

# Primary Health Network Mental Health Reform Lead Site Project

# LINK-ME; FIRST REPORT

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Kritharidis, Ms Konstancja Densley, Mr Jan Faller, and Dr Elsa Barton.

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# List of abbreviations

AIHW	Australian Institute of Health and Welfare
CACE	Complier average causal effect
CI	Confidence interval
CN	Care navigator
Coef	Estimated coefficient
DST	Decision support tool
EQ-5D-5L	EuroQol 5-dimension quality of life Questionnaire (5-level version)
FACRRM	Fellow of the Australian College of Rural and Remote Medicine
FRACGP	Fellow of the Royal Australian College of General Practitioners
GAD-2	Generalised Anxiety Disorder scale (2-item version)
GAD-7	Generalised Anxiety Disorder scale(7-item version)
GLM	Generalised linear model
GP	General practitioner
ICER	Incremental cost-effectiveness ratio
IRSAD	Index of Relative Socio-economic Advantage and Disadvantage
ITT	Intention to treat the minimum
К10	Kessler Psychological Distress Scale
MBS	Medicare Benefits Schedule
NTC	National trial coordinator
PBS	Pharmaceutical Benefits Scheme
PHN	Primary Health Network
PHQ-2	Patient Health Questionnaire (2-item version)
PHQ-9	Patient Health Questionnaire (9-item version)
PMHC MDS	Primary Mental Health Care Minimum Data Set
QALY	Quality adjusted life year
RR	Rate ratio
RTC	Regional trial coordinator
SD	Standard deviation
SMD	Standardised mean difference (also known as Cohen's d)
VAS	Visual analogue scale

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# **Executive summary**

#### **Introduction to Link-me**

Link-me is a systematic approach to stepped mental health care designed for delivery in general practice. It begins with a Decision Support Tool (DST) that uses a prognostic algorithm drawing on 23 self-report items to predict the likely severity of an individual's depressive and anxiety symptoms in three months' time. Patients complete the Link-me DST on a tablet device in their GP waiting room and receive feedback on their responses, an opportunity to identify mental health treatment priorities and reflect on their motivation to address these, and a treatment recommendation matched to their predicted symptom severity:

- Minimal/mild symptoms: low intensity service options matched to treatment priorities
- Severe symptoms: up to eight structured contacts with a trained health professional (care navigator) to develop and implement a structured care plan that meets patient needs. Care navigators receive brief training in motivational interviewing techniques and are supported to put these techniques into practice by a structured care planning tool embedded in a digital platform. They work as a clinical companion to the GP and have access to care package funding to provide financial support where cost is a barrier to care.

#### Recommendations

In an Australian-first individually randomised controlled trial, we worked with 3 PHNs and 23 general practices in 3 states to test the Link-me model of stepped mental health care. The trial saw over 15,000 primary care patients complete an eligibility screening survey in their GP waiting room. Of these, 2,100 went on to complete the Link-me DST, and 420 were offered care navigation. We found that the Link-me approach was well received and lead to improved mental health outcomes at low additional cost, with greater improvements seen the more elements of care navigation delivered. The trial therefore provides gold-standard evidence to support the Link-me approach to system design. We recommend:

- 1. That the Link-me approach to stepped mental health care be implemented via PHNs in a staged roll-out. PHNs could be resourced to identify general practices that would benefit most from implementing the Link-me approach.
- 2. That the Link-me approach should be considered for any new greenfield developments in adult mental health care, and could be investigated as an option for adult mental health centres.
- 3. That following the success of the Link-me approach with English-speaking primary care consumers, further investment is made in refining it for communities where languages other than English are spoken.
- 4. That following the success of the Link-me approach in mainstream general practice, consideration be given to how it could be refined for use within Aboriginal Community Controlled Health Services.

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To support these recommendations, we provide an implementation checklist (Appendix 10) identifying core components of Link-me that are required for delivery at scale, and specific activities to be conducted within each.

#### **Evaluation approach**

The evaluation of Link-me was informed by data collected through five key sources:

- 1. Link-me portal: including self-report surveys about demographics and clinical outcomes completed by all participants at trial enrolment and 6 months later, and care navigator notes.
- 2. Semi structured interviews (with regional trial coordinators, care navigators, GPs, and patients) about the Link-me experience, plus site visits to participating general practices.
- 3. GP and practice surveys: providing contextual information about the trial setting.
- 4. Meetings and workshops: conducted regularly with trial coordinators and care navigators to support the implementation of Link-me and address issues as they arose.
- 5. PHN and University records of the costs associated with Link-melimplementation.

These data sources were used to address five primary evaluation questions:

- 1. How was the clinical care coordination model (as defined above) for people with severe and complex mental illness implemented and what were the barriers and enablers?
- 2. Does clinical care coordination produce improved outcomes and experiences of care for people with severe and complex mental illness who are being managed by GPs in primary care?
- 3. What are the costs of delivering clinical care coordination for people with severe and complex mental illness who are being managed by GPs compared with usual care?
- 4. What are the costs, patient experiences and outcomes of streaming people with lower levels of clinical need who present to GPs for mental health assistance into low intensity services within a stepped care model?
- 5. To what extent is it feasible to implement nationally a decision support tool that guides GPs in identifying high and low need patients presenting for mental health assistance?

#### **Summary of findings**

#### **Clinical outcomes**

Over 24,000 patients were invited to take part in the Link-me trial. After excluding those who declined or were ineligible, the final sample comprised 1,671 participants (aged 40 years on average, 72% female) who were evenly classified into the minimal/mild and severe symptom groups by the Link-me DST, and randomly allocated to receive the Link-me intervention or usual care. Of the 420 people allocated to care navigation, 216 (51%) participated in at least one structured contact with a care navigator.

We found that overall, Link-me resulted in greater reductions in psychological distress at 6 months than usual care, with a standardised mean difference (also known as an effect size) of -0.10 (95% CI - 0.18 to -0.01). We observed no difference between arms in the minimal/mild symptom group, but

an effect size of -0.26 (95% CI -0.44 to -0.09) in the severe symptom group. This effect size increased with the number of elements of care navigation received.

We did not observe significant differences on secondary outcomes (including depression and anxiety severity and quality of life), however the pattern of results was consistent with the hypothesis that on average, the Link-me improved mental health outcomes over usual GP care.

#### **Experience of Link-me**

Barriers and enablers were identified in relation to three aspects of the implementation of Link-me, including uptake (at the practice and patient level), embedding the approach in the general practice (in particular, embedding care navigators), and engagement (of both patients and GPs with care navigators).

Patients in the minimal/mild group gave positive feedback about Link-me, expressing that it raised awareness of mental health issues and gave them a sense that GPs were open to talking about mental health concerns. These patients all found the Link-me DST easy to complete and useful, but there was variability in whether they recalled receiving information about relevant services.

The Link-me experience was also largely a positive one for patients allocated to care navigation. Where negative experiences were identified, these often related to structural issues (e.g., long wait lists, staff turnover at PHNs, and transport difficulties). Patients reported increased self-awareness from completion of the Link-me DST which was enhanced through conversation with care navigators, and suggested that an action plan increased their knowledge of supports and services and helped to developed greater insight and the opportunity for self-reflection. Patients reported greater feelings of connection as additional services and packages were put into place, and indicated a sense of increased self-confidence to maintain actions and plans beyond care navigation.

#### Costs

Just over one quarter (27%) of patients allocated to care navigation were approved for care package funding, and received an average of \$669 each.

We examined health sector costs (i.e., those spent on medical services, paid by patients or third parties) and total societal costs (i.e., health sector costs plus the cost of lost productivity). We found that Link-me was associated with higher mean health sector costs than usual care, by \$24 (95% CI \$8.3 to \$43.8) per person across all participants, and \$333 (95% CI \$125 to \$623) per person for the severe symptom group. We observed no significant differences in societal costs and or quality adjusted life years for the overall population or by symptom subgroups.

Across all participants, we observed an incremental cost per 1-point decrease in K10 score of \$1,018 (95% CI \$259 to \$10,471) from the health sector perspective and \$1,282 (95% CI Dominant to \$21,964) from the societal perspective. For the severe symptom group the incremental cost per 1-point decrease in K10 score was \$896 (95% CI 234 to 3,978) from the health sector perspective and \$1,359 (Dominant to 8,677) from the societal perspective.

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# 1. Background

#### 1.1. Chapter overview

This chapter sets the scene for this report, providing context to the evaluation of Link-me described in subsequent chapters. We discuss policy reforms in primary care and mental health care, the selection and focus areas of Primary Health Network mental health reform leaders, and the larger evaluation of activities conducted by these leaders in relation to the planning, integration and delivery of mental health services (in which this evaluation is nested). We close by presenting the objectives and primary questions guiding this evaluation, which the rest of the report seeks to address.

## 1.2. Primary mental health care reform

Inter-related sets of policy reforms in primary and mental health care have seen a significant shift in primary mental health care delivery in Australia in recent years. A 2014 review of Medicare Locals identified a need for fewer such meso-level organisations, improved clarity of vision and purpose, and greater integration of care with general practice at the centre [1]. As a result, the following year saw the 61 Medicare Locals dismantled and 31 Primary Health Networks (PHNs) established in their place. The objective of PHNs is to 'increase the efficiency and effectiveness of medical services for patients, particularly those at risk of poor health outcomes, and to improve coordination of care to ensure patients receive the right care in the right place at the right time [2].' Their mandate is to achieve this objective by understanding the needs of their communities, supporting GPs and other primary care providers in a variety of ways so that they can offer optimal care, and purchasing or commissioning services [2]. PHNs have an explicit focus on those in their communities who are most in need, including people with mental illness [2].

Mirroring these broader primary care reforms, a 2014 review of mental health programs and services identified a need for enhanced integration of mental health care, greater emphasis on the role of general practice, and a more targeted approach to matching the intensity of service provision to individual need [3]. The Australian Government's response to that review [4] led to an expanded role for PHNs in the planning and commissioning of primary mental health care services, via what is known as the Primary Mental Health Care Activity (the Activity) [5]. The Activity contributes to the objectives of the larger PHN Grant Program by 'increasing the efficiency and effectiveness of primary mental health and suicide prevention services for people with or at risk of mental illness and/or suicide, and improving access to and integration of primary mental health care at the right time' [5].

Under the Activity, pooled funding was made available to PHNs for service commissioning in six mental health priority areas – low intensity services; psychological therapies for underserviced populations; child and youth services; services for adults with severe and complex mental illness; Indigenous mental health services; and suicide prevention [5]. A commitment to two approaches to service delivery was expected to deliver positive outcomes:

- 1. Improved integration through the development of evidence-based regional mental health plans and service mapping to identify needs and gaps, reduce duplication, remove inefficiencies and encourage integration.
- 2. The implementation of person-centred stepped mental health care, in which a range of service types is available such that individuals can be matched to a level of care appropriate to their needs, making the best use of available workforce and technology within local regions [5].

## **1.3. The Primary Health Network Mental Health Reform Lead Site Project (Lead Site Project)**

All PHNs are funded to commission primary mental health services in the above priority areas, but 10 were selected to act as mental health reform leaders in the PHN Mental Health Reform Lead Site Project (Lead Site Project). These PHNs (Lead Sites) were tasked with providing enhanced services in nominated key focus areas (e.g., by fast-tracking their activity in these service areas, establishing different partnerships and funding arrangements, and/or trialling innovative approaches in terms of types and modes of commissioned services). The key focus areas are listed below (the first two are overarching areas, and the next three are service delivery areas).

- 1. Regional planning and service integration;
- 2. Stepped care;
- 3. Low intensity services;
- 4. Services for youth with or at risk of severe mental illness (youth enhanced services); and
- 5. Clinical care coordination for adults with severe and complex mental illness.

All 10 Lead Sites provided enhanced services in the first three of these areas, while a small number were selected to also focus on youth enhanced services and clinical care coordination (Table 1).

<sup>&</sup>lt;sup>1</sup> Suicide prevention activities sit outside the Lead Site Project, but are the focus of a parallel project known as the National Suicide Prevention Trial. Like the Lead Site Project, the National Suicide Prevention Trial involves selected PHNs providing enhanced suicide prevention activities. It involves 12 PHNs, four of which are also Lead Sites (Brisbane North, North Coast, North Western Melbourne, and Perth South).

#### Table 1. Lead site focus areas

	Regional planning / service integration	Stepped care	Low intensity services	Youth enhanced services	Clinical care coordination
Group 1					
Central Eastern Sydney	$\checkmark$	✓	✓		
Eastern Melbourne	$\checkmark$	$\checkmark$	$\checkmark$		
Murrumbidgee	✓	✓	✓		
Perth South	$\checkmark$	$\checkmark$	$\checkmark$		
Group 2					
Australian Capital Territory	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
South Eastern Melbourne	✓	✓	$\checkmark$	✓	
Tasmania	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
Group 3			0	_	
Brisbane North	$\checkmark$	$\checkmark$	1 AL		$\checkmark$
North Coast	$\checkmark$	$\checkmark$	1/2 of	1	$\checkmark$
North Western Melbourne	$\checkmark$	1	ED LANS		✓

## 1.4. Evaluation of the Lead Site Project

The evaluation of the Lead Site Project was guided by the Lead Site Project Evaluation Framework [6], and was conducted to gather information on the approaches taken by Lead Sites to the planning, integration and delivery of mental health services, and to identify the implications for future government policy and the activities of PHNs more generally.

The overall evaluation comprised two major parts (Part A and Part B), each with separate reporting requirements. Part A related to the first four of the five focus areas (regional planning and service integration, stepped care, low intensity services, and youth enhanced services). Data to inform this part of the evaluation were collected within all 10 Lead Site PHNs between September 2017 and April 2019, with the final report submitted in July 2019 [7].

Part B related to the fifth focus area (clinical care coordination for adults with severe and complex mental illness) and is the subject of this report. Only the Group 3 Lead Sites were involved in this part of the evaluation, and worked with the University of Melbourne to deliver and test the efficacy of a systematic approach to stepped mental health care and clinical care coordination based in general practice (this approach is henceforth referred to as Link-me).

#### **1.5. Objectives**

The Evaluation Framework outlined five objectives for Part B [6]:

- Describe the process of implementing a clinical care coordination model for people with severe and complex mental illness who are managed principally in general practice settings, delivered within a stepped care approach that matches services to patient need;
- b. Evaluate the cost and benefits of implementing this model in terms of:
  - The quality and outcomes of care;

- The costs to Government, providers and patients of service delivery compared with usual care;
- The patient experience of care, including take-up rates and the patient's journey through the care pathways set up by clinical care coordination; and
- Utilisation of mental health related services
- c. Assess the extent to which savings accrued from streaming people presenting to GPs for mental health assistance who have low needs for mental health care to less intensive service options will offset any additional costs of clinical care coordination and individually tailored care packages for people with severe and complex mental illness;
- d. In undertaking the above, develop a national decision support tool that can be used in all three PHN Lead Sites to assist GP practices in the stratification of patients presenting for mental health assistance, particularly targeted at the identification of severe and complex mental illness; and
- e. Identify the economic and service delivery implications of a national roll-out of the clinical care coordination model for future national policy directions in primary mental health care including possible changes to the Medicare Benefits Schedule (MBS) Better Access program.

## **1.6. Evaluation questions**

The Evaluation Framework outlined six primary evaluation Questions that guided the design and reporting of the Part B evaluation [6], as follows:

- 1. How was the clinical care coordination model (as defined above) for people with severe and complex mental illness implemented and what were the barriers and enablers?
- 2. Does clinical care coordination produce improved outcomes and experiences of care for people with severe and complex mental illness who are being managed by GPs in primary care?
- What are the costs of delivering clinical care coordination for people with severe and complex mental illness who are being managed by GPs compared with usual care?
- 4. What are the costs, patient experiences and outcomes of streaming people with lower levels of clinical need who present to GPs for mental health assistance into low intensity services within a stepped care model?
- 5. To what extent is it feasible to implement nationally a decision support tool that guides GPs in identifying high and low need patients presenting for mental health assistance?
- 6. What are the financial implications of the trial if a similar approach was implemented nationally?

This report addresses the first five of these questions using data collected between November 2017 and June 2019. At the time of writing, data collection was ongoing and due for completion in December 2019. Therefore while this report touches on question 6, a fully informed response to this question requires the complete dataset and as such will be provided in the final report to be submitted in July 2020.

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## 1.7. Summary

Recent mental health and primary care reforms aim to improve the efficiency and effectiveness of mental health care through providing an enhanced role for PHNs in this space. A small number of PHNs have been selected as mental health reform leaders in nominated key focus areas, with three allocated the focus area of clinical care coordination for adults with severe and complex mental illness. From 2017 to 2019, these three PHNs collaborated with the University of Melbourne to test the efficacy of clinical care coordination as delivered within a systematic approach to stepped mental health care in general practice (Link-me). The Link-me approach is described in detail in the next chapter.



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# 2. What is Link-me?

## 2.1. Chapter overview

As noted in the previous chapter, Link-me is a systematic approach to stepped mental health care in general practice. Here, we provide further information on why the Link-me approach is needed, and describe the Link-me decision support tool used to triage patients to an appropriate level of care. We then provide detail on these levels of care, including the clinical care coordination model offered to people with severe and complex needs, and provide an overview of the digital support platform underpinning the Link-me approach.

## 2.2. Background

Evidence shows that the majority of mental health problems are identified and managed in general practice [8], with approximately one quarter of Australian general practice patients reporting clinically significant mental health symptoms [9]. The nature of these symptoms varies widely, however, and a range of illness trajectories are evident [10]. Managing both the volume and heterogeneity of mental health presentations in general practice presents a substantial challenge, and both under- and over-treatment is common [11-13].

Stepped care approaches aim to address treatment mis match and deliver the least intensive intervention that will be effective for the individual's level of need; for those with more severe or complex needs, this may mean high intensity support to promote recovery. Stepped care is both a focus of current Australian policy reform as described in the previous chapter, and recommended by clinical guidelines [14]. While there is some evidence to suggest that stepped care is more effective than usual care in reducing the severity of depression and anxiety in primary care [15,16], there is as yet no consensus on the design of delivery of stepped care for mental health in primary care. Variation in the number of steps, content, care provider, and duration is evident, but the more fundamental difference is the step at which individuals enter the metal health care system. In this regard, two categories of stepped care exist; one in which all individuals requiring care are initially allocated to the lowest intensity treatment and sequentially 'stepped up' to the next level after failing to improve, and another in which the initial level of care is matched to symptom severity. The latter approach, also referred to as 'matched care' has the potential to considerably reduce time and distress for the individual affected [15]. However, it can also require significant work and specialised training on the part of the GP to determine the appropriate level of care, presenting a barrier to implementation [17,18].

There is a clear need for the development and testing of stepped care approaches that fit into the workflow of general practice and support GPs with the burden of their work rather than add to it. The Link-me approach to stepped care has been developed through 15 years of research involving hundreds of consultations with GPs, patients, and other relevant stakeholders to understand how mental health problems present and are managed in Australian primary care (for a full list of relevant work, refer to Appendix 1). It aims to overcome some of the limitations of previously reported stepped care models discussed above while retaining elements that appear promising (e.g., coordination by non-mental health specialists, lower steps comprising self-help across different

modalities, and higher steps comprising integration of multiple care providers). At its core, Link-me centres around the use of a brief patient-completed Decision Support Tool (DST) to predict the future severity of mental health symptoms and triage patients into level of care appropriate to their predicted symptom severity. In addition, by incorporating the principles of motivational interviewing [19] throughout, it also aims to encourage self-reflection, provide hope, and motivate individuals to engage with their own mental health care.

## 2.3. Decision support tool

The Link-me DST is a prognostic triage tool designed to be completed by adults in the general practice setting, using a tablet device. Its presentation was developed through an iterative development process employing user-centred design principles to ensure the information is presented in a way that is meaningful and engaging [20]. Example screenshots are presented in Appendix 2.

The Link-me DST builds on the previously developed *diamond* clinical prediction tool which predicts the severity of depressive symptoms at three months [21,22]. Adaptations to the *diamond* tool were made following advice from an Expert Advisory Panel that it include the prediction of anxiety symptoms as well as depression. By predicting the severity of both these common mental health conditions, the Link-me DST addresses the majority of mental health presentations in the Australian population [23]. The tool is designed to adopt a biopsychosocial approach to prognosis and comprises 23 items<sup>2</sup> assessing current depressive symptoms, current anxiety symptoms, lifetime history of depression, gender, living situation, ability to manage on available income, self-rated general health, and presence of chronic illness that affects the ability to carry out daily activities.

Two prognostic models embedded within the Link-me DST use an individual's responses to these items to predict symptom scores for anxiety and depression at three months. Based on their predicted score, individuals are classified into one of three symptom severity groups (minimal/mild, moderate, and severe). Given that an individual may be classified into different severity groups for anxiety and depression, a hierarchy was developed for the combined group which favours the more severe of the two, as depicted in Table 2. Our preliminary modelling using data from our *diamond* and Target-D studies [21,22] suggested that overall, approximately 65 percent of people would be stratified into the minimal/mild symptom severity group, 15 percent into the moderate group, and 20 percent into the severe group.

<sup>&</sup>lt;sup>2</sup> The *diamond* clinical prediction tool, on which the Link-me DST was based, comprised 17 items and predicted depression only. The additional 6 items relate to current anxiety symptoms and are included in the prognostic model for anxiety.

**Table 2.** Hierarchy of Link-me predicted symptom severity group classifications

	No anxiety symptoms	Mild anxiety symptoms	Moderate anxiety symptoms	Severe anxiety symptoms
No depressive symptoms	Not eligible	Minimal/mild	Moderate	Severe
Mild depressive symptoms	Minimal/mild	Minimal/mild	Moderate	Severe
Moderate depressive symptoms	Moderate	Moderate	Moderate	Severe
Severe depressive symptoms	Severe	Severe	Severe	Severe

Following completion of the 23 Link-me DST assessment items, individuals receive:

- A two-part reflection of their responses to these items, with separate summaries provided under the text "things seem to be OK for you in these areas right now" and on the next page, "things seem to be difficult for you in these areas right now". Feedback is provided across 13 content areas assessed by the Link-me DST and presented using both text and icons developed to reflect these content areas (Appendix 2).
- An opportunity to select mental health treatment priorities, where multiple 'difficult' areas are identified. Instructional text suggests that it can be difficult to work on many issues at once and that selecting one or two to focus on might be more achievable. To further encourage treatment engagement, individuals are then asked to reflect on the importance making changes in these areas, and their confidence in doing so.
- A treatment recommendation matched to their predicted symptom severity; either care navigation for those predicted to experience severe symptoms or low intensity services for those predicted to experience minimal/mild symptoms.<sup>3</sup>

# 2.4. Symptom severity-matched treatment

#### **2.4.1.** Low intensity services

Individuals predicted to have minimal/mild symptoms of depression and anxiety in three months' time are provided with low intensity service options across four modalities, including online, telephone, mobile app, or in-person services available in the local community (see example screenshot in (Appendix 2). The service options are matched to the areas of difficulty identified in the Link-me DST and/or prioritised by the participant. Initial service options were selected through consultation with the relevant PHN and are based on evidence of the effectiveness of the service itself (e.g. MindSpot [24]), the principles underpinning it (e.g. a cognitive behavioural therapy-based app), or the behaviours it facilitates (e.g. a local walking group to encourage exercise) [25]. Service options presented to individuals in this symptom severity group are drawn from an easily updated

<sup>&</sup>lt;sup>3</sup> Note that the Link-me DST also identifies a third group (those with moderate symptoms whose scores fall between the cut-offs for the minimal/mild and severe symptom groups); for the purposes of the current evaluation, this group are encouraged to discuss any mental health concerns they may have with their GP.

Excel spreadsheet that sits behind the Link-me digital support platform (see section 2.5 below). This spreadsheet is intended for regular updates to ensure accuracy and promote new services to individuals as they are established (through PHN commissioning or otherwise).

As well as viewing their treatment recommendations on the tablet device in their general practice immediately after completing the Link-me DST, individuals predicted to have minimal/mild symptoms are also emailed a copy of the recommendation with links to the relevant services, to refer back to as needed.

#### 2.4.2. Care navigation

Individuals identified as being likely to experience severe symptoms of depression or anxiety in three months are offered a model of clinical care coordination delivered in general practice referred to as care navigation, in which a trained health professional (care navigator) works collaboratively with patients and GPs to develop and implement a structured care plan that meets patient needs. The care navigator does not need to be a mental health specialist and is embedded in the general practice to act as a clinical companion to GPs, providing short-term assistance to identify and link patients in with appropriate services.

This intervention is informed by the principles of collaborative care, defined as: a) a multiprofessional approach, b) a structured management plan, c) scheduled patient follow-ups to foster uptake and engagement and provide opportunity for monitoring and review, and d) enhanced interprofessional communication [26] (Figure 1) Collaborative care is an augmented form of patient care first developed by Katon and colleagues in the United States [27] and is a regular feature in stepped care models [15]. However, while it has demonstrated effectiveness in improving mental health outcomes in primary care [28] it tends to target medication adherence rather than addressing patients' broader psychosocial needs and to date has not been successfully implemented in routine care (likely due at least in part to the level of specialist involvement required and associated costs). Link-me care navigation seeks to overcome these limitations by the addition of a digital support platform as a lifth key component of collaborative care (Figure 1). This platform supports the both the systematic identification (using the Link-me DST) of people who may be appropriate for this intervention, and the delivery of the intervention itself (see section 2.5 below for further details). Link-me care navigation is further informed by recognition that people with severe mental health symptoms often have multiple interacting physical, mental and social needs that present significant challenges to care and often result in poor clinical outcomes [29,30]. The intervention has therefore been designed to improve access to appropriate mental health treatment as well as to lifestyle and other interventions (e.g., community-based social supports) that might address other health and social issues that are affecting the person's mental health.

#### Figure 1. Conceptual model of care navigation



The conceptual model of care navigation onlined above is operationalised as depicted in Figure 2, with core features including:
The delivery of up to eight structured contacts to develop and implement a structured care

- The delivery of up to eight structured contacts to develop and implement a structured care plan (referred to as an 'action plan') to address the priorities the individual identified in the Link-me DST. These contacts may be in the form of a telephone or face-to-face appointment (conducted at the practice), depending on patient preference. Reminders of upcoming contacts are sent via phone, email, or SMS, and care navigators follow up with non-attenders to reschedule. As shown in Figure 2, for the majority of these structured contacts, the focus is generally expected to be on the implementation of the plan, including reviewing progress and providing support to identify and access appropriate services;
- An explicit person-centred focus, with development and implementation of the action plan led by the patient's own priorities and goals. These may be articulated spontaneously or elicited with assistance from the care navigator, using the principles of motivational interviewing;
- Close collaboration between the care navigator and GP, with the care navigator acting as clinical companion to the GP and the GP retaining final responsibility for endorsement of the action plan. Care navigators also seek advice from GPs as to whether and how to engage particular individuals;
- Access to additional funding (if required) via a 'care package' as described below;
- Explicit short-term involvement of the care navigator, with a clear plan for the GP and patient to continue working towards the patient's goals after the end of the care navigator's

involvement in the patient's care. This will generally occur after approximately three months, but the exact duration of care navigation is flexible and can be adapted to patient need.





\* F2F = face to face

This model of care navigation has been designed to be delivered by a registered health professional such as a registered nurse, and does not require specialist mental health training. To help patients identify what they want to achieve, and develop a plan for how to do so, care navigators receive training in the principles of motivational interviewing [31], as well as regular refresher sessions and written resources to refer to (including a manual outlining the approach and activities to be undertaken within care navigation, and motivational interviewing techniques used to achieve these). Importantly, the care navigator role is not one that provides mental health treatment (e.g., psychological therapy). Rather, the key role of the care navigator is to act as a clinical companion to the GP and to support the patient to set goals within their Link-me DST-identified priority areas, identify actions to take to meet these goals, and access services as required. For many patients,

these services might include those available through existing programs and funding sources (e.g., mental health professionals, drug and alcohol services, allied health). For others, a care package may be required to improve access to care. Patients may shift their goals and identified actions over the course of care navigation as need to meet their mental health needs.

#### 2.4.2.1. Care packages

Link-me care navigators have access to care package funding to assist patients to access services that are identified as necessary to improve the patient's mental health outcomes but may not currently accessible due to out of pocket costs. In the current model, care package funding is held by PHNs and care navigators submit requests to access funding for an individual according to a Department of Health guidance document outlining how and when this funding may be used (Appendix 3). Care packages are notionally allocated at an amount of AU\$2,000 per patient, although the total pool of funding is designed for flexible use across the population of care navigation recipients. The intention behind care package funding is that purchased services are typically those delivered by a clinical health professional, but funding may also support access to services delivered by others as ancillary to formal health care. This may include, for example, additional or alternative psychological services, other health professionals such as exercise physiologists or dietitians peer support services, vocational or educational support services, yoga or mindfulness courses, family support services, other individual assistance provided through community support agencies and gap payments for specialist care that cannot be accessed through other channels. Under the Link-me model, services accessed through care packages should generally be either evidence-based, or encourage behaviours or activities which have been shown to be effective in managing mental health [25]. Goods, inpatient care, and services funded through existing programs are out of scope. As noted above, GPs retain responsibility for endorsement of action plans and therefore use of care package funding is contingent on GP agreement that the nominated service may improve the person's mental health.

