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Understanding the Potential of a National Navigation Service to Support Perinatal and Infant Mental Health: An Evaluation Protocol

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Abstract

Introduction: Many parents and carers experience mental health challenges during pregnancy and early postpartum years, though there are cumulative shortfalls in the identification, follow-up, and treatment of those struggling with perinatal and infant mental health (PIMH) challenges. ForWhen is a new national navigation program in Australia that aims to improve outcomes for families by supporting parents and carers to access PIMH services. This paper presents the protocol of an evaluation of the ForWhen program, to be conducted over the first 3 years of its implementation. The specific objectives of the evaluation include examining the characteristics of navigation service delivery, its implementation and clinical impact, and identifying potential moderators of change.

Methods & Analysis: Utilising a mixed-methods design, this evaluation will incorporate three phases that reflect the stages of the program lifecycle: 1) program description, 2) implementation evaluation, and 3) outcomes evaluation. The evaluation will use a mix of quantitative and qualitative data including deidentified routinely collected service data, participant observations, semi-structured interviews, surveys and questionnaires, and a resource audit.

Discussion: Evaluation findings will be used to inform the development of a refined clinical navigation model, identify barriers and facilitators to successful navigation program implementation, examine the impact of the ForWhen program on client clinical outcomes and health service utilisation, and assess the cost-effectiveness and sustainability of a national navigation service in improving health outcomes for PIMH in Australia.

Ethics & Dissemination: This research was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH11611). This study was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12622001443785). Results will be disseminated at conferences, in scientific journals, and in a final evaluation report.

Keywords: program evaluation, protocol, navigation, perinatal and infant mental health

Article Summary: Strengths and limitations of this study

- Current evidence regarding the effectiveness of navigation programs for improving PIMH is sparse, and the findings of this evaluation will help to address this gap.
- The implementation evaluation will investigate how the ForWhen program is implemented in different local contexts, and barriers and facilitators to its success.

- The outcomes evaluation will use a realist perspective to investigate *how* the ForWhen program works, and *for whom*, to identify potential moderators of change.
- A randomised controlled study design was not feasible given the observational nature of the evaluation component. Therefore, we have adopted a pre/post design to examine clinical outcomes of the navigation intervention.

Introduction

Mental health difficulties occur commonly during pregnancy and the first year postpartum [1, 2], and are associated with a range of short- and long-term negative impacts for parents and carers, their families, and children [3, 4]. Addressing parent and carer mental health needs during the perinatal period is therefore of vital importance to protect both adult and infant mental health and wellbeing over the life course. Recent decades have seen increasing focus given to perinatal and infant mental health (PIMH) [5], with a range of government initiatives aimed at implementing universal psychosocial screening into routine antenatal and postnatal healthcare and improving treatment for PIMH, such as the *National Perinatal Depression Initiative* in Australia [6].

Despite increased awareness of, and screening for, PIMH issues, many expectant and new parents/carers are not screened for mental health during perinatal care or do not receive treatment for their distress. A systematic review of international English-language studies by Cox, Sowa [7] found cumulative shortfalls in recognition, initiation and adequacy of PIMH treatment, and treatment outcomes for women with antenatal or postnatal depression – which the authors termed the "perinatal depression treatment cascade" (p. 1190). Australia-based research has shown screening and treatment rates for PIMH issues to be particularly low for those from non-English speaking backgrounds [8], those in the private healthcare system [9], and for fathers or non-birth partners [10]. While Australian women have high uptake of primary health services during the perinatal period, uptake of specialist mental health services – even for those identified with moderate to high risk – is low [11]. Research from Australia and abroad has identified a number of patient, provider, and system-level barriers which help explain the gap between screening and treatment rates for PIMH including a lack of appropriate services, stigma, and difficulty navigating fragmented PIMH service landscapes [12-14].

PIMH Navigation Services as a Potential Solution

Navigation models have been proposed as a cost-effective way to improve access to mental health care services and support [15]. 'Navigation' is defined as a partnership between a patient and a navigator whose role is to guide patients through the complexities of the healthcare system, facilitate timely access to assessment and treatment, and foster patient self-management through education, capacity building, and support [16, 17]. A number of US-based navigation programs addressing PIMH have demonstrated positive outcomes including a reduction in maternal depression [18, 19], higher rates of postpartum visit attendance and depression screening [20], and enhanced utilisation of mental health services [21]. However, current evidence regarding the effectiveness of navigation for improving PIMH is sparse, with studies having adopted varied designs and outcome measures. There is also limited information available on navigation activities and services, navigator core competencies, or the ways in which various implementation components and contexts impact participant outcomes. Further research evaluating the efficacy and feasibility of navigation services for PIMH will be invaluable for understanding their potential in improving early intervention for parents and families, and for informing sustainable and effective program design in future.

ForWhen: A National Navigation Service for PIMH

In 2021, the Australian government funded ForWhen (www.forwhenhelpline.org.au) – a new national navigation service for parents and carers experiencing mental health concerns during pregnancy and the first year after birth, led by Karitane (www.karitane.com.au) and delivered around the country by a consortium of partners from the Australian Association of Parenting & Child Health (AAPCH; www.aapch.com.au), Parenting Research Centre (PRC; www.parentingrc.org.au) and the University of New South Wales (UNSW; www.unsw.edu.au). The ForWhen service proposes to address current PIMH treatment access shortfalls by providing "a national comprehensive stepped continuum of care for parents experiencing moderate to severe PIMH concerns, supporting these families to navigate the complex and fragmented PIMH service landscape" [22]. The ForWhen program was launched in February 2022, and comprised a national helpline staffed by clinically trained navigators based in each state and territory of Australia. ForWhen navigators have knowledge of local service systems and pathways within their jurisdictions, and work collaboratively with clients to understand their needs and connect them with appropriate support services.

ForWhen is a new service, and so its impact and effectiveness are currently not well understood. This paper presents the protocol of a program evaluation aimed at understanding the implementation and outcomes of the ForWhen service. The evaluation objectives are to: 1) describe the ForWhen service delivery model, 2) evaluate the implementation of the ForWhen service with a focus on acceptability, adoption, appropriateness, feasibility, fidelity, coverage, cost, and sustainability, and 3) examine outcomes experienced by clients who access the ForWhen service, and to identify potential moderators of change across different contexts and participant groups. This evaluation will be conducted over a 3-year period (2021-2024) and results will be used to make recommendations to guide future ForWhen service delivery, and to inform the development of similar programs in Australia and internationally.

Methods & Analysis

Study Design

During the early design and implementation stages of the ForWhen program, a program logic and corresponding outcomes chain was developed by the ForWhen consortium members, led by PRC and including representatives from AACPH and UNSW, and ForWhen steering committee members including consumer representatives (Fig. 1). This model was used to inform the evaluation design, questions, and methodology. Specifically, the evaluation protocol seeks to examine the outcomes articulated in the program logic model, and to assess the degree to which the intervention was implemented as intended. A mixed-methods evaluation protocol was developed using the steps outlined in the NSW Government Program Evaluation Guidelines [23] and the Centre for Disease Control (CDC) Framework for Program Evaluation in Public Health [24]. The program evaluation will incorporate three phases that reflect the stages of the program lifecycle: 1) Program Description, 2) Implementation Evaluation, and 3) Outcomes Evaluation (Table 1).

[Insert Figure 1 about here]

An early step of the evaluation will be to describe the program in detail (phase 1), and in doing so to articulate its goals and strategies, its capacity to effect change, and how it fits within the broader ecosystem of PIMH healthcare. The program description will set the frame of reference for subsequent evaluation activities, and facilitate subsequent efforts to connect the various program components to their effects [24]. This phase will focus specifically on documenting the service delivery model of the ForWhen program and characterising the activities and core competencies involved in navigation.

The implementation evaluation (phase 2) will be guided by the work of Proctor and colleagues [25], with a focus on key implementation outcome indices including acceptability, adoption, appropriateness, feasibility, fidelity, coverage, cost, and sustainability. These implementation outcomes serve as important preconditions for a program's success in effecting change in clinical or service outcomes [25]. Findings from the implementation evaluation will feed into an analysis of fidelity to the program model, the identification of facilitators and barriers to successful implementation, and an assessment of cost-effectiveness and longer-term sustainability.

The outcomes evaluation (phase 3) will draw on a realist evaluation perspective [26], acknowledging that health programs may have varying outcomes across contexts and participants [27]. Findings from the implementation and outcomes evaluations will be synthesised to investigate if the program is achieving its intended outcomes (e.g., improvements in wellbeing and service utilisation), for whom and under what circumstances, in order to identify factors that impact effectiveness and potential moderators of change.

