

# Primary Health Network Mental Health Reform Lead Site Project

LINK-ME: FINAL REPORT

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# List of abbreviations

CACE Complier average causal effect

CI Confidence interval
Coef Estimated coefficient
DST Decision support tool

EQ-5D-5L EuroQol 5-dimension quality of life Questionnaire (5-level version)

F2F Face-to-face

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)

GP General practitioner

ICER Incremental cost-effectiveness ratio

K10 Kessler Psychological Distress Scale

K10+ K10 plus four extension items

MBS Medicare Benefits Schedule

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

SD Standard deviation

SMD Standardised mean difference (also known as Cohen's d)

TIDieR Template for Intervention Description and Replication

VAS Visual analogue scale

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#### LINK-ME EVALUATION AT A GLANCE

#### This is the problem

- Australia has made large investments in primary mental health care reform, but is the investment reaching the right people, improving health outcomes and optimising patient experience?
- Stepped care approaches aim to deliver the least intensive intervention effective for an individual's level of need. The evidence is promising but it can be difficult to implement - How are people allocated to steps? How can it be done without causing burden for individuals or the GP?
- Digitally supported models of care offer potential to organise mental health care at 'scale' and better tailor treatment across the symptom severity spectrum.

#### This is what we did

- We developed the Link-me model, a digitally supported, systematic, holistic, person-centred approach to triaging mental health problems in general practice. Patients completed a nonintrusive Decision Support Tool (DST) on an iPad. Information about their biopsychosocial needs was used to triage them to low intensity (i.e., digital and self-help) or high intensity care (including 'care navigation', a form of care coordination).
- The Link-me model provided access to mental, physical and social care to improve mental health.
- We evaluated Link-me using a gold-standard randomised controlled trial conducted in 23 general practices across three states and three Primary Health Networks between 2017 and 2019.

#### What did we achieve?

- Reach: 15,474 GP patients completed Link-me screening on an iPad, and 2,098 went on to complete the Link-me DST (40% allocated to low intensity care and 40% to high intensity care).
- Clinical benefits: As a population-level system of care, Link-me was superior to usual care. In the group allocated to high intensity care, greater engagement with care navigation resulted in additional clinical benefits.
- Experiences of care: The Link-me model improved GP assessment and referral processes. Patients said it increased their self-awareness and capacity to take ownership of their care.
- Economic evaluation: We estimated that more than 10 million Australians could be screened in GP practices and the Link-me model offered at a cost of \$414 million per year.

#### What should happen next?

We propose six actions to develop and optimise Link-me and demonstrate its generalisability to different populations and contexts, supported by an iterative evaluation and learning cycle.



#### "LAURA" 22 years old

Laura was living at home with her parents, was employed full-time and had a good support network. Her job required her to work shifts across a 7-day roster which was difficult as it impacted her sleep pattern. This persistent tiredness resulted in her attention waning throughout the day, she lacked energy and her mood fluctuated. This was stressful and it affected her relationships.

Laura experienced moderate depression, had been diagnosed with bipolar disorder and was regularly seeing a psychologist. She rated her overall health as fair. Improving **sleep** and her **ability to complete daily activities** were two areas of focus for Laura.

The care navigator met with Laura's GP to discuss her goals and to set up a plan of action. Over several months, Laura met with both her GP and the care navigator to review her progress and refine her plan where needed. With encouragement, she was able to implement self-help strategies including use of the Headspace app for mindfulness and meditation, drew up daily task lists, set regular wake-up times, and started taking yoga classes that greatly improved her mood. Her GP suggested some medication for a period to help her feel less anxious. She had regular appointments with a psychiatrist, and also saw a psychologist when needed. The GP's referral to a dietitian helped put in place strategies to improve her eating – like keeping a food diary, decreased portion sizes, limited intake of fast food and soft drinks and more vegetables to her diet.

During her sixth and final appointment with the care navigator, Laura reported she had learned to recognise signs of stress and was coping a lot better at work. She would continue to see a psychologist as she needed and a psychiatrist every 3 months. The medication had also helped reduce her feelings of anxiety. Small things such as cooking and being more involved at home had helped her mood as did her improved sleep (despite the continued shift work). Laura made plans to travel overseas later in the year, and over the next 5 years planned to save up to buy her first home and maybe look towards other training opportunities to advance her career.

### "ALEX" 49 years old

Alex had been experiencing a severe mental disorder including anxiety which limited his ability to carry out his usual daily activities. Despite this he worked full-time. Alex lived alone and coping on his available income was difficult all the time. This caused him immense stress. He felt that if he could improve his **finances**, his **mood** would also improve greatly.

Alex and the care navigator agreed on some achievable goals and a plan forward. He was already seeing a psychologist as part of a Mental Health Treatment Plan initiated by his GP. Sessions with the psychologist were extremely helpful in providing coping strategies for him. The Link-me care packages were able to fund the gap fee for additional psychology sessions for Alex which was something he said he could not afford. His appointments were roughly every fortnight. "I would be in a very bad place if I couldn't see my psychologist", he said.

As well as health care support, Alex thought he could benefit by joining an online forum or downloading a mental health app to help him stay in a positive frame of mind. A Men's Shed was also something he was open to joining as this would provide him with a social outlet, improved confidence, and a broader support network.

Over time, the care navigator reported that Alex felt he was in a better financial position than he had been previously. As well as adjusting his daily spending, a charity-based financial counsellor was arranged to advocate for Alex and speak to his bank about consolidating debts and managing repayments. He was committed to getting his finances in order and generally hopeful about the future.

# **Executive summary**

#### Introduction to Link-me

In Australia, most mental health problems are managed by general practitioners (GPs). Individuals present with heterogeneous problems and illness trajectories, and between one-quarter and one-half report clinically significant symptoms. Managing the volume and heterogeneity of mental health problems in general practice is challenging, with both under- and over-treatment common. Recent mental health reforms have promoted stepped care as a way of improving the efficiency and quality of mental health care. In a stepped care model, there is a hierarchy of potentially effective treatments available (graded from least to most intensive). The initial aim is to match the least intensive intervention to the individual's level of need; later, the intensity of treatment can be stepped up or down according to changes in need. There is debate about the most efficient way to implement stepped care approaches in general practice. In particular, approaches that do not impose the burden of assessment on the GP, that match the level of care to the level of need, and that are affordable, feasible and acceptable to service users, are needed.

Link-me is a digitally supported, prognostic approach to stratifying general practice attenders with mental health problems to treatment that is matched to their needs. It begins with a Decision Support Tool (DST) that draws on 23 self-report items (that measure mental health and social factors) to predict the likely severity of an individual's depressive and anxiety symptoms in three months' time (minimal/mild, moderate, or severe) if there is no change in their current management plan. General practice attendees complete the Link-me DST on a tablet device in their GP's waiting room and receive feedback on their responses, an opportunity to identify mental health treatment priorities (including anxiety, mood, general health, finances and thoughts of self-harm or death) and to reflect on their motivation to address these. The process takes approximately five minutes. Using this information, a treatment recommendation matched to the individual's predicted symptom severity is generated and delivered via the tablet device:

- Minimal/mild prognostic group: low intensity service options matched to treatment priorities; or
- Severe prognostic group: care navigation, a model of care coordination that offers up to eight structured contacts with a trained health professional (care navigator) to develop and implement a structured care plan that meets the participants' self-reported 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 enable access to a range of health and social care services if cost is a barrier to care.

<sup>&</sup>lt;sup>1</sup> Treatment recommendations for the moderate prognostic group are not covered here, as this group was out of scope for the evaluation.

# **Evaluation approach**

The evaluation of Link-me is one of two components making up the Evaluation of the Primary Health Network Mental Health Reform Lead Site Project which was funded by the Australian Government Department of Health. The overall evaluation was guided by a Lead Site Project Evaluation Framework. For the Link-me component, the Framework specified six evaluation questions:

- 1. How was the clinical care coordination model 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?
- 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?

The evaluation of Link-me involved a stratified individually randomised controlled trial (the Link-me trial), which afforded the opportunity to conduct simultaneous outcome, economic, and process evaluations:

- The Link-me trial was designed to evaluate the <u>outcomes</u> of the Link-me intervention. The
  objective was to examine whether Link-me resulted in improvements in psychological
  distress (the primary outcome) and quality of life, days out of role, depressive symptoms,
  and anxiety symptoms (the secondary outcomes), when compared to usual care, at 6- and
  12-month follow-up.
- A parallel <u>process</u> evaluation gathered information from trial participants as well as GPs, care navigators and others involved in the delivery of Link-me services during the trial to gain insights about the implementation, participants' experiences of care, barriers and enablers of implementation of Link-me and to consider factors that could impact on a wider roll-out of Link-me.
- Alongside the trial, an <u>economic</u> evaluation sought to estimate the costs of Link-me based on the services used by participants in the trial and then to use the trial results coupled with other published information to estimate the population-level costs and effects of implementing Link-me in all GP practices across Australia.

The Link-me evaluation gathered information from multiple sources. Table i lists the data sources and shows their contributions to answering the six evaluation questions. By using more than one data source to answer each question we could complement the findings from one perspective or approach with another. Where findings coalesced, this increased our confidence in those findings.

**Table i.** Contribution of the five data sources to answering the evaluation questions.

Data source	Evaluation questions addressed
<b>Link-me portal</b> : including self-report surveys (about demographics and clinical outcomes completed by all participants at trial enrolment and at six and 12 months later), and care navigator notes	1, 2, 3, 4, 5
Interviews and site visits: interviews with regional trial coordinators, care navigators, GPs, and participants about the Link-me experience, plus site visits to participating general practices	1, 2, 4, 5
<b>GP and practices:</b> surveys and written feedback providing contextual information about the trial setting and reflections on the Link-me approach	1, 5
<b>Meetings and workshops</b> : conducted regularly with trial coordinators and care navigators to support the implementation of Link-me and address issues as they arose	1, 5
PHN and University records: including the costs associated with Link-me implementation	3, 5, 6

# **Key findings**

The Link-me evaluation was conducted over an 18-month period from July 2017 through December 2019. We worked with three Primary Health Networks and 23 general practices in three states (New South Wales, Victoria and Queensland) to test Link-me in a stratified randomised controlled trial. Between November 2017 and October 2018, over 15,000 general practice attendees completed an eligibility screening survey in their GP waiting room. Of these, 2,100 went on to complete the Link-me DST and 1,671 consented to participate in the trial. Across the duration of the evaluation, we also gathered information via interviews, surveys, workshops and other records to capture the perspectives of trial participant as well as GPs, care navigators and others involved in the delivery of Link-me services during the trial. Together, these data informed answers to the six evaluation questions, as summarised below.

# 1. How was the clinical care coordination model for people with severe and complex mental illness implemented and what were the barriers and enablers?

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).

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. Many GPs agreed that care navigation fitted easily into the general practice setting and that it should be implemented routinely. However, practical implementation issues were raised by some. One of these was lack of capacity to provide private space for care navigator appointments. Another was financial implications, namely the potential loss of income from providing private space to the care navigator rather than renting it out to another provider. Another was the leap of trust required to bring on a care navigator not previously known to the GP

to work with a vulnerable, high need group. Equally, care navigators sometimes experienced difficulty connecting with GPs in a timely manner to discuss risk management issues.