## 2.5. Digital support platform

Supporting the Link-me approach to care is a secure online platform comprising two interfaces. The first enables general practice patients to complete the Link-me DST using a tablet device. The second, an administration interface, auto-populates with patients completing the Link-me DST in real time, providing care navigators and GPs with immediate access to contact details and Link-me DST results for patients allocated to both minimal/mild and severe symptom groups. For those in the minimal/mild group, GPs and care navigators can also view information on the low intensity services recommended to the patient. For those in the severe symptom group, the online portal supports care navigators to step through the process of developing a structured care plan. It includes motivational interviewing-inspired prompts to enquire about and record the patient's current situation and past history (including medical, social, and psychological factors), consider treatment preferences, check current symptoms (including suicidality if indicated) and review Link-me DST responses, set treatment goals and identify actions to take, and review progress. At each contact, care navigators can add to or change the plan as needed, with each update saving as a separate file so previous versions can be reviewed at any time. Action plans can be downloaded as a PDF and printed for the patient to take home and refer back to as needed, and shared with the GP (e.g., via uploading to the patient's medical record at the practice) and other health professionals involved in

the patient's care as necessary. Care navigators can also record details of each contact with or on behalf of a patient, including duration, modality, and their reflections on what went well and any challenges they faced.

## 2.6. Summary

Link-me is a multifaceted, digitally-supported model of stepped care which aims to improve the efficiency and effectiveness of primary mental health care, by providing a systematic approach to triaging care at the general practice level. Key components include:

- A person-centred, motivational interviewing-informed approach
- Estimation of future depressive and anxiety symptom severity using purpose-developed prognostic algorithms (drawing data from the Link-me DST)
- Feedback to individuals on their Link-me DST responses
- An opportunity for individuals to set mental health treatment priorities
- A treatment recommendation matched to symptom severity group; either care navigation or low intensity services.
  - navigation or low intensity services.
     Care navigation for individuals predicted to have severe depressive/anxiety symptoms in three months: Up to eight structured contacts with a trained and registered health professional to develop and implement a care plan that is tailored to patient preferences, plus care packages to provide financial support where needed to access appropriate services.
     Low intensity services for individuals predicted to have minimal/mild
  - Low intensity services for individuals predicted to have minimal/mild depressive/anxiety symptoms in three months: Evidence-informed interventions that minimise or eliminate specialist contact time.

The Link-me approach to care as described above has been developed through extensive consultation with GPs, practice staff, primary care attendees with symptoms across the mental health spectrum, and other relevant stakeholders. Its effect on clinical outcomes, costs, and experiences of care is the subject of this evaluation, the approach to which is detailed in the next chapter.

# 3. Approach to the evaluation of Link-me

#### 3.1. Chapter overview

This chapter provides a comprehensive outline of the methodology used to evaluate the Link-me approach to care, including its effect on clinical outcomes, costs, and patient experiences. We describe the evaluation design and primary objectives, staffing and IT infrastructure supporting the evaluation, and the data sources used to address the primary evaluation questions. We then describe the setting the evaluation was conducted in, and the process by which participants were identified and enrolled.

## 3.2. Design

This evaluation used a stratified individually randomised controlled that design. General practice patients were randomly assigned to one of two trial arms, which received either:

- The Link-me intervention as described in Chapter 2 (including Link-me DST feedback, priority setting, and severity-matched treatment recommendations), with participants free to follow their treatment recommendation or not (hereafter, the intervention arm); or
- Usual care, plus some attention control in the form of a prompt on the tablet device to speak with their GP regarding any concerns they have about their mental health, and an emailed list of contacts for community based resources and services (hereafter, the comparison arm).

GPs were notified only of those patients allocated to the intervention arm (in both symptom severity groups), with notifications provided in writing by the care navigator using a standardised template<sup>4</sup>. All participants, regardless of symptom severity group or trial arm were free to continue or modify any treatment they were receiving at entry to the trial.

While the evaluation overall includes follow-up of individual participants at 6 and 12 months after they complete the Link-me DST, this report presents data collected from evaluation commencement to the conclusion of 6-month follow-up only (spanning the period July 2017 to June 2019). Details of the 12-month data collection activities and findings will be presented in a subsequent report, to be submitted in July 2020.

#### 3.2.1. Objective

The randomised controlled trial design afforded the opportunity to conduct simultaneous outcome, economic, and process evaluations of the Link-me approach to care. For the outcome evaluation, the

<sup>&</sup>lt;sup>4</sup> The approach to providing these written notifications varied depending on the preferences of the individual GP or their practice and was discussed and agreed upon at the commencement of care navigation in each practice.

primary objective of the trial was to determine the effect of Link-me on psychological distress at six months. Secondary objectives were to assess its effect on quality of life, days out of role, depressive symptoms, and anxiety symptoms.

The cost effectiveness evaluation aimed to estimate both the within-trial costs as well as develop a full economic model to evaluate population-level costs and effects.

Finally, for the process evaluation we aimed to understand the how and why of the results of the outcome evaluation (that is, what worked best in Link-me for whom, in what circumstances and when, and what were the contextual factors that supported or hindered this). Further, it aimed to explore any process issues that could potentially impact on a wider rollout and future implementation. A specific framework developed for examining implementation issues was selected for this purpose called Normalisation Process Theory [32]. This framework is explained in detail in the published protocol [33] and informed the findings presented in this report.

#### 3.2.2. Link-me portal

For the purposes of this evaluation, additional trial-specific components were incorporated into the online portal described in Chapter 2 including:

- Plain language statements and consent procedures in accordance with the National Statement on Ethical Conduct in Human Research [34], Participants consented to the trial by entering their name, date of birth, and contact details.
- Randomisation function, triggered automatically after the participant provided consent and completed the 23 Link-me DST assessment items, ensuring allocation concealment and minimising reporting and selection bias. The allocation sequence was computer-generated consecutively, using a biased coin algorithm [35], with allocation stratified by general practice and by predicted depressive and anxiety symptom severity at three months, as determined by the Link-me DST. This ensured that there were approximately equal numbers of participants in each trial arm within each symptom severity group.
- Follow-up data collection, with links to online surveys sent via automated email to all participants 2 weeks before their due date for the 6-month assessment.

#### 3.2.3. Staffing

Key roles in the Link-me trial, and the responsibilities associated with each, are described in Table 3. Note that the duration of trial involvement reflects the overall period of involvement for the relevant role and not necessarily the individuals filling it. In total, 37 people were employed to fill the roles in Table 3 over the course of the trial: two national trial coordinators (NTCs), four regional trial coordinators (RTCs), ten care navigators (CNs), sixteen recruitment assistants, and five survey assistants.

Not included in Table 3 but no less crucial to the implementation and evaluation of the Link-me trial were general practice staff including GPs, reception staff, and practice managers; PHN staff including managers and primary care liaison teams; and Department of Health staff who supported all aspects of the trial.

Table 3. Link-me staff roles and responsibilities

Role	Employer	Duration of trial involvement	Key responsibilities
National trial coordinator	University of Melbourne	July 2017 – December 2019	<ul> <li>Support practice recruitment and training</li> <li>Monitor and troubleshoot participant recruitment at all sites</li> <li>Monitor and support follow-up survey completion and uptake of care navigation</li> <li>Respond to care package queries (in vs out of scope)</li> <li>Attend trial meetings and report regularly to the Department of Health on progress</li> </ul>
Regional trial coordinator	PHNS	July 2017 – March 2019 (plus ad hoc oversight of care package payments until June 2019)	<ul> <li>Recruit general practices and consent and train practice staff (including those who join after initial training)</li> <li>Provide NTC with practice and GP names local low intensity service options</li> <li>Recruit care navigators and support in orienting to role and PHN</li> <li>Monitor participant recruitment at each practice</li> <li>Ensure trial and practice staff are adhering to trial protocol</li> <li>Support care navigator in accessing PHN-commissioned services</li> <li>Oversee development and approvals of care packages</li> <li>Attend trial meetings and report regularly to NTC on progress</li> </ul>
Care navigator	PHNs	July 2017 – March 2019	<ul> <li>Champion trial in practice</li> <li>Assist with patient recruitment</li> <li>Support practice staff with patient queries about the trial</li> <li>Support patients allocated to care navigation, as described in Chapter 2, including navigating available services and arranging care package funding</li> <li>Attend trial meetings and report regularly to RTC and NTC on progress</li> </ul>
Recruitment assistant	PHNs	April 2018 – October 2018	<ul> <li>Offer tablet device to all adults in general practice waiting room</li> </ul>
Survey follow-up assistant	University of Melbourne	May 2018 – December 2019	<ul> <li>Contact Link-me participants via phone, text, and email to encourage follow-up survey completion</li> </ul>

Note: NTC = National trial coordinator; RTC = Regional trial coordinator

As noted in Chapter 2 (section 2.4.1), the care navigator role was designed to be filled by a nonmental health specialist, and we developed a position description in consultation with the PHNs who ultimately recruited five registered nurses, two pharmacists, two psychologists, and one social worker to the role. All care navigators in the trial received a 1.5-day, face-to-face introductory training workshop in the Link-me approach to care (half day) and the motivational interviewing techniques used to support patients to develop action plans (full day). They were also provided with two face-to-face motivational interviewing refresher training sessions (see section 3.3.4 below) and a monthly 1-hour teleconference, where they had an opportunity to share experiences and seek input and advice from the motivational interviewing trainer. Following these meetings, all care navigators were provided with written motivational interviewing resources relevant to the questions raised (as required).

#### 3.3. Data sources

Data used to inform this report were drawn from five<sup>5</sup> key sources overtwo years, as depicted in Figure 3 and discussed in turn on the pages that follow.

<sup>5</sup> The Link-me evaluation overall is also informed by a sixth data source, not presented here. All Link-me participants are asked to provide consent for the research team to access routinely collected data about their use of health services and prescription medicines through the Medicare Benefits Schedule (MBS), Pharmaceutical Benefits Scheme (PBS), Primary Mental Health Care Minimum Data Set (PMHC MDS), and headspace. Permission is being sought to access these databases for the period 1 October 2016 to 31 December 2019. Consenting to provide access to this data is optional and participants can consent to provide access to all, none, or some of these databases. The consent process is ongoing and will conclude in December 2019, with requests made to the relevant bodies shortly thereafter and findings presented in the final report to be submitted July 2020.





**3.3.1.1.** Patient surveys Self-report survey data were collected between November 2017 and June 2019 and were provided by Link-me participants at two timepoints: at trial enrolment and six months later.<sup>6</sup> The enrolment survey can be considered in two parts; the brief eligibility screening survey completed by all general practice patients who took up the offer to complete it, and the baseline survey completed by those who were eligible for the trial and consented to take part. As mentioned above, the eligibility screening survey provided information on:

- Demographic characteristics: age, gender, Indigenous status, language spoken at home, highest level of education completed, labour force participation, health care card status.
- Clinical characteristics: depressive and anxiety symptom severity, use of medication for • mental health.

<sup>&</sup>lt;sup>6</sup> Participants complete a third survey at 12 months post trial enrolment; data collection for that survey is ongoing and will be presented in the final report as above.

Data collected within the baseline survey included the participants' reason for GP consultation, items required for the Link-me DST (including general health, living situation, financial stability, and depression history), and trial outcome measures as outlined in Table 4.

Outcome measure	Construct assessed	Number of items	Score range	Higher scores indicate
Kessler Psychological Distress Scale [K10: 36]	Psychological distress	10	10-50	Greater psychological distress
K10 extension items [K10+: 37]	Days out of role due to psychological distress	2	0 – 28	More days out of role
Patient Health Questionnaire – 9-item version [PHQ-9: 38]	Depressive symptom severity	9	0-27	More severe depression
Generalized Anxiety Disorder scale [GAD-7: 39]	Anxiety symptom severity	7	10-21 10-21	More severe anxiety
EuroQol 5-dimension quality of life questionnaire [EQ-5D- 5L: 40]		RELEAS	KALTH	
Utility weights	Quality of life	PIN5OF	0-1	Better quality of life
Visual analogue scale (VAS)	Overalthealth	ME 1	0 - 100	Better health

 Table 4. Summary of primary and secondary Link-me outcome measures

Note: The K10+ comprises four extension items but only two relate to days out of role. The first two items of the PHQ-9 and GAD-7 were completed as part of the eligibility screening survey and were not re-administered within the baseline survey.

At 6 months, participant Surveys comprised the measures in Table 4 plus an assessment of health service and other resource use [RUQ: 21,41,42] including the frequency, location and out of pocket costs for use of relevant health services, and the impact of mental health problems on productivity. These data were used to inform the cost effectiveness analysis. 6-month survey completion was encouraged using a range of strategies including automated email reminders, phone calls and text messages, the option of completing the survey over the phone or in hard copy, and finally, the option to complete only the K10 (i.e., the primary outcome measure).

#### 3.3.1.2. Care navigator notes

Between November 2017 and March 2018, for participants in the severe symptom group allocated to the intervention arm, care navigators recorded data relevant to care navigation through completion of structured forms in the Link-me portal. Data were entered into the portal during participant contacts, or transcribed soon thereafter, and included:

- Participants' current situation and past history (including medical, social, and psychological factors);
- Participants' treatment experiences and preferences;
- Current symptoms (K10)<sup>7</sup>;
- Treatment goals, planned actions, and required resources and referrals;
- Progress reviews; and
- Suicide risk assessments.

After each contact with, or on behalf of, a care navigation participant, care navigators also recorded information about the duration and modality of the contact and reflections on what went well and the challenges they faced in delivering the intervention.

In addition, after the commencement of the trial a general notes form was added to allow care navigators to record information that they did not consider a good fit for the structured forms above but felt was relevant to the delivery of care navigation. An upload function was also added to allow care navigators to upload documents relevant to participant's ongoing care, including but not limited to a handover summary provided to the treating GP.

### 3.3.2. Interviews and site visits

In order to inform the process evaluation of Link-me, between December 2018 and June 2019 we conducted a series of semi-structured telephone interviews with RTCs, CNs, and GPs and combined this information with notes taken during site visits to participating practices. Data collected through interviews and site visits included the experience of those involved in Link-me, as well as challenges and enablers to the implementation of the model.

In addition to implementation experiences we collected data with participants in the intervention group triaged to care navigation or low intensity services across the three PHNs and who had completed their 6-month survey. Further details of the process for inviting and conducting interviews are available in Appendix 4.

## 3.3.3. GP and practice surveys

At the time of general practice recruitment (which occurred over 12 months from August 2017), a representative from each practice was asked to complete a brief survey to allow a description of the trial sites. A separate survey was provided to individual GPs in order to collect data on characteristics such as their age, gender, country of graduation, years in general practice, proportion of consultations conducted in English or other languages, and their usual approach to mental health care.

### 3.3.4. Meetings and workshops

This data source includes minutes of regular meetings with RTCs and CNs, which were held from August 2017 (for RTCs) and November (for CNs) to February 2019. These meetings, conducted via teleconference, were initially held weekly before moving to a fortnightly schedule in June 2018 to

<sup>&</sup>lt;sup>7</sup> As part of the structured approach to care planning described in Chapter 2.4.1 (see especially Figure 2), care navigators were encouraged to engage participants in regular symptom monitoring through re-administration of the K10 at each contact. These assessments were designed to support care navigators and participants reflect on whether the action plan was appropriate (i.e., whether further supports were needed in the case of non-improvement over time) and were in addition to the administration of the K10 within the patient surveys completed at trial enrolment and 6-month follow-up.

allow longer meetings and more in-depth discussion of the issues at hand. Additional meetings were scheduled as required to discuss particular issues as they arose.

Joint RTC and CN workshops were held quarterly, and varied in both location and topic as shown in Table 5. Data collected at these workshops and used to inform this evaluation include observations and notes, photos, documents drafted within workshops, and feedback forms.

Date	Торіс	Location
14 November 2017	Motivational interviewing skills refresher, risk assessment, working in general practice	University of Melbourne
20 February 2018	Motivational interviewing skills refresher, patient and practice recruitment troubleshooting	North Coast PHN
8 June 2018	Enhancing GP and patient engagement in care navigation	North Western Melbourne PHN
21 September 2018	Modelling and mapping the process of care navigation	Department of Health

#### **3.3.5. PHN and University records**

Data collected by PHNs throughout the trial included information on:

- Care navigator employment, including salary, duration of employment and time fraction;
- Care packages, including the process of obtaining funding and making payments, and details of the care packages paid; and
- General practice recruitment, including the approach to recruitment, number of practices visited, reasons for non-participation.

Finally, we maintained records of costs associated with the establishment of Link-me (e.g., DST development, staff training, and purchase of tablet devices provided to general practices).

Table 6 on the following page provides an overview of the relationship between the data sources presented above and the primary evaluation questions, including an indication of where to find relevant information within this report.

**Table 6.** Primary evaluation questions, the data sources used to address them, and the relevant chapter of this report

Eva	luation question	Report chapter	Patient surveys	Care navigator notes	Patient interviews	Implementer interviews / site visits	Practice / GP surveys	Meetings / workshops	PHN / University records
1.	How was the clinical care coordination model for people with severe and complex mental illness implemented and what were the barriers and enablers?	5	✓	✓	NDER	✓	✓	~	
2.	Does clinical care coordination produce improved outcomes and experience of care for people with severe and complex mental illness who are being managed by GPs in primary care?	4,5	V	PELEA	HPC TH				
3.	What are the costs of delivering clinical care coordination for people with severe and complex mental illness who are being managed by GPs compared with usual care?	6	HASH	FIN MANY	< X				✓
4.	What are the costs, patient experiences and outcomes of streaming people with lower levels of clinical need who present to GPs for mental health assistance into low intensity services within a stepped care model?		ON FEP	<	~				
5.	To what extent is it feasible to implement nationally a decision support tool that guides GPs in identifying high and low need patients presenting for mental health assistance?	~ 7		✓		✓	$\checkmark$	~	✓
6.	What are the financial implications of the trial if a similar approach was implemented nationally?	n/a							✓

Note: Question 6 will be addressed in the final report submitted in July 2020, using the full trial dataset

## 3.4. Setting

RTCs in each PHN led the recruitment of general practices, typically in consultation with primary care liaison teams within their organisation. Initially, practices were eligible to take part if they: 1) saw at least 100 adults aged 18–75 per day; 2) used patient medical records software (to enable patient records to be easily updated with information relevant to Link-me participation); 3) agreed to a care navigator working in the practice to provide support for patients triaged into the severe symptom group; and 4) agreed to follow the trial protocol. The first two of these criteria were relaxed after insufficient eligible practices were identified.

Recruitment activities included both universal and targeted approaches. The former included, for example, placing expression of interest advertisements in PHN publications sent to all practices within the catchment. The latter included primary care liaison teams sending emails directly to practices they felt would meet the eligibility criteria. RTCs reported follow-up contact (via phone, email, and/or practice visits) with a total of 76 practices, 23 of which ultimately took part in the trial. In order to protect anonymity, each practice was assigned a unique number and is referred to by this identifier throughout this report. Key characteristics of these practices are summarised in Table 7 below.

	n 🖉	> (%)
Practice location		REXO
Rural	S'A	(39.1)
Suburban	12	M <sup>1</sup> (52.2)
Urban	$2^{\circ}$	(8.7)
IRSAD decile - Mean (SD)	ON 6Y	(3.0)
Type of practice		
Private general practice	20	(87.0)
Corporatised general practice	1	(4.3)
Community health centre	0	(0.0)
Other	2	(8.7)
Billing model		
Bulk bill	12	(52.2)
Mixed	11	(47.8)
Co-located services		
Psychologist	11	(47.8)
Counsellor	1	(4.3)
Practice nurse	15	(65.2)
Other	3	(13.0)

 Table 7. Self-reported characteristics of Link-me general practices (N = 23)

Note: Counts (n) and percentages (%) presented unless otherwise indicated. SD = standard deviation; IRSAD = Index of Relative Socio-economic Advantage and Disadvantage; scored from 1-10 where low scores indicate relatively greater disadvantage and lack of advantage and high scores indicate relative lack of disadvantage and greater advantage. Co-located services are not mutually exclusive and percentages therefore sum to greater than 100.

Within the 23 participating practices, 167 GPs consented to take part in the trial and returned the survey about their professional background, interests, and approaches. A summary of the key characteristics of these GPs is presented in Table 8 below, with detailed information about GPs' usual approach to managing mental health care available at Appendix 5.

	n	(%)
Gender		
Male	91	(54.8)
Female	75	(45.2)
Place of graduation		
Australia	87	(52.4)
Overseas	79	(47.6)
Location of working in general practice		
Australia only	109	(65.3)
Australia and overseas	58	(34.7)
FRACGP / FACRRM	111	(66.9)
Time spent on mental health skills training (past year)		
<1 hour	20	(12.2)
1-5 hours	66	(40.3)
6-10 hours	37	(22.6)
11-20 hours	17	(10.4)
>20 hours	24	(14.6)
Received assistance in completing mental health treatment plans	19	(11.7)
From a mental health nurse	5	(3.0)
From a practice nurse	2	(1.2)
From a medical student	2	(1.2)
From a psychiatrist	3	(1.8)
From another GP	2	(1.2)
Other A A A A A A A A A A A A A A A A A A A	5	(3.0)
	Mean	(SD)
Age (years)	48	(13)
Years in general practice		
In Australia	15	(14)
Overseas (n = 58)	3	(5)

Table 8. Key characteristics of Link-me GPs (N = 167)

Note: n = count; SD = standard deviation; FRACGP = Fellow of the Royal Australian College of General Practitioners; FACRRM = Fellow of the Australian College of Rural and Remote Medicine.

## 3.5. Participants

Link-me participants were recruited in the waiting room of each participating general practice. The duration of participant recruitment in each practice ranged from 3 to 49 weeks (Figure 4), with an average of 21 weeks. Some differences across PHNs were evident; participant recruitment occurred for an average of 28 weeks per practice in PHN A, 26 weeks in PHN B practices, and 9 weeks in PHN C practices. During this period, practices saw an average of 261 adult patients per week (range 149 – 516)<sup>8</sup>.





**Dates of participant recruitment** 

Adult patients attending participating practices during the recruitment window were assessed for eligibility via a two-stage process. First, recruitment staff engaged patients in a brief discussion to establish whether the person was:

- Aged 18–75 years;
- Sufficiently proficient in English to participate;
- Able to provide a phone number and email address;

<sup>&</sup>lt;sup>8</sup> This figure is based on data provided by 18 of the 23 practices; at the time of writing four practices were still being followed up and their data will be included in the final version of this report. One practice has closed since the conclusion of participant recruitment and therefore was unable to be contacted to provide this data

- A Medicare card holder (i.e., a permanent resident of Australia and therefore eligible for federally funded healthcare); and
- Able to provide informed consent.

Recruitment staff were encouraged to approach adult patients in the waiting room, regardless of their reason for presentation. They were, however, encouraged to use their judgement and not approach patients who were demonstrating signs of acute health problems (e.g., vomiting or in obvious pain). These patients were not excluded from the trial and recruiters could consider approaching them at another time (e.g., on their next visit to the practice).

All patients who indicated to the recruiter that they met the above criteria were invited to take part in the second step of the eligibility screening process. This entailed completing a brief survey on a hand-held tablet device. The survey comprised a series of demographic questions as well as a brief assessment of current mental health need. Patients were eligible for Link-me if they reported at least one of the following:

- a score of 2 or more on the 2-item version of the Patient Health Questionnaire [PHQ-2: 43];
- a score of 2 or more on the 2-item version of the Generalised Anxiety Disorder scale [GAD-2:
   44]; or
- current use of medication for mental health problems.

Patients who did not meet these criteria were exited from the survey at the point at which they were no longer eligible for the trial. They saw a screen that thanked them for their time and requested that they return the tablet device to reception. Recruiters were trained to check in with patients who agreed to complete the survey and offer assistance or answer questions where required.

Following this two-stage screening process, eligible patients received an invitation to take part in Link-me. On the tablet device, they read a plain language statement about the trial and were asked to give consent to participate (see 3.2.2). Patients who completed this form went on to complete the Link-me DST on the tablet device. Those who were classified into the minimal/mild or severe symptom groups were randomly allocated to either the intervention or comparison arm and are henceforth referred to as Link-me participants.<sup>9</sup>

### 3.5.1. Sample size

The primary outcome for the Link-me outcome evaluation was the difference in mean K10 scores between the intervention and comparison arms at 6 months. The target sample size allowed for sufficient power to undertake the primary analysis as well as sub-group analyses examining differences between trial arms within symptom severity groups. As fewer participants were anticipated to be allocated to the severe symptom group, the critical number was identified as being 352 participants per trial arm in the severe symptom group at baseline (or 704 participants in the

<sup>&</sup>lt;sup>9</sup> Patients who completed the Link-me DST and were classified into the moderate symptom group were not randomised; instead, all received advice to consult their GP about mental health concerns as described in the previous chapter. Patients falling into this group are not therefore considered Link-me participants in the true sense, although they were asked to complete the same 6-month follow-up survey as the randomised cohort in order to inform further validation of the prognostic algorithms embedded in the Link-me DST.

severe symptom group overall). Achieving this target was expected to result in a total sample size of approximately 1,498 and provide sufficient power (significance level = 5%, 2 sided hypothesis) to explore the clinical effectiveness of Link-me both within and across symptom severity groups, with clinical effectiveness defined as a standardised mean difference of 0.3 (or approximately 2.4 points on the K10; for further detail refer to Appendix 6).

## 3.6. Approvals and registration

The Link-me trial was approved by the University of Melbourne Human Research Ethics Committee (ID: 1749832).<sup>10</sup> The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ID: 12617001333303) in September 2017, with the combined statistical analysis plan for the outcomes and economic evaluations [45] uploaded to ACTRN in June 2019.

## 3.7. Summary

As a randomised controlled trial conducted within 23 general practices across three PHNs in Victoria, New South Wales and Queensland, this evaluation provided a unique opportunity to examine the operation of the Link-me DST, and the clinical outcomes, cost effectiveness, and experiences of the implementation of Link-me overall and the interventions within it. The trial aimed to recruit 1,498 participants; adults attending participating general practices were invited to complete a brief online survey on a tablet device, allocated to a predicted symptom severity group, and randomised to receive either the Link-me intervention or usual GP care. The evaluation is informed by a range of data sources providing both qualitative and quantitative data. The chapters that follow address five of the six primary evaluation questions using data collected to 6 month follow-up, and provide more detailed descriptions of the approach to analysis taken in each case.

<sup>10</sup> Request for consent to access MBS and PBS data was approved by the Commonwealth Department of Human Services (ID: MI8420).

# 4. Clinical outcomes

## 4.1. Chapter overview

This chapter presents data relevant to evaluation questions 2 and 4, examining the outcomes for both people with severe and complex mental illness and those with lower levels of clinical need. We provide a brief overview of the statistical analysis used to assess the effectiveness of Link-me on clinical outcomes at 6 months compared to usual care. This is followed by a descriptive summary of the flow of participants through the trial and comparison of the demographic and clinical characteristics of participants in each trial arm (intervention and comparison), both within and across symptom severity groups. The priority areas selected at baseline by participants in the intervention arm are also presented. Finally, in section 4.6 we provide the results of primary and secondary analyses, demonstrating the effect of Link-me on psychological distress, anxiety, depression, days out of role, and quality of life at 6 months. This section also considers the influence of different intervention elements on the effectiveness of care navigation.

**4.2. Data sources** Data presented in this chapter were collected from patient Surveys completed in the Link-me portal at baseline and 6 months. At baseline, this included importance and confidence scaling conducted within the Link-me DST, using a visual analogue scale where 1 = not at all important / confident and 10 = totally important / confident. The elements of care navigation delivered to each participant were assessed using information recorded in the care navigator portal (including number of structured care navigation contacts, content of action plans and free text notes, and GP handover documents) and data provided by PHNs on the care packages approved and funded.

# 4.3. Approach to analysis

In line with best practice for conducting randomised controlled trials, analyses reported in this chapter were conducted according to the publicly available statistical analysis plan [45]. All analyses were completed using Stata [46,47].

Primary analysis included all randomised participants regardless of whether they received all, part, or none of the treatment they were recommended, using multiple imputation to account for missing outcome data (see Appendix 6 further details). We estimated differences (and 95% confidence intervals) in mean K10 scores between the intervention and comparison arms using multiple linear regression, adjusting for baseline scores and symptom severity group. We also report standardised mean differences (SMDs, also known as Cohen's d [48]) to characterise the magnitude of differences in the outcome means between the trial arms (i.e., the effect size). For the K10 score where improvement is associated with lower scores, a SMD of zero is interpreted as no difference between trial arms, while a SMD of less than zero indicates a greater improvement in the intervention than the comparison arm (overall, the further away from zero, the greater the effect). Conversely, a SMD greater than zero indicates that an intervention is less effective that the comparator. To examine if missing outcome data and clustering of participants within general practices would impact the estimated between-arm differences in mean K10 score, we conducted two sensitivity analyses; the

first included only people who completed the relevant measure at 6 months; the second used the same subsample and adjusted for general practice as well. All analyses were conducted for the sample as a whole and within symptom severity groups, and were repeated for the secondary outcomes (PHQ-9 scores, GAD-7 scores, EQ-5D-5L VAS and utility scores).

For participants in the severe symptom group, we also conducted a series of complier average causal effect (CACE) analyses, to assess the magnitude of the benefit of receiving the different elements of care navigation. Care navigator and PHN records were reviewed for documented evidence of the following being delivered to each participant allocated to care navigation:

- 1. Participation in at least one structured contact with a care navigator and there was a match between the participant's priorities and the action plan they developed;
- 2. **#1 and** the care navigator recommended a specific and new referral or resource to the participant;
- 3. #2 and the participant was approved for care package funding; and
- 4. #3 and the approved funding was spent.

Using this hierarchy, four separate CACE analyses were conducted to examine the influence of each additional element of care navigation on psychological distress at 6 months. Where the primary analysis examines the effect of *offering* care navigation to participants (but they may receive none, some or all the elements of care navigation), CACE analysis investigates the effect of *receiving* these elements of the intervention.