Table 1. Evaluation questions and planned activities at three phases of the evaluation

Evaluation Question	Planned Activities
Phase 1: Program Description	
What is the service delivery model of the ForWhen program?	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
What are the core competencies and activities involved in navigation?	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Phase 2: Implementation Evaluation	
What is the service provision and coverage of the ForWhen program? *(adoption, fidelity, coverage)**	Analysis of routinely collected service provision data
What are barriers and facilitators to successful implementation of the ForWhen program around the country? *(feasibility, fidelity)*	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Do users report satisfaction with the ForWhen program? What factors do they perceive to have contributed to or impeded positive outcomes? *(appropriateness, acceptability)*	Brief exit survey administered to users (clients, family/friends, health professionals) at case closure; semi-structured interviews with users (clients, family/friends, health professionals)
Do stakeholders report satisfaction with the ForWhen program? Do they view the service as feasible and effective? *(appropriateness, acceptability, feasibility)*	Semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Does the service represent value for money? Do the benefits justify the costs? *(cost, sustainability)*	Resource audit and cost-benefit analysis by converting K10 to Quality-Adjusted Life Years (QALY)
Phase 3: Outcomes Evaluation	
Do clients report improvements in i) mental health, ii) quality of life, iii) help-seeking behaviour, iv) self-compassion and self-care, and v) early parenting experiences (parental self-efficacy, parent-child bonding)?	Analysis of routinely collected service provision data; 'snapshot study' to assess pre- to post-program changes on a range of additional relevant variables
How effective is the program in facilitating clients' timely access to, and engagement with, mental health services?	

Do program outcomes differ across demographic groups (e.g., age, symptom severity, location, cultural/linguistic background) or based on services provided (e.g., type of referred services, number of interactions with navigator)?	

**Proctor et al.'s key implementation outcomes [25]*

Patient and Public Involvement

The ForWhen steering committee includes consumer representation to provide input into service delivery and intended outcomes to be assessed in this evaluation.

Participants

Participants will include a range of users and stakeholders involved in the ForWhen program. User participants will include: *clients* (i.e., expectant or new parents/carers) who are facing PIMH challenges and who contact the ForWhen helpline to receive navigation services and support; *family/friends* (e.g., partner, grandparents) who access the ForWhen helpline seeking advice or information in how best to support a parent/carer struggling with PIMH issues; and *health professionals* who access the ForWhen helpline seeking advice or information in how to find appropriate treatment for someone in their care who is facing PIMH issues, or looking to refer a parent/carer into the service. Stakeholder participants will include ForWhen *navigators* (clinically trained staff from a range of professional backgrounds, e.g., midwifery, nursing, psychology, social work) who staff the national helpline and work one-on-one with users to provide support and navigation services to connect clients with appropriate PIMH treatment; *managers* who provide direct supervision to navigators; and *steering committee members* including the national director, PIMH experts, consortium representatives, and project and administrative staff.

Data Collection

A mix of quantitative and qualitative data will be utilised including deidentified routinely collected service data between February 2022 and June 2024, and a range of additional qualitative and quantitative data collected at various points over the 3-year evaluation period (Fig. 2) in order to achieve the evaluation aims.

[Insert Figure 2 about here]

Qualitative Data Collection

Participant observation. To describe the program and its implementation, a research team member will conduct participant observation at regular committee meetings during the early design and implementation phases of the service, over a period of approximately 6 months (Fig. 2). Meeting attendees will include ForWhen stakeholders representing different roles (e.g., steering committee members, managers, navigators), organisations, and jurisdictions. A researcher will record field notes during these meetings with a focus on documenting and describing the ForWhen service delivery model, governance structure and staff roles, barriers to implementation, and steps taken to address these barriers.

Semi-structured interviews. Semi-structured interviews will be conducted with stakeholders (navigators, managers, steering committee members) and users (clients, family/friends, health professionals) of the service at various points throughout its implementation (Fig. 2). Interviews with ForWhen navigators in the first year of the program will explore the service delivery model, core competencies and activities involved in navigation, and barriers and facilitators to early implementation of the service on the ground. Interviews with other ForWhen stakeholders (including managers and steering committee members) in the first year of the program will explore the governance structure, and barriers and facilitators to early implementation from a management and governance perspective. Follow-up interviews with ForWhen navigators and stakeholders in the third year of the program will explore program evolution, and stakeholder perceptions on longer-term feasibility and effectiveness of the service. Interviews with users (including clients, family/friends, or health professionals) in the second year of the program will explore reasons for accessing and satisfaction with the service, perceived outcomes and usefulness, and barriers and facilitators to positive outcomes.

Quantitative Data Collection

Review of routinely collected service data. As a routine part of the ForWhen program, data relating to individual clients and service provision is collected by navigators and managed via a Customer Relationship Management (CRM) database. At program entry (baseline), navigators administer the K10 as part of routine mental health assessment, and collect client data including demographic information and identified psychosocial risk factors during an intake interview (Fig. 3 and Table 2). Throughout each client's engagement with the program, individual service provision data including number and mode of contacts with the navigator, services provided by the navigator (e.g., psychoeducation), and the number and types of referrals made, are routinely recorded by navigators in the CRM database (Table 2). In the final year of the program, retrospective analysis of this routinely collected service data will be conducted in order to characterise the clients and service provision of the ForWhen program, evaluate changes in client psychological distress from ForWhen program entry to follow-up, and identify potential moderators of change.

Snapshot study. During a 6-month period in the second year of the program, the research team will recruit ForWhen clients (parents/carers) to a 'snapshot study' to evaluate the program's impact on additional parent and infant outcomes. All clients who access ForWhen during this study period will be eligible to participate, and those who opt-in will be asked to complete a series of validated questionnaires at baseline (within one week of accessing the service) and follow-up (10-12 weeks after program exit) either online or over the phone. Participants will also provide consent for this data to be linked to their client information held in the CRM database. Key variables of interest and accompanying questionnaires to be included in the snapshot survey are shown in Table 2.

Economic evaluation. A resource audit will be conducted to assess costs associated with: (i) resource allocation required for training and supervising navigators, and (ii) other costs associated with delivering the intervention (e.g., office space, staff salaries, equipment, technology). Further, mapping algorithms [28] will be used in order to convert change score using pre and post K10 scores to estimate the outcomes in terms of quality-adjusted life years (QALY) in the cost-benefit analysis.

[Insert Figure 3 about here]

Table 2. Quantitative data collection timepoints and information collected/measures administered

Timepoint	Dataset	Variable	Information/Measures
Program entry	Routinely collected service data – baseline	Demographic information	Navigator intake interview (e.g., age, sex, postcode, language, cultural background, relationship status, number of children)
		Client mental wellbeing	Kessler Psychological Distress Scale (K10) [29]
		Client psychosocial risk factors	Navigator intake interview (e.g., health insurance status, mental health history, family violence, physical or social isolation)
	'Snapshot study' – baseline	Parental self-efficacy	Me as a Parent – short form (MaaP-SF) [30]
		Quality of life	Personal wellbeing Index (PWI) [31]
		Help-seeking behaviours	General Help-Seeking Questionnaire (GHSQ) [32]
		Self-compassion and self-care	Parenting Research Centre questions (unpublished)
		Parent and infant bonding	Mother-to-Infant Bonding scale (MIBS) [33]
Program exit	Routinely collected service data – exit	Engagement with navigation service	Referral source, number and mode of contacts with navigator, services provided (e.g., psychoeducation), number and type of referrals made
		Satisfaction with navigation services	3 global questions from the Navigation Satisfaction Tool (NAVSAT) [34]
		Collaborative partnership with navigator	Consultation and Relational Empathy (CARE) measure [35]
10-12 week follow-up	Routinely collected service data – follow-up	Client mental wellbeing	Kessler Psychological Distress Scale (K10) [29]
		Engagement with referred service/s	Type of service, frequency, ongoing or completed
	'Snapshot study' – follow-up	Parental self-efficacy	Me as a Parent – short form (MaaP-SF) [30]
		Quality of life	Personal wellbeing Index (PWI) [31]
		Help-seeking behaviours	General Help-Seeking Questionnaire (GHSQ) [32]
		Self-compassion and self-care	Parenting Research Centre questions (unpublished)
		Parent and infant bonding	Mother-to-Infant Bonding scale (MIBS) [33]
		Satisfaction with navigation and referred service/s	Navigation Satisfaction Tool (NAVSAT) [34]

Data Analysis

Qualitative data including field notes and interview transcripts will be stored securely as electronic documents on a password protected computer. Interviews will be audio-recorded and transcribed verbatim. Qualitative data will be analysed using framework analysis, a thematic analytical method that involves data familiarisation, coding, developing a framework, indexing, charting, and interpretation [36]. Coding and analysis will be conducted using NVivo 12 software (QSR International). Quantitative data will be collected from the program's CRM database, exit surveys, and snapshot study questionnaires, and stored in a password protected database. Data will be analysed using appropriate descriptive and inferential statistics in SPSS Statistics (IBM). Changes in levels of psychological distress (K10), parenting self-efficacy (MaaP-SF), personal wellbeing (PWI), help-seeking behaviour (GHSQ), self-compassion and self-care (PRC questions), and mother-to-infant bonding (MIBS) from program entry to follow-up will be examined using a linear mixed models repeated measures design. The clinical significance of differences on study variables (from baseline to follow-up) will be assessed using Cohen's d with effect sizes evaluated using Cohen's [37] guidelines. Outcome variables will also be examined by subpopulation (e.g., symptom severity on intake, demographic factors), to assess whether different groups experience varying outcomes, and by intervention dosage (e.g., number of contacts with ForWhen navigator, duration from entry to exit, services provided), to identify factors that impact effectiveness and potential moderators of change. The cost/benefit analysis will be conducted using a comparison of the observed costs and clinical effects (expected non-inferiority) compared to a modelled counterfactual had the intervention not been provided.

