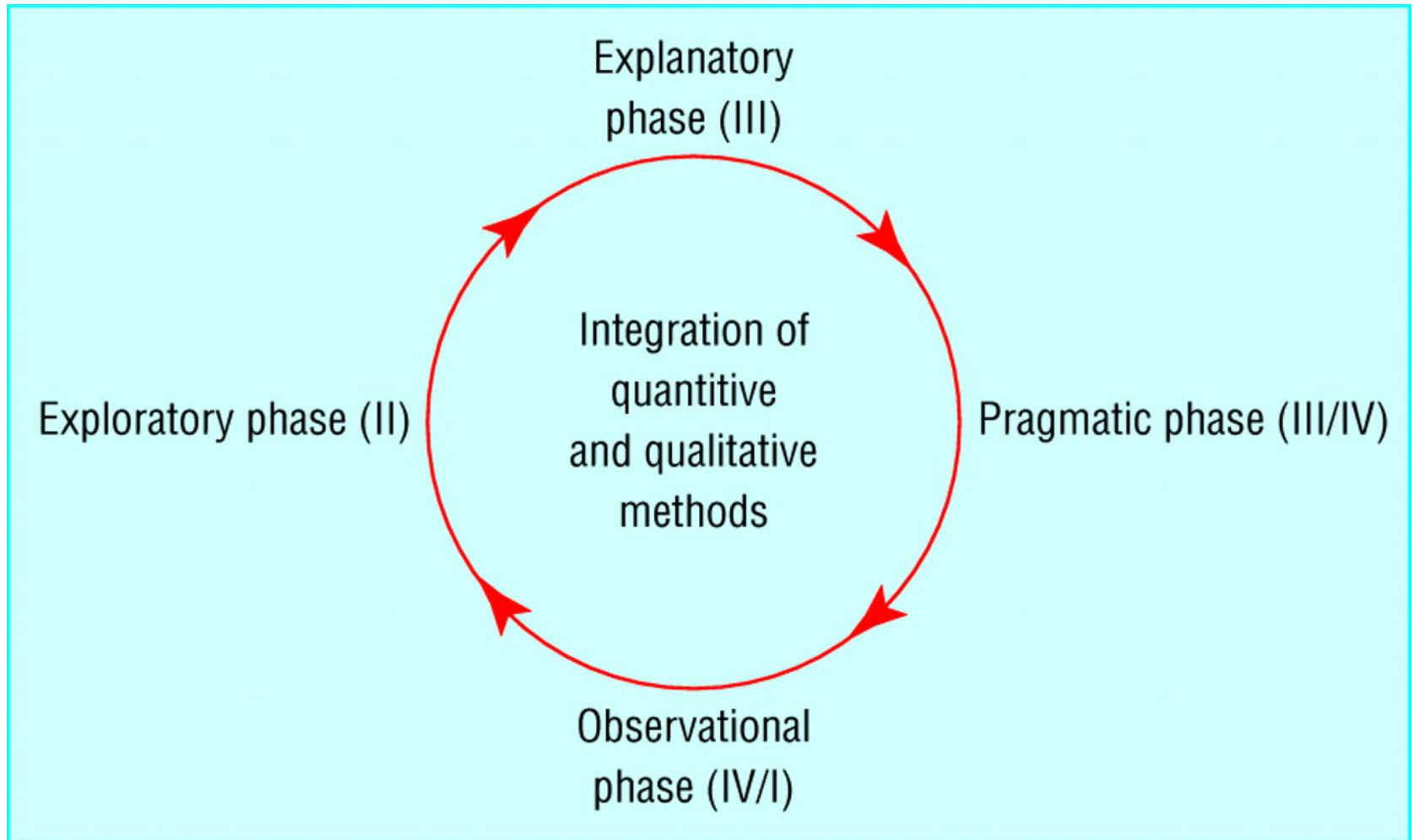
Phase III

Phase IV

Continuum of increasing evidence

Campbell, M. et al. BMJ 2000;321:694-696





Campbell, M. et al. *BMJ* 2000;321:694-696

Iterative view of development of randomised controlled trials of complex interventions



‘Theory’

PRISM

- Built on current knowledge base about maternal ill-health and women’s experiences and available empirical evidence for intervention strategies 😊 😊 😊
- *Explicit* embedding in: social theory 😞
theories of organisational change 😐
principles of community development 😊
- Question at grant interview:
“I can see it could work in practice, but will it work in theory?” 😞 😞 😞



Next grant application..

- “The development of social support networks in this project is primarily guided by Israel’s application of social network and social support theory to community level interventions...” AND
- “Entry, analysis of existing services and the design, initiation and sustainability of local programs will be based on Bracht and Kingsbury’s five-stage model [of community organisation principles in health promotion]...”



'Modelling' (Phase I)

- Intervention modelled on what women had told us in previous studies
- Discussions prior to submitting application for PRISM with key individuals in local government and primary care
- Prior to approaching local government, acceptability of intervention discussed with MAV
- Info packages & briefings with local govt prior to joining trial: very positively received
- Piloting of information kits with women (and also with fathers)
- Piloting of questionnaires, mail out processes (in early stages of main trial)



‘Exploratory trial’ (Phase II)

- No ‘exploratory trial’ phase in PRISM
- Critique of MRC Framework since 2000
 - Phases 0-2 seen as too linear
 - More likely that trial planning and intervention development happen concurrently
 - Emphasis now more on problem definition, understanding context, embedding evaluation of implementation processes (Campbell 2007)



‘Definitive randomised trial’ (Phase III)

- PRISM can reasonably be described as a definitive trial
 - ‘comparing a fully defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power.’



‘Long term implementation’ (Phase IV)

- ...only after evidence of Phase III trial effectiveness

and

- PRISM strategies did not improve maternal health outcomes

What is
PRISM

The background
and development
of PRISM

Key minimum
elements of
the PRISM
Program

Local PRISM
initiatives undertaken
in support of mothers

Support for program
implementation,
feedback to
communities and
monitoring activities

PRISM
results



Program of
Resources,
Information
and Support
for Mothers

www.latrobe.edu.au/mchr/prism