## 4.4. Baseline characteristics

Figure 5 shows the flow of general practice patients through the trial from invitation to 6-month follow up. Over 24,000 patients were invited to complete the eligibility screening survey, representing one quarter (range 3% to 68%) of the total patient population seen in practices during the recruitment period<sup>11</sup>. About two thirds of patients who were invited to complete the eligibility screening survey did so, and around half of those screened were eligible for the trial (for a comparison of screened patients were and were not eligible see Appendix 7)<sup>12</sup>. Just over 2,000 patients went on to complete the Link-me DST, of whom 20% reported moderate symptoms and were excluded from further analysis<sup>13</sup>, resulting in a final baseline sample of 1,671 participants who were randomly assigned to the intervention and comparison arm. The mean age of participants was 40 years (range 18 to 74 years) and consistent with the epidemiology of depression and anxiety [49] and the general practice patient population [50], the majority (72%) were female. Overall, the

<sup>&</sup>lt;sup>11</sup> Estimate based on total patient numbers provided by 18 practices and the number of patients invited to complete the eligibility screening survey in these practices only. Data collection relevant to this point is ongoing and this estimate will be updated in the final version of this report.

 $<sup>^{12}</sup>$  80% of patients were excluded due to having no mental health need (i.e., no current depressive or anxiety symptoms or use of medication for mental health). The other 20% of eligibility screening survey completers were excluded due to being outside the age range for the trial (18 – 75). This group were exited from the survey after meeting this exclusion criterion and therefore other demographic information and level of mental health need amongst this group is unknown.

<sup>&</sup>lt;sup>13</sup> As noted on page 13, while this group was excluded from the trial analyses, they completed all baseline measures and were asked to complete the 6-month follow-up survey. For the interested reader, characteristics of this group are presented at Appendix 8.

proportion of trial participants reporting Aboriginal and Torres Strait Islander descent (3.8%) was not dissimilar to the Australian population (3.3%) [51].

The Link-me DST classified 830 (50%) of participants into the minimal/mild symptom group and 841 (50%) into the severe symptom group. This even split was in contrast to our expectations; based on modelling conducted during Link-me DST development we expected the minimal/mild group to account for around three quarters of participants (see section 2.3 and Appendix 6). There may be several reasons for this unexpected result; the targeted recruitment of general practices in high needs areas, the selective recruitment of patients within practices, and the expansion of eligibility criteria from our previous Target-D trial [21] on which much of this modelling was based. Specifically, people with anxiety symptoms but not depression and those taking antipsychotic medication were eligible for Link-me but not Target-D, and this may have skewed the sample towards poorer mental health overall. Note that the apparently disproportionate number of participants classified into the severe symptom group may also reflect this group attending the GP more frequently and therefore having greater opportunity to be recruited to the trial [8,10]. It is also important to remember that the proportions of people classified into each symptom severity group are based only on people randomised within the trial and exclude patients with no symptoms of moderate symptoms. Taking these patients into account, both symptom severity groups would account for a much smaller proportion of the total general practice population.

. with no symptoms , with no symptoms , in severity groups would a , actice population.



#### Figure 5. Participant flow through the trial to 6 months

Table 9 shows the baseline characteristics of the participants by the two trial arms, for all trial participants and within each symptom severity group. There are two key observations to note here. First, the two trial arms were similar in their demographic and clinical profiles, overall and within each symptom severity group, indicating that randomisation was effective in balancing prognostic factors of the outcome at baseline and minimising selection bias. Hence, any observed mean outcome differences between trial arms at 6 months that is larger than would be expected by chance alone can be attributed to the intervention effect. Second, the minimal/mild and severe symptom groups differ in the expected directions, demonstrating that the Link-me DST triaged

participants appropriately. For example, for every two people of Aboriginal descent allocated to the severe symptom group, only one was identified to have minimal/mild symptoms. Participants in the severe symptom group were also more likely to report lower levels of education, to be out of the labour force (and the reason for that to be their own health), to hold a health care card, and to find it difficult or impossible to manage on their income. Almost everyone in the severe symptom group indicated a history of depression, over half were on medication for their mental health, and over half were seeing the GP in relation to their mental health (either alone or in combination with their physical health) on the day they were recruited to the Link-me trial.

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**Table 9.** Baseline characteristics of Link-me participants according to trial arm, in total and stratified by symptom severity group (N = 1671)

	All participants (comparison) (N = 837)	All participants (intervention) (N = 834)	Minimal/mild (comparison) (N = 416)	Minimal/mild (intervention) (N = 414)	Severe (comparison) (N = 421)	Severe (intervention) (N = 420)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	39.5 (14.8)	39.7 (15.1)	40.3 (15.1)	41.0 (15.5)	38.7 (14.5)	38.5 (14.6)
Psychological distress (K10)	24.6 (9.6)	24.6 (9.7)	17.3 (4,7)	16.9 (4.3)	31.9 (7.5)	32.2 (7.3)
Depressive symptom severity (PHQ-9)	11.7 (6.7)	11.7 (6.9)	5.9 (2.6)	5.8 (2.4)	17.4 (4.5)	17.5 (4.6)
Anxiety symptom severity (GAD-7)	9.4 (5.7)	9.5 (5.7) 🖉	5.2 (2.8)	5.2 (2.8)	13.4 (4.8)	13.7 (4.5)
Overall health (EQ-5D-5L VAS)	61.2 (22.1)	58.8 (23.4)	73.0 (16.7)	71.7 (18.1)	49.6 (20.6)	46.1 (21.0)
Quality of life (EQ-5D-5L utility weights)	0.60 (0.29)	0.59 (0.30)	0.78 (0.16)	0.78 (0.17)	0.42 (0.28)	0.40 (0.29)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Days totally out of role (K10+)	1 (0 to 5)	(0 to 5)	0 (0 to 1)	0 (0 to 1)	5 (1 to 12)	5 (1 to 14)
Days partially out of role (K10+)	4 (0 to 12)	3 (0 to 10)	1 (0 to 4)	0 (0 to 4)	8 (3 to 14.5)	7 (2 to 14)
	n (%)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	n (%)	n (%)	n (%)	n (%)
Gender		0, <u>8</u> ,				
Male	236 (28.2)	221 (26.5)	119 (28.6)	106 (25.6)	117 (27.8)	115 (27.4)
Female	600 (71.7)	609 (73.0)	297 (71.4)	307 (74.2)	303 (72.0)	302 (71.9)
Other	2(0.1)	4 (0.5)	0 (0.0)	1 (0.2)	1 (0.2)	3 (0.7)
Indigenous status	NS H B					
Aboriginal	29 (3.5)	27 (3.2)	10 (2.4)	9 (2.2)	19 (4.5)	18 (4.3)
Torres Strait Islander	0 (0)	2 (0.2)	0 (0)	0 (0)	0 (0)	2 (0.5)
Aboriginal and Torres Strait Islander	3 (0.4)	2 (0.2)	2 (0.5)	0 (0)	1 (0.2)	2 (0.5)
None of the above	805 (96.2)	803 (96.3)	404 (97.1)	405 (97.8)	401 (95.2)	398 (94.8)
Language mainly spoken at home						
English	812 (97.0)	797 (95.6)	397 (95.4)	387 (93.5)	415 (98.6)	410 (97.6)
Other	25 (3.0)	37 (4.4)	19 (4.6)	27 (6.5)	6 (1.4)	10 (2.4)

	All participants (comparison) (N = 837)	All participants (intervention) (N = 834)	Minimal/mild (comparison) (N = 416)	Minimal/mild (intervention) (N = 414)	Severe (comparison) (N = 421)	Severe (intervention) (N = 420)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Highest level of education attained						
Below Year 10	41 (4.9)	33 (4.0)	12 (2.9)	8 (1.9)	29 (6.9)	25 (6.0)
Year 10	70 (8.4)	84 (10.1)	31 (7.5)	34 (8.2)	39 (9.3)	50 (11.9)
Year 11	35 (4.2)	32 (3.8)	14 (3.4)	14 (3.4)	21 (5.0)	18 (4.3)
Year 12 or equivalent	149 (17.8)	163 (19.5)	77 (18.5)	64 (15.5)	72 (17.1)	99 (23.6)
Certificate III/IV	182 (21.7)	150 (18.0)	80 (19.2)	78 (18.8)	102 (24.2)	72 (17.1)
Advanced diploma / Diploma	103 (12.3)	113 (13.5)	55 (13.2)	50 (12.1)	48 (11.4)	63 (15.0)
Bachelor degree	161 (19.2)	157 (18.8)	91 (21.9)	94 (22.7)	70 (16.6)	63 (15.0)
Graduate diploma/Certificate	37 (4.4)	36 (4.3)	22 (5.3)	25 (6.0)	15 (3.6)	11 (2.6)
Postgraduate degree	59 (7.0)	66 (7.9)	34 (8.2)	47 (11.4)	25 (5.9)	19 (4.5)
Current employment status	91	S NY NE				
Employed	574 (68.6)	522 (62.6)	332 (79.8)	299 (72.2)	242 (57.5)	223 (53.1)
Unemployed, looking for and available to start work	78 (9:3) M	85 (10.2)	23 (5.5)	22 (5.3)	55 (13.1)	63 (15.0)
Not in labour force	185 (22.1)	227 (27.2)	61 (14.7)	93 (22.5)	124 (29.5)	134 (31.9)
Main activity for those not in labour force	O. K. V.					
Retired or voluntarily inactive	38 (20.3)	52 (22.7)	25 (40.3)	39 (41.1)	13 (10.4)	13 (9.7)
Home duties	23 (12.3)	14 (6.1)	7 (11.3)	6 (6.3)	16 (12.8)	8 (6.0)
Caring for children	14 (7.5)	39 (17.0)	5 (8.1)	19 (20.0)	9 (7.2)	20 (14.9)
Studying	16 (8.6)	27 (11.8)	7 (11.3)	11 (11.6)	9 (7.2)	16 (11.9)
Unable to work due to own illness, injury, or disability	67 (35.8)	72 (31.4)	6 (9.7)	7 (7.4)	61 (48.8)	65 (48.5)
Caring for an ill or disabled person	18 (9.6)	8 (3.5)	8 (12.9)	4 (4.2)	10 (8.0)	4 (3.0)
Working in an unpaid voluntary job	5 (2.7)	6 (2.6)	2 (3.2)	3 (3.2)	3 (2.4)	3 (2.2)
Other	6 (3.2)	11 (4.8)	2 (3.2)	6 (6.3)	4 (3.2)	5 (3.7)

	All participants (comparison) (N = 837)	All participants (intervention) (N = 834)	Minimal/mild (comparison) (N = 416)	Minimal/mild (intervention) (N = 414)	Severe (comparison) (N = 421)	Severe (intervention) (N = 420)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Health care card holder	329 (39.3)	370 (44.4)	115 (27.6)	125 (30.2)	214 (50.8)	245 (58.3)
Managing on your available income			A			
Easily	139 (16.6)	132 (15.8)	103 (24.8)	97 (23.4)	36 (8.6)	35 (8.3)
Not too bad	309 (36.9)	299 (35.9)	197 (47.4)	192 (46.4)	112 (26.6)	107 (25.5)
Difficult some of the time	252 (30.1)	254 (30.5)	99 (23.8)	110 (26.6)	153 (36.3)	144 (34.3)
Difficult all of the time	125 (14.9)	129 (15.5)	17 (4.1)	15 (3.6)	108 (25.7)	114 (27.1)
Impossible	12 (1.4)	20 (2,4)	(0.0)	0 (0.0)	12 (2.9)	20 (4.8)
Living alone	134 (16.0)	129 (15.5)	44 (10.6)	45 (10.9)	90 (21.4)	84 (20.0)
Self-rated health		(FLANKO	<			
Excellent	38 (4.5)	\$ 39 (4.7)	28 (6.7)	29 (7.0)	10 (2.4)	10 (2.4)
Very good	207 (24.7)	184 (22.1)	160 (38.5)	155 (37.4)	47 (11.2)	29 (6.9)
Good	302 (36.1)	321 (38.5)	175 (42.1)	183 (44.2)	127 (30.2)	138 (32.9)
Fair	210 (25.1)	203 (24.3)	50 (12.0)	42 (10.1)	160 (38.0)	161 (38.3)
Poor	80 (9.6)	87 (10.4)	3 (0.7)	5 (1.2)	77 (18.3)	82 (19.5)
Long-term illness which limits daily activities	324 (38.7)	345 (41.4)	81 (19.5)	88 (21.3)	243 (57.7)	257 (61.2)
Reason for visit to GP	564					
Physical health	438 (52.3)	413 (49.5)	285 (68.5)	275 (66.4)	153 (36.3)	138 (32.9)
Mental health and wellbeing	115 (13.7)	122 (14.6)	21 (5.0)	29 (7.0)	94 (22.3)	93 (22.1)
Both physical and mental health	206 (24.6)	212 (25.4)	57 (13.7)	50 (12.1)	149 (35.4)	162 (38.6)
None of these	78 (9.3)	87 (10.4)	53 (12.7)	60 (14.5)	25 (5.9)	27 (6.4)
History of depression	522 (62.4)	514 (61.6)	130 (31.3)	143 (34.5)	392 (93.1)	371 (88.3)
Currently taking medication for mental health	347 (41.5)	340 (40.8)	101 (24.3)	102 (24.6)	246 (58.4)	238 (56.7)

Note: SD = standard deviation, n = count, IQR = Inter quartile range. Variables contributing to the Link-me DST include: Depressive symptom severity, anxiety symptom severity, gender, managing on your available income, living alone, self-rated health, long-term illness which limits daily activities, and history of depression.

### 4.4.1. Mental health priority areas

After completing the Link-me DST assessment, participants in the intervention arm were provided with a summary of the areas in which they appeared to be experiencing difficulties, and were asked to select up to two of these to focus on. For participants whose scores indicated two or fewer areas of difficulty, these difficult areas were assigned as priorities (rather than participants selecting their own priority areas). The pattern of prioritisation of the areas of difficulty differed by symptom severity group. For the majority (75%) of the minimal/mild symptom group, two or fewer areas of difficulty were reported and priority areas were therefore assigned rather than selected. Priority areas most commonly selected/assigned in this group were energy (18%), ability to complete daily activities (16%), and interest or pleasure in doing things (15%) (Table 10). In the severe symptom group, the most common priorities were anxiety (39%), sleep (27%), and energy (23%). The emphasis on anxiety within this group is consistent with national data indicating that anxiety disorders are the most prevalent mental health conditions in the Australian population [49], and supports the need for tailored support to address this issue.

Ratings on the importance and confidence scales within the Link-me DST indicated that on average, compared to participants in the minimal/mild symptom group, those in the severe symptom group considered that it was more important to address their priorities; but were less confident.

	All participants (N = 834)	Minimal/mild symptom group (N = 414)	Severe symptom group (N = 420)
	Mean (SD)	Mean (SD)	Mean (SD)
Importance of change (1-10)	8,5 (2.1)	7.9 (2.5)	8.9 (1.7)
Confidence in changing (1-10)	6.2 (2.5)	6.9 (2.3)	5.6 (2.5)
	n (%)	n (%)	n (%)
Priority area			
Anxiety	185 (22.2)	22 (5.3)	163 (38.8)
Energy	170 (20.4)	75 (18.1)	95 (22.6)
Sleep	167 (20.0)	52 (12.6)	115 (27.4)
Mood	110 (13.2)	21 (5.1)	89 (21.2)
Health	106 (12.7)	40 (9.7)	66 (15.7)
Ability to complete daily activities	102 (12.2)	64 (15.5)	38 (9.0)
Interest or pleasure in doing things	100 (12.0)	60 (14.5)	40 (9.5)
Appetite	86 (10.3)	44 (10.6)	42 (10.0)
Self-image	79 (9.5)	19 (4.6)	60 (14.3)
Concentration	51 (6.1)	15 (3.6)	36 (8.6)
Finances	46 (5.5)	11 (2.7)	35 (8.3)
Thoughts of self-harm or death	28 (3.4)	1 (0.2)	27 (6.4)
Movement	16 (1.9)	4 (1.0)	12 (2.9)

Table 10. Priority areas selected by or assigned to participants in the intervention arm (N = 834)

Note: SD = standard deviation, n = count. Priority areas are not mutually exclusive as participants were assigned or able to select up to two priorities each.

## 4.5. Uptake of and engagement with care navigation

Of the 420 people allocated to the care navigation intervention, 216 (51%) participated in at least one structured contact with a care navigator. Overall the demographic or clinical characteristics between those who did and did not participate in a structured contact were similar, with a few exceptions as shown in Table 11 (note that in the interests of space, only a subset of characteristics of those provided in Table 9 are reported here; no differences were evident on characteristics not shown). People who attended at least one appointment were slightly older on average (41 vs 36 years old), and were more likely to identify as male (36% vs 18%), to have a long-term illness (65% vs 57%), and to select anxiety as one of their priority areas (43% vs 35%). On the other hand, those who did not participate in care navigation were more likely to be in the labour force (74% vs 63%), and were slightly more likely to select mood as a priority (27% vs 16%).



	Participated in ≥1 contact (N = 216)	No care navigation contacts (N = 204)
	Mean (SD)	Mean (SD)
Age (years)	41.1 (15.4)	35.8 (13.3)
Psychological distress (K10)	32.6 (7.6)	31.8 (6.9)
Depressive symptom severity (PHQ-9)	18.0 (4.6)	17.0 (4.5)
Anxiety symptom severity (GAD-7)	14.1 (4.7)	13.4 (4.3)
Overall health (EQ-5D-5L)	44.5 (21.4)	47.8 (20.6)
Quality of life (EQ-5D-5L)	0.4 (0.3)	0.4 (0.3)
Importance of change $(1-10)$	9.2 (1.6)	8.7 (1.8)
Confidence in changing $(1-10)$	5.3 (2.6)	5.9 (2.4)
	n (%)	n (%)
Gender	R.	
Female	137 (63.4)	165 (80.9)
Male	78 (36,1)	37 (18.1)
Other	1 (0.5)	2 (1.0)
Current employment status	AS DON	
Employed	140 (50.9)	113 (55.4)
Unemployed, looking for and available to start work	25 (11.6)	38 (18.6)
Not in labour force	81 (37.5)	53 (26.0)
Health care card holder	128 (59.3)	117 (57.4)
Long-term illness which limits daily activities	140 (64.8)	117 (57.4)
Priority areas		
Anxiety	92 (42.6)	71 (34.8)
Sleep	58 (26.9)	57 (27.9)
Energy	45 (20.8)	50 (24.5)
Mood	35 (16.2)	54 (26.5)
Health	33 (15.3)	33 (16.2)
Self-image	31 (14.4)	29 (14.2)
Ability to complete daily activities	25 (11.6)	13 (6.4)
Finances	22 (10.2)	13 (6.4)
Interest or pleasure in doing things	21 (9.7)	19 (9.3)
Appetite	20 (9.3)	22 (10.8)
Concentration	20 (9.3)	16 (7.8)
Thoughts of self-harm or death	13 (6.0)	14 (6.9)
Movement	7 (3.2)	5 (2.5)

**Table 11.** Baseline characteristics of people who did and did not participate in a care navigation contact (N = 420)

Note: n = count; SD = standard deviation. Priority areas are not mutually exclusive as participants were able to select up to two priorities each.

Among the 216 people who participated in at least one structured care navigation contact (face-to-face or telephone), the total number of contacts ranged from 1 to 17 with a mean of 5.3 (SD = 3.0) and mode was 8 (Figure 6). Note that while the intended model of care navigation was for people to participate in up to 8 structured contacts, over 10% participated in more than this.



**Figure 6.** Percentage of people who participated in one or more structured care navigation contacts by the number of contacts (N = 216)

The majority of people who participated in one or more structured care navigation contacts were able to identify actions to take that were relevant to improving their self-identified mental health priorities from the Link-me DST (Table 12). Where no match was identified, this was typically due to the participant commenting that the previously selected priority was no longer relevant, due to issues having resolved in that area or worsened in others, or other life events taking precedence (e.g., moving interstate). Nearly three quarters of care navigation participants received a new referral or recommendation of a specific resource or service (e.g., meditation group, 'Calm' mobile phone app) as a result of their Link-me action plan (a detailed description of these will be provided in the final Link-me report, submitted in 2020). Finally, care navigators secured approval for care package funding to support approximately half of those who participated in care navigation overall, with 85% of those participants accessing some or all of their approved services (Chapter 0 provides more information on care packages approved and funded).

**Table 12.** Frequency and percentage of people who participated in at least one structured carenavigation contact, by intervention elements received (N = 216)

Number of elements	Description of elements received	n (%)
1	Match between priority and action plan	188 (87.0)
2	1 + Specific referral to new service / resource documented	153 (70.8)
3	2 + Participant was approved for care package funding	112 (51.9)
4	3 + Participant used care package-funded service	95 (44.0)

Note: n = count. Each of the care navigation elements reported here were considered present if there was documented evidence of their delivery in the Link-me portal or PHN records. Reported elements are cumulative, so that the participants who received 4 are a subset of those who received 3, and so on.

## 4.6. Differences in mean outcomes between trial arms

Overall, the reduction in mean K10 scores at 6 months from baseline K10 scores (the primary outcome) was greater in the intervention arm than the comparison arm. In the primary analysis, the mean difference in K10 scores at 6 months between the intervention and comparison arms was 0.94 (95% CI -1.73 to -0.14) which equates to a small standardised mean difference of -0.10 (Table 13). However, the magnitude of the intervention effect differed for the two symptom severity groups.

The estimated mean difference between arms in the minimal/mild symptom group for K10 score at 6 months was 0.09 (95% CI -0.83 to 1.02). Although there was no evidence to support the hypothesis that two trial arms differed, there may have been a floor effect in this symptom severity group as on average their K10 score at baseline was 17.1 (SD = 4.5) with a minimum possible score of 10. The intensity of the intervention in this group was also lower by design.

We did observe a difference of -1.95 (95% CI -3.21 to -0.69) on mean K10 scores between trial arms in the severe symptom group (with similar results produced by the sensitivity analysis). This translates to a standardised mean difference of -0.26 (95% CI -0.44 to -0.09), which is comparable to the recommended cut off for clinical relevance in the treatment of depression [52]. The confidence bounds include our pre-specified clinically relevant standardised mean difference of 0.3 (see Chapter 3.5.1). This effect size is not only comparable with that seen in previous trials of collaborative care [28,53,54], but also in trials of pharmacotherapy and psychotherapy for depression [52,55]. Notably, in standard depression treatment trials this difference was obtained in comparison to placebo control whereas Link-me care navigation was compared to usual care. In the Australian mental health care context, each year 'usual care' sees the delivery of over 11 million Medicare subsidised mental health-specific services and over 35 million mental health-related prescriptions [56]. Achieving an improvement in outcomes in this saturated environment suggests a treatment option worth pursuing.

The CACE analysis showed increasingly large and more clinically meaningful effect sizes associated with delivery of additional elements of care navigation in intervention participants compared to individuals in the comparison arm who would have received the same elements had they been offered care navigation. People in the intervention arm who participated in at least one structured care navigation contact and developed an action plan matched to their priorities showed a 4.37point improvement (95% CI -7.19 to -1.57) in mean K10 scores over their counterparts in the comparison arm. For those who also received a specific recommendation or referral from their care navigator, the difference was -5.37 points on average (95% CI -8.87 to -1.86) between those who received these elements in the intervention arm and those who would have received the equivalent elements in the comparison arm if they were offered. Those in the intervention arm who had care package funding approved improved by -7.33 points on average over those in usual care had they been offered care navigation (95% CI -12.16 to -2.50), and for those who used their funding, the mean difference increased to -8.64 (95% CI -14.40 to -2.88). Note, the confidence intervals of the estimated mean differences increased (and precision therefore decreased) with each CACE analysis. This is because the proportion of participants decreased as the number of care navigation elements received increased.

We did not observe important mean differences on the secondary outcomes except anxiety symptoms, where participants in the severe symptom group allocated to care navigation improved by 1 point in mean GAD-7 scores compared to those in usual care (-0.98; 95% CI -1.90 to -0.06) (Table 14). However, the pattern of estimated effect sizes tended to favour the intervention and is consistent with the hypothesis that on average, care navigation improved mental health outcomes over usual GP care.

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Table 13. K10 psychological distress scores according to trial arm, in total sample and stratified by symptom severity group at 6 months (N = 1671)

	All participants	p value	Minimal/mild symptom group	p value	Severe symptom group	p value
Comparison, n	837		416		421	
Intervention, n	834		414		420	
Mean change, mean (SD) <sup>14</sup>						
Comparison	-0.43 (7.29)		2.10 (5.98)		-2.93 (7.59)	
Intervention	-1.35 (7.94)		2.34 (5.73)		-4.99 (8.13)	
Mean difference, Coef. (95% CI)			D <sup>Y</sup>			
Primary analysis <sup>15</sup>	-0.94 (-1.73 to -0.14)	.02	0.09 (-0.83 to 1.02)	.84	-1.95 (-3.21 to -0.69)	<.01
Sensitivity analysis <sup>16</sup>	-0.99 (-1.74 to -0.24)	<.01	0.07 (-0.84 to 0.99)	.87	-2.05 (-3.23 to -0.86)	<.001
Sensitivity analysis <sup>17</sup>	-0.99 (-1.74 to -0.24)	<.01	0.07 (-0.83 to 0.98)	.87	-2.05 (-3.23 to -0.87)	<.001
CACE analysis 18					-4.37 (-7.19 to -1.54)	<.01
CACE analysis <sup>19</sup>			P-C- ANO ACT		-5.37 (-8.87 to -1.86)	<.01
CACE analysis <sup>20</sup>			A P + Y		-7.33 (-12.16 to -2.50)	<.01
CACE analysis <sup>21</sup>			ALL AND ON		-8.64 (-14.40 to -2.88)	<.01
SMD (95% CI) <sup>22</sup>	-0.10 (-0.18 to -0.01)	.02	∽ < 0.02+0.18 to 0.23)	.84	-0.26 (-0.44 to -0.09)	<.01

Note: SD = Standard deviation; Coef. = Estimated coefficient; CI = Confidence interval SMD > Standardised mean difference; CACE = Complier average causal effect.

<sup>14</sup> Estimated using multiple imputation
<sup>15</sup> Mean for intervention arm minus mean for control arm estimated using linear regression adjusted for baseline outcome measure (all models) and symptom severity group (model with all participants only). Estimated using multiple imputation participants only). Estimated using multiple imputation.

<sup>16</sup> Sensitivity analysis using complete cases only with linear regression adjusted for baseline outcome measure (all models) and symptom severity group (model with all participants only).

<sup>17</sup> Same as 16 but adjusted for general practice treated as random intercept.

<sup>18</sup> CACE analysis undertaken in the severe symptom severity group only, for those with documented evidence of participation in at least one structured care navigation contact and a match between participant priorities and the action plan. Estimated using multiple imputation.

<sup>19</sup> CACE analysis: Same as 18 except for those with documented evidence of: 1) participation in at least one structured care navigation contact and a match between participant priorities and the action plan; and 2) a specific resource recommendation or referral to new service / provider.

<sup>20</sup> CACE analysis: Same as 18 except for those with documented evidence of: 1) participation in at least one structured care navigation contact and a match between participant priorities and the action plan; 2) a specific referral to new service / provider was documented; and 3) approval for care package funding.

<sup>21</sup> CACE analysis: Same as 18 except for those with documented evidence of: 1) participation in at least one structured care navigation contact and a match between participant priorities and the action plan; 2) a specific referral to new service / provider was documented; and 3) approval for care package funding; and 4) the participant used the care package-funded service.

<sup>22</sup> Mean difference in the primary analysis calculated relative to the pooled SD of baseline scores.

All participants Minimal/mild p value p value Severe symptom p value symptom group group Mean change, mean (SD)<sup>23</sup> Depressive symptom Comparison -1.73(5.65)0.21 (4.51) -3.65 (5.99) severity -2.13(5.85)0.05 (4.45) -4.28 (6.26) Intervention (PHQ-9) Mean difference, Coef. (95% CI) -0.18 (-0.91 to 0.55) Primary analysis<sup>24</sup> -0.39 (-1.03 to 0.26) .24 .62 -0.59 (-1.62 to 0.43) .26 Sensitivity analysis<sup>25</sup> -0.18 (-0.82 to 0.47) -0.07 (-0.86 to 0.71) .59 .86 -0.30 (-1.33 to 0.72) .56 0.08 (-0.86 to 0.70) Sensitivity analysis<sup>26</sup> -0.18 (-0.82 to 0.47) .59 -0.31 (-1.33 to 0.70) .85 .55 -0.07 (-0.37 to 0.22) SMD (95% CI)<sup>27</sup> -0.06 (-0.15 to 0.04) .24 .62 -0.13 (-0.36 to 0.09) .26 BEENPELL BE-OPHNA 15 H-0.54 (3.73) -0.56 (3.72) - INFORMATION Mean change, mean (SD)<sup>23</sup> Anxiety symptom Comparison -1.79(4.71)-3.02 (5.22) severity -2.36(5.09)Intervention -4.14 (5.62) (GAD-7) Mean difference, Coef. (95% CI) -0.51 (-1.04 to 0.03) Primary analysis<sup>24</sup> -0.02 (-0.62 to 0.58) -0.98 (-1.90 to -0.06) .95 .04 -0.35 (-0.91 to 0.20) U ARZI Sensitivity analysis<sup>26</sup> 0.10 (-0.55 to 0.75) -0.76 (-1.65 to 0.12) .09 .76 Sensitivity analysis<sup>27</sup> -0.35 (-0.90 to 0.20 .21 0.09 (-0.56 to 0.73) .79 -0.76 (-1.64 to 0.12) .09 SMD (95% CI)<sup>27</sup> -0.09 (-0.18 to 0.01) .06 -0.01 (-0.22 to 0.21) .95 -0.21 (-0.41 to -0.01) .04 Mean change, mean (SD)<sup>23</sup> Overall health S 4.06 (22.91) Comparison 1.97 (20.99) 6.13 (24.45) (EQ-5D-5L × 5.62 (22.41) 3.90 (20.04) 7.31 (24.38) Intervention

**Table 14.** Secondary outcomes in total sample and stratified by symptom severity group at 6 months (N = 1671)

Mean difference, Coef. (95% CI)

VAS)

<sup>&</sup>lt;sup>23</sup> Estimated using multiple imputation

<sup>&</sup>lt;sup>24</sup> Mean for intervention arm minus mean for control arm estimated using linear regression adjusted for baseline outcome measure (all models) and symptom severity group (model with all participants only). Estimated using multiple imputation.