Ethics & Dissemination

Researchers conducting the evaluation will have access to de-identified routinely collected service data, which will be used in aggregate analyses (no individual cases will be examined in isolation). For all additional data collection, participants will provide informed, written consent. Names and identifying information will be removed from qualitative data prior to publication, and quantitative data will only be used in aggregate analyses, to protect participant anonymity. This research was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH11611), and has been registered on the Australian New Zealand Clinical Trials Registry (ACTRN12622001443785).

This program evaluation will be an integral part of the implementation of the ForWhen service. Evaluation findings will be presented regularly to the program steering committee and national director with a view to, improving the service throughout the implementation period and translating findings into practice. Results will also be disseminated at conferences, in scientific journals, and in a final evaluation report.

Discussion

This protocol outlines the study design, methods, and analyses that will be used to conduct a comprehensive program evaluation of the ForWhen navigation service for PIMH in Australia. Navigation models have been adopted in a range of healthcare settings and services including PIMH [38], but their impact on clinical outcomes and evaluation of implementation including barriers and enablers in the engagement with PIMH services is currently not well understood. The findings of this evaluation will advance understanding on the potential of navigation services to enhance service connection and treatment for PIMH on a national scale, and help to inform sustainable and effective program design in future.

The planned evaluation does, however, have limitations. The most notable limitation is the ‘open trial’ study design to be utilised for the outcomes evaluation. A randomised controlled study design is not feasible given the program objective for system-wide changes, and the observational nature of the evaluation component. Given that the navigation service is designed to connect families with needed care and support, a challenge will be to disentangle the impact of the navigation intervention from the benefits conveyed by connected services. To mitigate this, we plan to administer follow-up measures relatively soon after intervention exposure (10-12 weeks), and to identify potential moderators of change in comparing participant outcomes by intensity and type of navigation services received. As the primary goal of navigation is in connecting clients to appropriate services, it will also be important to look beyond clinical outcomes and examine participants’ engagement with mental health treatment at follow-up, and their satisfaction with both the navigation and referred services.

This evaluation will make important contributions to the literature on navigation service models in improving PIMH care. First, it will be used to develop a detailed model of clinical navigation work and identify the core competencies and desired skillset of navigators, which may help inform other programs adopting similar models. Second, it will identify barriers and facilitators in successful navigation program implementation on both local and national scales. Third, it will examine the impact of a navigation service on clinical outcomes and health service utilisation among those facing PIMH issues in Australia. Fourth, the national dataset will provide an opportunity to identify patterns of need and service gaps among different demographic groups and jurisdictions throughout Australia, to inform future funding allocations and service delivery planning. And fifth, the evaluation will assess the cost-effectiveness and longer-term sustainability of a national navigation service in improving health outcomes for PIMH in Australia.

Author contributions: JK and VE conceived of the project and drafted the initial protocol. JK and SH refined the study design and protocol. JK and SH drafted the published protocol paper, and all authors provided feedback and approved the final version.

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Competing interests: JK works in a co-funded academic position with UNSW and Karitane (ForWhen lead agency).

References

1. Gavin, N.I., et al., *Perinatal depression: a systematic review of prevalence and incidence.* Obstetrics & Gynecology, 2005. **106**(5 Part 1): p. 1071-1083.
2. Leach, L.S., C. Poyser, and K. Fairweather-Schmidt, *Maternal perinatal anxiety: A review of prevalence and correlates.* Clinical Psychologist, 2017. **21**(1): p. 4-19.
3. Stein, A., et al., *Effects of perinatal mental disorders on the fetus and child.* The Lancet, 2014. **384**(9956): p. 1800-1819.
4. Ruffell, B., D.M. Smith, and A. Wittkowski, *The experiences of male partners of women with postnatal mental health problems: a systematic review and thematic synthesis.* Journal of Child and Family Studies, 2019. **28**(10): p. 2772-2790.
5. Howard, L.M. and H. Khalifeh, *Perinatal mental health: a review of progress and challenges.* World Psychiatry, 2020. **19**(3): p. 313-327.
6. Austin, M.-P., N. Reilly, and E. Sullivan, *The need to evaluate public health reforms: Australian perinatal mental health initiatives.* Australian and New Zealand journal of public health, 2012. **36**(3): p. 208-211.
7. Cox, E.Q., et al., *The perinatal depression treatment cascade: baby steps toward improving outcomes.* The Journal of Clinical Psychiatry, 2016. **77**(9): p. 20901.
8. Highet, N.J. and F. Bilbao, *The Western Perinatal Emotional Health Pilot Program: Final Report*. 2015.
9. Reilly, N., et al., *Disparities in reported psychosocial assessment across public and private maternity settings: a national survey of women in Australia.* BMC Public Health, 2013. **13**(1): p. 1-15.

10. Australian Government Productivity Commission [AGPC], *Mental Health Inquiry Report No. 95*. 2020: Canberra, ACT, Australia.
11. Schmied, V., et al., *Antenatal psychosocial risk status and Australian women's use of primary care and specialist mental health services in the year after birth: a prospective study.* BMC Women's Health, 2016. **16**(1): p. 69.
12. Austin, M.-P., N. Highet, and Expert Working Group, *Mental health care in the perinatal period: Australian clinical practice guideline*. 2017: Melbourne, Australia: Centre of Perinatal Excellence.
13. Brown, S. and C. Sprague, *Health care providers' perceptions of barriers to perinatal mental healthcare in South Africa.* BMC Public Health, 2021. **21**(1): p. 1905.
14. Byatt, N., et al., *Patient, provider, and system-level barriers and facilitators to addressing perinatal depression.* Journal of Reproductive and Infant Psychology, 2012. **30**(5): p. 436-449.
15. Knesek, G. and T. Hemphill, *Mental Health Navigation–a Model.* Health Promotion International, 2020. **35**(1): p. 151-159.
16. Kelly, K., S. Doucet, and A. Luke, *Exploring the roles, functions, and background of patient navigators and case managers: A scoping review.* International Journal of Nursing Studies, 2019. **98**: p. 27-47.
17. Freeman, H.P. and R.L. Rodriguez, *History and principles of patient navigation.* Cancer, 2011. **117**(15 Suppl): p. 3539-42.
18. Fallin-Bennett, A., et al., *Perinatal Navigator Approach to Smoking Cessation for Women With Prevalent Opioid Dependence.* West J Nurs Res, 2019. **41**(8): p. 1103-1120.
19. Silverstein, M., et al., *Patient navigation for depressed mothers in Head Start: A pilot study of intervention mechanism.* Journal of Community Psychology, 2017. **45**(4): p. 564-570.
20. Yee, L.M., et al., *Using a Patient Navigator to Improve Postpartum Care in an Urban Women's Health Clinic.* Obstet Gynecol, 2017. **129**(5): p. 925-933.
21. Diaz-Linhart, Y., et al., *Patient Navigation for Mothers with Depression who have Children in Head Start: A Pilot Study.* Social Work in Public Health, 2016. **31(6)**: p. 504-510.
22. Karitane, *Proposal for Pre-Budget Submission for Commonwealth funding 2021-2022*. 2021.
23. NSW Government, *NSW Government Program Evaluation Guidelines*. 2016.
24. Centers for Disease Control and Prevention [CDC], *Framework for Program Evaluation in Public Health*. 1999.
25. Proctor, E., et al., *Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda.* Adm Policy Ment Health, 2011. **38**(2): p. 65-76.
26. Pawson, R. and N. Tilley, *Realistic evaluation*. 1997: Sage.
27. Wand, T., K. White, and J. Patching, *Contemporary mental health program implementation and evaluation.* Issues in Mental Health Nursing, 2010. **31**(11): p. 716-722.
28. Gamst-Klaussen, T., et al., *Assessment of outcome measures for cost–utility analysis in depression: mapping depression scales onto the EQ-5D-5L.* BJPsych open, 2018. **4**(4): p. 160-166.
29. Kessler, R.C., et al., *Screening for serious mental illness in the general population.* Archives of general psychiatry, 2003. **60**(2): p. 184-189.

30. Matthews, J., et al., *Development and Validation of a Short-Form Parenting Self-Efficacy Scale: Me as a Parent Scale (MaaPs-SF).* Journal of Child and Family Studies, 2022: p. 1-11.

