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ORIGINAL ARTICLE

Protocol for a mixed methods process evaluation of the Promoting Resilience in Nurses (PRiN) trial

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ABSTRACT: Mental health nurses are exposed frequently to occupational stress and can experience a range of negative impacts on their well-being and intention to stay in the nursing workforce. Promoting Resilience in Nurses (PRiN) is a strength-based resilience education programme that incorporates evidence-based cognitive behavioural and interpersonal approaches with post-traumatic growth theory. A partially clustered randomized controlled trial at a large public mental health service will be used to examine the effects of PRiN on mental health nurses' coping self-efficacy, resilience, well-being, mental health, emotional regulation, post-traumatic growth, workplace belonging, and turnover intention as compared to controls. Process evaluations are increasingly used to help understand and interpret trial results for complex interventions. This paper describes the protocol for an embedded mixed methods process evaluation that aims to evaluate the PRiN programme implementation and identify factors that may explain variation in participant outcomes in the trial. Data collection includes a programme participant satisfaction survey; a follow-up semi-structured interview with selected programme participants; a unit/team manager survey on barriers and facilitators to staff recruitment and programme participation; and a fidelity checklist completed by programme facilitators. Normalisation Process Theory will be used to inform data analysis and integration. The findings will provide insights into factors that affect programme implementation, particularly in the context of the COVID-19 pandemic and may help explain differences in participant outcomes. Findings will also inform post-trial programme sustainability as well as potential future upscale and adaptation for implementation across healthcare settings.

KEY WORDS: COVID-19 pandemic, mental health nursing, process evaluation, randomized controlled trial, resilience programme.

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INTRODUCTION

This paper describes the study protocol of a process evaluation that aims to evaluate the implementation of the Promoting Resilience in Nurses (PRiN) resilience education programme for mental health nurses and to identify factors that may explain variation in participant outcomes. The process evaluation is being conducted in parallel with a partially clustered randomized controlled trial. This world-first trial examines the effect of PRiN on mental health nurses' coping self-efficacy, resilience, well-being, mental health, emotional regulation, post-traumatic growth, workplace belonging, and turnover intention in comparison with controls and in the context of a mentally and emotionally demanding work environment. The process evaluation will employ a mixed methods approach to gather data on the experiences of programme participants, and perspectives of programme facilitators and managers involved in recruiting staff into the PRiN trial. Normalisation Process Theory (NPT), a framework used to help explain the implementation of complex interventions in health settings, will inform data analysis and integration.

BACKGROUND

Maintaining a sustainable mental health nursing workforce is an ongoing challenge for many countries due to the undersupply of specialist mental health nurses (MHN) (Adams et al. 2021; Harrison et al. 2017). Recruitment in mental health nursing is challenging because of the global nursing shortage (Harrison et al. 2017; Redknap et al. 2015) and, more recently, because of the increasing care demand caused by the COVID-19 pandemic (Al Thobaity & Alshammari 2020). The mental health work environment is a further contributing factor, which has been associated with unpredictable risks to staff including interpersonal conflict with consumers and colleagues, client aggression, and suicidality (Foster et al. 2018). In addition, even though MHN comprise the largest proportion of the mental health workforce, mental health nursing is one of the least preferred specialist pathways for under-graduate and newly graduated nurses (Hooper et al. 2016; Hunt et al. 2020). Workplace stressors contribute to high turnover in the mental health nursing workforce compared with generalist nursing specialties (Huang et al. 2021; Redknap et al. 2015). Consequently, in Australia, there is a projected undersupply of approximately 18,500 MHN by 2030 (Health Workforce Australia 2014).