<sup>&</sup>lt;sup>25</sup> Sensitivity analysis using complete cases only with linear regression adjusted for baseline outcome measure (all models) and symptom severity group (model with all participants only).

<sup>&</sup>lt;sup>26</sup> Same as 25 but adjusted for general practice treated as random intercept.

<sup>&</sup>lt;sup>27</sup> Mean difference from 24 calculated relative to the pooled SD of baseline scores.

		All participants	p value	Minimal/mild symptom group	p value	Severe symptom group	p value
	Primary analysis <sup>24</sup>	0.03 (-2.50 to 2.56)	.98	1.08 (-2.30 to 4.46)	.53	-0.98 (-4.68 to 2.72)	.60
	Sensitivity analysis <sup>25</sup>	0.14 (-2.23 to 2.52)	.91	1.17 (-1.86 to 4.20)	.45	-0.78 (-4.42 to 2.87)	.68
	Sensitivity analysis <sup>26</sup>	0.10 (-2.26 to 2.47)	.93	1.17 (-1.84 to 4.19)	.44	-0.81 (-4.41 to 2.80)	.66
Quality of life (EQ-5D-5L)	Mean change, mean (SD) <sup>23</sup>						
	Comparison	0.03 (0.23)		0.00 (0,19)		0.05 (0.27)	
	Intervention	0.04 (0.24)		-0.00 (0.19)		0.07 (0.27)	
	Mean difference, Coef. (95% CI)			Mr. 82			
	Primary analysis <sup>24</sup>	0.01 (-0.02 to 0.03)	.67	0.00 (-0.03 to 0.03)	.95	0.01 (-0.03 to 0.06)	.59
	Sensitivity analysis <sup>25</sup>	0.00 (-0.02 to 0.03)	.91	0.00(+0.03 to 0.03)	.86	0.01 (-0.03 to 0.05)	.72
	Sensitivity analysis <sup>26</sup>	0.00 (-0.02 to 0.03)	.91	-0.00 (-0.03 to 0.03)	.86	0.01 (-0.03 to 0.05)	.72
Days out of role (K10+)	Mean change, mean (SD) <sup>23</sup>		. 8-4				
	Comparison	9.40 (10.31)	CT J	4.91 (8.09)		13.84 (10.34)	
	Intervention	8.86 (10.23)	Str. A.	4.27 (7.31)		13.40 (10.66)	
	Relative difference, RR (95% CI)	S					
	Primary analysis <sup>28</sup>	0.92 (0.78 to 1.08)	.30	0.88 (0.64 to 1.22)	.45	0.95 (0.81 to 1.11)	.54
	Sensitivity analysis <sup>29</sup>	0.91 (0.77 to 1.08)	.28	0.87 (0.62 to 1.21)	.41	0.95 (0.80 to 1.13)	.58
	Sensitivity analysis <sup>30</sup>	0.95 (0.92 to 0.99)	.02	0.89 (0.82 to 0.97)	<.01	0.97 (0.92 to 1.01)	.15

Note: SD = Standard deviation; Coef. = Estimated coefficient; RR = Rate ratio; Cl = Confidence interval.

<sup>&</sup>lt;sup>28</sup> Rate ratio estimated using negative binomial regression adjusted for baseline days out of role (all models) and symptom severity group (model with all participants only). Estimated using multiple imputation.

<sup>&</sup>lt;sup>29</sup> Sensitivity analysis using complete cases only with negative binomial regression adjusted for baseline days out of role (all models) and symptom severity group (model with all participants only).

<sup>&</sup>lt;sup>30</sup> Same as 29 but adjusted for general practice treated as random intercept.

## 4.7. Summary

This chapter reported the baseline characteristics of Link-me participants, the elements of care navigation received, and the effect of Link-me on mental health outcomes. Of the 2098 of eligible patients that had indicated a mental health need and completed the Link-me DST, 427 (20%) were classified into the moderate symptom group and were excluded from the trial analyses. Thus a total of 1,671 participants were included in primary analysis, exceeding the target sample size of 1,498. Although we anticipated that about one third of the trial participants would be classified into the severe symptom group, the number was balanced between this and the minimal/mild symptom group. The higher number of participants in the severe symptom group in our sample may be the result of several influencing factors including characteristics of the Link-me DST itself as well as the patient population within general practices engaged in the trial. Not surprisingly, the severe symptom group reported poorer physical and mental health than the minimal/mild symptom group, were more likely to experience social and economic disadvantage and expressed less confidence in their ability to address their priority areas.

Our analysis addressed two of the primary evaluation questions, namely questions 2 (whether care navigation produced improved outcomes for people with severe and complex mental illness who are managed in primary care), and 4 (the outcomes of streaming people with lower levels of clinical need into low intensity services). Overall the findings support the clinical effectiveness of the Linkme approach to mental healthcare. Taking the sample as a whole, we observed a 1-point greater improvement on average in participants allocated to the intervention arm than those in the comparison arm. Amongst participants in the severe symptom group allocated to the intervention arm, we observed a 2-point improvement in mean K10 scores compared to those allocated to usual GP care. Translated to an effect size of 0.26, this difference is comparable to that seen in trials of current gold standard mental health treatment [52,55], and was detected despite half of the participants in the intervention arm not taking up the offer of care navigation. In our CACE analyses, the effect sizes increased; the more elements of care navigation participants received, the greater their improvement in psychological distress. The 95 participants who accessed care package-funded services (44% of the 216 who participated in at least one structured care navigation contact) showed an average improvement in K10 scores of almost 9 points more than their counterparts in the comparison arm would have had they been offered these elements of care navigation. While the effect of the intervention on secondary outcomes of depressive and anxiety symptoms was less conclusive, this may have been in part due to the heterogeneity of the sample that included a mix of participants with either or both depressive and anxiety symptoms, which may have attenuated the observed effect sizes on symptom-specific measures.

In relation to evaluation question 4, we found that offering a selection of low intensity service options did not affect mental health outcomes for people with lower levels of clinical need at 6 months, relative to usual GP care. Crucially, this finding implies that while there was no observed clinical benefit to the intervention, it also did not cause harm. Whether it was acceptable to the people triaged to this group is a question addressed in the next chapter.

# 5. Implementation of Link-me

## 5.1. Chapter overview

This chapter addresses the implementation of Link-me in terms of evaluation questions 1 (the implementation of care navigation, including barriers and enablers), 2 (the experience of care navigation for patients with severe and complex mental illness), and 4 (patient experiences of triaging people with lower levels of clinical need to low intensity services). It highlights the common barriers and enablers encountered in the implementation of Link-me and examines the experiences of patients in both symptom severity groups who were randomly allocated to the intervention arm of the trial and received a severity-matched treatment recommendation. A patient-reported experiential model of care navigation is presented as developed from analysis of interview data.

**5.2. Data sources** Workshop findings, meeting notes during the implementation phases of the trial, and semistructured interviews conducted by telephone and video with 3 BTCs, 6 CNs, and 14 GPs were drawn on to inform findings about the implementation of care navigation, including its barriers and enablers. GPs who had patients randomised to care navigation were purposefully identified and invited to interview to capture differences in implementation and experiences from the practitioner perspective where possible. 34 GPs were approached to participate in an interview from 11 general practices across the three PHNs, 14 of whom took part. Experience data was collected by telephone with a sub-sample of trial participants randomly allocated to the intervention arm; a total of 76/217 eligible participants in the minimal/mild symptom group and 62/115 eligible in the severe symptom group were approached. Of these 31 participants triaged to low intensity services and 32 participants triaged to care navigation who were interviewed to explore experiences of care. Further details of sampling and recruitment procedures for interviews and the questions asked are outlined THE RE in Appendix 4.

## 5.3. Approach to analysis

Qualitative data collected from notes taken at regular meetings, observations and outcomes of workshops and transcripts of telephone interviews were reviewed for common themes related to care coordination implementation. This analytical approach involved reading transcripts for individually important themes and then identifying the themes shared across notes, observations and transcripts as per a thematic analysis method. Focused analysis was undertaken of care navigation patient interviews to explore the experiences of care taking note of shared experiences in relation to stages of the patient journey. Three journeys were developed for patients to guide the analysis and themes of core experiences were analysed and discussed.

## 5.4. Implementation of care navigation

Patients referred to barriers and enablers within three common themes related to the implementation of care navigation: uptake, embedding the intervention, and engagement.

#### 5.4.1. Uptake

RTCs suggested that overall uptake of the Link-me care navigation model by GPs was promoted by the idea of having a care navigator as a clinical companion and the patient being able to access tailored care package funding to meet their needs. Common concerns amongst GPs which inhibited uptake of care navigation were related to the issue of how risk would be managed for the patient and the uncertainty about having someone in their clinic who was not a member of the team. Some additional concerns were raised around the provision of a consulting room to a care navigator which for some practices represented a loss of income. GPs had mixed views about how effective it was for care navigators to coordinate referrals and linkages for patients. Some GPs were positive about this while others noted that a down side was the additional time that needed to be booked for GPs to write and approve referrals. In some instances, care navigators reported a perceived resistance from GPs to the Link-me Link-me DST being completed in the waiting room. They felt that this in turn affected patients' engagement in and uptake of Link-me. For example, one CN commented that:

there were a number of GPs who certainly didn't want to encourage Link-me involvement...I had someone on an iPad and - because we used to give patients the option, if they were starting it and the GP called them in, they could take it in with them and fill it out when they came back out. But Phad two GPs actually say, don't worry about that, you don't need to do it. That was quite a loud, vocal statement in the waiting room.

Uptake of care navigation was also affected by PHN staff turnover which resulted in some patients experiencing delays in their appointments and some staff in practices not being sure of who their care navigator was.

### 5.4.2. Embedding

It was very beneficial to have someone independent to review where everything was sitting and making suggestions and linking people in with the support services, because it is difficult to keep up to speed with who is doing what and what is available around the area. (GP)

For those GPs interviewed, Link-me was largely described as a positive experience, with many seeing the value of working with a care navigator. There was support for the role and some GPs expressed disappointment that the intervention had finished. GPs agreed that working with the CN did not impact significantly on their workload, and that they had received positive feedback from patients. GPs also agreed that the care navigation model worked easily in the general practice setting, particularly in practices where there is already a multidisciplinary team. GPs reported that care navigation worked well as it helped them to better support patients with mental health issues and raised both their own and their patients' awareness of available support services and resources.

There was overall support for care navigation from GPs who recognised the value of extra time being given to patients with higher needs. The Link-me DST was seen to be appropriate for the identification of the target populations; aside from challenges around how this should be completed and where, the GPs reported a good match between the results of the Link-me DST and the priorities that were set, and their clinical judgement. Few GPs were surprised by which patients were assigned to care navigation.

A particular value of the DST for GPs was in the identification of patients they had seen for some time, but who had not talked about their mental health issues. For example, one GP commented the Link-me DST "*was a good way to reach out to people who may be brushing their mental health issues aside*". Some also suggested that the Link-me DST gave patients who might have been stuck a bit of a prompt and provided them with a different professional to try and implement changes.

Several GPs did indicate that there was a need to orientate patients to the tablet-based survey as they reported that some patients had privacy concerns, thinking they had been targeted as a mental health patient and people knew their private information. Some GPs described the work that had been done at their practice to increase awareness of the tablet-based survey through posters, with the aim that patients would not think it was *"just another survey"*. This uncertainty around the Linkme DST completion in the waiting room was shared by other GPs who indicated in their telephone interviews that their preference would be to refer patients to care navigation during a consultation rather than referral occurring via tablet device in the waiting room. Overall, there were mixed views from GPs on whether the waiting room may not be the best place to raise the topic of mental health issues and they indicated that this may have put some patients off the survey.

There was a sense of variability in terms of how GPs saw the care navigator role and their understanding of Link-me broadly. Some GPs reported Link me was for those with a high risk of suicide that may have not otherwise been identified. Other GPs likened the role of the CN to an advocate, or a mental health nurse, while another GP thought the CN was a psychologist whose role was to provide counselling to patients. Some referred to the role as a counsellor, others used the term navigating care, psychologist and a coach "someone that has the time to listen with the aim of improving patients' mood and motivation to make changes in their life". Others described part of the intervention as "not just linking them into services but getting them through the door". Another CN explained part of their role was to ensure the linked-in service referral was a 'safe' one, that the patient knew what to expect and that the service was appropriate for the patient so there would be greater chance of attendance. CNs also reported an important part of their role was advocacy that included getting patients back on wait lists if they missed an appointment for some reason.

Common barriers identified by GPs to the delivery of care navigation included funding and availability of services, GP time, and communication with the care navigators. In terms of funding, the long waiting list for services in the public system was viewed as a significant barrier to care, particularly for those who did not have private health insurance. Some GPs stated that while access to care package funding through Link-me was great, *"it was like having a priority referral system pathway"*, but if this funding was not available it would make it difficult for patients to access the services they needed. In some areas (most notably within the regional areas), the lack of mental health professionals was a further barrier that care navigators could do little to address, with or without care package funding.

### 5.4.3. Engagement

Communication was critical to successful engagement between GPs and CNs. Several GPs identified that their own lack of time was a barrier to effective care navigation. They reported that they felt joint appointments were needed with the CN and patient, and they would have liked to have had more time for these discussions, but they could only allocate 10 to 15 minutes for each patient. A few other GPs mentioned there was no time allocated specifically for communication between

themselves and the CN, and they suggested that in any future rollout of Link-me, this need to be built into the model to ensure GPs were consistently and actively engaged in the care navigation process. As one GP commented, there was a need for "*better communication, we are always time poor and rushing but if GPs knew what was going on it would be a lot better*".

Some GPs described communication with the CN as excellent, with joint meetings between the GP, care navigator and the patient occurring regularly to discuss priorities and develop an action plan. GPs received emails providing patient updates and reports of progress and support services suggested and whether these had been acted upon. Other GPs and CNs referred to regular informal discussions often taking place in the tea room. There were some indications that the workplace culture at different practices may have contributed to different communication styles between CNs and GPs. One GP described the 'open door policy' in their practice that facilitated discussion of patients receiving care navigation as needed. However, other GPs described a lack of communication, particularly in practices where there was a higher turnover of care navigators. GPs at some of these practices reported never meeting the CN and the extent of their communication being an initial letter to say their patient had been allocated to care navigation. Another GP reported that the CN could not upload patient progress notes and reports on their patient record system, so they were not able to access notes to see how patients were going which proved a challenge for working as companions. Another GP reported not receiving information at the beginning of care navigation and not knowing what patients the CN was seeing. This GP reported they relied on patients to tell them when they had seen the care navigator, which prompted the GP to look for correspondence from the CN for the patient. Once patients were engaged in care navigation, ENs reported little drop out, but noted that a

Once patients were engaged in care navigation. ENs reported little drop out, but noted that a proportion of patients that could not be contacted despite multiple attempts through email, text messages and phone calls. Several reasons for non-engagement were noted, including the challenge posed by working in regional areas where anonymity and greater visibility for patients are issues. There was also a sense that patients with drug and alcohol issues did not take up the offer of care navigation due to privacy concerns, and it is possible that some patients felt anxious about addressing issues identified in the Link-me DST. Others actively declined participation, stating they were not expecting the level of involvement of care navigation and some patients did not see that there were any benefits to seeing a care navigator.

CNs also reported that some patients found it hard to set goals in relation to the priority areas the identified in the Link-me DST. There were also numerous access issues identified such as: a lack of service providers in some regions or no public transport, long waiting lists to see some medical specialists, past experiences with psychological counselling leaving patients not ready to re-engage, and social determinants of health such as transience, or work commitments and competing priorities. There were many examples of collaboration between GPs and CNs to enhance patient engagement in Link-me. One CN described adapting their management style, in accordance with the practice to identify what works for them prior to commencement of the trial and reported implementation of Link-me within the practice was "quite smooth". However, all CNs expressed a view that GP engagement and support for the trial was essential for patient engagement.

CNs who worked with a higher number of general practices found it harder to communicate with GPs about how patients in the trial were going and to work collaboratively. For example, one CN stated:

Essentially I work across four practices so it is quite a challenge I guess to try to build relationships with practice managers, reception team and the GPs. Obviously, all of those people are exceptionally busy and it's hard to get some time with them...If I were only based at one or two practices [then I would have more] opportunity to form a relationship and work collaboratively. because breezing in and out of too many practices you're not aware of who are the local service providers. You really have to be embedded in the practice, in the community. There are lots of service providers who do not have, for example, in the regional and remote area, they do not have a website. They are not in the Yellow Pages or the White Pages. They get their business through word of mouth.

Finally, complexity of patient issues was identified by care navigators as a challenge to patient engagement. GPs reported that their view was that patients who did not engage were very complex and non-compliant with care in general, and may have found care navigation too overwhelming. Complexity also presented a challenge for CNs in putting care packages together in a restricted amount of time, where it was sometimes overwhelming for patients to think they had to access numerous services within a 6-month period. One care navigator reported service providers in their region had refused to provide a service to some patients due to their very complex needs and past interactions. Despite this, patients reported generally positive experiences, as described below.

# 5.5. Patient experiences

I was seeing some doctors about poin stuff. I'm an ex-footballer and I'm 47 years old, but I've got a 100-year-old body from playing a lot of football and having accidents, and all types of things. So, I was seeing doctors and stuff about problems with limbs, depression and so forth. P think care navigation was created for people who are suffering from anxiety and depression, and who may not know that, and that they can actually get a different resource and potentially unclog some of the GPs. I imagine a lot of people go and see GPs to get pills for depression and pain and things like that. The Link-me program I think helps people to differentiate mental psychological problems from what a clinician, psychologists, psych nurse, psychotherapist, psychiatrist can offer.

This section turns to the experiences of care for people within the intervention arm within the minimal/mild and severe symptom groups. It provides an overview of experiences of those who received low intensity service options, and then focuses in detail on the experiences for those who received care navigation. To give context to these experiences, we first provide a description of the sub-sample of patients who were interviewed.

### 5.5.1. Sample and characteristics

Equal numbers of patients were interviewed across all three PHNs in the minimal/mild and severe symptom groups within the intervention arm (i.e., those provided with information on low intensity

services and allocated to care navigation respectively). Interviews with patients in the minimal/mild symptom group ranged from four minutes to 35 minutes and for the severe symptom group the range was between 20 and 40 minutes. The average age of interviewees was 44 years old. In both symptom severity groups, half the interviewees were in work with the other half out of work; in the minimal/mild symptom group over half of those out of work were retired. Most of the interviewees in the severe symptom group had six or more structured contacts with CNs (face-to-face or over the telephone), and 25 of the 31 (81%) had approved care package funding. Table 15 provides an overview of the characteristic of the patients intervieweed by symptom severity group.

	Minimal/mild	Severe symptom	
	symptom group	group	
	(N = 32)	(N = 31)	
	Mean (SD)	Mean (SD)	
Interview length (minutes)	9.4 (5.8)	23.6 (11.9)	
Days since randomisation	269.4 (47.8)	269.1 (49.8)	
Age (years)	44.3 (15.6)	44.0 (15.3)	
Importance of making a change in priority areas	7.7(2.6)	9.2 (1.3)	
Confidence in making a change in priority areas	J.4 (2.3)	5.5 (2.8)	
# care navigation appointments attended	() n/a	6.5 (2.2)	
	(%)	n (%)	
PHN	ALT		
A	2 (32)	10 (31)	
B	11 (36)	12 (38)	
C HALL	10 (32)	10 (31)	
Approved for care package funding	, 	25 (78)	
Gender (female)	23 (74)	24 (75)	
UN DU DE	n (%)	n (%)	
Aboriginal / Torres Strait Islander	1 (3)	0 (0)	
English is main language spoken at home	29 (90)	31 (100)	
Highest level of education			
Below year 10	0 (0)	3 (9)	
Year 10	2 (7)	2 (6)	
Year 11	1 (3)	2 (6)	
Year 12 / equivalent	4 (13)	9 (28)	
Certificate III/IV	4 (13)	5 (16)	
Advanced diploma / diploma	3 (10)	6 (19)	
Bachelor degree	10 (32)	4 (13)	
Graduate diploma / certificate	2 (7)	0 (0)	
Postgraduate degree	5 (16)	1 (3)	
Current employment			
Employed / working	17 (55)	15 (47)	
Unemployed	1 (3)	3 (9)	
Not in labour force	13 (42)	14 (44)	
Main activity for those not in labour force			
Caring for ill or disabled person	0 (0)	1 (3)	
Caring for children	2 (7)	0 (0)	
Home duties	1 (3)	3 (9)	
Retired or voluntarily inactive	7 (23)	1 (3)	

Table 15. Characteristics of interviewees in the intervention arm, by symptom severity group

	Minimal/mild	Severe symptom
	symptom group (N = 32)	group (N = 31)
	n (%)	n (%)
Studying	2 (7)	3 (9)
Unable to work due to own illness, injury, or disability	1 (3)	6 (19)
Lives alone	8 (26)	6 (19)
Managing on available income		
Easily / not too bad / difficult some of the time	31 (100)	26 (81)
Difficult all of the time / impossible	0 (0)	6 (19)
Holds a health care card	12 (39)	18 (56)
Takes medication for mental health	11 (36)	19 (59)
Reason for GP visit		
Mental health and wellbeing	2 (7)	6 (19)
Physical health	19 (62)	10 (31)
Both physical and mental health	4 (13)	14 (44)
None of these	6 (19)	2 (6)
Chronic illness	7 (23)	22 (69)
General health		
Excellent / very good / good	26 (84)	11 (34)
Fair / poor	5 (16)	21 (66)
Priority areas	Quinto the	
Anxiety	(1 (3)	17 (55)
Sleep	2 (6)	10 (32)
Energy	4 (13)	6 (19)
Health	5 (16)	6 (19)
Self-image	0 (0)	6 (19)
Mood	3 (9)	5 (16)
Ability to complete daily activities	5 (16)	3 (10)
Appetite O A	1 (3)	3 (10)
Concentration	1 (3)	2 (6)
Interest or pleasure in doing things	6 (19)	2 (6)
Thoughts of self-harm or death	0 (0)	1 (3)

Note: n = count; SD = Standard deviation. Priority areas are not mutually exclusive as participants were assigned or able to select up to two priorities each.

### 5.5.2. Experiences of being triaged to low intensity services

People allocated to the minimal/mild symptom group and triaged to low intensity services all recounted a positive experience of completing the tablet-based survey in the waiting room; they indicated that the survey was easy to complete and not onerous. Some people directly suggested that they did not feel they needed to follow up on anything and so they intentionally did not use the resources. Others mentioned that while they did not use the resources they would come back to them again in the future if they needed them; they had reviewed the list and noted things of benefit.

There was variability in terms of whether people in this group recalled receiving information about mental health resources and services via email. A few referred to a general resource card provided to all trial participants (which gave information about additional supports to access if required (e.g., Lifeline)) as the extra resources they were recommended. Many patients fed back that email was not the best way to reach them, and there was an indication that the recommended resources and

supports may have been accessed by some people more if they had been in hard copy formats and not only provided by email.

Overall, people interviewed from the minimal/mild symptom group were positive about Link-me being undertaken in general practices. They felt that it served to raise awareness of mental health issues and to give a sense that GPs would be open to talking about mental health issues if required. There were one or two patients who were disappointed not to have received more support, feeling that they could have benefited and that this would be a good early intervention and prevention approach.

### 5.5.3. Experiences of care navigation

To explore the care navigation experience, we developed an example of three typical patient journeys. The journeys were compiled from interview data, care navigator notes, records of the structured assessment using the K10 scores and documented handover summaries given to GPs at the conclusion of care navigation. These journeys were used to highlight the importance or early engagement ("Sally", 20 years old), development of a plan and learning new things ("Glenda", 31 years old), and building self-confidence to take ownership ("Peter", 33 years old). A synthesis of patient experiences is presented as a final patient-reported experiential model of care navigation.

## 5.5.3.1. Early engagement: Dialogue and insight

Building rapport as part of early engagement was essential to care navigation and for CNs, the Linkme DST provided a tool to facilitate rapport and engage patients. Patients who were interviewed expressed positivity about completing the tablet based survey in the waiting room, suggesting it enabled them to open up, reach out or just reflect. The Link-me DST meant that patient priorities had already been set out ahead of contact which lay the foundations for the first encounter and provided a point of entry for conversations about goal setting. This provided patients with a sense of continuity between completion of the survey in the waiting room and follow up contact from CNs inviting them to take part in care navigation. It also provided CNs with preliminary information about who patients were and what both parties might expect from care navigation.

In Chapter 4 we noted that the patients allocated to care navigation selected priorities related to anxiety (39%), sleep (27%) and energy (23%). We also noted that for this group, patients felt that addressing these priorities was important, but they had less confidence to do so than patients in minimal/mild symptom group. These priorities were also selected by those patients interviewed, with health and self-image also highly important to our interviewees. Despite the limitations of confidence, one patient interviewed described it this way:

People, especially myself, aren't going to reach out sometimes for that kind of help, because we don't know where to reach out to, or it's hard to go to the doctors and say, I need help. Whereas that iPad survey was perfect, because you could sit there and do it if you wanted to or not. Even if [the results were] that you were great and your emotions were great, then that is wonderful. You have that little thing there to make you think about yourself.

For some people the early engagement phase was more about talking through some of the things they felt were already known to them so they could actualise and realise what needed to change.

One patient interviewed suggested that the identification of priorities ahead acted as a prompt for them to conduct their own research on anxiety prior to the care navigation appointment. This illustrates how use of the Link-me DST prompted some self-reflection and self-knowledge generation for some people. One patient described the early stages of rapport building more around identification of supports:

Well, really, initially, the biggest problem was working out what support that might be available that would be helpful. That wasn't an easy one to come up with, but once that was [done]...insomuch as that if I knew myself what I needed by way of help I would have probably done it anyway. I'm not an idiot, so talking it through eventually got me where I thought I was anyway. It just helped me realise that at the end of the day.

Consideration of these experiences, alongside the breakdown of Sally's journey (Figure 7) shows the importance of the initial determination of priorities. This enabled a conversation to occur about the supports available that might help and the steps that might need to be taken to get there. The priorities set the scene and the context for care navigators to complete an action plan. This provided patients and CNs with a guide about what to expect in future discussions and contacts, and where patients might be directed within their communities.

#### Figure 7. Sally's journey through care navigation: Dialogue and insight

"I get very anxious with phone calls and calling people myself, so it was a bit of a struggle for me to ring the care navigator back to get the ball rolling. I did not realise the issues that I have with answering phone calls and replying to people...that they were not normal" (Sally, 20 years old)


### 5.5.3.2. Plan of action: Increased self-awareness and reflection

Look, at times I was suffering from deep depression and care navigation gave me some real solace.

CNs identified local supports and services and worked with GPs to establish appropriate referrals as part of the formulation of a plan. In our previous patient Sally's journey and now our second patient Glenda's (Figure 8), it is possible to see how the 'light touches' and flexible support options of emails and text messages in-between face to face contacts were used to engage and keep patients informed. Feeling supported over the course of the intervention may well have contributed to increased confidence to continue with activities and goals set. Once a plan had been formulated, CNs often needed to conduct additional research into local services and supports that may help patients achieve their goals but CNs also fed this information back to their patients. Patients experienced these updates positively and felt that the phone was a good option when work, family, study and other caring responsibilities were high. It gave people a sense that CNs were going the extra step for them and that someone was listening to their needs and acting on them, which was consistently noted as an important part of the care navigation experience for patients.

The work the CN did in-between contact sessions to identify a psychologist or other supports made a notable difference to patient experiences and ensured that people were connected with as many services and supports as were possible. Glenda's journey shows how her CN liaised with a specialist personality disorder service to follow up on a report whereas for Sally, after some preliminary engagement in extra exercise, the CN worked with her to access psychological services through her GP. Patients suggested they valued having the CN there to listen and assist them by discussing focus areas and linking them into services that they needed, they felt this provided them with extra space that was not possible in busy GP appointments. As one interviewee suggested:

I think the main thing was someone actually talking to you. There are different ways that people deal with anxiety and things like that, and I just found that often just talking would help.

The benefits of having someone to talk with was supported by other patients too. One patient also suggested that care navigation assisted to build extra skills in learning how to live with their depression. These skills and increased confidence appeared to carry over to others who described continuing with exercise routines (such as swimming and yoga) or appointments even when care navigation in the trial had finished. One patient commented that:

Just the fact that I was exercising more because the care navigator got me into the Pilates which I can do at home myself now, which is good. I mean I probably wouldn't have gone ahead and done that on my own at the time because of the cost of it and how things were going here, it was a bit difficult. But I was making time."