31. International Wellbeing Group, *Personal Wellbeing Index: 5th Edition*. 2013, Melbourne: Australian Centre on Quality of Life, Deakin University.

32. Wilson, C.J., et al., *Measuring help seeking intentions: properties of the general help seeking questionnaire.* 2005.

33. Taylor, A., et al., *A new Mother-to-Infant Bonding Scale: links with early maternal mood.* Archives of Women's Mental Health, 2005. **8**(1): p. 45-51.

34. Fishman, K.N., et al., *Satisfaction with mental health navigation services: Piloting an evaluation with a new scale.* Community Mental Health Journal, 2018. **54**(5): p. 521-532.

35. Mercer, S.W., et al., *The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure.* Family practice, 2004. **21**(6): p. 699-705.

36. Gale, N.K., et al., *Using the framework method for the analysis of qualitative data in multi-disciplinary health research.* BMC Medical Research Methodology, 2013. **13**(1): p. 117.

37. Cohen, J., *Statistical power analysis for the behavioral sciences*. 1988, New York: Routledge.

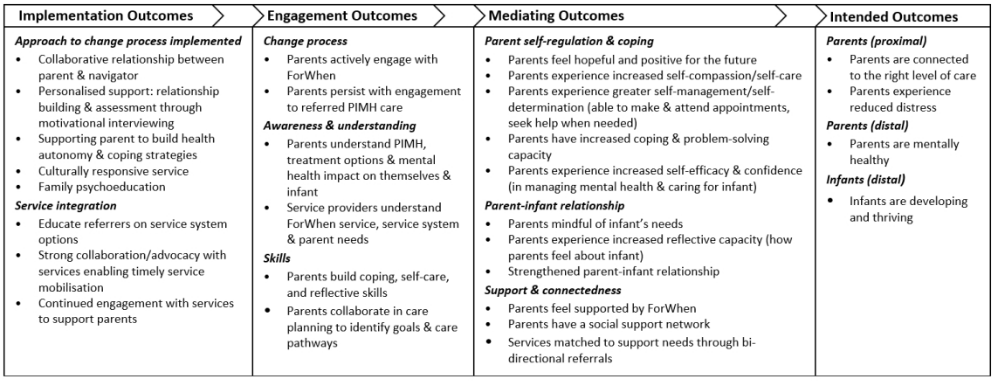
38. DiSanza, C.B., et al., *A Stepped Care Model of Patient Navigation to Enhance Engagement with Perinatal Mental Health Care.* Health Equity, 2020. **4**(1): p. 484-488.

Figure Legends:

Figure 1. The ForWhen outcomes chain

Figure 2. Data collection timepoints

Figure 3. Quantitative data collection timepoints during client journey



Implementation Outcomes

Approach to change process implemented
- Collaborative relationship between parent & navigator
- Personalised support: relationship building & assessment through motivational interviewing
- Supporting parent to build health autonomy & coping strategies
- Culturally responsive service
- Family psychoeducation

Service integration
- Educate referrers on service system options
- Strong collaboration/advocacy with services enabling timely service mobilisation
- Continued engagement with services to support parents

Engagement Outcomes

Change process
- Parents actively engage with ForWhen
- Parents persist with engagement to referred PIMH care

Awareness & understanding
- Parents understand PIMH, treatment options & mental health impact on themselves & infant
- Service providers understand ForWhen service, service system & parent needs

Skills
- Parents build coping, self-care, and reflective skills
- Parents collaborate in care planning to identify goals & care pathways

Mediating Outcomes

Parent self-regulation & coping
- Parents feel hopeful and positive for the future
- Parents experience increased self-compassion/self-care
- Parents experience greater self-management/self-determination (able to make & attend appointments, seek help when needed)
- Parents have increased coping & problem-solving capacity
- Parents experience increased self-efficacy & confidence (in managing mental health & caring for infant)

Parent-infant relationship
- Parents mindful of infant's needs
- Parents experience increased reflective capacity (how parents feel about infant)
- Strengthened parent-infant relationship

Support & connectedness
- Parents feel supported by ForWhen
- Parents have a social support network
- Services matched to support needs through bi-directional referrals

Intended Outcomes

Parents (proximal)
- Parents are connected to the right level of care
- Parents experience reduced distress

Parents (distal)
- Parents are mentally healthy

Infants (distal)
- Infants are developing and thriving

Figure 1. The ForWhen Outcomes Chain

683x263mm (57 x 57 DPI)

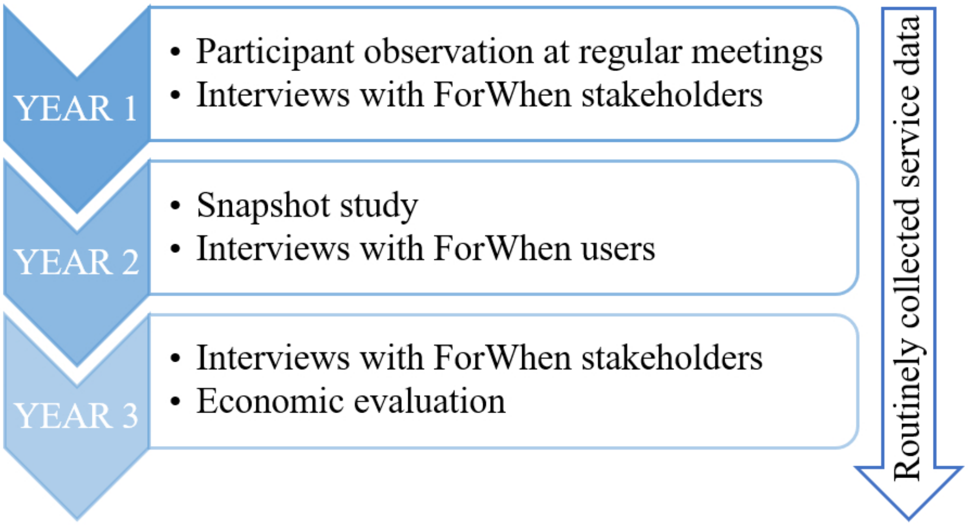


Figure 2. Data collection timepoints

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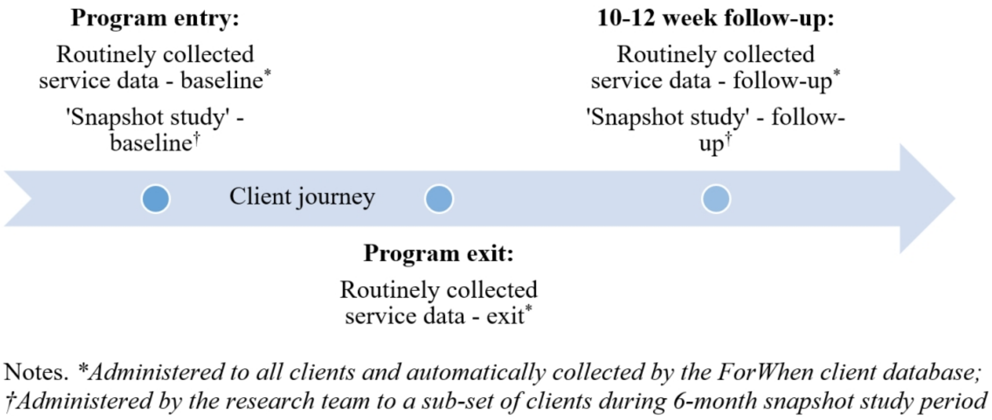

Figure 3. Quantitative data collection timepoints during client journey

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The ForWhen Australian Perinatal and Infant Mental Health Navigation Program: Evaluation Protocol

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The *ForWhen* Australian Perinatal and Infant Mental Health Navigation Program: Evaluation Protocol

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Abstract

Introduction: Many parents and carers experience mental health challenges during pregnancy and early postpartum years, and there are cumulative shortfalls in the identification, follow-up, and treatment of those experiencing perinatal and infant mental health (PIMH) challenges. ForWhen is a new national navigation program in Australia that aims to improve outcomes for families by supporting parents and carers to access PIMH services that best meet their needs. This paper presents the protocol of an evaluation of the ForWhen program, to be conducted over the first 3 years of its implementation. The specific objectives of the evaluation include examining the characteristics of navigation service delivery, its implementation and clinical impact, and identifying potential moderators of change.

Methods & Analysis: Utilising a mixed-methods design, this evaluation will incorporate three phases that reflect the stages of the program lifecycle: 1) program description, 2) implementation evaluation, and 3) outcomes evaluation. The evaluation will use a mix of quantitative and qualitative data including deidentified routinely collected service data, participant observations, semi-structured interviews, surveys and questionnaires, and a resource audit.

Discussion: Evaluation findings will be used to inform the development of a refined clinical navigation model, identify barriers and facilitators to successful navigation program implementation, examine the impact of the ForWhen program on client clinical outcomes and health service utilisation, understand how the program is/can be best embedded in the evolving service system, and assess the cost-effectiveness and sustainability of a national navigation program in improving health outcomes for PIMH in Australia.