Further challenges for MHN include working in resource-constrained healthcare settings with ongoing staff shortages (Joubert & Bhagwan 2018), poor skill mix (Baker et al. 2019; Jones & Gregory 2017), lack of organizational support (Foster et al. 2021), and heavy workloads (Cosgrave et al. 2018; Foster et al. 2021). These negative impacts can accumulate and cause significant burnout, compassion fatigue, job dissatisfaction, and career dropout (Joubert & Bhagwan, 2018). They are also detrimental to staff health, well-being, and practice. Hsieh et al. (2018), for instance, reported that 76% of assaulted MHN show depressive symptoms, while Kelly et al. (2016) found that anger (in response to workplace conflict with consumers and colleagues) was strongly correlated with negative physical health outcomes (e.g. cardiovascular disorders and poorer health habits) for MHN. In addition, MHN have reported that high-quality nursing care and strong therapeutic relationships with consumers can be compromised in workplaces that are not supportive of staff well-being (Foster et al. 2020; Huang et al. 2021; Roviralta-Vilella et al. 2019).

The COVID-19 pandemic has added to these challenges (Foye et al. 2021; Ward-Miller et al. 2021). On the one hand, mental health consumers are presenting with higher acuity, more severe mood symptoms, and an increased risk for suicidality (Kameg 2021). On the other, MHN are required to adapt to the rapidly changing landscape of patient care, including managing health service disruptions to 'business as usual', implementing high-level infection prevention control, and adopting technology (e.g. telemedicine) into care delivery (Li & Zhang 2020; Ward-Miller et al. 2021). Foye et al. (2021) conducted a mixed methods survey with n = 897 UK mental health nurses and found that 61.4% were concerned about keeping up with the rapid adaptation of the health service, 53.5% worried about being infected with COVID-19 at work, and ~40% believed that service restructuring could prevent consumers from receiving appropriate and timely care. Other concerns related to COVID-19 included a lack of personal protective equipment (Foye et al. 2021), changes to electroconvulsive therapy protocols due to the aerosolizing nature of the procedure (Ward-Miller et al. 2021), visitor restrictions that negatively impacted consumers' mental health (Li & Zhang 2020; Ward-Miller et al. 2021), and consumers' resistance to infection prevention protocol (e.g. refusing to wear mask or breaching social distancing) (Ward-Miller et al. 2021). There has never been a more pressing time for the implementation of interventions to strengthen and

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rostered release of staff from the health service.

To ascertain participant outcomes, a self-report questionnaire data with all the outcome measures will be collected over three time points from the programme and control groups: on entry to the study (T1), after programme delivery (T2), and three months after the programme (T3). The statistical models will provide robust tests that isolate effects of the respective primary and secondary outcomes, while controlling for a

support the psychological well-being and resilience of MHN.

Resilience, originally viewed as an individual trait, can be understood as a dynamic process of recovery and positive adaptation in the face of adversity (Reich et al. 2010). As a process, it involves interactions between a person's internal resources and the available external resources they use to support themselves during times of stress (Reich et al. 2010). This interaction can promote thriving and positive well-being outcomes (Fletcher & Sarkar, 2013; Foster et al. 2019; Reich et al. 2010; Ungar 2011). Importantly, resilience can be learned and improved through education and training (Foster, Shochet et al. 2018; Ungar 2021). While a systematic review indicates growing evidence on the outcomes of resilience programmes for the wider healthcare workforce (Cleary et al. 2018), there is little evidence on the outcomes and implementation of resilience programmes for mental health nursing (Foster et al. 2019). An integrative review of international mental health nursing literature found one feasibility study and no reports of large scale trials of resilience programmes in this specialty field (Foster et al. 2019), with one small pre/post study reported with the UK forensic nurses since then (Henshall et al. 2020).

Foster, Shochet et al. (2018) conducted a worldfirst pilot of the antecedent Promoting Adult Resilience (PAR) (Shochet et al. 2008) workplace resilience programme with MHN. Key findings included that equipping MHN with cognitive, emotional regulation, relational resilience strategies significantly improved their coping self-efficacy, mental health, and resilience and had the potential of increasing work satisfaction and retention (Foster, Shochet et al. 2018). The programme was found to be feasible and acceptable, with programme facilitators reporting high levels of programme fidelity and participants reporting high levels of satisfaction (Foster, Shochet et al. 2018). The PAR programme was subsequently tailored specifically for the mental health nursing workforce and comprises the current Promoting Resilience in Nurses (PRiN) programme being trialled.

