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’
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’ (e.g. 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]
<table>
<thead>
<tr>
<th>Key elements</th>
<th>Mechanisms/messages</th>
<th>Hypothesised outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDO/Stg C’tees</td>
<td>Enabling local engagement around support for mothers</td>
<td>More mother-friendly &amp; supportive communities</td>
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<tr>
<td>MCH/GP training</td>
<td>Health provider interest in skill development; improved responsiveness to maternal health issues</td>
<td>Mothers encouraged to talk about issues; feel listened to, problems addressed → better health</td>
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<td>Mothers Information kits</td>
<td>Common problems acknowledged; local services profiled; time-out valued; tool for MCHNs with mothers</td>
<td>Women better informed, feel less alone, more able to ask for help &amp; time-out</td>
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<tr>
<td>Voucher scheme</td>
<td>Chance for local businesses to express support for mothers; time-out options</td>
<td>Women feel supported and connected, less depressed</td>
</tr>
<tr>
<td>Befriending</td>
<td>More opportunities for women to make friends locally</td>
<td>Less isolation, more support, less depression</td>
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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

**Theory**
- Preclinical: Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues

**Modelling**
- Phase I: 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

**Exploratory trial**
- Phase II: Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative

**Definitive randomised controlled trial**
- Phase III: 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

**Long term implementation**
- Phase IV: Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term

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