In general, the care navigator role was embedded successfully into general practices. GPs valued the clinical companion role of the care navigator and appreciated the time they could dedicate to identifying services for participants and supporting their attendance at various appointments. GPs also welcomed the addition of care package funding for people who may not otherwise be able to afford necessary services. It was noted that care navigation may have prompted some participants who were 'stuck' to try a new approach and re-engage in services and may have resulted in progress not seen previously for some. Despite these identified benefits, there were variations in the extent to which GPs engaged with the care navigation model. These ranged from developing a truly collaborative care approach through to not having a solid understanding of the care navigator's role. Where engagement was low, care navigators reported some resistance to the DST being completed in the waiting room and participants' engagement in Link-me. GPs agreed that working with the care navigator did not impact significantly on their workload although some GPs mentioned the additional workload of approving and writing referrals initiated by the care navigator.

Care navigators were able to engage with participants with complex and challenging needs in a way that assisted their engagement with general practice and the wider service sector and reported low levels of dropout once participants were engaged. However, they had difficulty engaging a proportion of participants; possible contributing factors included being in a regional area, complexity including drug and alcohol issues, and negative expectations of care navigation. They reported that some participants experienced local-level structural barriers (such as a lack of service providers, lack of public transport, and long waiting lists for medical specialists in some regions) or other barriers (relating to past negative experiences of care, circumstance such as transience, or work commitments and competing priorities). They also noted that, for some participants, the task of setting goals was challenging. Communication was critical to successful engagement between GPs and care navigators. Care navigators noted that GP engagement was essential for participant engagement and described many examples of collaboration to achieve that end.

# 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?

In the Link-me trial, 420 participants in the severe prognostic group were allocated to receive care navigation, of whom 216 (51%) had at least one structured care planning contact with a care navigator over a median duration of 4 months. Their outcomes were compared to those of 421 people who received usual care. We found that those allocated to care navigation reported greater reductions in psychological distress (measured using the Kessler Psychological Distress Scale or K10) at six-month follow-up than those who received usual care, with a standardised mean difference (also known as an effect size) of -0.26 (95% CI -0.43 to -0.09). This difference is considered clinically meaningful and corresponds to the small-to-moderate effects observed in comparable studies. Among those who received at least one care navigation contact, we found that psychological distress decreased with each additional intervention element (action plan relevant to needs, referral or resources recommended by care navigator, approval for care package funding, and care package funding spent) received. By way of illustration, participants who had an action plan relevant to needs

had a mean 4-point improvement on the K10, relative to their counterparts who received usual care, and those who received all four elements of care navigation had a mean 8-point improvement.

At 12-month follow-up, the average psychological distress score for the intervention group was similar to that at six-month follow-up, however the magnitude of the difference between groups had attenuated. This indicates that care navigation resulted in more rapid reductions in psychological distress than usual care, and that the improvement was maintained beyond the duration of the intervention. The effect of the intervention on depressive and anxiety symptoms, days out of role and quality of life was less conclusive.

From the participants' perspectives, several elements of care navigation were identified as essential to successful implementation:

- Early engagement. The DST was completed by all participants even if they did not take up care navigation. People in the severe prognostic group said they felt comfortable completing the tablet-based survey in the waiting room and that it was easy to complete. They reported increased self-awareness from completing the Link-me DST. The information gathered via the DST enabled the care navigator to understand participants priorities prior to initial contact, freeing up time during the initial contact to establish rapport and, in turn, facilitate ongoing engagement.
- Developing a plan of action. Participants suggested that the action plan increased their knowledge of supports and services and helped to developed greater insight and the opportunity for self-reflection. They appreciated the affirmation of their needs through this process and the efforts the care navigators made to identify suitable supports relevant to their goals. In turn, participants reported positive effects on their motivation and selfconfidence.
- Referrals and linkages. Participants reported that having access to a wide range of local
  health and social services relevant to their own treatment goals was a strength of care
  navigation. The services used included counselling, social support groups and clubs,
  complementary therapies, dieticians, exercise groups, massage for pain management,
  psychological sessions, and financial and housing support. Participants said the financial
  support from the care packages facilitated their access, and that they experienced benefits
  from accessing these services. Where negative experiences were identified, these often
  related to structural issues (e.g., long wait lists, staff turnover at PHNs, and transport
  difficulties).
- Taking ownership. Participants said that care navigation supported their self-confidence in a
  way that allowed for them to build their goals on their own without the care navigator
  present. An indicator of this is that many participants continued with the activities they had
  received referrals for, even after care navigation had concluded.
- 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?

In the trial, just over one quarter (27%) of participants allocated to care navigation received care package funding, at an average cost of \$669 each (or \$178 per person when averaged across the 420 people allocated to care navigation). In all, approximately 30 different types of care package services

were used. The range encompassed: mental health services (e.g., psychology, psychiatry, and family therapy/counselling); allied health services (e.g., physiotherapy, nutrition/dietary services, and occupational therapy); medical specialists (e.g., pain specialists, rheumatology, and neurology); complementary therapies (e.g., massage, exercise, and yoga); support services; vocational services; and housing-related services. The most common care package services used were psychology services, physiotherapy, massage and exercise services. Compared to those allocated to usual care, participants allocated to care navigation were more likely to visit a GP (83.4% vs 75.8%), mental health nurse (18.1% vs 9.8%), or psychologist (62% vs 51.2%) in the 12 months since enrolling in the Link-me trial.

We examined total health sector costs (i.e., the costs of health services, paid by participants or third parties) and total societal costs (i.e., health sector costs plus the cost of lost productivity). Those allocated to care navigation had significantly higher mean health sector costs than usual care after six months, by \$340 (95% CI \$126 to \$644) per person. The differences had increased by 12-month follow-up (\$645, 95% CI -151.9 to 1817.8) but were not significantly different between the groups. We observed no significant differences in societal costs.

Over 12 months, the health sector cost of delivering care navigation to people with severe and complex mental illness was estimated at \$1144 per recipient and the incremental cost per 1-point decrease in K10 score was \$1326 from the health sector perspective and \$479 from the societal perspective. The per person costs are within the range reported in trials of comparable collaborative care programs (\$136-\$1900 average cost).

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?

In the Link-me trial, 414 participants in the minimal/mild prognostic group were allocated to receive a recommended pathway comprising low intensity services, and 416 were allocated to usual care. In terms of outcomes, we found no significant differences between those allocated to the low intensity pathway and those allocated to usual care on any of the included measures of outcome at either sixmonth or 12-month follow-up. Coupled with the results from the process and economic evaluations, we found no evidence that providing participants with information about these service options led to excessive use of services.

The process evaluation found that participants in the minimal/mild prognostic group gave positive feedback about Link-me, reporting that it raised awareness of their own mental health issues and gave them a sense that GPs were open to talking about mental health concerns. These participants found the Link-me DST easy to complete and useful, but there was variability in whether they recalled receiving information about relevant services. Even those who were aware of the receiving this information felt they didn't need to use it but considered it a resource to refer back to if needed.

In the minimal/mild prognostic group, those allocated to the low intensity service pathway had a significantly higher average mean health sector cost of \$59 (95% CI 6.1 to 133.8) at 12-month (but not six-month) follow-up. This higher cost corresponded to their greater use of any 'formal' health services (including health professional visits, medications, acute care and residential care) (55% compared to 45% in the usual care group), and of psychology services in particular (25% compared

to 19% in the usual care group). The intervention group were no more likely than the usual care group to use digital help or self-help. It should be noted that, in this pragmatic, real-world trial, we could not limit access to more intensive forms of care. Therefore, the minimal/mild prognostic group were not limited to only taking up the offer of low intensity care and they had the same access to psychological care as they would usually have. It is possible that by completing the DST and identifying priorities for action, people in this group were prompted to use government-funded psychological care (where that was available to them) in preference to the low intensity options.

# 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?

The process evaluation indicated that the Link-me DST can be routinely implemented and that care navigation is an acceptable and feasible model of clinical care coordination. Some impediments to smooth implementation were identified, but these could be readily addressed. Using the normalisation process theory framework, we examined feasibility issues in terms of four guiding concepts, summarised below:

- Coherence (how well was the Link-me approach understood by all stakeholders involved?):

  Overall, there was a good level of agreement about the role of the DST and the role of care navigator in the Link-me trial, yet this was not universal across or within practices. The tool worked well in identifying high and low need participants and could be successfully implemented into the work-flow of busy general practices. Options for the DST to be completed securely prior to the GP appointment (e.g., via mobile phone app) may be preferable for some people and may reduce demands on practice staff. There is a need to modify and validate the DST for specific populations including culturally and linguistically diverse people, and Abouginal and Torres Strait Islander people.
- Cognitive participation (how well did people engage with the Link-me approach?): There were many examples of active buy-in to this new way of working and positive feedback about both the DST and the care navigation approach. There were also times when this did not occur (e.g., in practices with large numbers of part-time staff). Targeted strategies are needed to generate awareness about the Link-me and clarify the purpose and role and potential benefits of the DST and care navigation.
- Collective action (how well did the Link-me approach fit into context, relationships, and workflows?): The care navigator role was perceived as having a good skill-set fit to the general practice setting and as addressing a known gap in GPs' capacity. Some workflow issues were identified (e.g., the increased workload of GPs in preparing written referrals to services identified by care navigators, and difficulties in timely sharing of information about recipients' progress and risk management issues). Future implementation could include a pre-implementation assessment of workflow to plan for the necessary communications to take place.
- Reflexive monitoring (how was the DST and Link-me appraised?): No practices involved in the Link-me trial reported evaluating the outcomes of the DST or care navigation using formal assessments or audits of their own records. That may be because they implemented Link-me

in the context of an evaluation. In any future roll-out, a formal system to monitor in the uptake of the DST and progress of participants in care navigation would be useful.

# 6. What are the financial implications of the trial if a similar approach was implemented nationally?

To address this question, we started by considering evidence from the Link-me trial overall, as this represents the outcomes and costs for Link-me as a system of care taking into account each end of the spectrum of severity of mental health needs and integrates a spectrum of services from low intensity online services to higher-intensity face-to-face services. Across all participants in the trial, those allocated to Link-me experienced a more rapid reduction in psychological distress than those allocated to usual care, with a standardised mean difference (effect size) at six-month follow-up of -0.09 (95% CI -0.17 to -0.01). At 12-month follow-up the improvements in the Link-me group were maintained but the difference between groups was no longer statistically significant. Across all participants, the average cost to the health sector of screening in GP waiting rooms was \$7.34 per person. Health sector costs were \$50 per person higher for those allocated to Link-me than those allocated to usual care, with a 1-point improvement on the K10 coming at a cost of \$2371 in addition to costs associated with usual care from a health sector perspective, and \$1217 from a societal perspective. That is, the observed improvements in outcome occurred in the context of higher costs.

As noted earlier, the likelihood of using formal health services and the average health sector cost at 12 months was higher among those allocated to Link-me in the minimal/mild prognostic group than those allocated to usual care, possibly driven by their greater use of psychology services. Thus, we did not find that triaging participants in the minimal/mild prognostic group to low intensity services led to a cost-saving that could offset the costs of intervention in the severe prognostic group. In fact, our findings suggest that exposure to the Link-me DST process did prompt some people in the minimal/mild group to access services, but they often did so through traditional treatment pathways if these were available to them, in preference to low intensity services.