Promoting Resilience in Nurses (PRiN) – Partially clustered randomized controlled trial

This is the first randomized controlled trial internationally to combine mental health nursing and resilience research to proactively address the problem of mental health nurses' workplace stress and associated

range of potential confounds. The trial has been prospectively registered on the Australian and New Zealand Clinical Trials Registry (registration number ACTRN12620001052921).

Process evaluation of the PRiN partially clustered randomized controlled trial

To support interpretation of the trial outcomes and refine the programme theory (Moore et al. 2015), a parallel embedded mixed methods process evaluation is being conducted alongside the trial. Process evaluations can be conducted post-intervention or run parallel to intervention trials, and there are an increasing number of process evaluations being conducted in parallel to trials (Grant et al. 2013). The aim of a process evaluation is to understand trial processes or mechanisms related to context, setting, programme delivery, and participants that influence participant outcomes and acceptability of the programme, including participants' views and experiences of the usefulness and value of the programme (Byng et al. 2008). The findings from a process evaluation can help to explain any human and organizational factors that could influence programme participation, as well as to inform future design and upscale of the programme to other participant populations (May et al. 2018; Moore et al. 2015). Process evaluations commonly comprise mixed methods data collection, where both quantitative and qualitative data are collected to provide complementary forms of evidence. To address the objectives for each evaluation component in this study, a combination of surveys and interviews will be used to gather data (Grant et al. 2013). We will also apply a theoretical framework, the Normalisation Process Theory (NPT), at the analysis and integration stages to deepen understandings of the factors that influence uptake and implementation of PRiN into the health service (Moore et al. 2015). The aims of this mixed methods process evaluation are to evaluate PRiN programme implementation and identify factors that may explain variation in participant outcomes in the trial.

METHODS

Study design

A parallel embedded mixed methods process design (Grant *et al.* 2013) will be used to evaluate the implementation of the Promoting Resilience in Nurses (PRiN) programme, and to identify factors that may

explain variation in participant outcomes in the randomized controlled trial.

Theoretical framework – normalisation process theory (NPT)

NPT is defined as a 'middle range theory', a generalizable framework for understanding the processes and critical factors relating to the implementation, integration, and normalization of a set of practices into a healthcare setting, such as the PRiN resilience programme (May et al. 2016, 2018). The four main constructs of NPT (see Table 1) focus on important aspects of individual and collective behaviours that influence the implementation process of an intervention (May et al. 2018). NPT can be included at any stage of a research project lifecycle (May et al. 2018) and has been successfully applied to qualitative, quantitative, and mixed methods designs to inform research questions, data collection, and analysis, or used as a theoretical lens to assist with interpreting study findings (May et al. 2018; McEvoy et al. 2014).

There are two main ways NPT will be used for the current process evaluation: to describe the implementation context and to support interpretation and explanation of the evaluation findings. NPT has been used extensively in many studies as a framework to understand human and organizational contexts around trials (May et al. 2018). The context includes any external factors that may act as barriers or facilitators to the implementation of the programme or its effects on the intended targets or recipients (Moore et al. 2015). An intervention might produce different effects in different contexts; thus, understanding the context is critical for analysis and generalization of the intervention into other settings (Moore et al. 2015). Secondly, NPT will be used to inform the analysis and interpretation of the results, as described in the Data Analysis section of this paper. Similarly to Nordmark et al. (2016), we will set out a data matrix to match the four core NPT constructs against our data sources to examine the theory's suitability to the study.

Promoting Resilience in Nurses (PRiN) programme

The PRiN© programme was developed by Ian Shochet and colleagues at Queensland University of Technology and tailored specifically for mental health nursing, including programme content, activities, and audiovisual clips relevant to this specialty field. This