Ethics & Dissemination: This research was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH11611). This study was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12622001443785). Results will be disseminated at conferences, in scientific journals, and in a final evaluation report.

Keywords: program evaluation, protocol, navigation, perinatal and infant mental health, help-line, telehealth

Article Summary: Strengths and limitations of this study

- A major strength of this evaluation is the multi-method, multi-informant approach to data collection
- Another study strength is the implementation evaluation, including an economic analysis, which will inform wider dissemination and scaling.
- A study weakness is the lack of a randomised controlled study design to test clinical outcomes.

Introduction

Mental health difficulties occur commonly during pregnancy and the first year postpartum [1, 2], and are associated with a range of short- and long-term negative impacts for parents and carers, their families, and children [3, 4]. Addressing parent and carer mental health needs during the perinatal period is therefore of vital importance to protect both adult and infant mental health and wellbeing over the life course. Recent decades have seen increasing focus given to perinatal and infant mental health (PIMH) [5], with a range of government initiatives aimed at implementing universal psychosocial screening into routine antenatal and postnatal healthcare and improving treatment for PIMH, such as the National Perinatal Depression Initiative in Australia [6].

Despite increased awareness of, and screening for, PIMH issues, many expectant and new parents/carers are not screened for mental health during perinatal care or do not receive treatment for their distress. A systematic review of international English-language studies by Cox, Sowa [7] found cumulative shortfalls in recognition, initiation and adequacy of PIMH treatment, and treatment outcomes for women with antenatal or postnatal depression – which the authors termed the "perinatal depression treatment cascade" (p. 1190). Australia-based research has shown screening and treatment rates for PIMH issues to be particularly low for those from non-English speaking backgrounds [8], those in the private healthcare system [9], and for fathers or non-birth partners [10]. While Australian women have high uptake of primary health services during the perinatal period, uptake of specialist mental health services is low. In an Australian study, for example, Schmied et al. showed that of a sample of women identified to be at moderate to high risk of PIMH, only ¼ had accessed mental health services by 12 months postpartum, and this was predominantly via telephone helplines [11]. Research from Australia and abroad has identified a number of patient, provider, and system-level barriers which help explain the gap between screening and treatment rates for PIMH including a lack of appropriate services, stigma, and difficulty navigating fragmented PIMH service landscapes [12-14].

PIMH Navigation Services as a Potential Solution

Navigation models have been proposed as a cost-effective way to improve access to mental health care services and support [15]. 'Navigation' is defined as a partnership between a patient and a navigator whose role is to guide patients through the complexities of the healthcare system, facilitate timely access to assessment and treatment, and foster patient self-management through education, capacity building, and support [16, 17]. A number of US-based navigation programs addressing PIMH have demonstrated positive outcomes including a reduction in maternal depression [18, 19], higher rates of postpartum visit attendance and depression screening [20], and enhanced utilisation of mental health services [21]. However, current evidence regarding the effectiveness of navigation for improving PIMH is sparse, with studies having adopted varied designs and outcome measures. There is also limited information available on navigation activities and services, navigator core competencies, or the ways in which various implementation components and contexts impact participant outcomes. Further research evaluating the efficacy and feasibility of navigation services for PIMH will be invaluable for understanding their potential in improving early intervention for parents and families, and for informing sustainable and effective program design in future.

ForWhen: A National Navigation Program for PIMH

In 2021, the Australian government announced that it would provide three years of funding to establish and deliver a new national navigation program for parents and carers experiencing mental health concerns during pregnancy and the first year after birth. Known as ForWhen, the program is led by Karitane (www.karitane.com.au) and delivered around the country by a consortium of partners from the Australian Association of Parenting & Child Health (AAPCH; www.aapch.com.au), Parenting Research Centre (PRC; www.parentingrc.org.au) and the University of New South Wales (UNSW; www.unsw.edu.au). ForWhen proposes to address current PIMH treatment access shortfalls by providing “a national comprehensive stepped continuum of care for parents experiencing moderate to severe PIMH concerns, supporting these families to navigate the complex and fragmented PIMH service landscape” [22]. Following a 7-month set-up phase (July 2021-January 2022), ForWhen was officially “launched” to the public in February 2022 with the opening of a national helpline staffed by clinically trained navigators based in each state and territory of Australia. ForWhen navigators have knowledge of local service systems and pathways within their jurisdictions, and work collaboratively with clients and health service professionals to understand their needs and connect them with appropriate support services.

ForWhen is a new program, and so its impact and effectiveness are currently not well understood. This paper presents the protocol of a program evaluation aimed at understanding the implementation and outcomes of the ForWhen program. The evaluation objectives are to: 1) describe the ForWhen service delivery model, 2) evaluate the implementation of the ForWhen program with a focus on acceptability, adoption, appropriateness, feasibility, fidelity, coverage, cost, and sustainability, and 3) examine outcomes experienced by clients who access the ForWhen program, and to identify potential moderators of change across different contexts and participant groups. This evaluation will be conducted over a 3-year period (July 2021- June 2024) and results will be used to make recommendations to guide future ForWhen service delivery, and to inform the development of similar programs in Australia and internationally.

Methods & Analysis

Study Design

During the early design and implementation stages of the ForWhen program, a program logic and corresponding outcomes chain was developed by ForWhen consortium members, led by PRC and with representatives from AACPH and UNSW, and the ForWhen steering committee (including consumer representatives) (Fig. 1). This model was used to inform the evaluation design, questions, and methodology. Specifically, the evaluation protocol seeks to examine the outcomes articulated in the program logic model, and to assess the degree to which the intervention was implemented as intended. A mixed-methods evaluation protocol was developed using the steps outlined in the NSW Government Program Evaluation Guidelines [23] and the Centre for Disease Control (CDC) Framework for Program Evaluation in Public Health [24]. The program evaluation will incorporate three phases that reflect the stages of the program lifecycle: 1) Program Description, 2) Implementation Evaluation, and 3) Outcomes Evaluation (Table 1).

[Insert Figure 1 about here]

An early step of the evaluation will be to describe the program in detail (phase 1), and in doing so to articulate its goals and strategies, its capacity to effect change, and how it fits within the broader PIMH healthcare ecosystem. The program description will set the frame of reference for subsequent evaluation activities, and facilitate subsequent efforts to connect the various program components to their effects [24]. This phase will focus specifically on documenting the service delivery model of the ForWhen program and characterising the activities and core competencies involved in navigation.

The implementation evaluation (phase 2) will be guided by the work of Proctor and colleagues [25], with a focus on key implementation outcome indices including acceptability, adoption, appropriateness, feasibility, fidelity, coverage, cost, and sustainability. These implementation outcomes serve as important preconditions for a program's success in effecting change in clinical or service outcomes [25]. Findings from the implementation evaluation will feed into an analysis of fidelity to the program model, the identification of facilitators and barriers to successful implementation, and an assessment of cost-effectiveness and longer-term sustainability.

The outcomes evaluation (phase 3) will investigate whether the program is achieving its intended outcomes (e.g., improvements in wellbeing and service utilisation), and, in acknowledgement that health programs may have varying outcomes across contexts and participants [26, 27], effort will also be made to ascertain the groups for, and circumstances under, which positive outcomes are/are not achieved.

Table 1. Evaluation questions and planned activities at three phases of the evaluation

Evaluation Question	Planned Activities
Phase 1: Program Description	
What is the service delivery model of the ForWhen program?	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
What are the core competencies and activities involved in navigation?	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Phase 2: Implementation Evaluation	
What is the service provision and coverage of the ForWhen program? *(adoption, fidelity, coverage)**	Analysis of routinely collected service provision data
What are barriers and facilitators to successful implementation of the ForWhen program around the country? *(feasibility, fidelity)*	Participant observation at committee meetings; semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Do users report satisfaction with the ForWhen program? What factors do they perceive to have contributed to or impeded positive outcomes? *(appropriateness, acceptability)*	Brief exit survey administered to users (clients, family/friends, health professionals) at case closure; semi-structured interviews with users (clients, family/friends, health professionals)
Do stakeholders report satisfaction with the ForWhen program? Do they view the program as feasible and effective? *(appropriateness, acceptability, feasibility)*	Semi-structured interviews with stakeholders (navigators, managers, steering committee members)
Does the program represent value for money? Do the benefits justify the costs? *(cost, sustainability)*	Resource audit to cost ForWhen and an economic analysis by converting K10 to health utilities, service use and productivity impacts, including a modelled counterfactual
Phase 3: Outcomes Evaluation	

Do clients report improvements in i) mental health, ii) quality of life, iii) help-seeking behaviour, iv) self-compassion and self-care, and v) early parenting experiences (parental self-efficacy, parent-child bonding)?	Analysis of routinely collected service provision data; 'snapshot study' to assess pre- to post-program changes on a range of additional relevant variables
How effective is the program in facilitating clients' timely access to, and engagement with, mental health services?	
Do program outcomes differ across demographic groups (e.g., age, symptom severity, location, cultural/linguistic background) or based on services provided (e.g., type of referred services, number of interactions with navigator)?	