This illustrates that the focused work of care navigation helped some people to develop new skills and actions to address mental health needs. Care navigators provided some patients with a person to be accountable to, a motivator and "*just sort of helping, supporting you, being there for you, trying to organise yourself.*" Many patients experienced this as a trusting relationship, "*never pushed, always on my own terms*".



"The care navigator listened to my circumstances and troubles and helped me find personal solutions that I now use throughout the day, everyday. I wouldn't be where I am today now – which is getting therapy and I've got my diagnosis now and I saw it as a pathway forward. It's helped to be guided by the care navigator. I don't think I would have found it by myself, without that extra assistance at that time." (Glenda, 31 years old)



Notes: CBT = Cognitive behavioural therapy; DBT = Dialectical behaviour therapy

### 5.5.3.3. Referrals and linkages: Self-activation and taking ownership

I was referred to a pain specialist in person as well as a couple of online groups...I was referred to other things like hydrotherapy and podiatry.

One of the strengths of the care navigation model for patients was the holistic approach to mental health care. This approach facilitated access to a wide range of local health and social services relevant to patients' own treatment goals. Glenda's journey (Figure 8) illustrates the new resources sometimes provided about support services for borderline personality disorder or a phone diary app, helped to encourage self-management approaches in between appointments and contacts. Patients also said that they learned new information from this sharing resources in this way. Some kept their action plans for reference and use at home too,

The [action plan] was really good and it was something I put in my diary at the back of my big diary, so that I had access to it whenever I felt like having a bit of a read, I could read it, go over what we discussed were good options forme.

Referrals to other services ranged from finding counsellors, to local social support groups and clubs, to psychological alternative therapies, dieticians, exercise groups, massage for pain management, psychological sessions, support groups for parents, to financial and housing support. There were some referrals to specialist services also such as eating disorder services and pain specialists as indicated in the quote above. In some cases, patients recounted that they were linked in with some of these services already such as physiotherapy and psychology, but care navigation provided them with increased access to resources to attend more frequently which they felt gave them good benefits and access they would not have had financially.

Finding the right support areas seemed to go smoothly given that CNs had usually spent time researching information and finding appropriate supports in between contacts with patients. There was a sense that CNs spent time developing an understanding of needs to provide tailored referrals, as one patient said, *"the care navigator wanted to get a better idea as to exactly what I needed most, rather than refer me onto somebody that wasn't really going to be of any benefit"*. Booking into some of the services particularly in regional areas remained a problem for patients. In some cases, this was due to the nature of invoicing and the continued issue that while a service could be identified, there were still wait lists for people to be seen. An additional barrier for regionally located patients suggested that, *"in a rural area, you don't have the choices that you have in a big city. You've kind of got to go with who is open, not who you prefer"*. Limited afterhours appointment options were also noted as barriers for people in work.

At the conclusion of care navigation, most of the patients we interviewed outlined that they had continued with the activities associated with their goals, whether this was attending a professional service or participating in a group or, continuing to increase their exercise routine and do this at home. This indicates that care navigation did provide people with a sense of confidence to enable them to continue to meet their goals beyond the face to face and phone contacts.

### Figure 9. Peter's journey through care navigation: Taking ownership and building self-confidence

"A big part of care navigation was it was easy for me to look back at what I was saying, what I was doing, and what I could do to change, or even to see that I don't need to change. I just need to look at it in a different light." (Peter, 36 years old)



### 5.5.3.4. Self-responsibility: Increased self-confidence

Care navigation was I suppose a more thorough way of getting to the root of a lot of the problems... I needed someone to help me put things back into perspective, and to get a grip again.

CNs provided patients with tools to support self-management and self-growth that steered people toward recovery. At the conclusion of care navigation, most patients we interviewed outlined that they had continued with the activity associated with the early goals set. This included attending professional services, participating in local groups, continuing with their exercise or using new mobile phone apps and strategies developed through the care navigation process. This highlighted how the care navigation process appeared to increase people's self-confidence to continue to build their goals on their own without the care navigator present. As noted in Peter's journey (Figure 9), care navigation provided tools and the opportunity for reflection not really provided in any other professional relationship for him to that point. Patients noted that,

I suppose [it helped me to get] a better understanding of how I was feeling and stuff like that. I suppose going through those questions [K10] all the time and feeding back to me that there was improvement from visit to visit, in some capacity, was just part of the process of recovery.

Patients felt that the provision of a print out of the action plan from the previous week to review and identify anything that needed to be attended to was helpful. This concept of tracking progress on feelings allowed some patients to gain insight into the changes they experienced each week, *"one week it would be worse and the next week it would be better. You could tell when things had happened that week and you could really evaluate yourself".* Patients mentioned returning to resources that CNs had given them after completion of the intervention particularly in the case of apps for finance and mindfulness to assist with sleep routines. In this case there were patients who said that they did not use all of the apps suggested to them due to limited interest in them or available time.

### 5.5.4. Experiential model of care navigation

Figure 10 represents the final experiential model of care navigation as developed from patientreported experiences. It highlights the intersection between the Link-me DST completion and care navigation in terms of key experiences discussed in patient interviews. The model illustrates how care navigation operated to build awareness, insight, connection and self-confidence in a way that enabled some people to take ownership of their care beyond the care navigation process. Figure 10. An experiential model of care navigation based on patient-reported experience



## 5.6. Summary

This chapter reported on the main themes from interviews with RTCs, CNs and GPs about the implementation of the Link-me model of mental health care. Prominent themes in the challenges for the uptake of Link-me in general practices were largely about a perception that model would increase workloads and the difficulties of releasing a room for care navigation. Related to this issue were matters of trust for GPs around a person not employed or known by the practice being based within the setting and seeing patients of the practice who were vulnerable with high needs. In contrast to this however, GPs did see the CN role as a clinical companion in a positive light and the provision of care package funding enabled further uptake.

In terms of the experiences of patients triaged to low intensity services or care navigation, our interviews confirmed that the Link-me DST was easy to complete, sometimes identified new needs, and allowed patients to set their priorities. There were some instances however where patients and practices would have preferred to offer private spaces for completion of the Link-me DST, out of busy waiting rooms. While patients in the minimal/mild symptom group had no problems completing the Link-me DST, few reported receiving further support information to their email addresses and fewer still engaged with these services. For this group overall there was a sense that they did not need to access the services where they were aware of them.

CNs and GPs involved in the delivery of the care navigation were largely positive. There were no surprises in terms of who was identified but from practice to practice there was considerable variation in the levels of engagement of GPs. Some GPs felt they did not fully understand the role of the care navigator and others met regularly and adopted a collaborative approach to patient care. An overwhelming positive theme from GPs was that care navigators could spend time with patients where they could not and that the role of the care navigator offered the potential for patients to make changes in areas they might have been thinking about but had not addressed with their GP. Adding a new person into the care team may have prompted some patients who had been stuck to try a new approach and re-engage in services in a way they had not before. Many of the GPs agreed that care navigation fitted easily into the general practice setting and was a program they wanted to

see continued to be offered to patients, however there were some challenges regarding making rooms available for ongoing care navigation.

From a patient perspective, experiences of receiving care navigation were largely positive. Where there were negative experiences it was often related to structural issues of long wait lists for services or uncontrollable factors such as a change to personnel in the care navigation delivery. Through analysis of the 31 patient interviews we were able to identify a commonly shared experiential model which saw patients come to reflect on priorities, learn new information, take ownership of their care and build self-confidence to continue with new practices and services once care navigation was completed. This experiential model can inform future optimisation of the stepped care model to closely align care navigation delivery with mechanisms of action to achieve best outcomes.



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# 6. Economic analysis

# 6.1. Chapter overview

This chapter presents data relevant to evaluation questions 3 and 4, examining the costs and outcomes of the Link-me intervention. It provides an overview of the methods used to calculate the costs included in the economic evaluation, and presents details of the care packages approved and accessed by participants in the severe symptom group allocated to care navigation. It also summarises the health care services and other resources used by people to manage their mental health across the symptom severity spectrum. We then describe the outcome measures and analytic techniques. The final sections report the results of our within-trial economic evaluation, taking both a health sector perspective (including health care system costs and the cost of the Link-me approach to triaging and tailoring care), and a limited societal perspective (including the cost of patients' lost productivity).

# 6.2. Data sources

The cost data presented in this chapter were collected from a variety of sources. Care package data provided by PHNs, University records, and data entered by care navigators in the Link-me portal were used to estimate the cost of screening and the delivery of care navigation. It was also important to capture the cost of other health care services used by participants during the trial period to account for any changes that may have occurred due to the intervention. The number and type of services (i.e., GP visits, hospital admissions, etc.) and medications were captured through the self-report resource use questionnaire completed by participants as part of the 6-month follow-up survey (section 3.3.1).<sup>31</sup> To understand the broader societal implications of the Link-me approach to care, the resource use questionnaire also incorporated questions about time absent from paid and unpaid work as well as days working at reduced capacity while at paid work (i.e., presenteeism).

It is worth noting that in completing the resource use questionnaire as part of their 6-month followup survey, some participants in the severe symptom group who were allocated to the intervention arm reported care navigator visits in the survey under allied health and 'other' services. Where it was explicit, we removed the counts of care navigation visits to avoid double counting and over inflating costs. However, there is still the possibility that participants reported care navigation visits as contacts with nurses, mental health nurses or psychology visits. We did not adjust for these potential sources of double counting in the preliminary analysis reported here. Participants also reported in the survey services paid for through care navigation packages. We carefully compared the care package details with participant reported resource use and adjusted the number of visits as needed to avoid this additional source of double counting. Standard Australian unit costs were

<sup>&</sup>lt;sup>31</sup> At 12-month follow up we will also have access to Medicare Benefits Schedule, Pharmaceutical Benefits Scheme and Primary Mental Health Care Minimum Data Set records for a subset of participants who have consented to us accessing this information. These administrative data sources will improve the reliability of the resource use data and precision of cost calculations.

applied to these resource use questions to calculate the cost of the services utilised by participants during the 6-month follow up period (see Appendix 6).

# 6.3. Descriptive analysis of resource use

### 6.3.1. Care packages approved and used

A total of 112 (27%) participants allocated to care navigation received funding for care packages across the three PHNs, with an average spend of \$669 per person (for the 112 participants who received a care package; \$178 per person when averaged out across the 420 people allocated to care navigation). Figure 11 provides a summary of the approved care package costs and the cost for services actually used and invoiced.



### Figure 11. Average cost of care packages per person, by PHN

Psychologists were the most frequently funded service through care packages with 48 participants receiving funding for a total of 461 sessions (Table 16). Other common uses of care package funding included physiotherapy (19 participants and 163 sessions), massage (typically remedial; 19 participants and 114 sessions), and exercise services including Tai Chi, Pilates, group fitness, and water-based exercise such as aquatherapy or swimming (18 participants and 236 sessions). The majority of people approved for a care package used at least some of their approved funding. However the extent to which the full amount was used varied across service types; for example, while on average 10 psychology sessions were approved per person, only 6 were accessed, while approved physiotherapy sessions were used in full by participants who accessed the service (an average of 8.6 sessions per person approved and used)<sup>32</sup>.

<sup>&</sup>lt;sup>32</sup> It is worth noting that in some cases, incomplete use of care package funding may be due to the service provider choosing to bulk bill the patient rather than invoice the PHN. We will explore this issue further in the final Link-me report.

Table 16. Summary of care package services and use

Service type	Participants with approved services n	Participants using the service n (%)	Total sessions approved n	Total sessions used n (%) <sup>33</sup>
Mental health		11 (70)		11 (70)
Psychology	48	38 (79)	461	213 (46)
Psychiatry	15	12 (80)	64	43 (67)
Family therapy/counselling	1	1 (100)	6	6 (100)
Mental health worker	1	1 (100)	10	10 (100)
Allied health		( )	-	- ( )
Physiotherapy	19	17 (89)	163	146 (90)
Nutrition/dietary services	10	8 (80)	58	32 (55)
Exercise physiologist	8	7 (88)	108	43 (40)
Occupational therapy	5	4 (80)	26	12 (46)
Chiropractic	3	3.(100)	21	19 (90)
Osteopathy	3	12 (67)	12	7 (58)
Podiatry	3 (	3 (100)	7	7 (100)
Other allied health professional	1	1 (100)	10	10 (100)
Medical specialists		1 al		
Pain specialist		7 (78)	26	23 (88)
Rheumatology	ET 3MA ST	3 (100)	4	3 (75)
Neurology	8 02 1	2 (100)	3	3 (100)
Gastroenterology / metabolic specialist	AL AL	2 (100)	4	4 (100)
Vascular specialist	1	1 (100)	2	1 (50)
Orthopaedic surgeon	OP 1	1 (100)	2	1 (50)
Dermatology	1	1 (100)	2	1 (50)
Alternative / complementary therapies				
Massage	19	16 (84)	114	87 (76)
Exercise <sup>34</sup>	18	12 (67)	236	135 (57)
Yoga	13	10 (77)	154	106 (69)
Meditation, mindfulness and related	8	5 (63)	28	8 (29)
training				
Acupuncture	5	4 (80)	44	29 (66)
Other <sup>35</sup>	2	1 (50)	20	10 (50)
Support service				
Vocational service	2	1 (50)	6	3 (50)
Housing related service	1	1 (100)	15	13.5 (90)
Other	1	0 (0)	1	0 (0)

Note: n = count. Some participants received funding for more than one service.

<sup>&</sup>lt;sup>33</sup> Percentage of sessions paid by PHN compared to the number of sessions approved for funding

<sup>&</sup>lt;sup>34</sup> Includes Tai Chi, Qi Gong, pilates personal training, group fitness, and water or swimming activities.

<sup>&</sup>lt;sup>35</sup> Includes defence and music classes.

### 6.3.2. Other resource use

In addition to informing our economic analysis, information from the resource use questionnaire was also used to examine the pattern of health and other service use across trial arms and symptom severity groups (Table 17). Overall, participants in the intervention arm were more likely to report the use of GPs (60% vs 52%), mental health nurses (8% vs 5%) and psychologists (40% vs 32%) than those in the comparison arm. Differences in service use varied across the two symptom severity groups. In the minimal/mild symptom group, the only observed difference was in relation to productivity, with participants in the intervention arm significantly less likely to report time off paid work in the past six months (42% vs 58%). In the severe symptom group, participants in the intervention arm were significantly more likely to report at least one visit to a GP (81% vs 72%), nurse (15% vs 9%), mental health nurse (16% vs 8%), psychologist (60% vs 47%), or other health professional (9% vs 4%) in the six months since enrolling in Link-me. Note that participants were asked to indicate their use of each service specifically for their mental health, and these figures may therefore underestimate participants' total use of these services.

Table 18 reports the mean number of services reported by participants for categories of service use. This table only included the people who reported any service use in the particular category. The number of psychologist visits and residential care days was significantly greater in the intervention arm than the comparison arm overall, and within the severe symptom group. There were no significant differences between trial arms found in the minimal mild symptom group in the number of times each service was accessed.

LISS WA Anin the seve Anis found in the min ad. Anis f **Table 17.** Participants self-reporting any use of specific services and time off work in the 6 months since trial enrolment, by trial arm and symptom severity group (N = 936)

Service type	All participants (comparison) N = 478	All participants (intervention) N = 458		Minimal/mild symptom group (comparison) N = 234	Minimal/mild symptom group (intervention) N = 2222		Severe symptom group (comparison) N = 244	Severe symptom group (intervention) N = 236	
	n (%)	n (%)	p value	n (%)	n (%)	p value	n (%)	n (%)	p value
GP	249 (52.1)	273 (59.7)	.02	74 (31.6)	82 (37.19	.22	175 (71.7)	191 (80.9)	.02
Nurse	24 (5.0)	36 (7.9)	.08	3 (1.3)	1 (0.5)	.31	21 (8.6)	35 (14.8)	.03
Mental health nurse	22 (4.6)	37 (8.1)	.03	2 (0.9)	× po(0.0)	.17	20 (8.2)	37 (15.7)	.01
Psychiatrist	78 (16.4)	90 (19.7)	.19	10 (4.3)	13 (5.9)	.45	68 (27.9)	77 (32.6)	.256
Psychologist	151 (31.7)	184 (40.3)	<.01	37 (15.9)	43 (19.4)	.33	114 (46.7)	141 (60.0)	<.01
Allied health	48 (10.1)	55 (12.0)	.34	10(4.3)	5 16 (7.2)	.18	38 (15.6)	39 (16.5)	.78
Other health professional	17 (3.6)	24 (5.3)	.20	67 (3.0) J	3 (1.4)	.23	10 (4.1)	21 (9.0)	.03
Online therapy	26 (5.5)	33 (7.3)	.26	6 (2.6)	10 (4.5)	.26	20 (8.2)	23 (9.9)	.52
Smartphone apps	84 (17.7)	80 (17.7)	(99)	29 (12.5)	28 (12.8)	.91	55 (22.7)	52 (22.3)	.92
Self-help (Books/DVDs)	94 (19.8)	109 (24.2)	JN 10	33 (14.2)	37 (17.1)	.41	61 (25.2)	72 (30.9)	.17
Ambulance	9 (1.9)	13 (2.9)	×33 ×	0 (0.0)	1 (0.5)	.30	9 (3.7)	12 (5.2)	.44
Emergency department	20 (4.2)	21 (4.7)	74	0 (0.0)	3 (1.4)	.07	20 (8.2)	18 (7.7)	.84
Time off paid work	181 (38.4)	164 (36.4)	<b>0</b> .53	80 (34.6)	57 (25.9)	.04	101 (42.1)	107 (46.5)	.33
Time off unpaid work	150 (31.8)	145 (32.2)	.90	38 (16.5)	45 (20.5)	.27	112 (46.7)	100 (43.5)	.49
Hospital	11 (2.3)	10 (2.2)	.91	0 (0.0)	1 (0.5)	.30	11 (4.6)	9 (3.9)	.70
Residential care	3 (0.6)	2 (0.4)	.70	0 (0.0)	0 (0.0)	n/a	3 (1.3)	2 (0.9)	.68
Medication	214 (45.1)	196 (43.2)	.55	56 (24.0)	59 (26.7)	0.51	158 (65.6)	137 (58.8)	.13

Note: Participants were asked about their use of services specifically for their mental health. All p values calculated using Chi-square test

Service type	All participants (comparison)	All participants (intervention)		Minimal/mild symptom group (comparison)	Minimal/mild symptom group (intervention)		Severe symptom group (comparison)	Severe symptom group (intervention)	
	Mean	Mean	р	Mean	Mean	р	Mean	Mean	р
	(min, max)	(min, max)	value	(min, max)	(min, max)	value	(min, max)	(min, max)	value
GP	4.35 (1,50)	4.05 (1,30)	.37	2.62 (1,26)	2.05 (1,8)	.07	5.1 (1,50)	4.9 (1,30)	.68
Nurse	2.61 (1,12)	3.56 (1,9)	.17	1 (1,1)	212,200	.45	2.85 (1,12)	3.6 (1,9)	.32
Mental health	3.81 (1,25)	5.19 (1,35)	.23	1 (1,1)	no observations	n/a	4.11 (1,25)	5.19 (1,35)	.37
Psychiatrist	3.35 (1,30)	3.89 (1,40)	.28	2 (1,5)	3 (1,8)	.22	3.54 (1,30)	4.04 (1,40)	.39
Psychologist	4.67 (1,26)	5.73 (1,30)	.01	3.24 (1,9)	4.28 (1,12)	.08	5.14 (1,26)	6.18 (1,30)	.05
Allied health	9.02 (1,90)	6.84 (0, 90)	.65	3.1 (1,8)	3.19 (1,10)	.34	10.58 (1,90)	8.51 (0,90)	.56
Other health professional	7.76 (1,52)	8.42 (1,52)	.83	6,29 (1,24)	18.33 (1,52)	.19	8.8 (1,52)	7 (1,26)	.59
Ambulance	1.44 (1,4)	1.23 (1,3)	.67	no observations	1 (1,1)	n/a	1.44 (1,4)	1.25 (1,3)	.70
Emergency department	2.15 (1,10)	1.33 (1,4)	.07	no observations	1 (1,1)	n/a	2.15 (1,10)	1.39 (1,4)	.12
Time off paid work (days)	31.86 (1,182)	40.2 (1,182)	0.14	18.48 (1,180)	20.81 (1,180)	.60	42.46 (1,182)	50.72 (1,182)	.32
Time off unpaid work (days)	40.31 (1, 182)	34.59 (1, 182)	.2\$	13.74 (1,90)	17.16 (1,100)	.33	49.33 (1,182)	42.34 (1,182)	.31
Hospital	9.55 (1,40)	11.44 (1,69)	.77	no observations	1 (1,1)	n/a	9.55 (1,40)	12.75 (1,69)	.64
<b>Residential care</b>	4.67 (1,12)	24.5 (19 <i>,</i> 30)	.02	no observations	no observations	n/a	4.67 (1,12)	24.5 (19,30)	.02

Table 18. Mean number of self-reported visits to services and days off work in the 6 months since trial enrolment, by trial arm and symptom severity group

Note: Participants were asked about their use of services specifically for their mental health. All p values calculated using negative binomial regression

# 6.4. Calculation of costs

### 6.4.1. Intervention costing

The cost of the Link-me intervention was calculated using a micro-costing approach, with the intervention divided into three components: the screening phase (i.e., completion of the Link-me DST in GP waiting rooms), the care navigation process and care packages (Table 19). Screening phase costs included those associated with IT/communication systems required to triage and follow patients, and the purchase of tablet devices for patients to use to complete the Link-me DST. The opportunity cost of a receptionist's time to hand out the devices and provide a brief introduction to the process was also estimated. The average health sector cost per person invited to complete the screening phase was estimated at \$7.34 for the base case analysis<sup>36</sup>. This cost does not include the initial development of the Link-me DST since these costs were already expended (sunk costs). When the initial development costs were included in the cost of screening the average cost per person increased to \$9.83.

The costing of care navigation included the training sessions for care navigators and the cost of care navigator time spent undertaking clinical duties (i.e., working with patients, liaising with the GP and other health professionals on their behalf, researching services, writing notes, and so on). Care navigators were asked to record, for each shift, the time they spent on these clinical tasks, trial specific tasks (e.g., trial-related meetings) and other activities (e.g., PHN staff meetings). In the base case analysis presented here we did not include trial-specific or other activities, but based our cost estimates on the average proportion of time spent in clinical activities (61%). This led to an estimated average health sector cost for care navigation of \$1,144 per person triaged to the severe symptom group and randomly allocated to the intervention arm (n = 420).

It is worth noting that in the trial, the Link-me model of stepped mental health care, including the delivery of care navigation, was most likely not running at full economic efficiency. This is because the rollout of the actual process of care navigation was still being fine-tuned, there was trial-related work required of care navigators, and there were likely "learning" effects being incurred. If Link-me was running at steady state the throughput of patients would be increased, learning effects finalised and therefore the average cost per person (as well as average cost per contact) would likely be reduced.

<sup>&</sup>lt;sup>36</sup> Base case analysis refers to the analysis which includes the most likely unit cost and outcome estimates. The base case analysis can be varied in sensitivity analyses where variations in costing (or outcomes) assumptions are made to determine any notable impacts on results.

### Table 19. Intervention costing

Item	Unit cost	Unit	Quantity	Total cost	Reference/Assumptions
Screening phase (all patients)					
Survey/DST development				\$61,423	
Survey/DST implementation and maintenance				\$153,000	
Tablet devices to undertake survey/DST	\$460.75	Each	39	\$17,969F	Assumes outright purchase; no maintenance and working condition at end of 1 year with 5% discount rate on resale price
Receptionist time to approach patients in waiting room <sup>37</sup>	\$23.39	Hours	410 LAS	<\$9, <del>5</del> 95	Assumes 1 minute of receptionist time per encounter; includes 25% on-costs
Subtotal without sunk costs			EL O	\$180,564	
Subtotal with sunk costs			2 Fill	\$241,987	
Average health sector cost/person invited to trial without sunk costs		CBH	(24,616)	\$7.34	Base case estimate applied to all participants in intervention arm but not control arm
Average health sector cost/person invited to trial (includes sunk costs)		THAT	24,616	\$9.83	To be applied in a sensitivity analysis
		I M RP	\$		
Care navigation (severe symptom group only)	UN				
Care navigator training - catering (one day session)	\$15.00	Per person	11	\$165	10 care navigators underwent training plus the trainer
Care navigator training - trainer cost (clinical psychologist)	\$1,277.64	Day	3	\$3,833	
Care navigator time (intervention efficiency as experienced in trial)	\$49.34	Hours	9,653	\$476,280	Assumes 61% of care navigator time was spent in clinical activities; includes 25% on-costs
Total care navigation cost as implemented in trial				\$480,278	

<sup>&</sup>lt;sup>37</sup> Hourly wage estimated using ABS Employee Earnings and Hours, Australia, May 2018; ANZSCO code 5421 Receptionist

Item	Unit cost	Unit	Quantity	Total cost	Reference/Assumptions
Average health sector cost/person with severe symptoms randomised to intervention arm			420	\$1,144	Base case using average within trial efficiency. Applied to participants in the severe symptom group and intervention arm only
Care packages	Specific to individual				Will be applied to individual participants
Note: DST = Decision support tool	THIS THE FRE	ENTHAS BE	EN PELLEAS	EDUNDER ACT 1982	

### 6.4.2. Total health sector costs

Health sector costs include those costs spent on medical services, paid by patients or third party payers. In this analysis total health sector costs were calculated for each participant as the sum of intervention costs (including screening, care navigation and care packages) and other health care resource use over the 6-month follow-up.

### 6.4.3. Total societal costs

The partial societal perspective incorporated the health sector costs described above, plus the cost of lost productivity. Participants were asked about the number of days (in the past six months) they had taken off from paid and unpaid work. They were also asked to report the number of days (in the past six months) when they were bothered by mental health problems while at work along with a question regarding their average capacity during these periods. The detailed methods for costing this information is contained in Appendix 6.

## 6.5. Analysis

The statistical analyses for the economic evaluation followed the principles detailed in Chapter 4 for the primary outcome analysis and employed an intention to treat (ITT) approach, where all individuals randomised were included in the analysis by their allocated trial arm status regardless of whether they received all, part or none of the intended intervention. Multiple imputation was used to account for missing cost and outcome data. The analyses reported in this chapter were also conducted according to the publicly available statistical analysis plan [45], with all analyses completed using Stata 15.0 [47].

The K10 psychological distress score, the primary outcome measure in this trial, was used to assess the benefit of the Link-me model of stepped mental health care. The difference in mean total health sector and societal costs between the intervention and comparison arms was compared to the mean difference in K10 scores between the intervention and comparison arms. These are presented as incremental cost-effectiveness ratios. We also calculated quality adjusted life years (QALY), using the Australian value set for the EQ-5D-5L to derive utility values at each assessment time point [57]. The utility values at baseline and 6 month follow-up were used to calculate total QALYs for each participant using the area under the curve method [58].

An analysis technique that accounts for the skewed nature of cost and QALY data (generalised linear models [GLM]) was used to estimate the differences between the intervention and comparison arms at six months with adjustment for symptom severity group (minimal/mild vs. severe) and baseline K10 scores. As with the primary analysis, general practice site was not included in the model for the primary analysis but included in a sensitivity analysis. Separate GLMs were used to estimate the difference in total health sector and societal costs as well as QALYs between the intervention and comparison arms at six months.

Incremental cost-effectiveness ratios (ICERs) were calculated as the difference in average costs between the two arms, divided by the difference in average outcome (i.e., K10 scores). Average ICERs and CIs were calculated using a nonparametric bootstrap procedure, with 1,000 iterations to reflect sampling uncertainty.

# 6.6. Findings

### 6.6.1. Health sector costs

Cost data was highly skewed with many participants reporting very low or no health sector costs. Overall, the intervention arm was found to have higher mean health sector costs than the comparison arm, with a mean difference or \$24 (95% CI \$8 to \$44) (Table 20). The mean difference varied by a few dollars between the primary and sensitivity analyses but remained statistically significant. The mean difference in health sector costs was larger for the severe symptom group which had a mean difference of \$333 (95% CI \$125 to \$623) for the primary analysis. The mean difference across the sensitivity analyses varied from \$227 (95% CI \$227 to \$514) to \$320 (95% CI \$94 to \$669) but remained statistically significant.

We observed no statistically significant difference between arms in the minimal/mild symptom group with a mean difference of \$25 (95% CI -\$7 to \$77). The sensitivity analyses also produced nonsignificant results, with mean differences of \$20 (95% CI \$-4 to \$60) and \$17 (95% CI \$-2 to \$50).

### 6.6.2. Societal costs

1982 There were no significant differences in mean societal costs between the intervention and comparison arms, overall or within symptom severity groups (Table 21). This pattern of results was observed in both the primary and sensitivity analyses.

### 6.6.3. Quality adjusted life years

Unsurprisingly, given there were no observed differences in quality of life (as reported in Chapter 4), we did not detect any significant differences in QALYs between the intervention and comparison arms across any levels of severity.

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**Table 20.** Health sector costs, including intervention costs, according to trial arm, in total sample and stratified by symptom severity group at 6 months (N = 1671)

	All participants	p value	Minimal/mild symptom group	p value	Severe symptom group	p value
Comparison, n	837		416		421	
Intervention, n	834		414		420	
Mean cost (SD) <sup>38</sup>			J.			
Comparison	\$1,282 (4,631)		\$311 (1,090)		\$2,240 (6,268)	
Intervention	\$2,237 (6,337)		\$436 (1,326) 50		\$4,012 (8,426)	
Mean difference, Coef. (95% CI)						
Primary analysis <sup>39</sup>	\$24 (8.3 to 43.8)	.001	\$25 (-6.9 to 77.4)	.15	\$333 (125.3 to 623.1)	<.0001
Sensitivity analysis <sup>40</sup>	\$20 (6.1 to 40.0)	<0.01	\$20 (-3.5 to 60.0)	.11	\$227 (45.1 to 514.4)	.01
Sensitivity analysis <sup>41</sup>	\$24 (7.3 to 46.3)	<0.01	\$17 (-2.2 to 49.6)	.09	\$320 (93.8 to 668.8)	<.01
Note: SD = Standard deviation; Coef. = Estim	nated coefficient; CI = Confid	ence interval.	BEE RUN OF			

<sup>&</sup>lt;sup>38</sup> Estimated using multiple imputation.