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Construct	Sub-construct	Description
1. Coherence	1.1 Differentiation	How the intervention and their objects are different from others
The work people do individually or collectively to make sense of the	1.2 Communal specification	Building a shared understanding of the aims, objectives and expected benefits of the intervention
intervention	1.3 Individual specification	Understanding the specific tasks and responsibilities around the intervention
	1.4 Internalization	Understanding the value, benefits, and importance of the intervention
2. Cognitive participation	2.1 Initiation	Whether key participants are working to drive the intervention forward
The relational work that people do to build and sustain a community	2.2 Enrolment	Strategies used to engage buy-in and sustain that engagement to secure implementation
of practices around the interven-	2.3 Legitimation	Participants believe it is right for them to be involved, and that they can make a valid contribution
	2.4 Activation	Participants collectively define the actions and procedures needed to sustain the intervention and to stay involved
3. Collective action The operational work that people	3.1 Interactional workability	Interactional work that people do with each other and with other elements of the intervention to operationalize it in everyday settings
do to enact the intervention	3.2 Relational integration	Knowledge work to build accountability and maintain confidence in the intervention
	3.3. Skill set workability	Allocation work that underpins the division of labour around the implementation
	3.4 Contextual integration	Allocation of resources, execution of protocols/policies and procedures
4. Reflexive monitoring Appraisal work people do to assess	4.1 Systematization	Collecting information to determine the effectiveness and usefulness of the intervention
and understand the ways the inter-	4.2 Communal appraisal	Participants evaluate the worth of the intervention together
vention affects themselves and others	4.3 Individual appraisal	Individual participants appraise the effect of the intervention on them experientially
	4.4 Reconfiguration	Redefining procedures or modifying practices

Adapted from May et al. (2015).

evidence-based programme has six modules and is delivered by trained facilitators (experienced senior MHN) face to face in a peer-group setting in 2×1 day workshops spread three weeks apart. The programme is multimodal and manualized, employing a range of teaching modalities including workbooks, PowerPoint, group discussion (large and small), and individual activities. 'Booster' activities are delivered by SMS to participants in between the two workshop days, as well as weekly activities for three weeks following completion of the final workshop. See Table 2 for an outline of the programme.

Setting

The study is being conducted in a tertiary metropolitan mental health service in Victoria, Australia. This is the largest public mental health service in the state, providing care across a catchment area with a population of over 1.5 million people. The service is comprised of six area health services spanning across the northern and western suburbs of Melbourne,

including nine mental health inpatient units and 19 mental health community teams. The service currently employs a total of 1144 registered and enrolled nurses.

Participants and recruitment

Programme fidelity checklist

To measure programme fidelity, all eight trained programme facilitators are eligible for recruitment. Relevant facilitators (two for each programme) will be approached by email prior to each programme, given participant information, and invited to complete hard copy fidelity checklists for each workshop.

Barriers and facilitators survey

To capture information from key organizational stakeholders on barriers and facilitators to staff recruitment into the study and programme participation, all managers and team leaders who have disseminated the study invitation to their staff will be eligible to take part in a survey addressing these issues. After each

TABLE 2 PRiN programme

Module	Content overview
1. We can all be resilient	Introduces programme, concept of resilience, and programme model
2. Cool and calm: understanding and managing stress	Identifies sources of stress and stress management and relaxation strategies
3. I am what l think and I can change what l think	Identifies unhelpful self-talk and strategies to challenge this and to think resiliently
4. Promoting positive relationships	Focuses on promoting harmony and practising empathic communication
5. Managing conflict and drawing strength from adversity	Ways to deal with conflict positively and drawing on support systems Explores post-traumatic growth and
6. Putting it all together	sense of belonging Focuses on creating well-being solutions and ending positively

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programme, relevant managers/team leaders will be invited by email to complete a brief online survey. The sample size will be determined by how many teams agree to be involved in the trial, estimated to be approximately $\sim n=25$.

Participant satisfaction survey

The sample size for the programme satisfaction survey is determined by the number of participants in each programme, which will be up to $\sim n=180$ registered and enrolled nurses during the study period. The inclusion criteria are enrolled or registered nurses employed at the health service at least 0.6 FTE who were randomized to the programme. They will be invited at the end of each programme to complete the survey.

Telephone semi-structured interview

On completion of each programme, to gain participants' perspectives on the programme, on the final page of the programme satisfaction survey, they will be invited to consent to be contacted for a follow-up semi-structured phone interview and to record their contact details. The contact details will be stored in a locked filing cabinet in the investigator's locked office. Based on the maximum total number of programme participants in the trial, up to three consenting participants per programme (i.e. up to n=30 participants) will be randomly selected for interview using simple random sampling method with a random number generator. We aim to reach data saturation during this process, where data become redundant and no new

information is found (Saunders $\it et~al.~2018$). However, saturation varies across studies and we will ultimately be guided by the data.