We then estimated the likely cost of scaling up Link-me to be delivered in all general practices across Australia, based on information from the trial and other published data. Under a base set of assumptions, we estimated the total annual cost of implementing Link-me nationally to be \$414 million. This cost comprised: \$10 million for screening, including the purchase of equipment, receptionist time to introduce the survey, and annual maintenance costs for the DST; \$173 million for care navigator wages (for 1782 care navigators); \$114,000 for care navigator training, and care package costs of \$230 million. Providing screening via a mobile phone app (or other options using the participants' own device) and providing care navigation via telehealth each resulted in small reductions in cost. Other scenarios (increasing the engagement with care navigation, number of care navigation contacts attended, and the number of people meeting criteria for care navigation) substantially increased costs. The projected cost for the care navigation component was in the range \$622 to \$798 per person per year. Notwithstanding likely differences in target populations, this compares favourably to published estimates of the costs of Australia's Partners in Recovery program (\$13,434 ongoing annual cost per person per year).

#### **Actions**

This Australian-first individually randomised controlled trial, conducted across three states in Australia, provided gold-standard evidence to support the Link-me approach to system design. We found that Link-me was well-received by GPs, resulted in positive experiences of care to participants, and led to improved mental health outcomes at reasonable additional cost, particularly for those with severe and complex needs. Together, these findings indicate that Link-me can successfully organise mental health care at scale for the general practice population and tailor treatment to individual need across the symptom severity spectrum.

We propose six actions to develop and optimise Link-me in readiness for routine implementation, supported by an iterative evaluation and learning cycle.

#### SIX ACTIONS TO OPTIMISE LINK-ME FOR ROUTINE IMPLEMENTATION

#### Action 1: Develop the Link-me digital platform

The Link-me model of care is a digitally supported, systematic, hollstic, person-centred approach to triaging mental health problems in general practice. Through the Link-me trial, we found that the digital platform was generally fit-for-purpose but is well suited to enhancements to extend its functionality. These include:

- Further refinement of the prognostic algorithm underpinning the Link-me DST and calibration as new data becomes available over time;
- Enhancing the interoperability of the platform with existing IT infrastructure such as practice software, the Primary Mental Health Care Minimum Data Set, and other practice-based screening tools.
- Optimising the platform to enable increased numbers of general practice attendees and care navigators using Link-me across more sites, taking into account data storage, ongoing management and security of the portal; and
- Developing and embedding tracking methods and criteria to inform decisions about 'stepping up' and 'stepping down' treatment intensity in response to changes in an individual's need.

#### Action 2: Adapt Link-me for telehealth delivery

The trial demonstrated that the Link-me model worked well in real-world general practice settings. It fit well into general practice workflows and participants liked that it placed their needs at the centre of care. In the trial, care navigation was offered via face-to-face attendance at general practices and telephone follow-up (as determined by care navigator and participant).

Link-me is well-suited to telehealth delivery. Telehealth delivery would make the model more flexible for delivery in a wide range of contexts and in response to 'shocks' such as natural disasters and pandemics, and to meet the needs of people in harder-to-reach groups such as those living in remote and regional areas. Key adaptations for telehealth delivery include:

- Making the Link-me DST available independently of the general practice setting (e.g., via a mobile phone app); and
- Adapting care navigator sessions for delivery via video-conference.

#### **Action 3: Optimise intervention components**

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. However, there is a clear need for further work to address treatment uptake and engagement in relation to both low and high intensity services:

- In the minimal/mild prognostic group, we found that those offered low intensity services via Link-me were more likely to use formal health services but were no more likely to use digital help or self-help. Link-me could be further optimised by exploring ways in which people with minimal/mild symptoms might be encouraged to use low intensity services.
- In the severe prognostic group, we found that additional clinical benefits accrued to
  participants who received a greater number of care navigation elements, but only half of
  those allocated to care navigation participated in any care navigation contacts. Strategies
  to optimise uptake of and adherence to care navigation elements could be pursued.

#### Action 4. Ensure general practice engagement

We found that ensuring practice engagement in Link-me was most successful when care navigators developed effective working relationships with practice staff (including GPs, practice manager, receptionists and others), and felt well supported by their Primary Health Network. Future work with GPs and care navigators could develop processes to improve workflow and interaction.

Further work to develop the Link-me digital platform to enable seamless inter-operability with the electronic medical record is also indicated. This would ensure that all the information that care navigators record would be available to the GP, thereby improving inter-professional communication and GP involvement.

# Action 5: Resources to support care navigation

It is important to remember that, while Link-me starts with a practice willing to be engaged and use a DST, it does not end there. Individuals must be supported to access appropriate care. For people in the severe prognostic group, resources to support the delivery of care navigation could be enhanced as follows:

- Refine the scope of the care packages. This might include providing alternative suggestions as to how to address the needs to general practice attendees where care package funds are out of scope;
- Streamline care package service delivery and payment to providers. Consideration should be given to how care packages and existing payment mechanisms can be integrated, to address structural barriers to payment, and the establishment of governance and monitoring frameworks to oversee the implementation and use of Link-me care packages.
- Develop a national care navigator workforce. This might include the development of an agreed role description and core skillset, national training and accreditation processes, arrangements for supervision, and options for sharing educational resources and facilitating peer support.

#### Action 6: Special populations and contexts

The Link-me trial findings are generalisable to the Australian general practice population, for several reasons. The trial was conducted in a large number of real-world, general practice settings. All adults attending the participating practices for any reason were eligible to be invited to complete the DST. Further, other than offering a new model of care coordination to people in the severe prognostic group, the referral pathways offered to participants in the intervention group were based on existing services in the participants' community. That said, the Link-me model was not specifically tailored for special population groups (e.g., people in remote communities, people with living with particular types of disability, people who speak a language other than English, people in communities affected by natural disasters, to name a few).

One potential future direction is to adapt or refine the Link-me for use with other population groups. Implementation in other communities could be evaluated to determine if the costs stay the same or increase, and whether those who receive Link-me find the model of care acceptable and adhere to it. Another option may be to explore the value of Link-me in other service contexts, and whether consumers and providers would engage with it, Relevant service contexts may include: public sector mental health services, where Link-me might be a useful adjunct to clinical case management, or in Aboriginal controlled mental health services (noting, however, that a holistic approach to care is the norm in these services).

### **Conclusions**

Effective primary mental healthcare depends on creating a system that general practice attendees can easily navigate and that is flexible to the way that symptoms and needs fluctuate. Effective referral management, which focusses on mechanisms for facilitating access to the most appropriate treatment, will likely be critical to achieving better system integration and continuity of care. 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' which enabled access to services to addressed their mental, physical and social needs. The gold-standard evidence generated by the trial provides reassurance that the Link-me model is effective and acceptable. Importantly, the trial also afforded an opportunity to learn what worked well and what could be improved to optimise Link-me in readiness for routine implementation.

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# 1. Background

# 1.1. Stepped care – a model for managing mental health in primary care

The majority of mental health problems are identified and managed in primary care [1] with between one quarter and one half of primary care attendees reporting clinically significant mental health symptoms [2]. The nature of these symptoms and illness trajectories varies widely [3]. Managing both the volume and heterogeneity of mental health problems in primary care is a substantial challenge, and both under- and over-treatment are common [4].

Stepped care approaches aim to address this treatment mismatch by delivering the least intensive intervention 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. For those with mild problems, low intensity options may be appropriate. As yet, however, there is no consensus on the design or delivery of stepped care for mental health in primary care. Variation in the number of steps, content, care provider, and duration is evident and, more fundamentally, it is unclear how to allocate people to an initial step. There are two approaches to this. In one, everyone requiring care is allocated to the lowest intensity treatment and sequentially 'stepped up' to the next level if their symptoms do not improve. In the other, the initial level of care is matched to the individual's symptom severity. The latter approach, also referred to as 'matched', 'targeted' or 'stratified' care, has the potential to considerably reduce time and distress for affected individuals and to enhance engagement in care [5, 6]. 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 [7, 8]. Matched care is usually based on current symptom severity, however an alternative may be to match care to predicted future needs (i.e. on a prognostic basis). A prognostic approach is particularly important in primary care because the GP is often the first health professional consulted, and must make decisions about whether the person is likely to benefit from minimal intervention, or if more specialised treatment is needed to change their illness trajectory [9].

Evidence suggests that stepped care is effective for the treatment of diagnosed depressive and anxiety disorders, usually as evidenced by improvement in symptom severity or reduced disorder prevalence [6, 10]. However, stepped care has not been found to prevent disorder onset in those with subclinical symptoms [10-14] and little is known about whether it reduces the severity of symptoms for people at the lower end of the severity spectrum [15]. Moreover, although the ability to prognostically match mental health needs to the best available treatment has been identified as an area requiring development [6, 16] and remains untested across both depressive and anxiety disorders.

# 1.2. The primary mental health care reform context in Australia

In Australia, the implementation of stepped mental health care in primary care has been accelerated through inter-related sets of policy reforms. 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 [17]. 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 [18].' 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 [18]. PHNs have an explicit focus on those in their communities who are most in need, including people with mental illness [18].

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 [19]. The Australian Government's response to that review [20] 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) [21]. 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 and suicide prevention services to ensure people with mental illness receive the right care at the right time' [21].

Under the Activity, pooled funding was made available to PHNs for service commissioning in six

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 [21]. 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 [21].

# 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):<sup>2</sup>

- 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).

Table 1. Lead site focus areas

	Regional planning / service integration	Stepped care	Low intensity services	Youth enhanced services	Clinical care coordination
Group 1			2 1/20		
Central Eastern Sydney	✓	1,5	(C) (X)		
Eastern Melbourne	✓	18/2	K. D.		
Murrumbidgee	$\checkmark$	2KX10	KKY		
Perth South	V .05	A MACK	<b>√</b>		
Group 2	8//	15/4 O.			
Australian Capital Territory	Soll		✓	✓	
South Eastern Melbourne	< /// < // <	M. 1	✓	✓	
Tasmania	" O'BY	<b>√</b>	✓	✓	
Group 3	Orch				
Brisbane North	(K)	✓	✓		✓
North Coast	× _	✓	✓		✓
North Western Melbourne	✓	✓	✓		✓

### 1.4. Evaluation of the Lead Site Project

The evaluation of the Lead Site Project was guided by the Lead Site Project Evaluation Framework [22], 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

<sup>&</sup>lt;sup>2</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 involved selected PHNs providing enhanced suicide prevention activities. It involves 12 PHNs, four of which were also Lead Sites (Brisbane North, North Coast, North Western Melbourne, and Perth South).

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 [23].

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 (known as Link-me) which included a model of clinical care coordination (known as care navigation) based in general practice.

### 1.5. Objectives

The Evaluation Framework outlined five objectives for Part B [22]:

- a. 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 evaluation questions that guided the design and reporting of the Part B evaluation [22], as follows:

- 1. How was the clinical care coordination model 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?
- 6. What are the financial implications of the trial if a similar approach was implemented nationally?

# 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 (care navigation) as delivered within a broader 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. Development

The Link-me approach is underpinned by 15 years of research involving GPs, primary care attendees, 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 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).

Link-me is a digitally supported, prognostic, approach to stratifying people with mental health problems in primary care to treatment that is matched to their needs. Link-me comprises two interrelated components: (1) a brief Decision Support Tool (DST) completed by the general practice attendee which stratifies them into one of three prognostic groups (minimal/mild, moderate, severe) based on current psychosocial factors and the predicted trajectory of their anxiety and depressive symptoms over the next three months if there is no change in their current management plan; and (2) depending on the severity of their symptoms, recommended treatment pathways (low or high intensity care). In addition, by incorporating the principles of motivational interviewing [24] throughout, it also aims to encourage self-reflection, provide hope, and motivate individuals to engage with their own mental health care. These components are described in detail below.