<sup>&</sup>lt;sup>39</sup> Mean for intervention arm minus mean for control arm estimated using generalised linear models (gamma family, log link) adjusted for baseline K10 (all models) and symptom severity group (model with all participants only). Estimated using multiple imputation.

<sup>&</sup>lt;sup>40</sup> Sensitivity analysis using complete cases only using generalised linear models (gamma family, log link) adjusted for baseline K10 (all models) and symptom severity group (model with all participants only).

<sup>&</sup>lt;sup>41</sup> Same as 40 but adjusted for general practice.

**Table 21.** Societal costs, including intervention and lost productivity costs, according to trial arm, in total sample and stratified by symptom severity group at 6 months (N = 1671)

	All participants	p value	Minimal/mild symptom group	p value	Severe symptom group	p value
Comparison, n	837		416		421	
Intervention, n	834		414		420	
Mean cost (SD) <sup>42</sup>						
Comparison	\$8,563 (19,170)		\$3,574 (10,945)		\$13,493 (23,566)	
Intervention	\$9,756 (21,421)		\$3,143 (10,570)		\$16,274 (26,091)	
Mean difference, Coef. (95% CI)			CHI CAL			
Primary analysis <sup>43</sup>	\$52 (-157.0 to 322.3)	.66	-\$41 (-369.5 to 483.8)	.85	\$731(-142.1 to 1831.3)	.11
Sensitivity analysis <sup>44</sup>	\$58 (-150.4 to 337.6)	.62	-\$5(-304.0 to \$19.5)	.98	\$512 (-145.4 to 1362.7)	.14
Sensitivity analysis <sup>45</sup>	\$71 (-185.4 to 409.9)	.62	\$97 (\$15.5 to 595.4)	.73	\$570(-136.3 to 1485.1)	.12
Note: SD = Standard deviation; Coef. = Estin	nated coefficient; CI = Confidenc	e interval.	BEE PRIM OF			

<sup>&</sup>lt;sup>42</sup> Estimated using multiple imputation.

<sup>&</sup>lt;sup>43</sup> Mean for intervention arm minus mean for control arm estimated using generalised linear models (gamma family, log link) adjusted for baseline K10 (all models) and symptom severity group (model with all participants only). Estimated using multiple imputation.

<sup>&</sup>lt;sup>44</sup> Sensitivity analysis using complete cases only using generalised linear models (gamma family, log link) adjusted for baseline K10 (all models) and symptom severity group (model with all participants only).

<sup>&</sup>lt;sup>45</sup> Same as 44 but adjusted for general practice.

### 6.6.4. Incremental cost-effectiveness ratios

The differences in costs, outcome measures and incremental cost-effectiveness ratios are reported in Table 22. The incremental cost per point change in the K10 score across all participants from the health sector perspective was \$1,018 (95% CI 259 to 10,471). From the societal perspective the cost per point decrease in the K10 was estimated at \$1,282 (95% CI Dominant to 21,964).

In the minimal/mild symptom group the cost per point decrease in K10 score was dominated from the health sector perspective since the costs were greater and the mean difference in K10 score was higher (indicating worse symptoms) in the intervention arm compared to the comparison arm. From the societal perspective, the costs were lower in the intervention arm, but the K10 scores indicated worse symptoms.

For the severe symptom group the incremental cost per point decrease in K10 score was \$896 (95% CI 234 to 3,978) from the health sector perspective and \$1,359 (Dominant to 8,677) from the societal perspective.

The incremental cost per QALY ratios were not calculated since there no significant differences in EQ-5D utility values or QALYs detected between the intervention and comparison arms.

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Table 22. Incremental cost-effectiveness ratios (based on unadjusted cost differences)

	Difference in mean costs (95% Cl)	Difference in mean effects (95% Cl)	ICER (95% CI)
All participants			
Health sector cost/change in K10 score	957 (448 to 1466)	-0.94 (-1.73 to -0.14)	1,018 (259 to 10,471)
Societal cost/change in K10 score	1205 (-665 to 3075)	-0.94 (-1.73 to -0.14)	1,282 (Dominant to 21,964)
Minimal/mild symptom group			
Health sector cost/change in K10 score	136 (-37 to 310)	0.09 (-0.83 to 1.02)	Dominated (Dominant to Dominated)
Societal cost/change in K10 score	-322 (-1752 to 1108)	0.09 (-0-83 to 202)	3,578 (Dominant to Dominated)
Severe symptom group		Str China	
Health sector cost/change in K10 score	1748 (751 to 2745)	-1 <b>.</b> 95 (-3.21 to -0.69)	896 (234 to 3978)
Societal cost/change in K10 score	2650 (-688 to 5987)	(1.95) 3.21 to -0.69)	1,359 (Dominant to 8,677)
Note: CI = Confidence Interval; ICER = Incremental Cost costs and greater benefits than the comparator.	-effectiveness ratio, based on bootstr	ap symulation; Dominated = Greater cost	s and less benefit than the comparator; Dominant = Le

# 6.7. Summary

This chapter provided the estimated cost of delivering the Link-me model of stepped mental health care, the additional resource use and lost productivity reported by participants, and the total health sector and societal costs for the intervention and control arms as well as incremental cost-effectiveness ratios. Our analysis sought to answer two of the primary evaluation questions, namely questions 3 (the costs of delivering care navigation to people with severe and complex mental illness) and 4 (the costs and outcomes of streaming people with lower levels of clinical need into low intensity services). Overall the results suggest that the average cost to the health sector of screening patients in GP waiting rooms was \$7.34 per patient. Health sector costs were \$24 per person higher in the intervention arm than the comparison arm, with a 1-point improvement on the K10 coming at a cost of \$1,018 in addition to costs associated with usual care. The cost per point decrease in the K10 was slightly higher from a societal perspective, at \$1,282 overall.

The health sector cost of delivering care navigation to people with severe and complex mental illness was estimated at \$1,144 per patient, with an incremental cost per point improvement on the K10 of \$896 from a health sector perspective and \$1,359 when productivity related costs were also considered. It is important to note that the analyses reported above used self-report data that includes both health care system costs (i.e., those paid by the government) as well as out of pocket costs paid by patients. The final analysis, to be conducted in 2020, will also be informed by Medicare claims data and will separate these costs out.

claims data and will separate these costs out. Overall, early indications suggest that triaging participants in the minimal/mild symptom group to low intensity services was not associated with lower costs that could be considered an offset to the increased costs of care in the severe symptom group. However, given that improvements in outcomes were observed this does not mean that Link-me is not a cost effective or an efficient intervention model but rather that improvements were observed within the context of higher costs. The longer-term evaluation will be important to determine whether the improvements in outcomes are continued as well as the observed cost differences. This longer-term data will also be used to estimate potential QALY gains. Even though differences in the EQ-5D-5L were not observed in this trial it may be the case that this very brief generic quality of life measure could not detect improvements in specific quality of life domains that may have been evident in the trial participants as the questionnaire simply did not measure these domains (e.g., self esteem). A published transformation algorithm from the K10 to other utility values will be used to estimate potential QALY improvements [59].

Finally, the cost estimates provided in this initial report were conservative and represent the largest expenditure expected. It is likely that the Link-me intervention, once implemented more broadly would be associated with increased efficiency and throughput. This may lead to lower per person costs with similar outcomes.

# 7. Interpretation and preliminary recommendations

# 7.1. Chapter overview

The Link-me trial described in the previous chapters provides an important step forward in our understanding of the outcomes, experiences, and costs associated with introducing a system of stepped mental health care into primary care. In this chapter, we provide a summary of the trial itself and of the findings as they relate to the first four primary evaluation questions. We then address the fifth evaluation question: the extent to which it is feasible to implement nationally a model of care that guides GPs in identifying high and low need patients presenting for mental health assistance and links them in with the services they need to improve their mental health. In doing so, we consider each of the core elements of Link-me required for a national rollout (namely, engaged general practices, a skilled care navigator workforce, a secure web platform, and care packages). We present some of the issues identified and how they were addressed within the trial context and

discuss options to refine the approach in the future. **7.2. Trial overview** Between August 2017 and September 2018, three regional trial coordinators successfully recruited 23 general practices, and over 15,000 adult patients in these practices completed the eligibility screening survey, whilst waiting to visit their GP, to determine eligibility for the Link-me trial. Of these, approximately half reported some form of current mental health need (i.e., symptoms of depression or anxiety or medication use for mental health) and were invited to participate in the randomised trial testing the benefits of the Link-me model of care. After completing the consent procedures, around 2,100 adults completed the Link-me DST in their GP waiting room. This achievement in conjunction with good follow-up rates saw us comfortably meet our target of being able to track the six-month outcomes of 352 participants identified as being likely to experience ongoing severe depressive or anxiety symptoms. This achievement, and the use of a randomised controlled trial design and multiple data sources in the evaluation, provide the highest level of scientific evidence supporting the effectiveness and acceptability of the Link-me approach to mental health care.

We note that although the use of a randomised controlled trial design is a major strength of this evaluation, it also introduced some extra work. A randomised trial design requires additional and important work for all involved, including RTCs, CNs, GPs, and patients, in order to collect the information required to provide high level evidence and adhere to the national guidelines on conducting ethical research. Trial-specific work (such as the need for patients to provide informed consent and agree to be randomised) not relevant to the outcomes, experiences, and costs associated with the Link-me model of care are not discussed below.

# 7.3. Summary of findings by primary evaluation question

### 7.3.1. How was care navigation implemented and what were the barriers and enablers?

#### 7.3.1.1. What we set out to do

We sought to address this question by implementing care navigation in 23 general practices and collecting information through interviews, meeting notes, and workshop findings about the experience of care navigation across different sites. We defined the Link-me model of care navigation as one in which a health professional worked collaboratively with patients and GPs to develop and implement a structured care plan designed to meet patient-identified priorities. Our intention was that care navigators would not require specialist mental health training. We also expected the CN to become an integral part of the general practice who would feel comfortable in the practice and would see patients within the practice location. To support a generalist model of health care, we designed a position description which outlined the skill set that a CN needed, a brief training package and a digitally-supported care planning toolkit to guide their work as they went about working with the results of the Link-me DST and the patient identified priorities. We were explicit in the CN training that their role was to navigate care and work closely with the GP in the practice, and not to serve as therapist or clinician. Key to our approach was the notion that supporting patients to address long term physical or social problems could have a major impact on AT HAS INFINE mental health outcomes.

#### 7.3.1.2. What we found

Our findings support the feasibility of delivering care navigation in the general practice setting. Generally speaking, the Link-me DST was acceptable to GPs and their patients (with mixed views on exactly when and where the tool should be completed for example, in a private room, or during a consultation, or ad hoc in the waiting room). Our interview data found that people who participated in care navigation found the experience beneficial, and the Link-me DST served as a prompt to reflect on priorities ahead of meeting with care navigators. Some people did report the experience as being life changing, building confidence and developing skills that they continued to use once care navigation had been completed. Overall, most of the GPs valued the role of the care navigator, and care navigators found the role rewarding. We identified a number of enabling factors that support the implementation of care navigation, including: the recruitment of health professionals with a skill set well matched to the requirements of the role; a user-friendly web platform to guide the delivery of structured care planning; and care navigators being well embedded, supported by their PHN, and having clear lines of accountability and reporting. The conceptual importance of the motivational interviewing-inspired approach used in Link-me was borne out in the care navigator experience, with all care navigators considering this approach an integral component of the role (see Chapter 5).

### 7.3.2. What are the costs of delivering care navigation for people with severe and complex mental illness who are being managed by GPs compared with usual care?

#### 7.3.2.1. What we set out to do

In understanding the costs associated with delivering care navigation, we first aimed to examine the components of care packages approved and used by participants, as well as health and other resource use more broadly. We then aimed to estimate the cost of the components of the Link-me intervention including the screening (i.e., Link-me DST completion) and care navigation phases. Our economic analysis also aimed to evaluate the cost of other health care use and impacts on productivity to understand if there were any changes that might occur due to the intervention. In this report we used a within-trial method to conduct preliminary analysis relevant to this evaluation question; the overall framework for the economic evaluation includes modelling to evaluate population-level costs and effects. We will conduct this modelling when the full trial dataset is available in 2020 and present the findings in the Link-me report. لكالر

#### 7.3.2.2. What we found

,090 Data provided by PHNs indicated that 27 percent of participants triaged to care navigation were approved for care package funding, and that the average care package cost for these participants was \$669 (substantially less than the proposed budget of \$2,000 per person). Care packages were used to fund a range of services across mental and allied health, medical specialists, alternative and complementary therapies, and other support services. As would be expected given the role of care navigators in linking patients into services, people triaged to care navigation also reported greater use of health services more broadly than their counterparts in the comparison arm; they were more likely to report vising a GP, nurse, mental health nurse, psychologist, or other health professional in the six months since enrolling in link me. From the health sector perspective, the total cost of delivering care navigation for people in the severe symptom group was estimated at an additional \$333 per patient (a statistically significant increase over usual care). From a societal perspective (i.e., including costs related to productivity), there was no significant difference in cost associated with care navigation. Incremental cost effectiveness ratios showed that the cost of a 1-point decrease in K10 score was \$896 from the health sector perspective and \$1,359 from the societal perspective. Given the time-limited nature of the trial, reported costs may be considered the upper estimate of the true costs associated with delivering care navigation, and would likely reduce over time once the intervention became established.

### 7.3.3. Does care navigation produce improved outcomes and experiences of care for people with severe and complex mental illness who are being managed by GPs in primary care?

#### 7.3.3.1. What we set out to do

We set out to introduce a systematic approach to identifying patients who might benefit from care navigation. This began by asking patients to complete the Link-me DST on a tablet-device. The Linkme DST is underpinned by a population health approach to primary care which identifies patients likely to have mild, moderate, or severe symptoms of depression or anxiety in three months' time. We surveyed all patients in each of these symptom severity groups six months later to determine

their health outcomes. We used this survey data to assess whether care navigation (including symptom feedback, priority setting, and up to eight structured care navigation contacts) improved K10 psychological distress at 6 months, relative to usual GP care. We also looked at the effectiveness of care navigation on secondary outcomes including depression, anxiety, days out of role, and quality of life. We aimed to understand the experience of care by interviewing a sub-set of people from each PHN who had participated in at least one structured care navigation contact.

### 7.3.3.2. What we found

The analyses presented in Chapter 4 indicate that care navigation reduces psychological distress. Overall, we found a 2-point mean difference in K10 scores between participants allocated to receive care navigation and usual GP care. The more elements of care navigation received, the greater the effect on psychological distress; for example, people who developed an action plan relevant to their needs, were provided with specific service recommendations by their care navigator, and were approved for and accessed care package-funded service showed a 9-point improvement in K10 scores relative to their counterparts receiving usual GP care. We found no significant effect on secondary outcomes. Although there is no assumption that all patients allocated to the severe symptom group require the full course of 8 structured contacts, or care package funding, further efforts to optimise this intervention, including improving uptake and engagement, appear warranted given its effect on clinical outcomes and positive feedback from participants, GPs, and care navigators.

# 7.3.4. What are the costs, patient experiences and outcomes of streaming people with lower levels of clinical need into low intensity services?

# 7.3.4.1. What we set out to $d_{0}$

Using the Link-me DST completed by GP patients on a tablet-device, we aimed to identify people likely to experience minimal/mild symptoms of depression or anxiety and randomly allocated them to receive: a) symptom feedback, priority setting, and a selection of low intensity service options relevant to their priorities, or b) usual GP care. Costs, outcomes, and experiences were assessed as described above for the severe symptom group (see 7.3.2.1 and 7.3.3.1).

### 7.3.4.2. What we found

Providing relevant low intensity service options to people classified into the minimal/mild symptom group had no effect on costs or clinical outcomes at 6 months, although people in this group were less likely to report taking time off paid work in the six months since enrolling in the trial. They also had positive feedback about completing the Link-me DST in their GP waiting room, but some either did not remember or had not accessed the support services they were recommended. Among those that remembered but had not accessed the services, there was a sense that they were not required but could be referred back to at a later date if needed. There are nonetheless significant learnings to be made about the impact of triaging to low intensity services when delivered at scale that could inform future directions for low intensity service design and evaluation, and we will address these further in future reports. Further work to monitor the effect of updating treatment options for this group as newly commissioned services are established may provide insight into which services are more acceptable or relevant to patient needs.

# 7.4. Considering the feasibility of a national implementation

The findings above indicate that the Link-me approach to mental healthcare can improve clinical outcomes at relatively low cost, and that its delivery in the general practice setting is well received by both GPs and patients. As such, further exploration of Link-me as a model of care that can be implemented nationally appears warranted and we therefore turn our attention to evaluation question 5. Our experience in the trial suggests that a successful national implementation of the Link-me model of care includes the rollout of four key components. Specifically, Link-me requires engaged general practices, an appropriately skilled care navigator workforce, a secure web platform, and the approval and delivery of care packages (Figure 12); issues to consider in relation to each of these core elements are outlined in turn below. Crucially, each of these elements must integrate seamlessly with the existing healthcare system, taking into account the availability and accessibility of services across all levels of care, existing referral pathways, and payment mechanisms (e.g., Medicare item numbers) to service providers for Link-me related care in this light, it is important to remember that while Link-me starts with a practice willing to be engaged and use a decision support tool, it does not end there. It is widely accepted that screening alone is insufficient and this approach is not recommended [60,61]; critical is the next step, in which people are supported to access appropriate care. The Link-me trial findings indicate that prognosis based triage to appropriate stepped care offerings results in good outcomes overall and better outcomes when people access the recommended treatment. Further our findings also highlight the importance of the reflection and engagement elements of the Link-me DST, all 31 care navigation participants we interviewed referred to the benefits of some priorities having been pre-established before their first contact with the care navigator. However, there is a clear need for further work to address treatment uptake and engagement in relation to both low and high intensity services. THIS THE PYTHE



### Figure 12. Core components of Link-me required for national implementation

Ś We found that ensuring practice engagement on Link-me was most successful where CNs developed effective working relationships with practice staff (including GPs, practice manager, receptionists and others), and felt well supported by their PHN. To facilitate this approach in future, PHNs may consider the crucial role of primary care liaison teams in working with practices to support an intensive induction period for care navigators, in which the care navigator has time to get to know all practice staff and the primary care and mental health teams within the PHN. In addition, the role of care navigators as a conduit between GPs and the PHN would provide a valuable incentive for practices; helping them stay up to date with services available in the local area as well as feeding back to the PHN about other services that might be required to meet the needs of the local patient population (e.g., pain clinics, financial planning services).

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Within practices implementing the Link-me approach to stepped care, identifying mental health need and triaging into appropriate care requires patients to be invited to complete the Link-me DST on a tablet device. Having engaged reception staff who are systematic in their approach to offering the tablet device is key here. While the best way to integrate this task into existing workflows may differ across practices, there is a clear role for care navigators in overseeing the process and checking in regularly with the reception staff to ensure they are not introducing a 'selection bias' into the approach. It is also important that reception staff work within an environment supportive of Link-me, where all practice staff see the value in ensuring that every adult has the chance to do a self-assessment of their mental health and receive support if required. The initial set up and ongoing engagement of Link-me practices will therefore need to include training and support for practice

staff to develop buy-in to the Link-me approach and a shared understanding of their roles and responsibilities (and those of the PHN). Development of Standard Operating Procedures will be required to ensure that tablets are secure and in good working order, and some practices may also require IT upgrades to support compatibility with the secure Link-me web platform.

Clearly, there is work to be done in building general practice capacity to work within the Link-me model of stepped care, using the Link-me DST to triage patients to structured care navigation or low intensity services. It is therefore worth considering alternative models; for example, releasing the Link-me DST as a publicly available mobile phone app, for members of the community to use when and where they like, or establishing a care navigator workforce for general practices to use as they see fit. On the face of it, these options may seem reasonable. However, they raise a host of other potential issues and medicolegal implications. Widespread access to the Link-me DST runs counter to its intended use as a tool to support, not replace, clinical judgment, and its development and validation in the primary care setting. Further, while it may offer some benefit through self-assessment, it would not address the need identified by people in the severe symptom group for further support to connect and engage with their care navigator. Consider also that unrestricted access to care navigators would not address the need for more efficient allocation to effective care in general practice.

### 7.4.2. Skilled care navigator workforce

Key enablers to the development of a national care navigator workforce include recruitment of individuals with a skill set aligned to the role, access to up-to-date resources and training, and provision of ongoing supervision and support. The care navigator role was designed to be implemented at scale and the position description was developed with this in mind. Importantly, the care navigator was expected to act as a support (rather than a therapist) to the patient and a clinical companion to the GP. This role requires a person with excellent self-awareness, open-mindedness and communication skills. We have modified the position description used in the trial for a national rollout to make these relational elements more explicit (see Appendix 9).

Once care navigators with a suitable skill set are employed, there is a need to ensure they receive training in the motivational interviewing-inspired approach from accredited Link-me trainers. To enhance feasibility of delivering this training where and when required, we suggest developing an online care navigator 'one-stop-shop'. This would allow care navigators to complete initial and refresher training modules as needed, receive alerts about updated locally and nationally relevant resources, and potentially have access to expert support through webinars or message boards. Such a resource would also have the potential to encourage a sense of community and professional belonging amongst care navigators, through for example a chat function allowing them to interact with their colleagues and draw on each other's experiences and advice.

### 7.4.3. Secure web platform

Through the trial we found that the Link-me DST patient interface is generally fit-for-purpose and would likely require only cosmetic changes prior to a national rollout, to further enhance engagement with the tool and the treatment recommendations it provides. The predictive algorithm that underpins the Link-me DST could benefit from future refinements and would need periodic calibration checks, in line with best practice.

On the other hand, further investment in improving the functionality and look and feel of the care navigator portal is recommended as this is in an earlier stage of development and could benefit from investment in user-centred design. This initial cost would likely be offset by saved CN time and improved impact of the model of care.

The implementation and sustainability of Link-me nationally would also benefit from upgrades to some fundamental aspects of the web platform. For example, enhancing interoperability of the platform with existing IT infrastructure such as practice software, the PMHC MDS, and potentially other practice-based screening tools would substantially reduce the administrative burden on care navigators, ensure GPs were kept informed of their patient's Link-me progress, and reinforce the role of the care navigator as a clinical companion to the GP.

The web platform would also need to be optimised for increased patient and care navigator numbers across more sites (e.g., increased hosting and user support, database capacity), and consideration given to data storage and ongoing management and security of the portal (including the provision and revocation of access with turnover of personnel). In this respect it may be worth considering the aspects of the web platform that require consistency across sites and those that are flexible and could be de-centralised. The latter could be managed by an appropriate member of staff at each PHN, and include activities such as the creation and management of user profiles and monitoring and updating of low intensity service options. Developing clear roles and responsibilities for the maintenance of an up-to-date menu of services for people with minimal/mild symptoms to select from will be key in optimising uptake and engagement with these services in future.

### 7.4.4. Care packages

Delivery of care packages to date suggests that care navigators are judicious in their use of this funding and proactive in identifying and linking patients in with appropriate care package-funded services. The guidance document provided by the Department of Health appears to have achieved sufficient clarity on services that are in and out of scope while allowing for flexibility, and requires minimal revisions to be relevant for a national rollout. Topics to consider for future iterations of this document include expanding the list of explicitly in or out of scope services, providing alternative suggestions as to how to address patient needs where care package funds are out of scope <sup>46</sup>, and providing resources to support clear communication around the approval of services to both patients and providers. Some of the more frequent grey areas raised in the trial that could be considered for discussion in the guidance document include legal fees (including legal aid gap fees), education fees, psychological or psychiatric assessments for children of care navigation participants, and transport to and from care navigation and other health-related appointments.

Once a particular service is deemed in scope, there is a need for streamlined business systems and procedures to ensure prompt delivery of services and payments to providers. One option may be to

<sup>&</sup>lt;sup>46</sup> Where care packages were out of scope, care navigators were typically proactive in identifying options for participants to make the best use of their available income in order to ultimately access relevant services on their own. Examples include providing information about applying for health and other concession cards, linking participants with financial counsellors, and working with the GP to support applications to the NDIS for those who were eligible. The Department of Health also provided assistance by suggesting alternatives where requests for care package funding were denied.

implement a preferred provider type model nationally, whereby service organisations or individuals providers apply for Link-me accreditation and are registered on a database accessible through the care navigator web platform for easy referral and payment. Any such model should of course retain flexibility and allow patients to access non-preferred providers where appropriate (e.g., due to patient preference for a particular provider or novel uses of care package funding not previously considered). Consideration must also be given to how care packages and existing payment mechanisms can be integrated, to address structural barriers to payment identified during the trial (e.g., use of care packages to pay gap fees for Medicare-funded services). It will also be important to establish ongoing governance and monitoring frameworks to oversee the implementation and use of Link-me care packages, and existing initiatives such as home care packages may provide useful examples of these.

# 7.5. Preliminary recommendations

In an Australian-first individually randomised controlled trial, we found that the Link-me approach is well received and leads to improved mental health outcomes at low additional cost. The trial therefore provides gold-standard evidence to support the Link-me approach to system design.

Based on this evidence we put forward four key recommendations for the future, as follows:

- 1. That the Link-me approach to stepped mental health care be implemented via PHNs in a staged roll-out. PHNs could be resourced to identify general practices that would benefit most from implementing the Link-me approach.
- 2. That the Link-me approach should be considered for any new greenfield developments in adult mental health care, and could be investigated as an option for adult mental health centres.
- That following the success of the Link-me approach with English-speaking primary care consumers, further investment is made in refining it for communities where languages other than English are spoken.
- 4. That following the success of the Link-me approach in mainstream general practice, consideration be given to how it could be refined for use within Aboriginal Community Controlled Health Services.

To support the adoption of these recommendations, we provide an implementation checklist at Appendix 10. The checklist outlines the essential activities to be undertaken within each of the four core elements outlined in section 7.4 above. By using it to develop and track their implementation strategy, organisations can support continued evaluation and improvement of the Link-me approach.

# 7.6. Summary

With support from the three PHNs involved we successfully conducted a gold-standard randomised controlled trial testing the effectiveness of the Link-me model of stepped mental health care, which included the delivery of an innovative model of care navigation with access to additional funding via 'care packages'. We were able to demonstrate that the introduction of a whole of practice approach and care navigation resulted in better mental health for participants than usual general practice care. The gold-standard evidence generated by the trial provides support for a staged rollout of the

Link-me approach to care through PHNs and new adult mental health care settings, and itself contributes to the feasibility of such a rollout. By providing reassurance that the Link-me model is effective and acceptable, the findings presented in this report can enhance buy-in from people on the ground. Importantly, the trial also afforded an opportunity to learn what worked well and what could be improved to enhance the feasibility of scaling up Link-me into routine care across Australia. We identified four core components of Link-me that are required for delivery at scale, and used trial findings within each of these to develop an implementation checklist. Data collection is ongoing and a final report will be submitted in July 2020.