**Proctor et al.'s key implementation outcomes [25]*

Patient and Public Involvement

The ForWhen steering committee includes consumer representation to provide input into service delivery and intended outcomes to be assessed in this evaluation. Specifically, one of the Steering Committee members is a consumer with lived experience of perinatal mental illness, who leads consultation more broadly through a number of different consumer groups/networks. A ForWhen consumer & Community Engagement Framework has also been developed to guide program implementation and the overall evaluation across the three phases.

Participants

Participants in this evaluation will include a range of users and stakeholders involved in the ForWhen program. User participants will include: *clients* (i.e., expectant or new parents/carers from across all states and territories of Australia) who are facing PIMH challenges and who contact the ForWhen helpline to receive navigation services and support; *family/friends* (e.g., partner, grandparents) who access the ForWhen helpline seeking advice or information in how best to support a parent/carer struggling with PIMH issues; and *health professionals* who access the ForWhen helpline seeking advice or information in how to find appropriate treatment for someone in their care who is facing PIMH issues, or looking to refer a parent/carer into the program. Stakeholder participants will include ForWhen *navigators* and *aboriginal liaison workers* (clinically trained, 'place-based' staff from a range of professional backgrounds, e.g., midwifery, nursing, psychology, social work) who staff the national helpline and work one-on-one with users to provide support and navigation services to connect clients with appropriate PIMH treatment; *managers* who provide direct supervision to navigators; and *steering committee members* including the national director, PIMH experts, consortium representatives, and project and administrative staff.

Data Collection

A mix of quantitative and qualitative data will be utilised including deidentified routinely collected service data between February 2022 and June 2024, and a range of additional qualitative and quantitative data collected at various points over the 3-year evaluation period (Fig. 2) in order to achieve the evaluation aims.

[Insert Figure 2 about here]

Qualitative Data Collection

Participant observation. To describe the program and its implementation, a researcher will conduct participant observation at regular committee meetings during the early design and implementation phases of the program, over a period of approximately 6 months (Fig. 2). Meeting attendees will include ForWhen stakeholders representing different roles (e.g., steering committee members, managers, navigators), organisations, and jurisdictions. The researcher will record field notes during these meetings with a focus on documenting and describing the ForWhen service delivery model, governance structure and staff roles, barriers to implementation, and steps taken to address these barriers.

Semi-structured interviews. Semi-structured interviews will be conducted with stakeholders (navigators, managers, steering committee members) and users (clients, family/friends, health professionals) of the program at various points throughout its implementation (Fig. 2). Interviews with ForWhen navigators in the first year of the program will explore the service delivery model, core competencies and activities involved in navigation, and barriers and facilitators to early implementation of the program on the ground. Interviews with other ForWhen stakeholders (including managers and steering committee members) in the first year of the program will explore the governance structure, and barriers and facilitators to early implementation from a management and governance perspective. Follow-up interviews with ForWhen navigators and stakeholders in the third year of the program will explore program evolution, and stakeholder perceptions on longer-term feasibility and effectiveness of the program. Interviews with users (including clients, family/friends, or health professionals) in the second year of the program will explore reasons for accessing and satisfaction with the program, perceived outcomes and usefulness, and barriers and facilitators to positive outcomes.

Quantitative Data Collection

Review of routinely collected service data. As a routine part of the ForWhen program, data relating to individual clients and service provision is collected by navigators and managed via a Customer Relationship Management (CRM) database. At program entry (baseline), navigators administer the K10 as part of routine mental health assessment, and collect client data including demographic information and identified psychosocial risk factors during an intake interview (Fig. 3 and Table 2). Throughout each client's engagement with the program, individual service provision data including number and mode of contacts with the navigator, services provided by the navigator (e.g., psychoeducation), and the number and types of referrals made, are routinely recorded by navigators in the CRM database (Table 2). In the final year of the program, retrospective analysis of this routinely collected service data will be conducted in order to characterise the clients (e.g., demographics, K10 scores and psychosocial risks) and service provision of the ForWhen program, evaluate changes in client psychological distress from ForWhen program entry to follow-up, and identify potential moderators of change.

Snapshot study. During a 6-month period in the second year of the program, the research team will recruit ForWhen clients (parents/carers) to a 'snapshot study' to evaluate the program's impact on additional parent and infant outcomes. All clients who access ForWhen during this study period will be eligible to participate, and those who opt-in will be asked to complete a series of validated questionnaires at baseline (within one week of accessing the program) and follow-up (10-12 weeks after program exit) either online or over the phone. Participants will also provide consent for this data to be linked to their client information held in the CRM database. Key variables of interest and accompanying questionnaires to be included in the snapshot survey are shown in Table 2. ***Economic evaluation.***

An exploratory economic evaluation will estimate the potential cost effectiveness and return-on-investment from both a health and societal perspective [28]. A within-trial analysis will estimate the costs of delivering ForWhen, including: (i) navigator salary (and oncosts), training and pro-rata supervision, and (ii) associated direct costs, such as office space, equipment, technology. The utilisation of referral services will be tracked and costed using MBS fee schedules (including out-of-pocket costs, where relevant). The main study outcome of K10 will then be converted to health utilities as the measure of effectiveness, with before and after measures (6 months). A literature review will be conducted to generate a plausible counterfactual regarding services utilisation and K10 scores in the absence of ForWhen [29]. Economic modelling will then project longer term impacts of ForWhen and the counterfactual on sustained changes in K10 scores and ongoing service use (health and social services), and productivity impacts where K10 scores are a validated predictor [30, 31]. A probability sensitivity analysis (PSA) and value of information analysis (VOI) will make the economic case to invest in long term follow-up data to replace model assumptions with observed data [32]. Key economic metrics of value will be the incremental cost effectiveness ratio (ICER) and a (pragmatic) social return on investment (SROI), using all costs and outcomes data. Finally, a Budget Impact Analysis (BIA) will the estimate the investment costs if ForWhen was implemented nationally.

[Insert Figure 3 about here]

Table 2. Quantitative data collection timepoints and information collected/measures administered

Timepoint	Dataset	Variable	Information/Measures
Program entry	Routinely collected service data – baseline	Demographic information	Navigator intake interview (e.g., age, sex, postcode, language, cultural background, relationship status, number of children)
		Client mental wellbeing	Kessler Psychological Distress Scale (K10) [33]
		Client psychosocial risk factors	Navigator intake interview (e.g., health insurance status, mental health history, family violence, physical or social isolation)
	'Snapshot study' – baseline	Parental self-efficacy	Me as a Parent – short form (MaaP-SF) [34]
		Quality of life	Personal wellbeing Index (PWI) [35]
		Help-seeking behaviours	General Help-Seeking Questionnaire (GHSQ) [36]
		Self-compassion and self-care	Parenting Research Centre questions (unpublished)
		Parent and infant bonding	Mother-to-Infant Bonding scale (MIBS) [37]
Program exit	Routinely collected service data – exit	Engagement with navigation program	Referral source, number and mode of contacts with navigator, services provided (e.g., psychoeducation), number and type of referrals made
		Satisfaction with navigation services	3 global questions from the Navigation Satisfaction Tool (NAVSAT) [38]
		Collaborative partnership with navigator	Consultation and Relational Empathy (CARE) measure [39]
10-12 week follow-up	Routinely collected service data – follow-up	Client mental wellbeing	Kessler Psychological Distress Scale (K10) [33]
		Engagement with referred service/s	Type of service, frequency, ongoing or completed
	'Snapshot study' – follow-up	Parental self-efficacy	Me as a Parent – short form (MaaP-SF) [34]
		Quality of life	Personal wellbeing Index (PWI) [35]
		Help-seeking behaviours	General Help-Seeking Questionnaire (GHSQ) [36]
		Self-compassion and self-care	Parenting Research Centre questions (unpublished)
		Parent and infant bonding	Mother-to-Infant Bonding scale (MIBS) [37]

	Satisfaction with navigation and referred service/s	Navigation Satisfaction Tool (NAVSAT) [38]

Data Analysis

Qualitative data including field notes and interview transcripts will be stored securely as electronic documents on a password protected computer. Interviews will be audio-recorded and transcribed verbatim. Qualitative data will be analysed using framework analysis, a thematic analytical method that involves data familiarisation, coding, developing a framework, indexing, charting, and interpretation [40]. Coding and analysis will be conducted using NVivo 12 software (QSR International).

