# **BMJ Open** ForWhen Australian perinatal and infant mental health navigation programme: 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 programme 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 programme, 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 and analysis Utilising a mixed-methods design, this evaluation will incorporate three phases that reflect the stages of the programme life-cycle: (1) programme 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, semistructured 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 programme implementation, examine the impact of the ForWhen programme on client clinical outcomes and health service utilisation, understand how the programme is/can be best embedded in the evolving service system, and assess the cost-effectiveness and sustainability of a national navigation programme in improving health outcomes for PIMH in Australia.

Ethics and 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.

#### **INTRODUCTION**

Mental health difficulties occur commonly during pregnancy and the first year postpartum<sup>12</sup> and are associated with a range of short-term and long-term negative impacts

ny D Lawson,<sup>4</sup> Valsamma Eapen <sup>®</sup> <sup>1,5,6</sup> STRENGTHS AND LIMITATIONS OF THIS STUDY ⇒ A major strength of this evaluation is the multimeth-od, multi-informant approach to data collection. ⇒ Another study strength is the implementation eval-uation, including an economic analysis, which will inform wider dissemination and scaling. ⇒ A study weakness is the lack of a randomised con-trolled study design to test clinical outcomes. for parents and carers, their families, and children.<sup>3</sup> <sup>4</sup> Addressing parent and carer mental health needs during the perinatal period is, therefore, of vital importance to protect both adult and infant mental health protect both adult and infant mental health and well-being over the life course. Recent a decades have seen increasing focus given to text perinatal and infant mental health (PIMH),<sup>5</sup> with a range of government initiatives aimed at implementing universal psychosocial as screening into routine antenatal and postnatal healthcare and improving treatment for PIMH, such as the National Perinatal Depression Initiative in Australia.<sup>6</sup>

≥ Despite increased awareness of, and screening for, PIMH issues, many expectant and new parents/carers are not screened ng, for mental health during perinatal care or do not receive treatment for their distress. A systematic review of international English-<u>0</u> language studies by Cox *et al*<sup>7</sup> found cumulative shortfalls in recognition, initiation and adequacy of PIMH treatment, and treatment outcomes for women with antenatal or post-natal 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,<sup>8</sup> those in the private healthcare system,<sup>9</sup> and for fathers or non-birth partners.<sup>10</sup> 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

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et al showed that of a sample of women identified to be at moderate to high risk of PIMH, only one-fourth had accessed mental health services by 12 months post partum, and this was predominantly via telephone helplines.<sup>11</sup> 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.<sup>12–14</sup>

#### PIMH navigation services as a potential solution

Navigation models have been proposed as a cost-effective way to improve access to mental healthcare services and support.<sup>15</sup> '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.<sup>16 17</sup> A number of US-based navigation programmes addressing PIMH have demonstrated positive outcomes including a reduction in maternal depression,<sup>18</sup> <sup>19</sup> higher rates of postpartum visit attendance and depression screening,<sup>20</sup> and enhanced utilisation of mental health services.<sup>21</sup> 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 programme design in future.

#### ForWhen: a national navigation programme for PIMH

In 2021, the Australian government announced that it would provide 3 years of funding to establish and deliver a new national navigation programme for parents and carers experiencing mental health concerns during pregnancy and the first year after birth. Known as ForWhen, the programme is led by Karitane (www.karitane.com. au) and delivered around the country by a consortium of partners from the Australian Association of Parenting and 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'.<sup>22</sup> Following a 7-month setup 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. For When 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 programme, and so its impact and effectiveness are currently not well understood. This paper presents the protocol of a programme evaluation aimed **p** at understanding the implementation and outcomes of the ForWhen programme. The evaluation objectives are to: (1) describe the ForWhen service delivery model, (2) evaluate the implementation of the ForWhen programme with a focus on acceptability, adoption, appropriate-ness, feasibility, fidelity, coverage, cost and sustainability and (3) examine outcomes experienced by clients who access the ForWhen programme, 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 uses of similar programmes in Australia and internationally.

#### Study design

related During the early design and implementation stages of the ForWhen programme, a programme logic and corre-sponding outcomes chain was developed by ForWhen consortium members, led by PRC and with representatives from AAPCH and UNSW, and the ForWhen steering committee (including consumer representatives) (figure 1). This model was used to inform the evaluation design, questions and methodology. Specifically, the evaluation protocol seeks to examine the outcomes **a** articulated in the programme 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 Programme Evaluation Guidelines<sup>23</sup> and the Centre ھ for Disease Control Framework for Programme Evaluation in Public Health.<sup>24</sup> The programme evaluation will incorporate three phases that reflect the stages of the programme life-cycle: (1) programme description, (2) implementation evaluation and (3) outcomes evaluation able 1). An early step of the evaluation will be to describe **G** (table 1).

the programme in detail (phase 1), and in doing so to  $\overline{\mathbf{g}}$ articulate its goals and strategies, its capacity to effect change, and how it fits within the broader PIMH healthcare ecosystem. The programme description will set the frame of reference for subsequent evaluation activities, and facilitate subsequent efforts to connect the various programme components to their effects.<sup>24</sup> This phase will focus specifically on documenting the service delivery model of the ForWhen programme and characterising the activities and core competencies involved in navigation.