Data collection

Programme fidelity checklist

For each programme delivery, all consenting programme facilitators will be asked to complete the hard copy program fidelity checklist (~10 min). Consent will be implied through completion of the checklist. The checklist was originally developed by the PRiN programme developers. Programme fidelity is measured with ranking each aspect of the programme delivered from 'completed' to 'incomplete'. Facilitators also rate overall participant engagement and usefulness of activities in each programme module from 1/'not at all' to 5/ 'very', and to rank (1-3) each module from 'completed' to 'incomplete', with open-ended comment sections for all modules and overall comments for any factors affecting overall programme delivery including the venue, communication with participants, technical difficulties, or other factors.

Barriers and facilitators survey

Perceived barriers and facilitators to programme implementation will be measured through a brief (~5 min to complete) nine-item purpose-built online survey, with the survey link distributed to relevant managers by email. Based on the pilot study, the survey was developed by the researchers to elicit feedback on organizational factors affecting study recruitment participation. Four open-ended questions will ask stakeholders to identify facilitators, benefits, and barriers in relation to staff participation in the programme, and five questions will ask managers to rate on a fivepoint Likert scale from 'strongly disagree' to 'strongly agree' and provide brief explanation for their responses, on the process of inviting staff to participate in the trial, rostering issues related to staff participation, and perceptions about the programme's benefits to staff and their clinical practices.

Participant satisfaction survey

Programme satisfaction and perceived utility will be measured through a short (~10 min) hard copy survey given to participants at programme completion. The purpose-built survey was originally developed by the programme developers, trialled in the pilot study, and modified for the current programme. The survey comprises 15 quantitative survey questions and three short-

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answer open-ended responses. Participants are asked to rate on a five-point Likert scale ('not at all' to 'a great deal'), their experience of the programme, how the programme can be improved, the usefulness of the programme to help them manage stress and interpersonal conflict, and the value of the programme to their professional practice and personal life.

Telephone semi-structured interview

Participant perspectives on the personal and professional impacts of the programme will be elicited through a short (~30 min) follow-up audiotaped semistructured telephone interview. This method of interview was chosen as it is a viable and effective qualitative interview approach (Drabble et al. 2016) and is convenient and flexible for participants, particularly those spread across locations (Roller & Lavrakas 2015), as is the case for staff in this health service, which is located across a wide geographical area. Participants will confirm their informed consent through audio-recorded verbal assent prior to interview commencement. The interview contains five main topic areas, with prompts: two on participants' experience of the programme and helpful components of programme delivery, and three on the influence of the programme on their personal life and professional practice, including how COVID-19 has affected them and their practice in the health service. The interviews will be transcribed verbatim, de-identified, and integrated with written field notes following each interview.

Data analysis

Quantitative data

For the fidelity checklist, items will be descriptively analysed and reported according to percentage of completion, while participant engagement and item usefulness will be descriptively reported with mean and standard deviation. The satisfaction survey and the barriers and facilitators survey will also be analysed descriptively with means and standard deviations using the Statistical Package for the Social Sciences (SPSS) for Windows (IBM Corp, Armonk, USA). Findings from each data set will then be included for triangulation and data integration.

Oualitative data

Qualitative data will be organized and managed using NVivo software. Open-ended written data (fidelity checklist, manager survey, and participant satisfaction

survey) will be entered into an Excel spreadsheet. Interview transcripts and open-ended responses will be subjected to the six-stage thematic analysis by Braun and Clarke (2006) using an inductive approach in accordance with the exploratory nature of the study methodology. For each data set, the process involves researchers familiarizing with the data through immersion in data, reading for key concepts, and identifying preliminary themes. Next, codes and sub-codes will be generated and synthesized into categories and sorted into major themes. Each theme is anticipated to produce key findings for data integration. In addition. themes will be mapped onto the four main NPT constructs to facilitate interpretation of the overall results and draw conclusions on PRiN programme implementation in the health service.