Quantitative data will be collected from the program's CRM database, exit surveys, and snapshot study questionnaires, and stored in a password protected database. Data will be analysed using appropriate descriptive and inferential statistics in SPSS Statistics (IBM). For each of the key outcome measures [psychological distress (K10), parenting self-efficacy (MaaP-SF), personal wellbeing (PWI), help-seeking behaviour (GHSQ), self-compassion and self-care (PRC questions), and mother-to-infant bonding (MIBS)], sensitivity analyses will be conducted prior to undertaking the main quantitative analysis (e.g., to test the influence of outliers, missing data, protocol deviations). A linear mixed models repeated measures design will then be used to examine changes on these key outcome variables from program entry to follow-up. . The clinical significance of differences on study variables (from baseline to follow-up) will be assessed using Cohen's d with effect sizes evaluated using Cohen's [41] guidelines. Power calculations suggest that with power of .80 and alpha .05, a sample size of N=90 would enable detection of small-to-moderate effect size changes on key variables (e.g., depression symptoms assessed using the K10 and parenting self-efficacy assessed using the MaaP-SF). Based on early service utilisation data, we expect an anticipated sample size for the snapshot study of approximately n=200-250, indicating that the sample will be adequately powered. With the larger sample, we will also be able to conduct secondary analyses to explore factors that impact effectiveness. Several variables will be tested as potential outcome moderators: depression symptom severity on intake, place of residence (e.g., metropolitan versus regional/remote, and callers living in the different states and territories of Australia), intervention dosage (e.g., number of contacts with ForWhen navigator, duration from entry to exit, services provided).

Ethics & Dissemination

Researchers conducting the evaluation will have access to de-identified routinely collected service data, which will be used in aggregate analyses (no individual cases will be examined in isolation). For all additional data collection, participants will provide informed, written consent. Names and identifying information will be removed from qualitative data prior to publication, and quantitative data will only be used in aggregate analyses, to protect participant anonymity. This research was approved by South Western Sydney Local Health District Human Research Ethics Committee (2021/ETH11611), and has been registered on the Australian New Zealand Clinical Trials Registry (ACTRN12622001443785).

This evaluation will be an integral part of the implementation of the ForWhen program. Evaluation findings will be presented regularly to the program steering committee and national director, with a view to improving the program throughout the implementation period and translating findings into practice. Results will also be disseminated at conferences, in scientific journals, and in a final evaluation report.

Discussion

This protocol outlines the study design, methods, and analyses that will be used to conduct a comprehensive evaluation of the ForWhen navigation program. Navigation models have been adopted in a range of healthcare including PIMH [42], but their impact on clinical outcomes and evaluation of implementation including barriers and enablers in the engagement with PIMH services is currently not well understood. The findings of this evaluation will advance understanding on the potential of navigation programs such as ForWhen to enhance service connection and treatment for PIMH on a national scale, and help to inform sustainable and effective program design in future.

The planned evaluation does, however, have limitations. The most notable limitation is the ‘open trial’ study design to be utilised for the outcomes evaluation. A randomised controlled study design is not feasible given the program objective for system-wide changes, and the observational nature of the evaluation component. Given that the ForWhen navigation program is designed to connect families with needed care and support, a challenge will be to disentangle the impact of the navigation intervention from the benefits conveyed by connected services. To mitigate this, we plan to administer follow-up measures relatively soon after intervention exposure (10-12 weeks). We also plan to explore potential moderators of change (e.g., intensity and type of navigation services received). As the primary goal of navigation is to connect clients to appropriate services, it will also be important to look beyond clinical outcomes and examine participants’ engagement with mental health treatment at follow-up, and their satisfaction with both the navigation and referred services.

This evaluation will make important contributions to the literature on navigation service models in improving PIMH care. First, it will be used to develop a detailed model of clinical navigation work and identify the core competencies and desired skillset of navigators, which may help inform other programs adopting similar models. Second, it will identify barriers and facilitators in successful navigation program implementation on both local and national scales. Third, it will examine the impact of a national navigation program on clinical outcomes and health service utilisation among those facing PIMH issues in Australia. Fourth, the national dataset will provide an opportunity to identify patterns of need and service gaps among different demographic groups and jurisdictions throughout Australia, which will be used to inform future funding allocations and service delivery planning. And fifth, the evaluation will assess the cost-effectiveness and longer-term sustainability of a national navigation program in improving PIMH health outcomes in Australia.

Author contributions: Jane Kohlhoff and Valsamma Eapen conceived of the project and drafted the initial protocol. Jane Kohlhoff and Sophia Harris refined the study design and protocol. Jane Kohlhoff, Sophia Harris and Kenny Lawson drafted the published protocol paper, and all authors provided feedback and approved the final version.

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Competing interests: JK works in a co-funded academic position with UNSW and Karitane (ForWhen lead agency).

References

1. Gavin, N.I., et al., *Perinatal depression: a systematic review of prevalence and incidence.* Obstetrics & Gynecology, 2005. **106**(5 Part 1): p. 1071-1083.
2. Leach, L.S., C. Poyser, and K. Fairweather-Schmidt, *Maternal perinatal anxiety: A review of prevalence and correlates.* Clinical Psychologist, 2017. **21**(1): p. 4-19.
3. Stein, A., et al., *Effects of perinatal mental disorders on the fetus and child.* The Lancet, 2014. **384**(9956): p. 1800-1819.
4. Ruffell, B., D.M. Smith, and A. Wittkowski, *The experiences of male partners of women with postnatal mental health problems: a systematic review and thematic synthesis.* Journal of Child and Family Studies, 2019. **28**(10): p. 2772-2790.
5. Howard, L.M. and H. Khalifeh, *Perinatal mental health: a review of progress and challenges.* World Psychiatry, 2020. **19**(3): p. 313-327.

6. Austin, M.-P., N. Reilly, and E. Sullivan, *The need to evaluate public health reforms: Australian perinatal mental health initiatives.* Australian and New Zealand journal of public health, 2012. **36**(3): p. 208-211.
7. Cox, E.Q., et al., *The perinatal depression treatment cascade: baby steps toward improving outcomes.* The Journal of Clinical Psychiatry, 2016. **77**(9): p. 20901.
8. Highet, N.J. and F. Bilbao, *The Western Perinatal Emotional Health Pilot Program: Final Report*. 2015.
9. Reilly, N., et al., *Disparities in reported psychosocial assessment across public and private maternity settings: a national survey of women in Australia.* BMC Public Health, 2013. **13**(1): p. 1-15.
10. Australian Government Productivity Commission [AGPC], *Mental Health Inquiry Report No. 95*. 2020: Canberra, ACT, Australia.
11. Schmied, V., et al., *Antenatal psychosocial risk status and Australian women's use of primary care and specialist mental health services in the year after birth: a prospective study.* BMC Women's Health, 2016. **16**(1): p. 69.
12. Austin, M.-P., N. Highet, and Expert Working Group, *Mental health care in the perinatal period: Australian clinical practice guideline*. 2017: Melbourne, Australia: Centre of Perinatal Excellence.
13. Brown, S. and C. Sprague, *Health care providers' perceptions of barriers to perinatal mental healthcare in South Africa.* BMC Public Health, 2021. **21**(1): p. 1905.
14. Byatt, N., et al., *Patient, provider, and system-level barriers and facilitators to addressing perinatal depression.* Journal of Reproductive and Infant Psychology, 2012. **30**(5): p. 436-449.
15. Knesek, G. and T. Hemphill, *Mental Health Navigation–a Model.* Health Promotion International, 2020. **35**(1): p. 151-159.
16. Kelly, K., S. Doucet, and A. Luke, *Exploring the roles, functions, and background of patient navigators and case managers: A scoping review.* International Journal of Nursing Studies, 2019. **98**: p. 27-47.
17. Freeman, H.P. and R.L. Rodriguez, *History and principles of patient navigation.* Cancer, 2011. **117**(15 Suppl): p. 3539-42.
18. Fallin-Bennett, A., et al., *Perinatal Navigator Approach to Smoking Cessation for Women With Prevalent Opioid Dependence.* West J Nurs Res, 2019. **41**(8): p. 1103-1120.
19. Silverstein, M., et al., *Patient navigation for depressed mothers in Head Start: A pilot study of intervention mechanism.* Journal of Community Psychology, 2017. **45**(4): p. 564-570.
20. Yee, L.M., et al., *Using a Patient Navigator to Improve Postpartum Care in an Urban Women's Health Clinic.* Obstet Gynecol, 2017. **129**(5): p. 925-933.
21. Diaz-Linhart, Y., et al., *Patient Navigation for Mothers with Depression who have Children in Head Start: A Pilot Study.* Social Work in Public Health, 2016. **31(6)**: p. 504-510.
22. Karitane, *Proposal for Pre-Budget Submission for Commonwealth funding 2021-2022*. 2021.
23. NSW Government, *NSW Government Program Evaluation Guidelines*. 2016.
24. Centers for Disease Control and Prevention [CDC], *Framework for Program Evaluation in Public Health*. 1999.
25. Proctor, E., et al., *Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda.* Adm Policy Ment Health, 2011. **38**(2): p. 65-76.
26. Pawson, R. and N. Tilley, *Realistic evaluation*. 1997: Sage.