# 2.2. Decision support tool

At the core of Link-me is the Link-me DST. The 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 [25]. Example screenshots are presented in Appendix 2.

Link-me is based on our previously developed Target-D approach which uses the *diamond* clinical prediction tool to match management options to the predicted severity of depressive symptoms at three months. Following advice from an Expert Advisory Panel, the *diamond* prognostic algorithm was adapted to include anxiety symptom severity. By predicting the severity of both anxiety and depressive symptoms, the Link-me DST addresses the majority of mental health presentations in the Australian population [26]. We also provided a broader range of treatment options for those matched to low intensity care, and for high intensity care, we expanded the care navigation workforce to include other (non-nurse, non-mental health specialist trained) health professionals, and reduced the financial barriers to care for those triaged to care navigation.

The DST was informed by a biopsychosocial approach to prognosis and comprises 23 items<sup>3</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 algorithms embedded within the Link-me DST use an individual's responses to these items to predict symptom scores for anxiety and depression, respectively, at three months. Based on their predicted score, individuals are classified into one of three prognostic 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 which favours the more severe of the two, as depicted in Table 2. Details of the 23 items and an example of the hierarchical classification are provided in Appendix 3.

Table 2. Hierarchy of Link-me predicted prognostic group classifications

	No anxiety symptoms	Mild anxiety symptoms	Moderate anxiety	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

The two algorithms embedded within the Link me DST were developed and validated using the data collected from the Target-D randomised controlled trial [27]. The C-statistic, used to assess whether the model can differentiate between two people with different outcomes, was 0.78 (95% CI 0.75 to 0.81) for the combined prognostic groups, and was comfortably within the typical range of 0.60 and 0.85 for prognostic models [28].

Preliminary modelling using data from our *diamond* and Target-D studies [27, 28] suggested that overall, approximately 65 percent of people would be stratified into the minimal/mild prognostic group, 15 percent into the moderate group, and 20 percent into the severe prognostic group.

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 (see example in Appendix 2).

<sup>&</sup>lt;sup>3</sup> The *diamond* clinical prediction tool, on which the Link-me DST was based, comprised 17 items and predicted depressive symptoms only. The additional 6 items relate to current anxiety symptoms and are included in the prognostic model for anxiety.

- An opportunity to select mental health treatment priorities (if 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>4</sup>

The DST process takes approximately five minutes per person.

## 2.3. Symptom severity-matched treatment

#### 2.3.1. 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 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 (see Appendix 4) and are based on evidence of the effectiveness of the service itself (e.g. MindSpot [29]), 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) [30]. Service options presented to individuals in this prognostic group are drawn from an easily updated Excel spreadsheet that sits behind the Link-me digital support platform (see section 2.4 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).

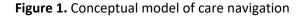
As well as viewing their treatment recommendations on the tablet device in their general practice immediately after completing the Link-me DST, individuals predicted to have minimal/mild symptoms are also emailed a copy of the recommendation with links to the relevant services, to refer back to as needed.

#### 2.3.2. Care navigation

Individuals predicted 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 the individual and GPs to develop and implement a structured care plan that meets the individual's 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 the individual in with appropriate services.

<sup>&</sup>lt;sup>4</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 prognostic groups); for the purposes of the current evaluation, this group are encouraged to discuss any mental health concerns they may have with their GP.

This intervention is informed by the principles of collaborative care, defined as: a) a multiprofessional approach, b) a structured management plan, c) scheduled follow-ups with recipients to foster uptake and engagement and provide opportunity for monitoring and review, and d) enhanced interprofessional communication [31] (Figure 1). Collaborative care is an augmented form of care first developed by Katon and colleagues in the United States [32] and is a regular feature in stepped care models [6]. However, while it has demonstrated effectiveness in improving mental health outcomes in primary care [33], it tends to target medication adherence rather than addressing the individual's 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 fifth key component of collaborative care (Figure 1). This platform supports 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 2.4 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 [34, 35]. 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.

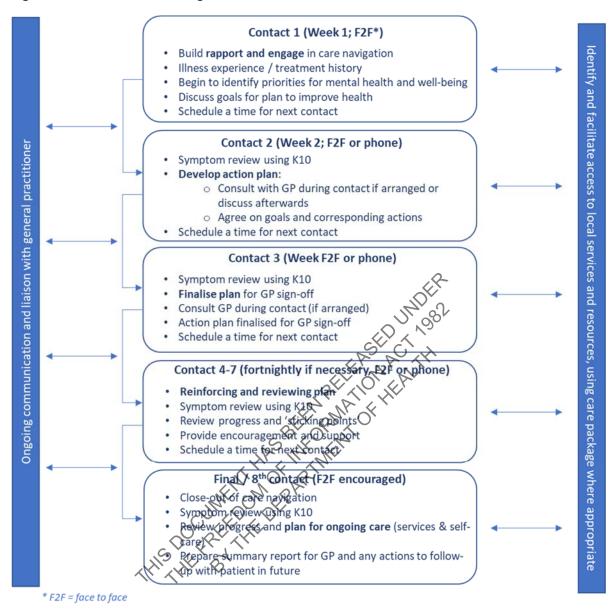




The conceptual model of care navigation outlined above is operationalised as depicted in Figure 2, with core features including:

- The delivery of up to eight structured contacts to develop and implement a structured care 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 the individual's preference. Reminders of upcoming contacts are sent via phone, email, or short message services (SMS), and care navigators follow up with non-attendees 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 individual'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 pavigator, with a clear plan for the GP and
  recipient to continue working towards the recipient's goals after the end of the care
  navigator's involvement. This will generally occur after approximately three months, but the
  exact duration of care navigation is flexible and can be adapted to recipient's need.

Figure 2. Overview of care navigation



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 individual's 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 [36], 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 individual 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, 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. Individuals may shift their goals and identified actions over the course of care navigation to meet their mental health needs.

#### 2.3.2.1. Care packages

Link-me care navigators have access to care package funding to assist individuals to access services that are identified as necessary to improve their mental health outcomes but may not currently be 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 5). Care packages are notionally allocated at an amount of AU\$2,000 per person, 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 [30]. 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.

# 2.4. Digital support platform

Supporting the Link-me approach to care is a secure online platform comprising two interfaces. The first enables general practice attendees to complete the Link-me DST using a tablet device. The second, an administration interface, auto populates with information completed in the Link-me DST in real time, providing care navigators and GPs with immediate access to contact details and Link-me DST results for those allocated to both minimal/mild and severe prognostic groups. For those in the minimal/mild prognostic group, GPs and care navigators can also view information on the low intensity services recommended. For those in the severe prognostic 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 individual'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 individual to take home and refer back to as needed, and shared with the GP (e.g., via uploading to the individual's medical record at the practice) and other health professionals involved in their care, as necessary. Care navigators can also record details of each contact with or on behalf of an individual, including duration, modality, and their reflections on what went well and any challenges they faced.

## 2.5. Summary

Link-me is a digitally supported model of stratified 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 prognostic group; either care 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 the individual's preferences, plus care packages to provide financial support where needed to access appropriate services.
  - 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. Evaluation of Link-me

## 3.1. Overview of the evaluation design

The evaluation of Link-me had a stratified individually randomised controlled trial design (the Link-me trial) at its core, which afforded the opportunity to conduct simultaneous outcome, economic, and process evaluations of Link-me.

First and foremost, the Link-me trial was designed to evaluate the <u>outcomes</u> of the Link-me intervention. Briefly, general practice attendees were randomly assigned to one of two trial arms, which received either:

- The Link-me intervention, 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 promot 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).

For participants in both arms, outcomes were assessed via the completion of self-report measures of psychological distress (the primary outcome) and quality of life, days out of role, depressive symptoms, and anxiety symptoms (the secondary outcomes) at trial enrolment, six-month follow-up and 12-month follow-up.<sup>5</sup> In this trial, we tested the primary hypothesis that using the DST to stratify patients into mental health prognostic groups (minimal/mild and severe) and provide matched treatment recommendations (low or high intensity) would result in greater reductions in psychological distress at six-month follow-up, relative to usual care. Our secondary hypothesis was that treatment differences would be upheld within prognostic groups (a subgroup analysis).

In the parallel <u>process</u> evaluation, data collection was nested within various stages of the Link me trial and gathered information from trial participants as well as GPs, care navigators and others involved in the implementation and delivery of Link-me. The process evaluation was designed to provide insights into the 'how' and 'why' of the results of the outcome evaluation (that is, how the Link-me intervention was implemented, 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 and sustainability.

Alongside the outcome and process evaluations, an <u>economic</u> evaluation was also conducted. First, the costs and outcomes of the Link-me intervention within the randomised trial were used to estimate the within-trial costs of the Link-me intervention. Second, the within-trial costs were complemented with other published data and extended to a full estimation of the population-level costs of implementing Link-me in routine GP care across Australia. A health sector perspective was adopted as the primary perspective; this includes costs borne by the government as a third-party payer in addition to out of pocket costs incurred by participants when accessing health care. A

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<sup>&</sup>lt;sup>5</sup> We also conducted 18-month follow-up of participants who entered the trial in the early stages.

partial societal perspective, which includes absenteeism and presenteeism effects on productivity for study participants, was adopted as a secondary perspective.

## 3.2. Approvals, registration and protocol

The Link-me trial was approved by the University of Melbourne Human Research Ethics Committee (ID: 1749832). The trial was prospectively registered on the Australian and New Zealand Clinical Trials Registry (ACTRN, ID: 12617001333303) in September 2017, with the combined statistical analysis plan for the outcomes and economic evaluations [37] uploaded to ACTRN in June 2019. Further details of the design of the Link-me trial can be found in the published protocol [38]. In conducting the trial, no substantive modifications were made to the published trial protocol [38].

## 3.3. Trial-specific resources

#### 3.3.1. Link-me portal

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

- Plain language statements and consent procedures in accordance with the National Statement on Ethical Conduct in Human Research [39]. 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 [40], 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 prognostic 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 six-month and 12-month assessments.

#### 3.3.2. 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, four regional trial coordinators, ten care navigators, 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> <li>Champion trial in practice</li> <li>Assist with recruitment of trial participants</li> <li>Support practice staff with queries from</li> </ul>
Care navigator	рниз	July 2017 – March 2019	<ul> <li>Champion trial in practice</li> <li>Assist with recruitment of trial participants</li> <li>Support practice staff with queries from potential participants about the trial</li> <li>Support participants 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>

**Notes**: NTC = National trial coordinator; RTC = Regional trial coordinator

As noted in Chapter 2 (section 2.3.2), the care navigator role was designed to be filled by a non-mental 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 participants to develop action plans (full day). They were also provided with two face-to-face motivational interviewing refresher training sessions (see section 3.4.4 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).

#### 3.4. Data sources

Data to inform the evaluation were drawn from five<sup>6</sup> key sources, as depicted in Figure 3 and discussed in turn on the pages that follow.

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<sup>&</sup>lt;sup>6</sup> A further intended data source, external service utilisation data, is not included here. All Link-me trial participants were asked to provide consent for the research team to be supplied with 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. This consent was optional and participants could consent to the supply of data from all, none, or some of these datasets. The request for MBS and PBS data was approved by the Commonwealth Department of Human Services (ID: MI8420) in April 2020; data supply is pending. PMHC MDS and headspace data have not been sought based on advice from the Department of Health that these data cannot be linked to individual-level data captured via the Link-me portal.