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

The ForWhen outcomes chain. PIMH, perinatal and infant mental health. Figure 1

The implementation evaluation (phase 2) will be guided by the work of Proctor *et al*,<sup>25</sup> 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 programme's success in effecting change in clinical or service outcomes.<sup>25</sup> Findings from the implementation evaluation will feed into an analysis of fidelity to the programme 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 programme is achieving its intended outcomes (eg, improvements in well-being and service utilisation), and, in acknowledgement that health programmes may have varying outcomes across contexts and participants,<sup>26 27</sup> effort will also be made to ascertain the groups for, and circumstances under, which positive outcomes are/are not achieved.

#### 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 and Community Engagement Framework has also been developed to guide programme 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 programme. User participants will include: clients (ie, expectant or new parents/carers from across all states and territories

Protected by copyright, includi of Australia) who are facing PIMH challenges and who contact the ForWhen helpline to receive navigation services and support; family/friends (eg, partner, grandparents) who access the ForWhen helpline seeking advice **G** or information in how best to support a parent/carer struggling with PIMH issues; and health professionals ſe who access the ForWhen helpline seeking advice or information in how to find appropriate treatment for someone Ö in their care who is facing PIMH issues, or looking to refer a parent/carer into the programme. Stakeholder participants will include ForWhen navigators and aboriginal liaison workers (clinically trained, 'place-based' staff from a range of professional backgrounds, for example, 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 . ح direct supervision to navigators; and steering committee training, and simi members including the national director, PIMH experts, consortium representatives, and project and administrative staff.

#### **Data collection**

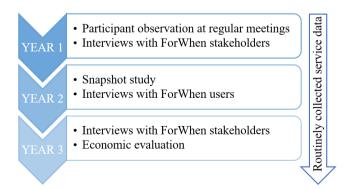
A mix of quantitative and qualitative data will be used including deidentified routinely collected service data technologies between February 2022 and June 2024, and a range of additional qualitative and quantitative data collected at various points over the 3-year evaluation period (figure 2) in order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

#### Qualitative data collection

#### Participant observation

To describe the programme and its implementation, a researcher will conduct participant observation at regular committee meetings during the early design and implementation phases of the programme, over a period of approximately 6 months (figure 2). Meeting attendees will include ForWhen stakeholders representing different roles (eg, steering committee members,

| Evolution models  | hases of the evaluation  |
|---|--|
| Evaluation question   | Planned activities   |
| Phase 1: programme description  |  |
| What is the service delivery model of the ForWhen programme?  | Participant observation at committee meetings;<br>semistructured interviews with stakeholders (navigators,<br>managers, steering committee members)  |
| What are the core competencies and activities involved in navigation?   | Participant observation at committee meetings;<br>semistructured interviews with stakeholders (navigators,<br>managers, steering committee members)  |
| Phase 2: implementation evaluation  |  |
| What is the service provision and coverage of the ForWhen programme? (adoption, fidelity, coverage)*  | Analysis of routinely collected service provision data   |
| What are barriers and facilitators to successful<br>implementation of the ForWhen programme around the<br>country? (feasibility, fidelity)  | Participant observation at committee meetings;<br>semistructured interviews with stakeholders (navigators,<br>managers, steering committee members)  |
| Do users report satisfaction with the ForWhen programme?<br>What factors do they perceive to have contributed to or<br>impeded positive outcomes? (appropriateness, acceptability)  | Brief exit survey administered to users (clients, family/<br>friends, health professionals) at case closure; semistructure<br>interviews with users (clients, family/friends, health<br>professionals) |
| Do stakeholders report satisfaction with the ForWhen programme? Do they view the programme as feasible and effective? (appropriateness, acceptability, feasibility)   | Semistructured interviews with stakeholders (navigators, managers, steering committee members)   |
| Does the programme represent value for money? Do the benefits justify the costs? (cost, sustainability)   | Resource audit to cost ForWhen and an economic analysis<br>by converting K10 to health utilities, service use and<br>productivity impacts, including a modelled counterfactual                         |
| Phase 3: outcomes evaluation  |  |
| Do clients report improvements in (1) mental health, (2) quality<br>of life, (3) help-seeking behaviour, (4) self-compassion and<br>self-care, and (5) early parenting experiences (parental self-<br>efficacy, parent–child bonding)?  | Analysis of routinely collected service provision data;<br>'snapshot study' to assess preprogramme to postprogramme<br>changes on a range of additional relevant variables                             |
| How effective is the programme in facilitating clients' timely access to, and engagement with, mental health services?  |  |
| Do programme outcomes differ across demographic groups<br>(eg, age, symptom severity, location, cultural/linguistic<br>background) or based on services provided (eg, type of<br>referred services, no of interactions with navigator)? |  |
| *Proctor et al's key implementation outcomes. <sup>25</sup>   |  |
|   |  |
| managers, navigators), organisations and jurisdictions.<br>The researcher will record field notes during these meet-<br>ngs with a focus on documenting and describing the  | ForWhen service delivery model, governance structu<br>and staff roles, barriers to implementation and ste<br>taken to address these barriers.  |
| YEAR 1<br>• Participant observation at regular meetings<br>• Interviews with ForWhen stakeholders<br>• Snapshot study<br>• Interviews with ForWhen users  | Semistructured interviews<br>Semistructured interviews will be conducted with stak<br>holders (navigators, managers, steering committe<br>members) and users (clients, family/friends, heal            |
| • Snapshot study<br>• Interviews with ForWhen users   | professionals) of the programme at various poin<br>throughout its implementation (figure 2). Interviews wi<br>ForWhen navigators in the first year of the programm                                     |