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# Appendix 1. Work informing Linkme

The Link-me model of care builds upon almost 15 years of work we have conducted to understand how mental health problems present and are managed in primary care. Hundreds of GPs, patients, and carers have contributed to this process, a brief overview of which is as follows:

2001-2002	Management of Depression (MoD) study
	Objective: Sought to describe depression management in general practice, in
	psychological strategies.
	Participants: 153 Victorian GPs.
	<i>Key reference:</i> McGarry H, Hegarty K, Gunn J. How do Victorian GPs manage patients with depression? <i>Australian Family Physician</i> 2005; 34: 603. <u>https://www.ncbi.nlm.nih.gov/pubmed/15999175</u>
2003-2005	diamond pilot study
	Objective: To explore the patient, practitioner and systems factors affecting
	setting.
	S B KO N
	<i>Participants:</i> 646 GP patients and 2 GPs from 2 regional general practices.
	Study overview: http://bic///2pAm20d
2005	diamond consortium
	Objective: Establishment of a depression research network.
	Participants: A mutidisciplinary team consisting of 92 members.
	Study overview: <u>http://bit.ly/2qHaJkS</u>
2005-2015	diamond cohort study
	<i>Objective:</i> Explore the course and management of depression in the primary care setting.
	Participants: 789 GP patients with depressive symptoms identified via
	screening almost 8000 primary care attendees.
	Key references: Gunn J, et al. Who is identified when screening for depression is undertaken in general practice? Baseline findings from the Diagnosis, Management and Outcomes of Depression in Primary Care (diamond) longitudinal study. <i>Medical Journal of Australia</i> 2008; 188: S119-125. <u>https://www.ncbi.nlm.nih.gov/pubmed/18558911</u>

	Gunn J, et al. The association between chronic illness, multimorbidity and depressive symptoms in an Australian primary care cohort. <i>Social Psychiatry and Psychiatric Epidemiology</i> 2012; 47: 175-184. <u>http://bit.ly/2q0BHY4</u>
	Gunn J, et al. A trajectory-based approach to understand the factors associated with persistent depressive symptoms in primary care. <i>Journal of Affective Disorders</i> 2013; 148: 338-346.
	https://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+23375580
	Ambresin G, et al. What factors influence long-term antidepressant use in primary care? Findings from the Australian diamond cohort study. <i>Journal of Affective Disorders</i> 2015; 176: 125-132. http://bit.ly/2pHfknH
	Davidson S, et al. Mental health interventions and future major depression among primary care patients with subthreshold depression. <i>Journal of Affective Disorders</i> 2015; 177: 65-73.
	https://www.ncbi.nlm.nih.gov/pubmed/25745837
2006	MoD 2 study
	<i>Objective:</i> Examine changes in patient management and referral for care following the introduction of the Better Outcomes in Mental Health Care Initiative (BOiMHC)
	Participants: 133 Victorian GPs.
	HET ONNOF
	Key reference: McGarry H et al. Managing depression in a changing primary mental
	healthcare system: Comparison of two snapshots of Australian GPs'
	treatment and referral patterns. <i>Mental Health in Family Medicine</i> 2009; 6: 75-83. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2777605/</u>
2006	RE-ORDER phase 1
	<i>Objective:</i> To relexamine the way in which people experiencing depression are cared for in the community.
	Participants: 576 patients with depressive symptoms.
	Key references:
	Dowrick C, et al. Resilience and depression: perspectives from primary care.
	Health 2008; 12: 439-452. <u>https://www.ncbi.nlm.nih.gov/pubmed/18818274</u>
	Boardman F, et al. Resilience as a response to the stigma of depression: A
	mixed methods analysis. <i>Journal of Affective Disorders</i> 2001; 135: 267-276.
	http://bit.ly/2p87XUt
	Kokanovic R, et al. Maps, models, and narratives: The ways people talk about depression. <i>Qualitative Health Research</i> 2013; 23: 114-125. http://bit.ly/2qH151t
2006	RF-ORDER phase 2
	<i>Objective:</i> To elicit the ideas of stakeholders about the best ways to manage depression in primary care; create a list of key elements based on their

	particular perspectives; and gain consensus about the most significant elements to be included in the management of depression in primary care.
	<i>Participants:</i> 586 stakeholders from the government, non-government (included consumer and carer organisations, education, emergency services), allied health and health sectors and academics.
	<i>Key reference:</i> Palmer V et al. Diverse voices, simple desires: A conceptual design for primary care to respond to depression and related disorders. <i>Family Practice</i> 2010; 27: 447-458. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2908158/
2006	
2006	<b>Chiective:</b> To develop practice level improvements informed by the
	theoretical framework of complexity theory.
	<i>Participants:</i> 4 privately owned GP clinics, 1 corporate GP clinic, 1
	community health centre.
	<i>Key references:</i> Gunn J et al. Embedding effective depression care: using
	theory for primary care organisational and systems change. Implementation
	Science 2010; 5: 62-76.
	https://www.ncbi.nlm.nih.gov/pmc/akticles/PMC2925331/
	Gunn L et al. Re-organising the care of depression and related disorders in
	the Australian Primary Health Care Setting. A report submitted to the
	Australian Primary Health Care Research Institute. Canberra, APHCRI, 2008.
	http://files.aphcri.anu.edu.av/research/full_report_13593.pdf
2010	LCC2AN A C
2010	Objective: To develop and pilot a social prescription tailored treatment plan
	for patients with depression and anxiety and comorbid chronic physical
	illness , , , , , , , , , , , , , , , , , ,
	Privice Andrews CD eligies & 10 perticute with despection and
	anxiety
	Study overview: <u>http://bit.ly/2q0UGlh</u>
2013	Emotional goal modelling for the development of a clinical prediction tool
	<i>Objective:</i> To obtain the views of stakeholders about the development of a
	clinical prediction tool to identify people at risk of persistent depression.
	Participants: 4 GPs, 1 psychologist, 3 researchers.
	Reference: Alatawi F. Mendoza A. Miller T. Psychologically-driven
	requirements engineering: A case study in depression care. 25 <sup>th</sup> Australasian
	Software Engineering Conference (ASWEC), pp 41-50.
	https://bit.ly/2K2sRRq
2014	Development of the <i>diamond</i> clinical prediction tool
	<i>Objective:</i> Develop a prognostic tool to predict future depression severity
	among primary care patients with current depressive symptoms at three
	months.

	Participants: 593 diamond participants
	<i>Reference:</i> Chondros P, et al. Development of a prognostic model for predicting depression severity in adult primary patients with depressive symptoms using the diamond longitudinal study. <i>Journal of Affective Disorders</i> 2017; 227: 854-860. <u>10.1016/j.jad.2017</u>
2014	Development of a clinical predication tool online platform
	<i>Objective:</i> Employ a user-centred design approach to a developing a digital platform through which to deliver the <i>diamond</i> clinical prediction tool, ensuring it is engaging and meets patient need.
	<i>Participants:</i> 16 healthy participants and 8 patients with current depressive symptoms.
	<i>Reference:</i> Wachtler et al. Development of a mobile clinical prediction tool to estimate future depression severity and guide treatment in primary care: User-centered design. <i>JMIR mHealth and uHealth</i> 2018; 6: e95. https://mhealth.jmir.org/2018/4/e95/
2014-2018	Target-D randomised controlled trial
	Objective: Target-D aimed to test whether using the diamond clinical prediction tool to tailor treatment recommendations to an individual's predicted depression symptom seventy is a clinically effective and economically efficient way of reducing depression symptoms, relative to usual care. Participants: 18,035 Victorian GP patients screened and almost 1,868 randomised, followed up at 3 and 12 months. Trial protocol: Gunn Let al. Target-D: A stratified individually randomized controlled trial of the diamond clinical prediction tool to triage and target treatment for depressive symptoms in general practice: Study protocol for a randomized controlled trial. <i>Trials</i> 2017; 18: 342. https://doi.org/10.1186/s13063-017-2089-y
2015	Depression monitoring in the general practice setting
2013	<i>Objectives:</i> Investigate the concept of recovery from depression from the patient perspective.
	<i>Participants:</i> 576 RE-ORDER patients and 8 case studies with patients, GPs and carers.
	<i>Key references:</i> Johnson C, Gunn J, Kokanovic R. Depression recovery from the primary care patient's perspective: 'Hear it in my voice and see it in my eyes'. <i>Mental Health in Family Medicine</i> 2009; 6: 49-55. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2777597/</u>
	Johnson C. An exploration of monitoring people with depression in the general practice setting (PhD Thesis). https://minerva-access.unimelb.edu.au/handle/11343/55698

2015 –	Development of a motivational interviewing-inspired approach to working with patients with multimorbidity
	<i>Objectives</i> : Investigate the potential for motivational interviewing skills to be applied when working with general practice patients who have
	multimorbidity, and develop resources to support the implementation of these skills.
	Participants: 6 registered nurses
	<i>Key references:</i> McKenzie K, Pierce D, Gunn J. A systematic review of motivational interviewing in healthcare: the potential of motivational interviewing to address the lifestyle factors relevant to multimorbidity. <i>Journal of Comorbidity</i> 2015; 5: 162-174. <u>10.15256/joc.2015.5.55</u>
	McKenzie K, Pierce D, Gunn J. Guiding patients through complexity:
	Motivational interviewing for patients with multimorbidity. <i>Australian Journal of General Practice</i> 2018; 47: 8. <u>https://bit.ly/2JSJUX9</u>
	McKenzie K et al. Development of a care navigation intervention for people living with mental-physical multimorbidity. Manuscript in development.
2016	Patient perspectives of nurse-delivered collaborative care for depression
	Objective: To investigate how collaborative care for the management of
	depressive symptoms.
	<i>Participants:</i> 12 GP patients with severe depressive symptoms; reported in unpublished student thesis
2016 -	Antidepressant management in general practice
2010	Objectives: Explore how patients and GPs understand antidepressant
	medication management of depression, and how to support appropriate use and cessation.
	Participants: 8 GPs and 9 people with a history of long-term use of
	antidepressants to date; study is ongoing.
2016 —	Factors influencing uptake of and adherence to internet-based cognitive behavioural therapy
	Objective: To explore patients' expectations and experiences of internet-
	based cognitive behavioural therapy to further our understanding the factors influencing the uptake and adherence of these programs.
	<i>Participants:</i> 10 GP patients with depressive symptoms; reported in unpublished student thesis.
2017	Primary care patients' preferences related to treatment for subthreshold depressive symptoms
	Objective: To explore primary care patients' preferences related to
	non-pharmacological and self-help strategies.
	<i>Participants:</i> 14 GP patients with subthreshold depressive symptoms; manuscript under review.

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# **Appendix 2. Example Link-me DST** screenshots

# **Question pages**



# Symptom feedback



# **Priority setting**



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## **Treatment recommendations**

### Severe symptom group



# **Appendix 3. Care package guidance**

Final at 12.10.17

### PHN Lead Site Evaluation Link-me Trial

Guidance on funding and data collection for additional elements of complex care packages

#### (Department of Health guidance)

### Purpose

To provide guidance to Regional Trial Coordinators and Care Navigators on:

- the types of services that can be funded as additional elements of complex care packages;
- the suggested process for managing the regional approval arrangements for purchase of additional services for patients; and
- the special data collection requirements for patients who receive additional services.

### Background

- 1. Patients identified as having a severe and complex mental illness, who agree to participate and are allocated to the intervention group will be provided with an **individual care package**, designed and planned in collaboration with the Care Navigator. This is a key role of the Care Navigator.
- 2. Individual care packages can include two broad groups of services:
  - Services available as part of the usual health system that the individual may not be currently accessing. These can include, for example, existing services commissioned by the PHN, referral to a private psychiatrist or psychologist through the MBS system, or having a mental health nurse assigned to assist the GP on clinical management including outreach and home-based work.
  - Additional support services not usually available in the primary mental health care suite of services for people presenting with severe and complex mental health problems, funded from Lead PHN funding.
- 3. Additional funding has been provided to the three PHNs involved in the Link-me trial to enable payment for agreed additional services provided to those in the study who are assigned to the intervention arm of the severe and complex group.
- 4. Only these three PHNs have the flexibility to use funds for such purposes. As noted in the Department of Health guidance documentation released to support mental health reforms:
  - only the three lead PHNs are expected to deliver clinical care packages for those with severe and complex mental illness that entail use of additional funds provided as part of overall Lead Site funding;

 by the end of the trial, a broader national roll-out of innovative funding models to support clinical care coordination and packaged care arrangements will be based on the lessons derived from the three Lead PHNs.<sup>1</sup>

### What additional services can be purchased?

- 5. Prior to deciding that the patient be provided additional services funded from the PHN special funding, it is essential to establish that their individualised care plan makes best use of services available through current health and social support services available in the region that the individual may not be currently accessing. It is anticipated that in the majority of cases, the individual care plan will entail linking the person to these services rather than funding new services that are not part of the existing service offer. Examples include:
  - Referral to a private psychiatrist or psychologist through the MBS
  - Assignment of a mental health nurse to assist the GP in clinical management (including outreach and home-based work)
  - Referral to a service provider commissioned through the local PHN.
- 6. In cases where the patient is assessed as requiring additional services, these services need to meet two essential criteria:
  - a. Additional services purchased by the PHN should be confined to those identified as critical to improving the person's mental health. Services may include those targeted at physical health needs where these are regarded as contributing to, or arising from, the patient's mental ill health. The need for such services should be documented in the patient's individual care plan as endorsed by their GP
  - b. Any additional services purchased need to supported by evidence that such services are effective in contributing to positive mental health outcomes.
- 7. The special funds provided to PHNs to support the Link-me trial are **for purchase of services only and not goods**.
- 8. Additional services included in individual care packages will typically be health services delivered by a clinical health professional but may be delivered by others as ancillary to formal health care.
- 9. Eligible services are those delivered in community settings and do not include public or private inpatient care (same day and overnight).
- 10. Services eligible for funding do not include funded psychosocial disability services that are delivered through other programs, both state and Commonwealth. However, this does not exclude funding of ancillary social support services necessary to promote

<sup>&</sup>lt;sup>1</sup> Department of Health 2016. Primary mental health care services for people with severe mental illness. See <u>http://www.health.gov.au/internet/main/publishing.nsf/Content/PHN-Mental Tools</u>

gains in the person's mental health where these are delivered under the guidance of a health professional.<sup>2</sup> As examples:

- a social support agency may be funded to assist a client who requires help in securing safe and affordable housing where lack of such is identified as a significant contributor to their current mental health condition; or
- a peer support worker could be funded to provide coaching and support to a client in connecting with social networks to reduce their isolation.
- 11. Services not usually classified as mental health services may be purchased but only where these are identified as critical to improving mental health outcomes. Examples include funding a dietitian or nutritionist to advise a client on weight loss, or funding an exercise physiologist to assist the client increase their activity levels.
- 12. Funding may also be used to pay for medical and allied health gap fees where these are preventing the person from accessing necessary services. Examples include payment of the gap fee for the client to be assessed by a psychiatrist; and payment of gap fees for the individual to be treated by a psychologist, where these are documented as critical components of the individual mental health plan.

### How the arrangements can be implemented

- 13. Assessment of the patient's need for additional services should be made by Care Navigators as part of the overall development of individual care plans.
- 14. Where additional funding is required to implement the individual care plan, this should be sourced from the Link-me Trial PHN budgets. Arrangements for approval of individual cases should be made by the PHN possibly through the PHN Regional Trial Coordinators.
- 15. For clients requiring additional services to be funded from the PHN special budget, a cap of \$2000 per client is recommended.

## Data collection requirements

- Information on services used by patients in the complex care group is essential to enable care packages to be described and costed for the evaluation of the national trial.
- Services used will fall into one of five categories, coded as A to E in the table below. Although only services in categories A, B and C are funded by PHNs, we need to know about other services that the consumer receives for the purposes of the evaluation.

<sup>&</sup>lt;sup>2</sup> Health professionals are those registered as such under the relevant professional Boards of the Australian Health Practitioner Regulation Agency (AHPRA), or social workers who are members of the Australian Association of Social Workers (AASW).

• The five categories are summarised below, along with any data collection implications for Care Navigators and Trial Coordinators.

Service category		How data will be collected for the	Implications for Care	
		evaluation	Navigators and Trial	
			Coordinators	
Α.	Service contacts with Care	Data will be recorded and stored in	Contacts with Navigators will	
	Navigators for patients	the Link-me data capture system	need to be recorded on an	
	assigned to the		occasion of service basis.	
	intervention arm			
B.	Additional services	Services need to be recorded using	A process for recording and	
	purchased from the special	the agreed system for classifying and	coding additional services	
	Link-me Trial funding	capturing data (see below).	willneed to be implemented	
	managed by PHNs		within each PHN region.	
		Data will be recorded and stored in	Options include using	
		the Link-me data capture system	invoices submitted by	
		St G	additional service providers	
			as triggers for data recording	
		att a long the	either by the Care Navigator	
		EEE EMA OF F	or Regional Trial Coordinator.	
C.	Services provided by PHN-	Services provided by PHN-	Nil.	
	commissioned	commissioned providers will be		
	organisations that are in-	collected in the PMHC Minimum Data	But the national evaluators	
	scope for PMHC MDS	Set and is the responsibility of those	will need to ensure capacity	
	reporting	providers. PMHC MDS data will be	for generating SLK-581 keys	
		provided to the evaluators and	within the Link-me specific	
	SVX	inkage will be via the SLK-581	data collection.	
	(HICHE	statistical linkage key.		
_				
D.	Medicare-subsidised	From Medicare records of actual use,	Regional Trial Coordinators	
	medical and allied health	provided at study end by the	will be required to assist in	
	services plus PBS	Department of Human Services for	tollowing up participants to	
	pharmaceuticals	consenting patients.	return Medicare consent	
			forms via the Link- me portal.	
Ε.	Mental health services	Service utilisation for these types of	Regional Trial Coordinators	
1	provided by state and	services will be captured by a specific	will be required to follow-up	
1	territory government-	service history survey of all trial	participants to prompt their	
1	funded agencies including	patients conducted at the conclusion	completion of service	
1	NGOs; private hospital	of their involvement.	utilisation surveys via the	
1	services;		Link-me portal.	

• An important implication of the above is that Care Navigators do not need to record any specific information on the PMHC Minimum Data Set. All data reported by Navigators will be reported and stored on the specific Link-me data collection established for the trial.

# Recording details of 'additional services' provided to intervention group patients that are funded by the PHN

- 16. All additional services approved and funded by the PHN need to be recorded for the study. As noted, this is necessary both to describe the types of services provided to the patient as well as assign a cost to the overall package.
- 17. The Link-me data collection requires the following data to be recorded for each additional service provided. Where multiple additional services are provided within a single contact, coding should be based on the main service as identified in the individual care plan.

Data item	Response options	Details
PHN Code	PHN201	North Western Melbourne
	PHN109	North Coast
	PHN301	Brisbane North
Patient ID	The unique identifier assigned to the patient	Éach patient in the study will
	at registration	have a trial-specific unique ID.
Date of service	DDMMYYYY &	For Date fields, data must be
	A MANNEN	recorded in compliance with the
	AN A ANN	standard format used across the
	ALL A OPT	National Health Data Dictionary;
	UNITO OF	specifically, dates must be of
		fixed 8 column width in the
	O LA VII	format DDMMYYYY, with
		leading zeros used when
		necessary to pad out a value.
		For instance, 13th March 2008
		would appear as 13032008
Service type49	1. Support service - Vocational	Services to assist the person in
		gaining or securing employment
	2. Support service - Educational	Services to assist the person
		enter, or begin, an education
		program.
	3. Support service – Housing related	Services to assist the person
		obtain, or maintain, suitable
		housing.

<sup>&</sup>lt;sup>49</sup> The proposed code list aims to classify additional services to meaningful groups.

	1		
	4.	Support service – Other	Services to provide other
			personal support
	5	Family therapy/counselling	Services to assist the natient
	5.		and the information
			and their family.
	6.	Meditation, Mindfulness and	Structured training programs to
		related training	assist the person in dealing with
			stress.
	7.	Nutrition/Dietary services	Services to assist the person
			with dietary or putrition
			management
	0	Evereice physiologist	Engagement of recordinal
	ð.	Exercise physiologist	Engagement of recognised
			exercise physiology practitioner
			to assist the person in
			establishing a physical exercise
			nrogram
		$\sim$	
	q	Drug and alcohol counselling	Services to assist the nerson
	5.		
		E A A	manage a substance abuse
			problem.
	10.	Other allied health service	Services delivered by another
		$\mathcal{O}^{V}$	allied health practitioner not
		S. N. K.	described elsewhere in this list.
		KHY KIN KNI	
	11.	MBS gap payment – Psychiatrist	
		Nr. On LP	
	<u>,</u> 12.	MBS gap payment – Psychologist	
	$\sim$		
C	13.	MBS gap payment – Other allied	
		Realth	
	14	Other additional service	
	14.		
Cost to PHN	Enter in	whole dollars	This is the amount paid by the
			PHN for the service
1	1		1

24. The Department recommends that reporting of the additional service use data be managed by Regional Trial Coordinators. Triggers to prompt data entry would be the receipt of invoices from the providers of services, events that may not necessarily be visible to Care Navigators. However, each PHN should establish a reporting process that best suits their local arrangements.

### Specific questions that may be asked by Care Navigators

#### How should I make arrangements for additional services to be approved by my PHN?

Speak with your Regional Trial Coordinator about this. Arrangements will vary across the trial PHNs but generally the Trial Coordinator will be the contact point for approval.

### Do all patients consenting to participate in the study need to be recorded in the PMHC MDS by the **Care Navigator?**

No. Any data collected in the PMHC MDS will be only for those patients using other PHNcommissioned and is the responsibility of other service providers as a general requirement of PMHC MDS reporting.

#### How much does a Care Navigator need to know about the PMHC MDS?

While data recording to the PMHC MDS by Care Navigators is not required, it will be useful for Navigators to be broadly familiar with the reporting requirements. This will help in communicating with any PHN-commissioned providers engaged by the Navigators as part of individual care plans.

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# Appendix 4. Interview questions and sampling

# Care navigator and regional trial coordinator Interviews

RTCs and CNs were asked to describe how they came to be in their role and what led them to taking the role on. The interviews commenced with people being asked to describe a typical day as related to specific roles and what day to day activities were. These questions provided background information to prior experiences of working within PHNs or the mental health setting and gave insight into the motivations for taking on roles. Interviewees were asked to reflect on the early days of implementation of Link-me in the PHNs and the general practice settings. They shared their experiences with recruitment of practices and patients, undertaking training and participating in different workshops organised by the University, and ongoing engagement with the broader PHN and practices about Link-me. Interviewees reflected on elements of their roles and were asked to identify the perceived challenges and opportunities and ways of working. In some cases, this provided insight into challenges of implementing the care navigator role within the general practice context or, reaching patients. Information was shared about the kinds of care packages that were developed and how care navigators identified services for patients involved in the trial. Interviewees were asked to think about the role of care navigation going forward within the future of mental health care and to share what their felt their biggest learning from being involved in Link-me was.

## Care navigator interview questions

- 1. Could you start by describing the recruitment process you were involved in within general practices and what you did?
- 2. Could you tell me more now about a typical day for you when you are meeting patients and delivering care?

Prompt: what other activities are you involved in within the PHN?

- 3. How did you coordinate care for patients with severe and complex mental illness? Describe some of the processes you used.
- 4. Prompt: could you tell me a bit more about care package usage at all?
- 5. Thinking about the care navigation portal can you tell me what worked well and what didn't work so well?
- 6. Tell me about what aspects of Link-me you'd like to see your practice and staff keep doing?

## **Regional trial coordinator interview questions**

- 1. Could you start by describing for me a typical day for you? Tell me about your role and what your day to day work involves?
- 2. Take me through the approach to recruit used by your PHN, how did you contact general practices? What did you share with them?

- 3. After practices were recruited could you describe how your PHN kept people informed about Link-me and its progress?
- 4. Could you describe your role in working across the primary care sector in terms of linking care navigation with other services in the community?

# **GP** interviews

34 GPs were invited to participate in a telephone interview and 14 interviewed from 11 general practices across the three PHNs. 18 GPs actively declined with no interest or did not respond to the invitation. 5 GPs had left the practice or were had moved to another when we approached them to be interviewed, 2 practices had closed and were no longer operating. Between two and four contacts were made to GPs before they responded.

The majority were female (11); 3 GPs were located in PHN A; 6 in PHN B, and 5 in PHN C.

### **GP** interview questions

- Tell me about being involved in Link-me describe your experiences of working with care navigators in the general practice setting?
- 2. How has the Decision Support Tool (DST) aligned with your clinical judgement? You might like to think about whether there were any surprises for you about the different groups people were allocated to.
- 3. What are the key barriers to putting this model into practice on a routine basis?
- 4. Can you describe how having Link-me in the practice in an ongoing way could be achieved?
- 5. Is there anything missing from Link-me that you would add into it if you had a chance to do so?

# Participant interviews

Interviews were conducted with participants triaged to care navigation and low intensity services across the three PHNs. Sampling occurred in December 2018 and February 2019 and identified participants in each group who had completed their 6-month survey but not yet reached the 12 month timepoint. This window was selected so as to avoid contaminating the primary outcome assessment at 6 months, while being as close to trial enrolment as possible so as to increase the likelihood of the participant remembering the detail of their Link-me experience. A list of participants meeting these criteria within each intervention group was sorted in random order within each general practice, with a goal of interviewing 10 participants per severity group per PHN. The first participant in each practice was contacted by a trained research assistant and invited to participate in a telephone interview. Each participant received up to three phone calls at weekly intervals and two SMSs, after which (or sooner if the interview was declined) the research assistant commenced contacting the next person on the list for that practice.

### **Interview questions**

### Minimal / mild symptom group: Triaged to low intensity services

- 1. After you completed the iPad in the waiting room, can you recall the support information that you were provided and describe for me what that included? Prompt: can you remember the name of the specific websites or programs offered?
- 2. From the things that were suggested, had you heard of or seen any of those before?
- 3. For the ones that you hadn't seen, did you go and visit them and undertake the activities or read about them? If yes, can you describe the program and what it involved?
- 4. Can you describe for me any surprises, or things you learned that were different from completing the iPad in the waiting room?
- 5. Is there anything you would suggest could be different in the future?

### Severe symptom group: Triaged to care navigation

- 1. Can you describe what happened for you after you completed the iPad and become involved in the Link-me study?
- 2. Take me through what an appointment with the care pavigator was like?
- 3. What was your experience of completing the plan with the care navigators? Were there any 4P surprises or new things that you learned?
- 4. Could you describe any challenges of accessing any of the supports that you decided on together with your care navigator? Prompt, think about the time it took to get back to the care navigator or organise referrals and other appointments?
- 5. What do you suggest could be done differently next time?



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# Appendix 5. GP approach to mental health care

**Table A5-1.** Scheduled GP follow-up and after hours care for patients with mental health problems (N = 167)

	n	(%)
First follow up appointment for patients with mental health problems		
The next day	1	(0.6)
Within a week	73	(44.5)
Within a fortnight	58	(35.4)
Within a month	R14	(8.5)
Within 3 months	NP 21	(0.6)
Varies depending on severity	S 17	(10.4)
I would not schedule a follow up appointment	C A O	(0.0)
After hours care arrangements	A	
Share with GPs in practice	63	(38.0)
Deputising locum service	57	(34.3)
Collaboration with local hospital	46	(27.7)
None	24	(14.5)
Lifeline ET AL OPT	9	(5.4)
CAT team	8	(4.8)
Provide own	5	(3.0)
Share with other practices	4	(2.4)
Other Charles Contract Contrac	10	(6.0)

**Table A5-2.** Strategies used when seeing adult patients with mental health problems in the past 12 months, by proportion of patients used with (N = 167)

Strategy	Use with no patients n (%)	Use with very few patients n (%)	Use with about one quarter of patients n (%)	Use with about half of patients n (%)	Use with about three quarters of patients n (%)	Use with almost all patients n (%)
Assess						
Conduct structured symptom assessment (e.g., K10, PHQ-9)	3 (1.9)	10 (6.2)	12 (7.5)	20 (12.4)	27 (16.8)	89 (55.3)
Ask about drug and alcohol intake	0 (0.0)	3 (1.9)	7 (4.3) 00	10 (6.2)	27 (16.7)	115 (71.0)
Advise						
Provide psychoeducation	7 (4.4)	6 (3.8)	V18 (11.3)	32 (20.1)	35 (22.0)	61 (38.4)
Provide printed educational resources	30 (18.8)	44 (27.5)	36 (22.5)	23 (14.4)	16 (10.0)	11 (6.9)
Encourage exercise	0 (0.0)	5 (3.1)	10 (6.2)	13 (8.1)	19 (11.8)	114 (70.8)
Provide diet/nutrition advice	6 (3.7)	12 (7.4)	<sup>M</sup> 015 (9.3)	24 (14.8)	28 (17.3)	77 (47.5)
Provide advice on getting a good night's sleep	1 (0.6)	3 (129) O 1 A 1 A 1	20 (12.3)	21 (13.0)	35 (21.6)	82 (50.6)
Teach mediation and/or relaxation techniques	41 (25.6)	33 (20.6)	33 (20.6)	14 (8.8)	17 (10.6)	22 (13.8)
Recommend	JN.	0.00				
Online program	35 (50.0)	50 (31.1)	25 (15.5)	25 (15.5)	12 (7.5)	14 (8.7)
Арр	56 (34.8)	45 (28.0)	27 (16.8)	13 (8.1)	7 (4.3)	13 (8.1)
Self-help book	<71 (44.4) ♦	52 (32.5)	16 (10.0)	13 (8.1)	5 (3.1)	3 (1.9)
Counsel						
Supporting counselling	2 (1.2)	8 (4.9)	21 (13.0)	28 (17.3)	29 (17.9)	74 (45.7)
Drug and alcohol counselling	12 (7.5)	25 (15.5)	35 (21.7)	31 (19.3)	16 (9.9)	42 (26.1)
Structured problem solving	34 (21.4)	47 (29.6)	26 (16.4)	22 (13.8)	12 (7.5)	18 (11.3)
Family or marital counselling	27 (16.9)	54 (33.8)	31 (19.4)	23 (14.4)	11 (6.9)	14 (8.8)
Cognitive behavioural therapy	54 (33.3)	39 (24.1)	24 (14.8)	15 (9.3)	16 (9.9)	14 (8.6)
Hypnosis	147 (92.5)	10 (6.3)	0 (0.0)	1 (0.6)	1 (0.6)	0 (0.0)

Strategy	Use with no patients n (%)	Use with very few patients n (%)	Use with about one quarter of patients n (%)	Use with about half of patients n (%)	Use with about three quarters of patients n (%)	Use with almost all patients n (%)
Prescribe						
Benzodiazepines	14 (8.8)	117 (73.1)	23 (14.4)	5 (3.1)	1 (0.6)	0 (0.0)
Antipsychotics	27 (16.9)	109 (68.1)	18 (11.3)	3 (1.9)	3 (1.9)	0 (0.0)
Refer						
Psychologist	0 (0.0)	4 (2.5)	25 (15.4)	40 (24.7)	65 (40.1)	28 (17.3)
Counsellor	23 (14.6)	48 (30.4)	32(20.3)	22 (13.9)	26 (16.5)	7 (4.4)
Family therapy	28 (17.7)	76 (48.1)	30 (19,0)	12 (7.6)	9 (5.7)	3 (1.9)
Mental health nurse	92 (57.1)	47 (29.2)	8 (5.0)	5 (3.1)	7 (4.3)	2 (1.2)
Psychiatrist	5 (3.2)	77 (49.7) 🟑	G2 (33.5)	16 (10.3)	4 (2.6)	1 (0.6)
Other strategies	4 (33.3)	5 (41.7)	P (2 (16.7)	0 (0.0)	0 (0.0)	1 (8.3)

28 (17..., 92 (57.1) 5 (3.2) 77 (49.7) 4 (33.3) 5 (41.7) 4 (33.3) 5 (41.7) 70 (49.7) 4 (33.3) 5 (41.7) 70 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 (49.7) 71 This page intentionally left blank

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# Appendix 6. Detailed statistical information

# Sample size

Our primary aim was to test for a difference in mean K10 scores between arms at 6 months. However, because our secondary aim was to test for differences between arms separately for the minimal/mild symptom group and the severe symptom group, we based our sample size calculation on being able to detect differences on the secondary hypotheses. Guided by previous work, we assumed that around 15% of people would be classified as having moderate symptoms and therefore be excluded from the trial. Of the remainder, three quarters would be identified as belonging to the minimal/mild symptom group and one quarter would be in the severe symptom group. Because the severe symptom group is assumed to be the smaller of the two groups, we used this as the basis for sample size calculations. Assuming 80% power and a 5% significance level for a two-tailed test for the sub-group analysis, our calculations suggested we needed 352 participants (176 per arm) in the severe symptom group for a standardised effect size of 0.3 (equivalent to a mean difference of 2.4 points on the K10). For the minimal/mild symptom group, we anticipated a smaller effect size as this group will have had have lower (10 scores at baseline and received less intensive treatment. Therefore, to detect a standardised effect size of 0.2 (equivalent to a difference in means of 1.6 points on the K10) we required 788 participants (394 per arm) in the minimal/mild symptom group. However, given the assumed unequal distribution of participants in the two symptom groups (76.5% vs 23.5%), the required sample was 1,146 patients (573 per arm) at followup. Allowing for 50% attrition over 12 months, we aimed to recruit a total sample of 2,996 patients at baseline. During recruitment, bowever, tower people completed screening and consented to participate than had been expected, and among those who completed screening more were in the severe symptom group than we had anticipated. As a result, we randomised only 1,671 participants (841 in the severe symptom group and 830 in the mind/moderate group). Thus the total number of participants randomised was lower than we had determined in our sample size calculations because the symptom severity groups were more evenly balanced than had been anticipated. This meant that we had greater than 80% power to test for between-arm differences for the severe symptom group at 6 months. However, sample size for the minimal/mild symptom group did not reach the required sample size to test for a difference of 0.2SD with 80% power.