Participant survey (enrolment) ink-me portal Participant survey (6 month follow-up) Participant survey (12 month follow-up) Care navigator notes Interviews and site GP & Data source Surveys and written feedback Meetings and Workshops Meetings 01-Jul-17 **Data collection period** 3.4.1.1. Participant surveys Julient Self-report surveys

**Figure 3.** Sources and timeline of data collection

Self-report survey data were collected from Link-me trial participants at three timepoints: trial enrolment, six-month follow-up and 12-month follow-up. Enrolment survey data was collected between November 2017 and October 2018. The enrolment survey was completed on the tablet device in the GP waiting room. It consisted of two parts; the brief eligibility screening survey completed by all general practice attendees 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.

The brief eligibility screening survey captured information about:

- 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.

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<sup>&</sup>lt;sup>7</sup> The subset of participants who enrolled in the trial up to and including 30 April 2018 were also invited to provide survey data at 18-month follow-up.

The baseline survey captured information about 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.

The primary outcome was the change in scores on the Kessler Psychological Distress Scale [41] (K10) at six-month follow-up. Total K10 scores range from 10 to 50, with higher scores indicating greater levels of psychological distress. Secondary outcomes were change in K10 scores at 12-month follow-up, and the following at both six- and 12-month follow-up: change in depressive symptom severity (Patient Health Questionnaire or PHQ-9 [42]), anxiety symptom severity (Generalized Anxiety Disorder scale or GAD-7 [43]) and quality of life and overall health (EuroQol 5-dimension quality of life questionnaire or EQ-5D-5L [44]). Days out of role due to psychological distress (K10+) [45] at 6 and 12-month follow-up was included as a secondary outcome. All measures are summarised in Table 4 and described in detail elsewhere [38].

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

Outcome measure	Construct assessed	Number of items	Score range	Higher scores indicate
Kessler Psychological Distress Scale (K10) [41]	Psychological distress	10 P	10-50	Greater psychological distress
K10 extension items (K10+) [45]	Days out of role due to psychological distress	A OF HER	Ő – 28	More days out of role
Patient Health Questionnaire – 9-item version (PHQ-9) [42]	Depressive symptom severity	9	0 – 27	More severe depression
Generalized Anxiety Disorder scale (GAD-7) [43]	Anxiety symptom severity	7	0 – 21	More severe anxiety
EuroQol 5-dimension quality of life questionnaire (EQ-5D-5L) [44]	STATE OF			
Utility weights	Quality of life	5	0 – 1	Better quality of life
Visual analogue scale (VAS)	Overall health	1 (	0 – 100	Better health

**Notes**: 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.

Six-month and 12-month follow-up survey data were collected from May 2018 to June 2019 and November 2018 to December 2019, respectively. The follow-up surveys comprised the measures in Table 4 plus a Resource Use Questionnaire (RUQ) [27, 46, 47] that assessed the frequency, location and out of pocket costs for use of relevant health services, and the impact of mental health problems on productivity. The RUQ data were used to inform the cost effectiveness analysis. Sixmonth and 12-month follow-up 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).

#### 3.4.1.2. Care navigator notes

Between November 2017 and March 2019, for participants in the severe prognostic group allocated to the intervention arm, care navigators recorded data relevant to care navigation through completion of structured forms in the online 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>8</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.

## 3.4.2. 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 regional trial coordinators, care navigators, and GPs who had experience of one of their practice attendees in the care navigation intervention, 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, we conducted telephone interviews with two groups of participants from across the three PHNs.: (1) a subset of the intervention group triaged to care navigation and; a (2) subset of the intervention group triaged to low intensity services, after they had completed their six-month survey. Further details of the process for inviting and conducting interviews are available in Appendix 6.

<sup>&</sup>lt;sup>8</sup> As part of the structured approach to care planning described in Chapter 2 (section 2.3.2, see especially Figure 2), care navigators were encouraged to engage participants in regular symptom monitoring through readministration 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 participant surveys completed at trial enrolment and 6-month follow-up.

We also selected a small number of participants who were in the 18-month follow-up group to examine in depth their referral pathways and experience of care navigation.

#### 3.4.3. GP and practices

#### 3.4.3.1. 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.

#### 3.4.3.2. Written feedback from GPs

Participating GPs were offered the opportunity to participate in a GP Research Activity conducted in accordance with the Royal Australian College of General Practitioners (RACGP) Quality Improvement and Continuing Professional Development (QI&CPD) Program for the 2017-2019 triennium (accredited activity no. 165618). The four learning objectives of the activity were for GPs to:

- 1. demonstrate an understanding of the trial as outlined in the study protocol;
- 2. demonstrate an understanding of the Link me model of care navigation by describing how it may benefit one patient in their practice.
- 3. reflect on the barriers and enablers to working with a 'clinical companion' (care navigator) in the management of mental health problems for some patients; and
- 4. compare and contrast the characteristics of their own practice patient population compared with all patients enrolled in the trial.

### 3.4.4. Meetings and workshops

This data source included:

- Regular meetings with regional trial coordinators and care navigators. These were held from August 2017 (for regional trial coordinators) and November (for care navigators) to February 2019. These meetings, conducted via teleconference, were initially held weekly before moving to a fortnightly schedule in June 2018 to 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 regional trial coordinator and care navigator workshops. These face-to-face workshops held quarterly and varied in both location and topic as shown in Table 5. Data collected at these workshops included observations and notes, photographs, documents drafted within workshops, and feedback forms.
- Whole of practice meetings with GPs and/or staff in one PHN region. We conducted
  visits to practices and gathered information through discussions with staff (GPs,
  registrars, practice nurses, managers and sometimes receptionists) as an
  'implementation case study'.

Table 5. Link-me face-to-face workshops with regional trial coordinators and care navigators

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, participant and practice recruitment troubleshooting	North Coast PHN
8 June 2018	Enhancing GP and participant engagement in care navigation	North Western Melbourne PHN
21 September 2018	Modelling and mapping the process of care navigation	Department of Health

#### 3.4.5. 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.

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).

## 3.4.6. Relationship between data sources and evaluation questions

Table 6 on the following page provides an overview of the relationship between the data sources presented above and the six evaluation questions, and where to find the corresponding findings within this report.

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

Eva	luation question	Participant surveys	Care navigator notes	Participant interviews	Implementer interviews / site visits	GPs and practices	Meetings / workshops	PHN / University records	Report chapter
1.	How was the clinical care coordination model for people with severe and complex mental illness implemented and what were the barriers and enablers?	✓	✓		MOER	✓	✓		5
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?	<b>√</b>	<b>√</b>	A RELEASE	DIMPER ACTHA AEATHA				4, 5
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?	<b>√</b>	AT NO A	KORNIO L				<b>√</b>	6
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?	HE DO FEEL OF	CONTROLL OF THE PROPERTY OF TH	✓					4, 5, 6
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?	✓	✓	✓	✓	✓	✓	✓	5
6.	What are the financial implications of the trial if a similar approach was implemented nationally?	✓						✓	

## 3.5. Link-me trial design and procedures

#### **3.5.1.** Setting

The Link-me trial was a pragmatic stratified two-arm randomised controlled trial undertaken in three Australian states (New South Wales, Victoria, Queensland). It was conducted in collaboration with three PHNs. These are Australia's meso-level organisations responsible for the planning and commissioning of primary mental health services.

Regional trial coordinators 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 medical records software (to enable general practice attendee 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 participants triaged into the severe prognostic group; and 4) agreed to follow the trial protocol. Desirable but not essential criteria were seeing at least 100 attendees aged 18-75 per day and use of electronic medical records. 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 PBN 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. Regional trial coordinators reported follow-up contact (via phone, email, and/or practice visits) with a total of 80 practices, 23 of which ultimately took part in the trial. Common reasons for non-participation included some or all of the GPs not wanting to participate (reasons not reported, 12 practices), not having space for a care navigator (10 practices), and other issues taking priority within the practice (e.g., organisational or staffing changes) (6 practices). Five practices reported clinical barriers to participation (e.g., concerns around risk management or support available to participants after the end of care navigation).

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.

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

	n	(%)
Practice location		(70)
Rural	9	(39)
Suburban	12	(52)
Urban	2	(9)
IRSAD decile - Mean (SD)	6	(3)
Type of practice		
Private general practice	20	(87)
Corporatised general practice	1	(4)
Community health centre	0	(0)
Other	2	(9)
Billing model		
Bulk bill	12	(52)
Mixed	110	(48)
Co-located services	0,100	
Psychologist	SV 11	(48)
Counsellor	EN PITH	(4)
Practice nurse		(65)
Other	EN MACE Y 3	(13)

**Notes**: 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. Colocated 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 7.

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

	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 CURLD OF	5	(3.0)
O DE ANY	Mean	(SD)
Time spent on mental health skills training (past year)  <1 hour  1-5 hours  6-10 hours  11-20 hours  >20 hours  Received assistance in completing mental health treatment plans  From a mental health nurse  From a practice nurse  From a medical student  From a psychiatrist  From another GP  Other  Age (years)  Years in general practice  In Australia  Overseas (n = 58)	48	(13)
Years in general practice		
In Australia	15	(14)
Overseas (n = 58)	3	(5)

**Notes**: 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.

#### 3.5.2. Participant eligibility

Adults attending participating practices for any reason were approached in the waiting room by practice employees (e.g., receptionists) or trial staff (e.g., research assistants) and who engaged them in a brief discussion to establish whether they were: a) aged 18-75 years; b) proficient in English; c) able to provide a phone number and email address; d) a Medicare card holder (i.e., eligible for federally funded healthcare); and e) able to provide informed consent. Recruitment staff were encouraged to approach adults in the waiting room, regardless of their reason for presentation. They were, however, encouraged to use their judgement and not approach individuals who were demonstrating signs of acute health problems (e.g., vomiting or in obvious pain). These individuals were not excluded from the trial and recruiters could consider approaching them at another time (e.g., on their next visit to the practice).

Those who met these criteria were invited to complete a brief eligibility screening survey on a tablet device, which asked basic demographic information and assessed current mental health need. Individuals were eligible for the trial if they reported current depressive and/or anxiety symptoms, indicated by:

- a score of 2 or more on the 2-item version of the Patient Health Questionnaire (PHQ-2) [48];
- a score of 2 or more on the 2-item version of the Generalised Anxiety Disorder scale (GAD-2) [43]; or
- current use of medication for mental health problems.

Individuals who did not meet these criteria were unlikely to have symptoms and hence were exited from the survey. 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 individuals who agreed to complete the survey and offer assistance or answer questions where required.

Eligible general practice attendees were invited to take part in Link-me. They read a plain language statement about the trial on the tablet and were asked to enter their contact details into an online form to indicate their consent to participate.

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 PHNA, 26 weeks in PHN B practices, and 9 weeks in PHN C practices. During this period, practices saw an average of 261 adults per week (range 149 – 516).<sup>9</sup>

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<sup>&</sup>lt;sup>9</sup> This range is based on data obtained from 18 of the 23 practices.