professionals) of the programme at various points throughout its implementation (figure 2). Interviews with ForWhen navigators in the first year of the programme will explore the service delivery model, core competencies and activities involved in navigation, and barriers and facilitators to early implementation of the programme on the ground. Interviews with other ForWhen stakeholders (including managers and steering committee members) in the first year of the programme will explore the

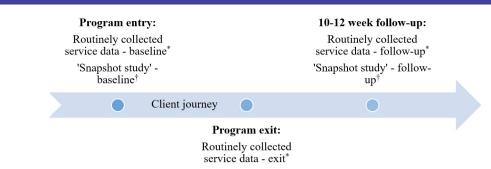


Figure 3 Quantitative data collection time points during client journey. Notes. \*Administered to all clients and automatically collected by the for when client database; †Administered by the search team to a sub-set of clients during 6-month snaoshot study period.

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 programme will explore programme evolution, and stakeholder perceptions on longer-term feasibility and effectiveness of the programme. Interviews with users (including clients, family/friends or health professionals) in the second year of the programme will explore reasons for accessing and satisfaction with the programme, 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 programme, data relating to individual clients and service provision is collected by navigators and managed via a Customer Relationship Management (CRM) database. At programme 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 (figure 3 and table 2). Throughout each client's engagement with the programme, individual service provision data including number and mode of contacts with the navigator, services provided by the navigator (eg, 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 programme, retrospective analysis of this routinely collected service data will be conducted in order to characterise the clients (eg, demographics, K10 scores and psychosocial risks) and service provision of the ForWhen programme, evaluate changes in client psychological distress from ForWhen programme entry to follow-up, and identify potential moderators of change.

### Snapshot study

During a 6-month period in the second year of the programme, the research team will recruit ForWhen clients (parents/carers) to a 'snapshot study' to evaluate the programme's impact on additional parent and infant outcomes. All clients who access ForWhen during this study period will be eligible to participate, and those

Protected by copyright who opt-in will be asked to complete a series of validated questionnaires at baseline (within 1 week of accessing the programme) and follow-up (10-12 weeks after programme exit) either online or over the phone. Participants will also provide consent for this data to be linked , includi to their client information held in the CRM database. Key variables of interest and accompanying questionnaires to Bui 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 related from both a health and societal perspective.<sup>28</sup> A withintrial analysis will estimate the costs of delivering ForWhen, including: (1) navigator salary (and oncosts), training and **5** pro-rata supervision and (2) associated direct costs, such as office space, equipment, technology. The utilisation of 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.<sup>29</sup> 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.<sup>30 31</sup> A probability sensitivity analysis and value of information analysis will make the economic case to invest in longterm follow-up data to replace model assumptions with the incremental cost-effectiveness ratio and a (pragmatic) social return on investment union. observed data.<sup>32</sup> Key economic metrics of value will be social return on investment, using all costs and outcomes data. Finally, a budget impact analysis will the estimate the investment costs if ForWhen was implemented nationally.