# Imputation of missing outcome data

Primary analysis was conducted using an intention-to-treat (ITT) approach, where all randomised participants were included regardless of whether they received all, part, or none of the treatment they were recommended. Imputed datasets were used for all descriptive and inferential assessments to address attrition bias. We generated the imputed datasets using multiple imputation (pooled estimates of 50 datasets) by use of a fully conditional approach for all outcomes. Specifically, we used chained equations to generate imputed data with predictor variables being all primary and secondary outcomes measured at baseline and at 6 months plus treatment arm, general practice, age and sex. All measures were imputed using linear regression except days out of role, which was imputed using predictive mean matching. Imputations were performed separately for each symptom severity group.

Estimates of the treatment effect – the mean difference between treatment arms – and the 95% confidence intervals, were calculated using multiple linear regression with adjustment for baseline scores and symptom severity group. We also report standardised mean differences, calculated as the effect size divided by the pooled standard deviation of baseline scores. Sensitivity analyses were done by repeating the primary analysis using complete case analysis (i.e., using the non-imputed dataset) and with additional adjustment for practice effects using linear mixed effects regression with random-intercepts for GP practice. Sub-group analyses in each symptom severity groups followed the same analytic strategy with the exception that symptom severity group was used as a stratification factor instead of a covariate. Similar analyses were performed for the secondary outcomes (PHQ-9 scores, GAD-7 scores, EQ5D-5L VAS and utility scores).

# **CACE** analysis

The effects of receiving more components of care navigation in the severe symptom group was investigated using a complier average causal effect (CACE) analysis, where delivery of the intervention was defined in four ways representing an increasing number of care navigation elements received: (1) participants attended at least one appointment with a care navigator and there was a match between their priorities and the action plan they developed; (2) as for 1 and there was evidence of the care navigator recommending a specific and new referral or resource to the participant; (3) as for 2 and the participant was approved for care package funding; and (4) as for 3 and the participant used at least some of their care package funding. The delivery of each of these elements in care navigator notes and/or PHN records was coded as a binary variable (which is referred to as the "compliance variable" and is coded yes / no) by one of three coders and a random 10% of cases re-coded by a second person blind to the initial coding. This process identified only one discrepancy which was resolved through discussion with a third coder. A separate CACE analysis was performed for each of the four definitions above. This was achieved using two-stage least squares instrumental variable regression where the compliance variable was the binary indicator variable (described above) and were trial arm was the instrumental variable for compliance with the intervention. This analysis also adjusted for baseline K10 scores and was undertaken using imputed datasets.

# **Costing other resource use**

The resource use questionnaire completed as part of the 6-month survey asked participants to report the number of health professional visits (e.g., GP, psychologists, etc), acute care services (e.g., hospitalisations, emergency department visits, ambulance trips), residential care, self-help materials (e.g., online programs, apps and books) and medications to manage their mental health. Health professional visits were costed based on the location of the visit as shown in Table 16. For visits at a doctor's room or private practice, a weighted average cost paid by the government for the corresponding health professional, derived from the MBS item reports was used [62]. Services that occurred in other settings (e.g., community health clinics, hospital outpatient clinics, etc.) were costed using the National Hospital Cost Data Collection Tier 2, non-admitted service event costs.

Since a standard co-payment for health professional visits is not in place under the MBS, participants were asked to report estimated out of pocket costs paid for these services. Participants also reported the cost of self-help resources which were included in out of pocket costs.

Pharmaceutical Benefits Scheme (PBS) item prices were used to calculate the government and patient out of pocket costs for covered medications [63]. Online Australian retail pharmacy sites were accessed to determine patient costs for other medications and supplements not covered by the PBS (i.e., Chemist Warehouse, MyChemist, Pharmacy online, Pharmacy direct).

Hospital stays were costed using an average cost for mental health admissions reported by the Australian Institute of Health and Welfare (AIHW). The cost of an ambulance call was based on a national average cost [64]. Emergency department services were costed using a national average cost from the National Hospital Cost Data Collection. The cost of a day in a residential care unit was estimated from an AIHW mental health services report.

Costs were obtained for the 2018/2019 financial year where possible. If unit costs were reported for previous years, they were inflated to 2018/2019 costs using the AIHW total health price index.

Table A6-1. Unit cost sources	SHO X
Resource	Source of unit costs
GP, practice nurse, mental health nurse, psychiatrist and psychologist	APERTIC HEAV
Consulting rooms or private practice	MBS item reports
Other locations	National Hospital Cost Data Collection
Allied and other health professionals	NE
Acupuncture, Audiologist, Breast screening, Chiropractor, DBT group therapy, Dietitian, Exercise physiology, Holter monitoring, Midwife, Nurse practitioner, Occupational therapist, Optometrist, Osteopath, Other specialist, Pain specialist, Physiotherapy, Podiatry, Social Work	MBS item reports
Mental health admission	National Mental Health Report (Department of Health)
Palliative care and Drug and Alcohol workers	National Hospital Cost Data Collection
Disability support officer	National Disability Insurance Scheme
Kinesiology, Counselling	Assumed from other comparable professions
Massage, Personal trainer, and Yoga	Average unit cost reported in care packages
Helpline, Hypnotherapist, Naturopath	Public Health Insurance Administration Council
Dentists	Australian Prudential Regulation Authority
Other healthcare resources	
Ambulance	Productivity Commission Report on Government Services
Emergency department	National Hospital Cost Data Collection
Hospital and residential care unit admission	Australian Institute of Health and Welfare
Specialist/community based units	National Mental Health Report (Department of Health)

Resource	Source of unit costs
Medications	
PBS listed drugs	PBS Ex-manufacturer prices
Non-listed drugs and supplements	Online average (Chemist Warehouse,
	MyChemist, Pharmacy online, Pharmacy direct)
National average expenditure on supplements	Australian Institute of Health and Welfare
Productivity	
Hourly wage rate	Australian Bureau of Statistics

Note: MBS = Medicare Benefits Schedule; PBS = Pharmaceutical Benefit Scheme

# **Costing lost productivity**

The human capital approach was used to value lost paid productivity using an average hourly wage rate calculated from the average weekly earnings reported by the Australian Bureau of Statistics plus 25% overhead costs [65]. Time off from unpaid activities (i.e., housework) was valued at 25% of the average wage rate plus overhead costs to represent the value of participants' lost leisure time [66].

Presenteeism was valued by first calculating the reduced work capacity by subtracting the numeric response regarding the amount of normal work capacity achieved on the days affected by mental health problems from 10 (full work capacity). That result was then divided by 10 to provide a decimal value representing the percentage of time loss in a day, this figure was then multiplied the number of days reported working but bothered by mental health problems and further multiplied by 7.6 hours (estimated in a full-time workday). The resulting value provided the number of hours lost due to presenteeism which was then valued in Australian dollars using the average wage rate plus overhead costs noted above.

# Appendix 7. Characteristics of patients screened

Of the 15,474 patients who completed the eligibility screening survey in their GP waiting room, 1,500 (10%) were outside the age range and were exited from the survey at the first question. The remaining 13,974 completed the full eligibility screening survey; 57% of this group were eligible for the trial and 43% reported no mental health need (i.e., no current anxiety or depressive symptoms or use of medication for mental health. Characteristics of these two groups are compared in Table A7-1 below.

**Table A7-1.** Characteristics of patients who completed the eligibility screening survey: Ineligible vs

 eligible (N = 13974)

	Ineligible (N = 5989)	Eligible (N = 7985)
	Mean (SD)	Mean (SD)
Age (years)	46.89 (16.32)	41.23 (15.56)
Depressive symptoms (PHQ-2)	0.20 (0.41)	2.43 (1.65)
Anxiety symptoms (GAD-2)	0.24 (0.44)	2.57 (1.80)
	( <sup>10</sup> , <sup>10</sup> n (%)	n (%)
Gender	K	
Male	2394 (40.0)	2629 (32.9)
Female	3591 (60.0)	5343 (66.9)
Other Charles Charles	4 (0.1)	13 (0.2)
Indigenous status		
Aboriginal	132 (2.2)	273 (3.4)
Torres Strait Islander	5 (0.1)	17 (0.2)
Aboriginal and Torres Strait Islander	10 (0.2)	12 (0.2)
None of the above	5842 (97.5)	7683 (96.2)
Language mainly spoken at home		
English	5668 (94.6)	7548 (94.5)
Other	321 (5.4)	437 (5.5)
Highest level of education attained		
Below Year 10	364 (6.1)	518 (6.5)
Year 10	898 (15.0)	1098 (13.8)
Year 11	292 (4.9)	405 (5.1)
Year 12 or equivalent	1184 (19.8)	1577 (19.7)
Certificate III/IV	830 (13.9)	1419 (17.8)
Advanced diploma / Diploma	787 (13.1)	1002 (12.5)
Bachelor degree	966 (16.1)	1221 (15.3)
Graduate diploma / Certificate	247 (4.1)	284 (3.6)
Postgraduate degree	421 (7.0)	461 (5.8)
Current employment status		
Employed	4181 (69.8)	5290 (66.2)
Unemployed, looking for and available to start work	184 (3.1)	667 (8.4)

	Ineligible (N = 5989)	Eligible (N = 7985)
	n (%)	n (%)
Not in labour force	1624 (27.1)	2028 (25.4)
Main activity for those not in labour force		
Retired or voluntarily inactive	948 (57.9)	614 (29.9)
Home duties	187 (11.4)	242 (11.8)
Caring for children	104 (6.4)	232 (11.3)
Studying	86 (5.3)	163 (7.9)
Unable to work due to own illness, injury, or disability	85 (5.2)	490 (23.9)
Caring for an ill or disabled person	58 (3.5)	133 (6.5)
Working in an unpaid voluntary job	60 (3.7)	61 (3.0)
Other	108 (6.6)	117 (5.7)
Health care card holder	1991 (33.2)	3271 (41.0)
Currently taking medication for mental health	6 (0.1)	2762 (34.6)

Of the 7,985 patients who were eligible for the trial, 2,304 (29%) provided consent to take part. The characteristics of those who did and did not consent are compared in Table A7-2. **Table A7-2.** Characteristics of patients who completed the eligibility screening survey and were eligible for the trial: Not consented vs consented (N = 7985)

	Not consented	Consented
	(N = 5681)	(N = 2304)
A C	Mean (SD)	Mean (SD)
Age (years)	41.52 (15.71)	40.53 (15.17)
Depressive symptoms (PHQ-2)	2.30 (1.58)	2.73 (1.79)
Anxiety symptoms (GAD-2)	2.39 (1.74)	3.01 (1.88)
CUNED DE	n (%)	n (%)
Gender		
Male	1983 (34.9)	646 (28.0)
Female Chick	3692 (65.0)	1651 (71.7)
Other	6 (0.1)	7 (0.3)
Indigenous status		
Aboriginal	202 (3.6)	71 (3.1)
Torres Strait Islander	15 (0.3)	2 (0.1)
Aboriginal and Torres Strait Islander	7 (0.1)	5 (0.2)
None of the above	5457 (96.1)	2226 (96.6)
Language mainly spoken at home		
English	5327 (93.8)	2221 (96.4)
Other	354 (6.2)	83 (3.6)
Highest level of education attained		
Below Year 10	410 (7.2)	108 (4.7)
Year 10	845 (14.9)	253 (11.0)
Year 11	320 (5.6)	85 (3.7)
Year 12 or equivalent	1157 (20.4)	420 (18.2)
Certificate III/IV	968 (17.0)	451 (19.6)
Advanced diploma / Diploma	702 (12.4)	300 (13.0)
	Not consented (N = 5681)	Consented (N = 2304)
-----------------------------------------------------	-----------------------------	-------------------------
	n (%)	n (%)
Bachelor degree	798 (14.0)	423 (18.4)
Graduate diploma / Certificate	187 (3.3)	97 (4.2)
Postgraduate degree	294 (5.2)	167 (7.2)
Current employment status		
Employed	3789 (66.7)	1501 (65.1)
Unemployed, looking for and available to start work	447 (7.9)	220 (9.5)
Not in labour force	1445 (25.4)	583 (25.3)
Main activity for those not in labour force		
Retired or voluntarily inactive	461 (31.7)	153 (25.7)
Home duties	186 (12.8)	56 (9.4)
Caring for children	161 (11.1)	71 (11.9)
Studying	106 (7.3)	57 (9.6)
Unable to work due to own illness, injury, or	311 (21.4)	179 (30.0)
disability	JR1 82	
Caring for an ill or disabled person	98 (6.7)	35 (5.9)
Working in an unpaid voluntary job	46 (3,2)	15 (2.5)
Other	87 (6.0)	30 (5.0)
Health care card holder	2306 (40.6)	965 (41.9)
Currently taking medication for mental health	1740 (30.6)	1022 (44.4)
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# Appendix 8. Characteristics of the moderate symptom group

Of the 2,098 people who consented to participate in the Link-me trial, 427 (20%) were predicted to have moderately severe symptoms of depression or anxiety and were not included in the main trial analysis. However these individuals received the same information and completed the same baseline and 6 month measures as those in the minimal/mild and severe symptom groups who were randomly allocated to the comparison arm of the trial. Information on baseline characteristics of the moderate symptom group is presented in Table A8-1, along with the comparison arm participants in each of the other two symptom severity groups.



**Table A8.1.** Baseline characteristics of participants in the comparison arm, in total and stratified by symptom severity group (N = 1671)

	All participants	Minimal/mild symptom	Moderate symptom group	Severe symptom group
	(N = 1264)	group (N = 416)	(N = 427)	(N = 421)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	40.75 (15.25)	40.30 (15.11)	43.17 (15.81)	38.74 (14.50)
Psychological distress (K10)	23.31 (8.90)	17.28 (4.68)	20.72 (6.56)	31.89 (7.50)
Depressive symptom severity (PHQ-9)	10.51 (6.25)	5.86 (2.55)	8.19 (3.90)	17.44 (4.52)
Anxiety symptom severity (GAD-7)	8.47 (5.43)	5.24 (2.81)	6.71 (4.43)	13.44 (4.77)
Overall health (EQ-5D-5L VAS)	62.73 (21.08)	72.98 (16.67)	65.67 (18.59)	49.62 (20.64)
Quality of life (EQ-5D-5L utility weights)	0.62 (0.27)	0.78 (0.16)	0.67 (0.20)	0.42 (0.28)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Days totally out of role (K10+)	0 (0 to 5)	0 (0 to 4)	0 (0 to 3)	5 (1 to 12)
Days partially out of role (K10+)	3 (0 to 5	→1 (0, to 4)	3 (0 to 7)	8 (3 to 15)
	n (%)	(%) (%)	n (%)	n (%)
Gender	、 、	A NI II		
Male	353 (27.9)	(28.6)	117 (27.4)	117 (27.8)
Female	909 (71,9)	297 (71.4)	309 (72.4)	303 (72.0)
Other	2 (0,2)	0 (0.0)	1 (0.2)	1 (0.2)
Indigenous status				
Aboriginal	38(3.0)	10 (2.4)	9 (2.1)	19 (4.5)
Torres Strait Islander	× (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aboriginal and Torres Strait Islander	3 (0.2)	2 (0.5)	0 (0.0)	1 (0.2)
None of the above	1223 (96.8)	404 (97.1)	418 (97.9)	401 (95.2)
Language mainly spoken at home				
English	1229 (97.2)	397 (95.4)	417 (97.7)	415 (98.6)
Other	35 (2.8)	19 (4.6)	10 (2.3)	6 (1.4)
Highest level of education attained				
Below Year 10	61 (4.8)	12 (2.9)	20 (4.7)	29 (6.9)
Year 10	125 (9.9)	31 (7.5)	55 (12.9)	39 (9.3)
Year 11	44 (3.5)	14 (3.4)	9 (2.1)	21 (5.0)

	All participants (N = 1264)	Minimal/mild symptom group (N = 416)	Moderate symptom group (N = 427)	Severe symptom group (N = 421)
	n (%)	n (%)	n (%)	n (%)
Year 12 or equivalent	221 (17.5)	77 (18.5)	72 (16.9)	72 (17.1)
Certificate III/IV	265 (21.0)	80 (19.2)	83 (19.4)	102 (24.2)
Advanced diploma / Diploma	159 (12.6)	55 (13.2)	56 (13.1)	48 (11.4)
Bachelor degree	241 (19.1)	91 (21.9)	80 (18.7)	70 (16.6)
Graduate diploma / Certificate	55 (4.4)	22 (5.3)	18 (4.2)	15 (3.6)
Postgraduate degree	93 (7.4)	34 (8.2)	ନ୍ତି 34 (8.0)	25 (5.9)
Current employment status				
Employed	855 (67.6)	332 (79.8)	281 (65.8)	242 (57.5)
Unemployed, looking for and available to start work	112 (8.9)	23 (5,5)	34 (8.0)	55 (13.1)
Not in labour force	297 (23.5)	61 (14.7)	112 (26.2)	124 (29.5)
Main activity for those not in labour force		BH PHY		
Retired or voluntarily inactive	88 (29.0)	\$ 25 (40.3)	50 (43.1)	13 (10.4)
Home duties	37 (12.2)	(11.3)	14 (12.1)	16 (12.8)
Caring for children	24 (7.9)	5 (8.1)	10 (8.6)	9 (7.2)
Studying	26 (8,6)	7 (11.3)	10 (8.6)	9 (7.2)
Unable to work due to own illness, injury, or disability	83(27,4)	6 (9.7)	16 (13.8)	61 (48.8)
Caring for an ill or disabled person	23 (7.6)	8 (12.9)	5 (4.3)	10 (8.0)
Working in an unpaid voluntary job	8 (2.6)	2 (3.2)	3 (2.6)	3 (2.4)
Other	14 (4.6)	2 (3.2)	8 (6.9)	4 (3.2)
Health care card holder	496 (39.2)	115 (27.6)	167 (39.1)	214 (50.8)
Managing on your available income				
Easily	229 (18.1)	103 (24.8)	90 (21.1)	36 (8.6)
Not too bad	471 (37.3)	197 (47.4)	162 (37.9)	112 (26.6)
Difficult some of the time	392 (31.0)	99 (23.8)	140 (32.8)	153 (36.3)
Difficult all of the time	158 (12.5)	17 (4.1)	33 (7.7)	108 (25.7)
Impossible	14 (1.1)	0 (0.0)	2 (0.5)	12 (2.9)

	All participants (N = 1264)	Minimal/mild symptom group (N = 416)	Moderate symptom group (N = 427)	Severe symptom group (N = 421)
	n (%)	n (%)	n (%)	n (%)
Living alone	212 (16.8)	44 (10.6)	78 (18.3)	90 (21.4)
Self-rated health				
Excellent	61 (4.8)	28 (6.7)	23 (5.4)	10 (2.4)
Very good	319 (25.2)	160 (38.5)	A 112 (26.2)	47 (11.2)
Good	489 (38.7)	175 (42.1)	187 (43.8)	127 (30.2)
Fair	299 (23.7)	50 (12.0)	89 (20.8)	160 (38.0)
Poor	96 (7.6)	3 (0.7)	16 (3.7)	77 (18.3)
Long-term illness which limits daily activities	481 (38.1)	81 (19.5)	157 (36.8)	243 (57.7)
Reason for visit to GP			•	
Physical health	664 (52.5)	285 (68.5)	226 (52.9)	153 (36.3)
Mental health and wellbeing	168 (13.3)	21 (5.0)	53 (12.4)	94 (22.3)
Both physical and mental health	310 (24.5)	57 (13.7)	104 (24.4)	149 (35.4)
None of these	122 (9.7)	53(12.7)	44 (10.3)	25 (5.9)
History of depression	814 (64.4)	130 (31.3)	292 (68.4)	392 (93.1)
Currently taking medication for mental health	598 (47.3)	101 (24.3)	251 (58.8)	246 (58.4)

Note: SD = standard deviation, n = count, IQR = Inter quartile range. Variables contributing to the Link-me DST include: Depressive symptom severity, anxiety symptom severity, gender, managing on your available income, living alone, self-rated health, long-term illness, which limits daily activities, and history of depression.

**Table A8-2.** 6-month outcomes of participants for comparison arm, in total and stratified by symptom severity group (N = 875)

	All participants (N = 875)	Minimal/mild symptom group (N = 291)	Moderate symptom group (N = 297)	Severe symptom group (N=287)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Psychological distress (K10)	23.05 (7.87)	19.40 (6.09)	20.96 (6.34)	28.94 (7.58)
Depressive symptom severity (PHQ-9)	9.02 (6.03)	6.16 (4.45)	7.40 (4.68)	13.53 (6.10)
Anxiety symptom severity (GAD-7)	6.83 (5.19)	4.86 (4.02)	5.52 (4.38)	10.14 (5.41)
Overall health (EQ-5D-5L VAS)	67.02 (20.88)	74.23 (17.27)	71.06 (19.41)	55.74 (20.96)
Quality of life (EQ-5D-5L utility weights)	0.65 (0.27)	0.76 (0.18)	0.71 (0.22)	0.47 (0.31)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Days totally out of role (K10+)	0 (0 to 3)	0 (0 to 1)	0 (0 to 2)	3 (0 to 10)
Days partially out of role (K10+)	3 (0 to 7)	0 10 to 5	2 (0 to 5)	6 (2 to 13)

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## Appendix 9. Revised care navigator position description

The care navigator position description was initially developed in 2017, in consultation with the three participating Lead Site PHNs. Blue highlighting in the text below indicates our suggested revisions in light of trial findings.

[PHN] is seeking to appoint a number of Practice Based Mental Health Care Navigators to work within general practices to implement a new model of mental health care being undertaken in conjunction with the PHN. You will have a central role in linking patients in with services relevant to their needs, following the collaborative care model. Training in this model of care will be provided. You will be based at general practice sites, and will conduct scheduled face-to-face and telephone follow-up of eligible patients and develop a structured management plan in collaboration with patients and their GP. Your role is to help patients navigate the health care system rather than to deliver mental healthcare. This will involve working as a clinical companion alongside GPs and nurses within the general practice, and you will also facilitate communication between other health care professionals involved in the management of patients. In addition, you will maintain close links with the PHN mental health and primary care liaison team. This position will suit candidates with a clinical background who are seeking a flexible, challenging, and rewarding role that provides the opportunity to work closely with members of the community to improve their mental health.

### **Selection criteria**

#### Essential

- AHPRA- or AASW-registered health professional;
- Significant clinical experience working in a general practice setting;
- Well developed and accurate record keeping skills and attention to detail;
- Demonstrated ability to meet targets and report regularly on progress;
- Demonstrated professionalism and the ability to work effectively with minimal supervision;
- Excellent interpersonal and interprofessional communication skills (written and verbal), to communicate effectively with colleagues, patients and all stakeholders;
- The capacity to use judgment, independence, and problem solving in everyday work;
- Demonstrated ability to work positively as part of a team;
- Demonstrated knowledge of the social determinants of health and their impact on mental health;
- Demonstrated advocacy and negotiation skills;
- Demonstrated commitment to and/or experience with working with people experiencing mental health problems;

- Demonstrated ability to consider a range of perspectives with an open mind;
- Demonstrated knowledge of mental health service sector.

#### Desirable

- Experience working with electronic medical records and general practice software (e.g., Best Practice, Medical Director, Zedmed)
- Confidence in using online systems and tools to research relevant resources and support referrals;
- Understanding of evidence-based practice and adherence to clinical protocol;
- Basic theoretical knowledge of motivational interviewing;
- Understanding of continuous quality improvement programs;
- Experience working with Aboriginal people, programs, and organisations.

#### **Special requirements**

 A current driving license is required as the successful applicant(s) must be able to independently travel to general practices and the PHN office using either personal or Fleet vehicle.

#### **Key responsibilities**

- Oversee and champion the implementation of Link-me in each practice;
- Support reception staff to systematically invite adult patients in waiting room to take part and assist with responding to enquiries about Link-me;
- Contact patients allocated to receive care navigation, introduce the approach and schedule an appointment to meet the patient in the general practice;
- Conduct up to eight structured contacts with patients, adhering to protocol, to develop and implement a structured care plan;
- Navigate available services, link patient in as appropriate, and build organisational and mental health sector relationships to improve service provision;
- Request and support payments for care package-funded services as required (PHN-commissioned and otherwise);
- Collaborate closely with GPs, multidisciplinary team, and care stakeholders;
- Ensure patients' electronic medical record is kept up to date with relevant Link-me information;
- Occupational Health and Safety (OH&S) and Environmental Health and Safety (EH&S) responsibilities.

### **Appendix 10. Implementation checklist**

The checklist below is designed to support implementation of Link-me. Consideration should be given to the roles and responsibilities, documentation and additional support required for the completion of each required activity. Note that these activities are designed with flexibility in mind and while all are considered essential for successful implementation, the way in which they are conducted may be adapted to suit local requirements. Other activities and tasks may also be necessary to support the implementation of Link-me and should be added to this checklist as they are identified to support continuous evaluation and quality improvement.

Required activity	Roles / responsibilities	Additional information	Start date	End date
Engaged general practices		LA A A		
Encourage primary care liaison teams to work closely with practices to support induction period for care navigators, in which the care navigator is able to develop strong working relationships with practice staff and the PHN mental health team	NTHAS BEEN PE	ENTION AL		
Promote the role of care navigators as a conduit between the practice as an incentive to practice engagement	OCUME ON TEL			
Formalise the role of care navigators as overseeing and championing Link-me in practices, including supporting reception staff to systematically offer the tablet device to all adult patients	THISTHEFE			
Promote a whole-of-practice approach, where all staff see the value in Link-me, understand their role in it, and receive training and support to fulfil this role				

Required activity	Roles / responsibilities	Additional information	Start date	End date
Develop Standard Operating Procedures				
to ensure tablets are maintained in good				
working order				
Where necessary, support practices to				
upgrade IT to ensure interoperability				
with the secure Link-me web platform				
Skilled care navigator workforce		1 -		
Recruit health professionals with a skill		NOV OL		
set aligned to the position description		J1.081		
Ensure all care navigators receive				
training in the Link-me motivational				
interviewing-inspired approach from				
accredited trainers, and access to up-to-	A A			
date resources and support	ENMA	× ×		
Foster a sense of professional belonging	BH Price			
amongst care navigators	S'A IN			
Secure web platform	HARE IN YOUR			
Ensure platform updates are	En O. E.			
communicated to users in a timely	ME ON FRI			
manner, and that users receive	$(\mathcal{Y})$			
additional training as required				
Ensure all users are operating correct	SUXA			
version of platform and related materials 🛛 📈				
Ensure interoperability with existing IT				
infrastructure, and advise of any				
incompatibilities				
Monitor patient, care navigator, and site				
numbers to enable sufficient hosting and				
user support				
Ensure access rights (i.e., list of users)				
and low intensity service options are				
kept up to date				

Required activity	Roles / responsibilities	Additional information	Start date	End date
Care packages				
Ensure timely communication of updates to care package guidance to care navigators, GPs, and other service providers as relevant Develop resources to support clear				
communication around care package approvals to service providers and patients		UNDER UNDER		
Develop streamlined business processes to ensure prompt delivery of services and payments to providers	ELEAST	PC TH		
Consider options to integrate care packages with existing funding mechanisms	BEENPERTIO	XEC .		
Establish ongoing governance and monitoring, looking to existing initiatives as a guide	NT HAS INFINEN			
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