Mixed methods analysis and integration

Integration is the interaction between qualitative and quantitative data and is an essential aspect of mixed methods research to obtain greater knowledge yield compared with independent analysis of the data (O'Cathain et al. 2010). Following the data triangulation protocol used by Farmer et al. (2006), each key finding from each data set will be matched against similar key findings from the other three data sets to create a 'convergence coding matrix'. We will then compare and triangulate the findings to establish whether they are in agreement (data converging), partial agreement (data complementing each other), dissonant (conflict exists between the data), or silent (only one data source contained the data) (Morton et al. 2021; O'Cathain et al. 2010).

Ethics

The trial and process evaluation have been approved by the Melbourne Health Office for Research (HREC/56912/MH-2020) and relevant University Human Research Ethics Committees (2020-127RC). All participants will receive relevant participant information and provide informed consent prior to data collection. Data will be de-identified and aggregated.

DISCUSSION

In this paper, we have described the study protocol for a parallel process evaluation in a partially clustered randomized controlled trial of the PRiN resilience programme for MHN. The evaluation has been designed to identify barriers and facilitators to PRiN

implementation and provide an understanding of organizational and staff-related factors that might influence trial outcomes. Publication of process evaluation protocols is considered 'best practice' and is important for improving the standards of trials (Moore *et al.* 2015). By publishing the study protocol, our methodological choices are made transparent and the importance of process evaluation in complex intervention trials is highlighted. This will be the first published process evaluation nested within the design of an intervention that aimed to improve the resilience of MHN. We anticipate the study will contribute new knowledge to the emergent literature of implementation research in the field of mental health nursing.

The strengths of this process evaluation include the use of a mixed methods approach to provide quantitative and qualitative data from a range of key stakeholders: programme participants, programme facilitators, and health service managers. By studying the implementation process using different methods and then triangulating the findings, we will obtain a more comprehensive understanding on factors that influenced implementation, how the programme was received, and participant views of the value of PRiN. Another strength of the evaluation is the use of the NPT framework to inform data analysis and to deepen understanding of influential factors of PRiN uptake and implementation into the health service. Formal theories and frameworks are often underused in process evaluations (McIntyre et al. 2020), even though they can provide sensitizing concepts that enhance understanding of how the intervention was integrated into practice and highlight the mechanisms that affect programme implementation and trial outcomes (Nilsen 2015). Using this framework in the current study will extend understandings of PRiN programme implementation in a large public mental health service. NPT has been used extensively in prior qualitative or quantitative studies, but only in a few mixed methods studies (May et al. 2018). The current study will be a valuable contribution to knowledge in demonstrating the applicability of the NPT framework to mixed methods research and to mental health nursing research.

As with all studies, there are some potential limitations. First, the study is being conducted in a large public metropolitan health service and the findings may not be generalizable to other contexts. It is also possible that participants with negative experiences will not participate, and this may limit feedback that would inform improvements in programme delivery and implementation.

CONCLUSION

This study will be the first theory-based process evaluation embedded in a partially clustered randomized controlled trial of the PRiN resilience education programme for mental health nurses in the Australian context. Outcomes of the evaluation will provide insights into the factors that affect the process of implementing the programme in a large public mental health service in the context of the COVID-19 pandemic and may help explain differences in participant outcomes. The study will add to better understandings on the value of process evaluation in mental health nursing research. Findings will also inform post-trial programme sustainability as well as potential future upscale and adaptation for implementation across healthcare settings.

RELEVANCE TO CLINICAL PRACTICE

The PRiN resilience education programme provides nurses with skills and strategies to improve their wellbeing and resilience. This is especially relevant for practice given the challenges posed by the COVID-19 pandemic for health services and healthcare professionals. This process evaluation will evaluate the implementation of the PRiN programme, identify factors that can help explain any variation in participant outcomes, and inform future dissemination of the programme to other health services. Findings on the implementation of a resilience programme in a large public mental health service may also positively impact the MHN workforce recruitment and retention crisis. The process evaluation will provide useful information on the value of resilience education for MHN in managing workplace stress, resolving interpersonal conflict, and maintaining their psychological well-being.

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