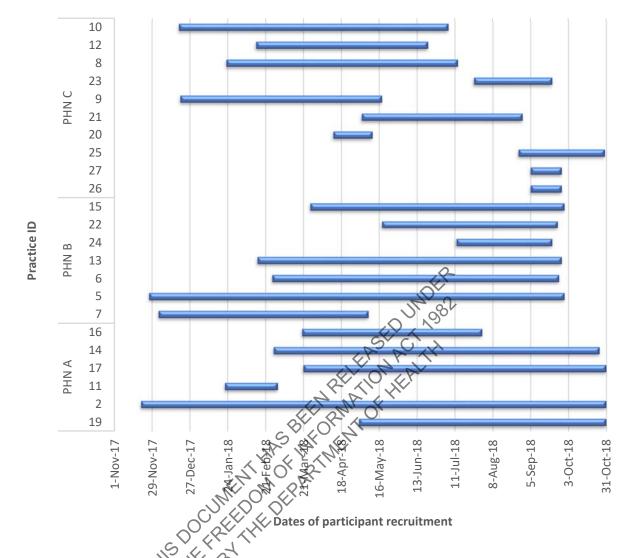


Figure 4. Duration of participant recruitment in each of the Link-me general practices (N=23)

## 3.5.3. Treatment allocation

Consenting general practice attendees completed the Link-me DST on the tablet and were classified into one of the three prognostic groups. Those who were stratified into the minimal/mild or severe prognostic groups were individually randomised to either the intervention or comparison arm and are henceforth referred to as Link-me participants. The moderate group were not eligible for inclusion and were thus excluded from the trial.

#### 3.5.3.1. Intervention arm

All participants randomly allocated to the intervention arm received automated feedback on their responses via the tablet device and were then guided via the online tool to set individual mental health priorities and rate their motivation to address these priorities. Based on their prognostic group, they were then allocated to low or high intensity treatment. The treatment in each prognostic group is summarised in Chapter 2 (section 2.3) (see Appendix 8 for a more detailed description). Participants in both prognostic groups were free to take up their recommended treatment or not, to discuss it with their GP or not, and to continue or modify any treatment they were receiving at entry to the trial.

#### 3.5.3.2. Comparison arm

All participants in the minimal/mild and severe prognostic groups randomly allocated to the comparison arm received advice, on the tablet and via automated email sent on completion of the Link-me DST, to discuss any mental health concerns with their GP. Participants were free to continue or modify any treatment they were receiving at entry to the trial. They were not provided with feedback on their Link-me DST responses – including the prognostic group they were classified into – nor guided to set priorities or reflect on motivation.

#### 3.5.4. Randomisation and masking

After providing consent and completing the Link-me DST assessment component (which classified participants into prognostic groups), participants in the minimal/mild or severe prognostic groups were individually randomised, in a 1:1 ratio, to receive either the trial intervention or usual care with attention control. Randomisation was stratified by general practice and prognostic group and was triggered automatically within the trial's online administration portal, with the allocation sequence computer-generated consecutively using a biased coin algorithm. No one involved in recruitment, intervention delivery, or follow-up had access to the allocation schedule.

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

Due to the nature of the intervention, participants were unable to be blinded to their treatment allocation. Research assistants contacting participants to encourage completion of outcome measures at follow-up were unaware of individual participants' prognostic group or trial arm allocation. Unblinding of the investigator team, including the statistician responsible for the analyses, occurred after completion of the analysis of six-month outcomes (the timepoint for analysing the primary hypothesis, see below).

#### 3.5.5. Sample size

We powered our study to test for treatment differences within prognostic groups. Sample size calculations were based on detecting a standardised mean difference (SMD) of 0.3 in the severe prognostic group (equivalent to a mean difference of 2.4 points on the K10) and a smaller SMD of 0.2 in the mild/minimal group (equivalent to a mean difference of 1.6 points). Based on our Target-D study [27] we assumed that 15% of participants would be classified into the moderate group and therefore excluded from the trial. The remainder were assumed to be stratified into the minimal/mild and severe prognostic groups at a ratio of approximately 3:1 [38]. Sample size calculations further assumed 50% attrition over 12 months, a 5% significance level testing a 2 sided hypothesis and 80% power for each subgroup analysis. We therefore aimed to recruit 1498 participants. With this sample size we were projected to be able to detect a SMD of 0.17 (approximately 2.4 points on the K10) with 90% power on the primary hypothesis.

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<sup>&</sup>lt;sup>10</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.

## 3.6. Summary

This evaluation sought to examine whether Link-me is effective and cost-effective for people with a severe or minimal/mild prognosis as predicted by the DST, whether these people had positive experiences of care, and whether it would be feasible to implement Link-me in general practices across Australia. The evaluation had a randomised controlled trial at its core, which afforded the opportunity to conduct simultaneous outcome, economic, and process evaluations. The chapters that follow organise the findings in relation to the outcomes evaluation (Chapter 4), process evaluation (Chapter 5) and economic evaluation (Chapter 6). Each chapter provides a description of the approach to analysis taken in each case.

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## 4. Outcome evaluation

## 4.1. Summary of approach

This chapter presents findings related to the outcomes of Link-me for people in the severe prognostic group (evaluation question 2) and minimal/mild prognostic group (evaluation question 4). The data used to address these questions were collected from participant surveys completed in the Link-me portal at baseline, six- and 12-month follow-up. 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.

Analysis was by intention to treat and was conducted using Stata 16.1 [49]. Multiple imputation was used for all descriptive and inferential analyses to address attrition bias. Fifty imputed datasets were generated using chained equations and stratified by treatment acm and prognostic groups. All imputed variables were simulated using linear regression except days out of role, which was simulated using predictive mean matching (see Appendix 9):

We estimated the mean difference between the intervention and comparison arms in the change in K10 scores at six-month and 12-month follow-up (from baseline) using multiple linear regression. We entered trial arm as a binary variable and adjusted for baseline K10 scores and prognostic group. We report these findings on the original metric and as SMDs. We undertook two sensitivity analyses. First, to examine whether missing outcome data influenced the main findings, we conducted a complete case analysis (i.e., using non-imputed data). Second, to determine whether clustering within general practices had an impact on the findings, we made a further adjustment by using the complete case data to fit a linear mixed effects model with a random intercept for practice. All analyses were conducted for the sample as a whole (the primary hypothesis, see Chapter 3 section 3.1) and within the two prognostic groups (the secondary hypotheses) and repeated for the secondary outcomes (K10 at 12 months; PHQ-9, GAD-7, and EQ-5D-5L at six- and 12 month follow-up). We followed a similar analytic strategy for days out of role, except that negative binomial regression was used to estimate treatment arm differences and the outcome was the count of days at each time point (not a change from baseline).

For participants in the severe prognostic group, we also conducted 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:

- a. Participation in at least one structured contact with a care navigator and a match between the participant's priorities and the treatment plan they developed (yes or no).
- b. (a) and the care navigator recommended a specific and new referral or resource to the participant (yes or no).
- c. (b) and the participant was approved for care package funding (yes or no).
- d. (c) and the approved funding was spent (yes or no).

Using this hierarchy, four separate CACE analyses were conducted to examine the influence of receiving each additional element of care navigation on mean differences in K10 scores. This was done using two-stage least squares instrumental variable regression where each of the elements above was entered as a binary coded endogenous variable (element delivered vs. element not delivered) and trial arm was entered as an exogenous instrumental variable. The model also included baseline K10 scores and was estimated using multiple imputation.

#### 4.2. Results

#### 4.2.1. Sample characteristics

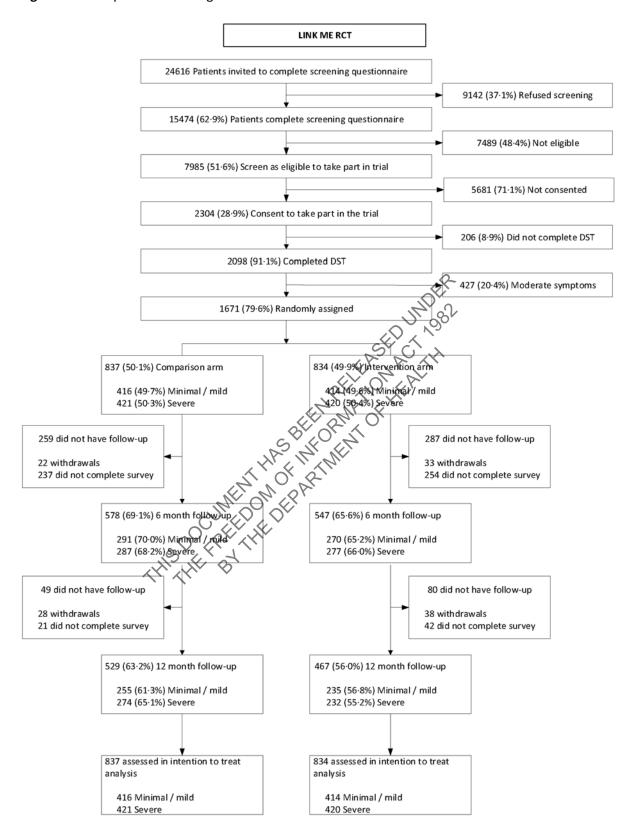
Figure 5 shows the flow of participants through the trial. 24,616 patients were invited to complete the eligibility screening survey, representing one quarter of the total patient population seen in participating general practices during the recruitment period (21 November 2017 – 31 October 2018). Approximately two-thirds of participant who were invited to complete the eligibility screening survey did so, and around half of those screened were eligible for the trial. Characteristics of participants who completed the eligibility screen in their GP waiting room are shown in Appendix 10.

2,304 participants consented to participate in the trial and went on to complete the Link-me DST, of whom 20% were classified into the moderate prognostic group and were thus excluded from the trial. The baseline sample therefore comprised 1,674 participants. Follow-up data were collected between 21 May 2018 and 17 December 2019 and were available for 67% and 60% of trial participants at six-month and 12-month follow-up respectively.

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<sup>&</sup>lt;sup>11</sup> Although this group was excluded from the trial, they completed all baseline measures and were asked to complete the 6-month and 12-month follow-up surveys.

Figure 5: Participant flow through the trial



The DST classified 830 of the 1,671 participants (50%) into the minimal/mild prognostic group and 841 (50%) into the severe prognostic group, allocated evenly to intervention and comparison arms. Baseline demographic and clinical characteristics of the two trial arms are shown in Table 9. The mean age of participants was 40 years (range 18 to 74 years) and, consistent with the epidemiology of depression and anxiety [50] and the general practice patient population [51], the majority (72%) was female. Overall, the proportion of trial participants reporting Aboriginal and Torres Strait Islander descent (3.8%) was not dissimilar to the Australian population (3.3%) [52].

The two trial arms were similar in their demographic and clinical profiles, overall and within each prognostic 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 that is larger than would be expected by chance alone can be attributed to the intervention effect.

Participants in the severe prognostic group had higher mean scores on the K10, PHQ-9 and GAD-7 scores than those in the minimal/mild prognostic group. They 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 prognostic 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. These patterns indicate that the Link me OST triaged participants appropriately.