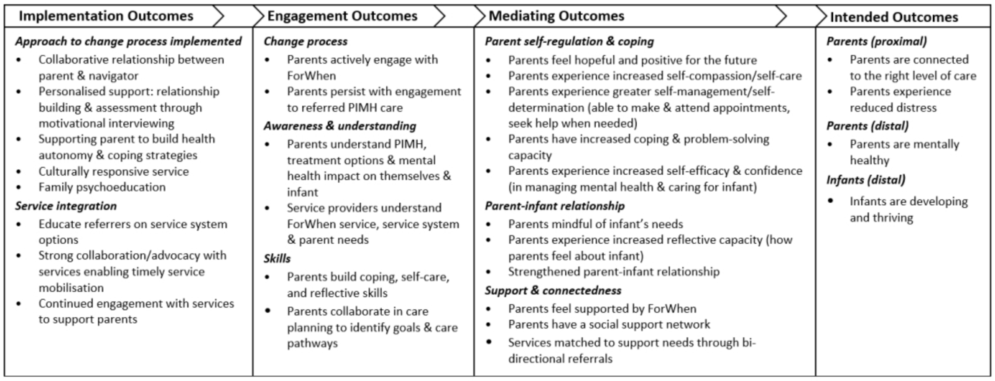
27. Wand, T., K. White, and J. Patching, *Contemporary mental health program implementation and evaluation.* Issues in Mental Health Nursing, 2010. **31**(11): p. 716-722.
28. Drummond, M.F., et al., *Methods for the economic evaluation of health care programmes*. 2015: Oxford university press.
29. Stein, A., et al., *Effects of perinatal mental disorders on the fetus and child.* Lancet, 2014. **384**: p. 1800-1819.
30. Lawson, K.D., et al., *A Dynamic Approach to Economic Priority Setting to Invest in Youth Mental Health and Guide Local Implementation: Economic Protocol for Eight System Dynamics Policy Models.* Frontiers in Psychiatry, 2022. **13**.
31. Australian Government, *Productivity Commission, Mental Health, Inquiry Report*. 2020, Canberra.
32. Briggs, A.H., et al., *Model parameter estimation and uncertainty analysis: a report of the ISPOR-SMDM Modeling Good Research Practices Task Force Working Group–6.* Medical decision making, 2012. **32**(5): p. 722-732.
33. Kessler, R.C., et al., *Screening for serious mental illness in the general population.* Archives of general psychiatry, 2003. **60**(2): p. 184-189.
34. Matthews, J., et al., *Development and Validation of a Short-Form Parenting Self-Efficacy Scale: Me as a Parent Scale (MaaPs-SF).* Journal of Child and Family Studies, 2022: p. 1-11.
35. International Wellbeing Group, *Personal Wellbeing Index: 5th Edition*. 2013, Melbourne: Australian Centre on Quality of Life, Deakin University.
36. Wilson, C.J., et al., *Measuring help seeking intentions: properties of the general help seeking questionnaire.* 2005.
37. Taylor, A., et al., *A new Mother-to-Infant Bonding Scale: links with early maternal mood.* Archives of women's mental health, 2005. **8**(1): p. 45-51.
38. Fishman, K.N., et al., *Satisfaction with mental health navigation services: Piloting an evaluation with a new scale.* Community Mental Health Journal, 2018. **54**(5): p. 521-532.
39. Mercer, S.W., et al., *The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure.* Family practice, 2004. **21**(6): p. 699-705.
40. Gale, N.K., et al., *Using the framework method for the analysis of qualitative data in multi-disciplinary health research.* BMC Medical Research Methodology, 2013. **13**(1): p. 117.
41. Cohen, J., *Statistical power analysis for the behavioral sciences*. 1988, New York: Routledge.
42. DiSanza, C.B., et al., *A Stepped Care Model of Patient Navigation to Enhance Engagement with Perinatal Mental Health Care.* Health Equity, 2020. **4**(1): p. 484-488.

Figure Legends:

Figure 1. The ForWhen outcomes chain

Figure 2. Data collection timepoints

Figure 3. Quantitative data collection timepoints during client journey



Implementation Outcomes	Engagement Outcomes	Mediating Outcomes	Intended Outcomes
Approach to change process implemented • Collaborative relationship between parent & navigator • Personalised support: relationship building & assessment through motivational interviewing • Supporting parent to build health autonomy & coping strategies • Culturally responsive service • Family psychoeducation ***Service integration*** • Educate referrers on service system options • Strong collaboration/advocacy with services enabling timely service mobilisation • Continued engagement with services to support parents	***Change process*** • Parents actively engage with ForWhen • Parents persist with engagement to referred PIMH care ***Awareness & understanding*** • Parents understand PIMH, treatment options & mental health impact on themselves & infant • Service providers understand ForWhen service, service system & parent needs ***Skills*** • Parents build coping, self-care, and reflective skills • Parents collaborate in care planning to identify goals & care pathways	***Parent self-regulation & coping*** • Parents feel hopeful and positive for the future • Parents experience increased self-compassion/self-care • Parents experience greater self-management/self-determination (able to make & attend appointments, seek help when needed) • Parents have increased coping & problem-solving capacity • Parents experience increased self-efficacy & confidence (in managing mental health & caring for infant) ***Parent-infant relationship*** • Parents mindful of infant's needs • Parents experience increased reflective capacity (how parents feel about infant) • Strengthened parent-infant relationship ***Support & connectedness*** • Parents feel supported by ForWhen • Parents have a social support network • Services matched to support needs through bi-directional referrals	***Parents (proximal)*** • Parents are connected to the right level of care • Parents experience reduced distress ***Parents (distal)*** • Parents are mentally healthy ***Infants (distal)*** • Infants are developing and thriving

Figure 1. The ForWhen Outcomes Chain

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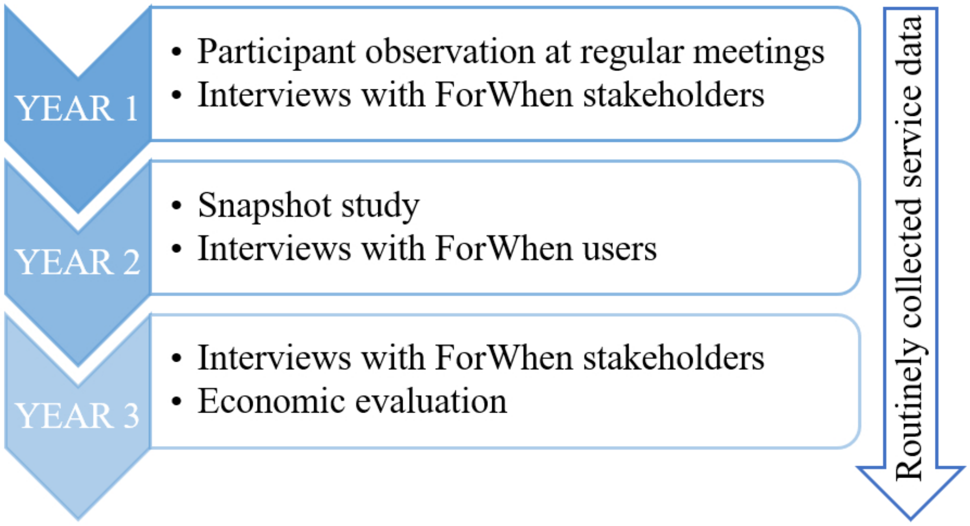

Figure 2. Data collection timepoints

410x237mm (57 x 57 DPI)

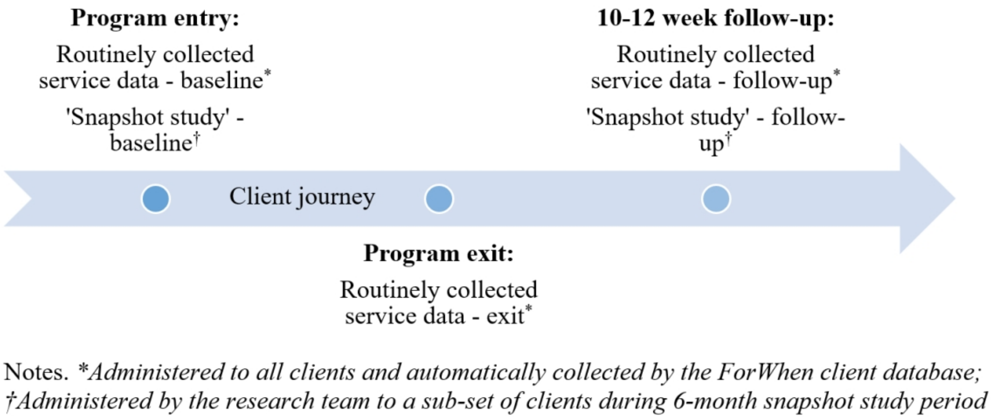

Figure 3. Quantitative data collection timepoints during client journey

632x270mm (57 x 57 DPI)