### **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,

₫

uses

Dd

| Time point   | Dataset   | Variable   | Information/measures  |
|--|---|--|---|
| Programme<br>entry<br>Routinely<br>collected<br>service<br>data—<br>baseline<br>'Snapshot<br>study'—<br>baseline | ,   | Demographic information  | Navigator intake interview (eg, age, sex, postcode, language, cultural background, relationship status, no of children)   |
|  |   | Client mental well-being   | Kessler Psychological Distress Scale (K10) <sup>36</sup>  |
|  | Client psychosocial risk factors                        | Navigator intake interview (eg, health insurance status, mental health history, family violence, physical or social isolation) |   |
|  |   | Parental self-efficacy   | Me as a Parent-short form <sup>37</sup>   |
|  | •   | Quality of life  | Personal well-being Index <sup>38</sup>   |
|  | Daseime   | Help-seeking behaviours  | General Help-Seeking Questionnaire (GHSQ) <sup>39</sup>   |
|  |   | Self-compassion and self-care  | Parenting Research Centre questions (unpublished)   |
|  |   | Parent and infant bonding  | Mother-to-Infant Bonding scale (MIBS) <sup>40</sup>   |
| exit collected service   |   | Engagement with navigation programme   | Referral source, no and mode of contacts with navigator, service provided (eg, psychoeducation), no and type of referrals made  |
|  | service<br>data—exit                                    | Satisfaction with navigation services  | Three global questions from the Navigation Satisfaction Tool (NAVSAT) <sup>41</sup>   |
|  |   | Collaborative partnership with navigator   | Consultation and Relational Empathy measure <sup>42</sup>   |
| follow-up  | Routinely<br>collected<br>service<br>data-<br>follow-up | Client mental well-being   | Kessler Psychological Distress Scale <sup>36</sup>  |
|  |   | Engagement with referred service/s   | Me as a Parent-short form <sup>37</sup><br>Personal well-being Index <sup>38</sup><br>General Help-Seeking Questionnaire (GHSQ) <sup>39</sup><br>Parenting Research Centre questions (unpublished)<br>Mother-to-Infant Bonding scale (MIBS) <sup>40</sup><br>Referral source, no and mode of contacts with navigator, service<br>provided (eg, psychoeducation), no and type of referrals made<br>Three global questions from the Navigation Satisfaction Tool<br>(NAVSAT) <sup>41</sup><br>Consultation and Relational Empathy measure <sup>42</sup><br>Kessler Psychological Distress Scale <sup>36</sup><br>Type of service, frequency, ongoing or completed<br>Me as a Parent-short form <sup>37</sup><br>PWI <sup>38</sup><br>GHSQ <sup>39</sup><br>Parenting Research Centre questions (unpublished)<br>MIBS <sup>40</sup><br>Navigation Satisfaction Tool (NAVSAT) <sup>41</sup> |
|  | 'Snapshot<br>study'—<br>follow-up                       | Parental self-efficacy   | Me as a Parent-short form <sup>37</sup>   |
|  |   | Quality of life  | PWI <sup>38</sup>   |
|  |   | Help-seeking behaviours  | GHSQ <sup>39</sup>  |
|  |   | Self-compassion and self-care  | Parenting Research Centre questions (unpublished)   |
|  |   | Parent and infant bonding  | MIBS <sup>40</sup>  |
|  |   | Satisfaction with navigation<br>and referred service/s   | Navigation Satisfaction Tool (NAVSAT) <sup>41</sup>   |

developing a framework, indexing, charting and interpretation.<sup>33</sup> Coding and analysis will be conducted using NVivo V.12 software (QSR International).

Quantitative data will be collected from the programme'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, version 27 Statistics (IBM). For each of the key outcome measures (psychological distress (K10), parenting self-efficacy (MaaP-SF), personal well-being (PWI), help-seeking behaviour (General Help-Seeking Questionnaire), self-compassion and self-care (PRC questions) and mother-to-infant bonding), sensitivity analyses will be conducted prior to undertaking the main quantitative analysis (eg, 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 programme 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<sup>34</sup> guidelines. Power calculations suggest that with power of 0.80 and

alpha 0.05, a sample size of N=90 would enable detection Al training, of small-to-moderate effect size changes on key variables (eg, 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 Ś 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 (eg, metropolitan vs regional/ remote, and callers living in the different states and territories of Australia), intervention dosage (eg, number of **B** contacts with ForWhen navigator, duration from entry to exit, services provided).

Researchers conducting the evaluation will have access to deidentified 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 programme. Evaluation findings will be presented regularly to the programme steering committee and national director, with a view to improving the programme 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 programme. Navigation models have been adopted in a range of healthcare including PIMH,<sup>35</sup> 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 programmes such as ForWhen to enhance service connection and treatment for PIMH on a national scale, and help to inform sustainable and effective programme 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 programme objective for system-wide changes, and the observational nature of the evaluation component. Given that the ForWhen navigation programme 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 (eg, 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 programmes adopting similar models. Second, it will identify barriers and facilitators in successful navigation programme implementation on

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