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

	All participants (comparison) (n=837)	All participants (intervention) (n=834)	Minimal/mild prognostic group (comparison) (n=416)	Minimal/mild prognostic group (intervention) (n=414)	Severe prognostic group (comparison) (n=421)	Severe prognostic group (intervention) (n=420)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age in 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)	C5.9 (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 (%)	n (%)
Sex	236(28.2)					
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	1 (0.1)	4 (0.5)	0 (0.0)	1 (0.2)	1 (0.2)	3 (0.7)
Indigenous status						
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						

	All participants (comparison) (n=837)	All participants (intervention) (n=834)	Minimal/mild prognostic group (comparison) (n=416)	Minimal/mild prognostic group (intervention) (n=414)	Severe prognostic group (comparison) (n=421)	Severe prognostic group (intervention) (n=420)
_	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
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)
ighest level of education attained			71/08/			
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	\$9 (7.0)	66 (7.9)	34 (8.2)	47 (11.4)	25 (5.9)	19 (4.5)
urrent employment status	C ( ) ( ) ( ) ( )					
Employed	\$9 (7.0) \$74 (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)	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)
lain activity for those not in labour force						
Retired or voluntarily inactive	36 (19.5)	52 (22.9)	24 (39.3)	39 (41.9)	12 (9.7)	13 (9.7)
Home duties	23 (12.4)	13 (5.7)	7 (11.5)	5 (5.4)	16 (12.9)	8 (6.0)
Caring for children	14 (7.6)	39 (17.2)	5 (8.2)	19 (20.4)	9 (7.3)	20 (14.9)
Studying	16 (8.6)	27 (11.9)	7 (11.5)	11 (11.8)	9 (7.3)	16 (11.9)
Unable to work due to own illness, injury, or disability	67 (36.2)	71 (31.3)	6 (9.8)	6 (6.5)	61 (49.2)	65 (48.5)

	All participants (comparison) (n=837)	All participants (intervention) (n=834)	Minimal/mild prognostic group (comparison) (n=416)	Minimal/mild prognostic group (intervention) (n=414)	Severe prognostic group (comparison) (n=421)	Severe prognostic group (intervention) (n=420)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Caring for an ill or disabled person	18 (9.7)	8 (3.5)	8 (13.1)	4 (4.3)	10 (8.1)	4 (3.0)
Working in an unpaid voluntary job	5 (2.7)	6 (2.6)	2(3.3)	3 (3.2)	3 (2.4)	3 (2.2)
Other	6 (3.2)	11 (4.8)	2 (3.3)	6 (6.5)	4 (3.2)	5 (3.7)
Health care card holder	329 (39.3)	370 (44.4)	2 (3;3) 115 (27.6)	125 (30.2)	214 (50.8)	245 (58.3)
Managing on your available income		KA.	/ BO KK			
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 (0.0)	12 (2.9)	20 (4.8)
Living alone	134(16.0)	20 (2.4)	44 (10.6)	45 (10.9)	90 (21.4)	84 (20.0)
Self-rated health	CAMILOO, O					
Excellent	>>> >0.\\\ E1\\\\	39 (4.7)	28 (6.7)	29 (7.0)	10 (2.4)	10 (2.4)
Very good		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						
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)

	All participants (comparison) (n=837)	All participants (intervention) (n=834)	Minimal/mild prognostic group (comparison) (n=416)	Minimal/mild prognostic group (intervention) (n=414)	Severe prognostic group (comparison) (n=421)	Severe prognostic group (intervention) (n=420)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
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)

Currently taking medication for mental health 347 (41.5) 340 (40.8) 101 (\$4.3\$) 102 (24.6) 246 (58.4) 238 (56.7)

Notes: SD = standard deviation, n = count, IQR = Inter quartile range. Variables contributing to the Link-me BS Proclude: 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. Discrepancies in totals due to missing responses.

#### 4.2.2. 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 number and pattern of priorities differed by prognostic group. For three-quarters (75%) of the minimal/mild prognostic group, two or fewer areas of difficulty were reported and therefore these were assigned as their priority areas. The remaining one-quarter (25%) reported more than two priority areas and so were asked to select which two they wanted to focus on. 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 prognostic 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 [50], 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, those in the severe prognostic group gave greater importance to addressing their priorities than those in the minimal/mild prognostic group, but they were less confident about changing.

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

	( ) O ( )								
Importance of change (1-10) Confidence in changing (1-10) Priority area Anxiety	All participants (N = 834)	Minimal/mild prognostic group (N = 414)	Severe prognostic 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)						
115167	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)						

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

#### 4.2.3. 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 (face-to-face or telephone). The few differences in demographic or clinical characteristics between those who did and did not participate in a structured contact are shown in Table 11. People who had at least one contact were: slightly older on average (41 vs 36 years old); more likely to identify as male (36% vs 18%), to have a long-term illness (65% vs 57%); and were less likely to be in the labour force (26% vs 38%). They were also more likely to select some priority areas - namely anxiety (43% vs 35%), ability to complete daily activities (12% vs 6%), and finances (10% vs 6%) - and were less likely to select mood as a priority area (16% vs 27%).

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

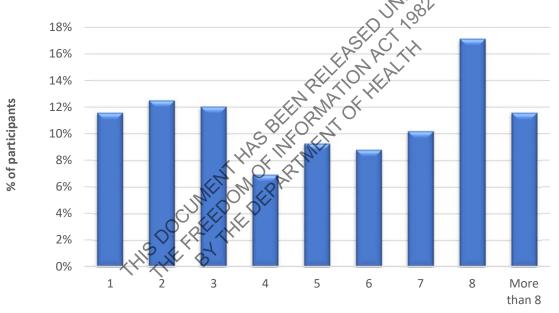
Age (years)  Psychological distress (K10)  Depressive symptom severity (PHQ-9)  Anxiety symptom severity (GAD-7)  Overall health (EQ-5D-5L)  Quality of life (EQ-5D-5L)  Importance of change (1 – 10)  Confidence in changing (1 – 10)  Gender  Female  Male  Other  Current employment status  Employed  Unemployed, looking for and available to start work	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)	\$2.6 (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)
ME ON PA	n (%)	n (%)
Gender		
Female	137 (63.4)	165 (80.9)
Male	78 (36.1)	37 (18.1)
Other	1 (0.5)	2 (1.0)
Current employment status		
Employed	110 (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)

	Participated in ≥1 contact (N = 216)	No care navigation contacts (N = 204) Mean (SD)
	Mean (SD)	
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)

**Notes**: 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, 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)



Number of structured care navigation contacts

Among the 216 people who participated in at least one structured care navigation contact, we then examined the percentage who received the various 'elements' of care navigation. Considering each element separately, we found that 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. 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. Finally, care navigators secured approval for care package funding to support approximately half of those who

participated in care navigation overall. Chapter 6 provides more information on the content of the care packages that were approved and funded.

Table 12 considers the elements cumulatively, showing that 44% received all four elements.

**Table 12.** Frequency and percentage of people who participated in at least one structured care navigation 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)

**Notes**: 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.

#### 4.2.4. Outcomes

For the primary hypothesis, we found a greater reduction in mean K10 scores at six-month follow-up in the intervention arm than the comparison arm (Table 13). The between-arm mean K10 score difference was -0.88 (95% CI -1.66 to -0.11, p = 0.03) equating to a SMD of -0.09. In subgroup analysis, the mean difference between arms in the minimal/mild prognostic group was 0.16 (95% CI -0.76 to 1.08, p = 0.73); in the severe prognostic group it was -1.92 (95% CI -3.16 to -0.67, p = 0.003), equivalent to an SMD of -0.26. Results for all sensitivity analyses were similar.

At 12-month follow-up there was no evidence of a treatment effect on mean K10 scores overall or in the minimal/mild prognostic group. There was some evidence of an attenuated effect within the severe prognostic group, with a mean difference in K10 scores between trial arms of -1.24 (95% CI - 2.53 to 0.05, p = 0.06), equivalent to an SMD of -0.17 (Table 13 and Figure 7).

Table 13. K10 Psychological distress scores according to trial arm, in total sample and stratified by prognostic group

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Intervention, n	837		416		421	
Comparison, n	834		414		420	
Six-month follow-up						
Mean change, mean (SD) [1]			18-			
Comparison	-0.32 (7.40)		2.18 (6.20)		-2.78 (7.66)	
Intervention	-1.18 (8.09)		2.50 (5.80)		-4.81 (8.37)	
Mean difference, Coef. (95% CI)						
Primary analysis [2]	-0.88 (-1.66 to -0.11)	0.03	0.16 (-0.76 to 1.08)	0.73	-1.92 (-3.16 to -0.67)	0.003
Sensitivity analysis [3]	-0.99 (-1.74 to -0.24)	0.01	0.16 (-0.76 to 1,08) 0.07 (-0.84 to 0.99) 0.07 (-0.83 to 0.98) 0.04 (-0.17 to 0.24)	0.87	-2.05 (-3.23 to -0.86)	<0.001
Sensitivity analysis [4]	-0.99 (-1.74 to -0.24)	0.01	0.07 ( <sub>0</sub> .83 to 0.98)	0.87	-2.05 (-3.23 to -0.87)	<0.001
CACE analysis [5]			PLY PRIVO.		-4.28 (-7.05 to -1.51)	0.003
CACE analysis [6]			S. N. S.		-5.27 (-8.70 to -1.83)	0.003
CACE analysis [7]			HI & II LEW.		-7.19 (-11.93 to -2.46)	0.003
CACE analysis [8]		(E)	M. ORT		-8.48 (-14.14 to -2.81)	0.003
SMD (95% CI) [9]	-0.09 (-0.17 to -0.01)	0.03	0.04 (-0.17 to 0.24)	0.73	-0.26 (-0.43 to -0.09)	0.003
12-month follow-up		2 XX	& *			
Mean change, mean (SD) [1]	.5	" FLY				
Comparison	-0.88 (7.83)	W Ø	1.68 (6.15)		-3.42 (8.44)	
Intervention	-1.41 (7.85)		2.00 (6.14)		-4.77 (7.89)	
Mean difference, Coef. (95% CI)						
Primary analysis [2]	-0.55 (-1.39 to 0.30)	0.21	0.13 (-0.90 to 1.16)	0.80	-1.24 (-2.53 to 0.05)	0.06
Sensitivity analysis [3]	-0.59 (-1.39 to 0.20)	0.14	0.21 (-0.75 to 1.17)	0.67	-1.42 (-2.68 to -0.16)	0.03
Sensitivity analysis [4]	-0.59 (-1.38 to 0.21)	0.15	0.22 (-0.73 to 1.17)	0.65	-1.42 (-2.67 to -0.16)	0.03
CACE analysis [5]					-2.76 (-5.64 to 0.11)	0.06
CACE analysis [6]					-3.39 (-6.95 to 0.16)	0.06

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
CACE analysis [7]					-4.64 (-9.51 to 0.23)	0.06
CACE analysis [8]					-5.47 (-11.21 to 0.28)	0.06
SMD (95% CI) [9]	-0.06 (-0.14 to 0.03)	0.21	0.03 (-0.20 to 0.26)	0.80	-0.17 (-0.34 to 0.01)	0.06

Notes: SD = Standard deviation; Coef. = Estimated coefficient; CI = Confidence Interval; SMD = Standardised mean difference. [1] Estimated using multiple imputation. [2] Mean for intervention arm minus mean for comparison arm estimated using linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [3] Sensitivity analysis using complete cases only with linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). [4] Same as 3 but adjusted for general practice using a linear mixed effects model with practice as a random intercept. [5] CACE analysis: undertaken in the severe prognostic group only. Conducted using two-stage least squares instrumental variable regression where the adherence variable is a binary coded variable representing participants attended at least one appointment with the care navigator and there was a match between participant priorities and the afternation and the participant priorities and the afternative variable is a binary coded variable representing (a) the participant had at least one surfuced using multiple imputation. [7] CACE analysis: Same as 5 except the adherence variable is a binary coded variable representing (a) the participant was approved for care package funding. Estimated using multiple imputation. [8] CACE analysis: Same as 5 except the adherence variable is a binary coded variable representing (a) the participant was approved for care package funding. Estimated using multiple imputation. [8] CACE analysis: Same as 5 except the adherence variable is a binary coded variable representing (a) the participant had at least one structured contact with the care navigator and there was a match between participant priorities and the treatment plan, (b) a referral was made to other services, (c) the participant variable representing (a) the participant had at least one such participant variable representing (a) th

**Figure 7.** Mean change in K10 psychological distress scores at six- and 12-month follow-up from baseline by trial arm, in total and stratified by prognostic group

Note: Means and confidence intervals estimated using multiple imputation

The CACE analysis showed larger and more clinically meaningful effect sizes associated with delivery of additional elements of care navigation in the severe prognostic group (Table 13; see Table 12 for number receiving each element). At six months, those who were able to identify actions that were relevant to improving their mental health priorities from the Link-me DST had a mean K10 improvement of 4.28 points (95% CI -7.05 to -1.51, p < 0.01) over their counterparts in the comparison arm. Participants who received all four elements of care navigation had a mean difference of -8.48 (95% CI -14.14 to -2.81, p < 0.01) compared to those in the comparison arm who would have received these elements had they been offered care navigation. At 12-month follow-up, the magnitude of the treatment effect had attenuated but the pattern of results still favoured the intervention.

We observed few meaningful differences on any secondary outcomes, and those that were observed were not robust to sensitivity analyses (Table 14). No serious harms or unintended effects were reported.

Table 14. Secondary outcomes according to trial arm, in total sample and stratified by prognostic group

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Depressive symptom severity (PHQ-9)			progressic group		Promb	
Six-month follow-up						
Comparison, mean (SD)	-1.69 (5.78)		0.25 (4.68)		-3.61 (6.11)	
Intervention, mean (SD)	-2.02 (5.95)		0.08 (4.57)		-4.08 (6.41)	
Mean difference, Coef. (95% CI) [1]	-0.31 (-0.98 to 0.35)	0.35	-0.20 (-0.97 to 0.56)	0.60	-0.43 (-1.50 to 0.64)	0.43
Mean difference, Coef. (95% CI) [2]	-0.18 (-0.82 to 0.47)	0.59	<-0.07 (-0.86 to 0.71)	0.86	-0.30 (-1.33 to 0.72)	0.56
Mean difference, Coef. (95% CI) [3]	-0.18 (-0.82 to 0.47)	0.59	-0.08 (-0.86 to 0.70)	0.84	-0.31 (-1.33 to 0.70)	0.55
SMD (95% CI) [4]	-0.05 (-0.14 to 0.05)	0.35	12. 20	0.60	-0.09 (-0.33 to 0.14)	0.43
12-month follow-up		0.35 0.46 0.61				
Comparison, mean (SD)	-2.02 (5.88)	EL SUL	-0.30 (4.28)		-3.71 (6.69)	
Intervention, mean (SD)	-2.28 (5.84)	160.14	-0.18 (4.61)		-4.36 (6.16)	
Mean difference, Coef. (95% CI) [1]	-0.25 (-0.93 to 0.42)	0.46	0.10 (-0.69 to 0.90)	0.80	-0.61 (-1.65 to 0.43)	0.25
Mean difference, Coef. (95% CI) [2]	-0.18 (-0.86 to 0.50)	0.61	-0.01 (-0.79 to 0.77)	0.97	-0.35 (-1.46 to 0.76)	0.54
Mean difference, Coef. (95% CI) [3]	-0.18 (-0.86 to 0.50)	0.60	-0.04 (-0.81 to 0.73)	0.93	-0.35 (-1.46 to 0.75)	0.53
SMD (95% CI) [4]	-0.04 (-0.14 to 0.06)	0.46	0.04 (-0.28 to 0.36)	0.80	-0.13 (-0.36 to 0.09)	0.25
Anxiety symptom severity (GAD-7)	SOFFE					
Six-month follow-up	THISHE BY					
Comparison, mean (SD)	-1.74 (4.80)		-0.47 (3.89)		-2.99 (5.27)	
Intervention, mean (SD)	-2.31 (5.29)		-0.55 (3.82)		-4.06 (5.92)	
Mean difference, Coef. (95% CI) [1]	-0.51 (-1.05 to 0.03)	0.07	-0.08 (-0.72 to 0.57)	0.81	-0.93 (-1.82 to -0.04)	0.04
Mean difference, Coef. (95% CI) [2]	-0.35 (-0.91 to 0.20)	0.21	0.10 (-0.55 to 0.75)	0.76	-0.76 (-1.65 to 0.12)	0.09
Mean difference, Coef. (95% CI) [3]	-0.35 (-0.90 to 0.20)	0.21	0.09 (-0.56 to 0.73)	0.79	-0.76 (-1.64 to 0.12)	0.09
SMD (95% CI) [4]	-0.09 (-0.18 to 0.01)	0.07	-0.03 (-0.26 to 0.20)	0.81	-0.20 (-0.39 to -0.01)	0.04
12-month follow-up						
Comparison, mean (SD)	-2.17 (5.10)		-0.83 (3.72)		-3.50 (5.86)	

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Intervention, mean (SD)	-2.48 (5.29)		-0.71 (3.90)		-4.23 (5.86)	
Mean difference, Coef. (95% CI) [1]	-0.23 (-0.87 to 0.40)	0.47	0.11 (-0.56 to 0.79)	0.74	-0.58 (-1.60 to 0.44)	0.26
Mean difference, Coef. (95% CI) [2]	-0.18 (-0.76 to 0.41)	0.55	0.16 (-0.48 to 0.81)	0.62	-0.53 (-1.50 to 0.44)	0.28
Mean difference, Coef. (95% CI) [3]	-0.18 (-0.77 to 0.41)	0.55	0.16 (-0.48 to 0.80)	0.62	-0.53 (-1.49 to 0.44)	0.28
SMD (95% CI) [4]	-0.04 (-0.15 to 0.07)	0.47	0.04 (-0.20 to 0.28)	0.74	-0.13 (-0.35 to 0.09)	0.26
Overall health (EQ-5D-5L VAS)			1/10/85			
Six-month follow-up			10,100			
Comparison, mean (SD)	3.94 (24.17)	2	2:12 (22.33) 3.76 (19.63) 0.78 (-2.40 to 3.96)		5.74 (25.70)	
Intervention, mean (SD)	5.59 (22.54)		3.76 (19.63)		7.40 (24.93)	
Mean difference, Coef. (95% CI) [1]	0.11 (-2.43 to 2.65)	0.93	3.76 (19.63) 0.78 (-2.40 to 3.96)	0.63	-0.53 (-4.44 to 3.38)	0.79
Mean difference, Coef. (95% CI) [2]	0.14 (-2.23 to 2.52)	170 04/2	1.17 (-1.86 to 4.20)	0.45	-0.78 (-4.42 to 2.87)	0.68
Mean difference, Coef. (95% CI) [3]	0.10 (-2.26 to 2.47)	× ~~~~	1.17 (-1.84 to 4.19)	0.44	-0.81 (-4.41 to 2.80)	0.66
12-month follow-up	, AL	0.93				
Comparison, mean (SD)	3.75 (25.79)	2	0.73 (23.19)		6.73 (27.76)	
Intervention, mean (SD)	5.99 (24.88)	7.	1.27 (22.70)		10.66 (25.99)	
Mean difference, Coef. (95% CI) [1]	0.61(-2.32/to 3.54)	0.68	-0.38 (-4.41 to 3.65)	0.85	1.61 (-2.72 to 5.95)	0.46
Mean difference, Coef. (95% CI) [2]	0.06 (-2.64 to 2.75)	0.97	0.30 (-3.16 to 3.76)	0.86	-0.14 (-4.29 to 4.00)	0.95
Mean difference, Coef. (95% CI) [3]	-0.07 (-2.74 to 2.59)	0.96	0.30 (-3.13 to 3.74)	0.86	-0.32 (-4.33 to 3.69)	0.88
Quality of life (EQ-5D-5L utility)	\\\.\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\					
Six-month follow-up						
Comparison, mean (SD)	0.02 (0.24)		-0.00 (0.20)		0.05 (0.28)	
Intervention, mean (SD)	0.03 (0.25)		-0.00 (0.21)		0.07 (0.28)	
Mean difference, Coef. (95% CI) [1]	0.01 (-0.02 to 0.04)	0.63	0.00 (-0.03 to 0.03)	0.96	0.02 (-0.03 to 0.06)	0.53
Mean difference, Coef. (95% CI) [2]	0.00 (-0.02 to 0.03)	0.91	-0.00 (-0.03 to 0.03)	0.86	0.01 (-0.03 to 0.05)	0.72
Mean difference, Coef. (95% CI) [3]	0.00 (-0.02 to 0.03)	0.91	-0.00 (-0.03 to 0.03)	0.86	0.01 (-0.03 to 0.05)	0.72
12-month follow-up						

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Comparison, mean (SD)	0.04 (0.25)		0.02 (0.20)		0.06 (0.29)	
Intervention, mean (SD)	0.02 (0.26)		-0.02 (0.20)		0.06 (0.30)	
Mean difference, Coef. (95% CI) [1]	-0.02 (-0.05 to 0.01)	0.17	-0.04 (-0.07 to -0.00)	0.03	-0.01 (-0.06 to 0.05)	0.79
Mean difference, Coef. (95% CI) [2]	-0.03 (-0.06 to 0.00)	0.07	-0.03 (-0.06 to 0.00)	0.08	-0.02 (-0.07 to 0.02)	0.33
Mean difference, Coef. (95% CI) [3]	-0.03 (-0.06 to -0.00)	0.05	-0.03 (-0.06 to 0.00)	0.08	-0.03 (-0.07 to 0.02)	0.29
Days out of role (K10+)			12/05			
Six-month follow-up			10,190			
Comparison, mean (SD)	9.59 (10.34)		5.13 (8.32)		13.99 (10.25)	
Intervention, mean (SD)	8.84 (10.19)		4.46 (7.45)		13.15 (10.67)	
Relative risk, RR (95% CI) [5]	0.90 (0.76 to 1.07)	0.23	0.88 (0.63 to 1.23)	0.45	0.93 (0.79 to 1.09)	0.35
Relative risk, RR (95% CI) [6]	0.91 (0.77 to 1.08)	( 0.2×	0.87 (0.62 to 1.21)	0.41	0.95 (0.80 to 1.13)	0.58
Relative risk, RR (95% CI) [7]	0.95 (0.92 to 0.99)	0.02	0.89 (0.82 to 0.97)	0.005	0.97 (0.92 to 1.01)	0.15
12-month follow-up	ZI CAL	The ME				
Comparison, mean (SD)	9.40 (10.53)	2	4.77 (7.92)		13.98 (10.77)	
Intervention, mean (SD)	8.77 (9.98)	~	4.86 (7.80)		12.63 (10.38)	
Relative risk, RR (95% CI) [5]	0.96 (0.81 to 1.14)	0.64	1.05 (0.76 to 1.45)	0.76	0.89 (0.75 to 1.06)	0.19
Relative risk, RR (95% CI) [6]	0.96 (0.80 to 1,16)	0.69	1.09 (0.76 to 1.55)	0.65	0.89 (0.73 to 1.07)	0.21
Relative risk, RR (95% CI) [7]	0.9\$ (0.91 to 0.99)	0.02	1.07 (0.98 to 1.16)	0.14	0.91 (0.87 to 0.96)	<0.001

Notes: SD = Standard Deviation; Coef. = Estimated coefficient; RR ( Rate ratio; CI = Confidence Interval. [1] Mean for intervention arm minus mean for comparison arm estimated using linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [2] Sensitivity analysis using complete cases only with linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). [3] Same as 2 but adjusted for general practice treated as random intercept. [4] Mean difference from 1 calculated relative to the pooled SD of baseline scores. [5] Rate ratio estimated using negative binomial regression adjusted for baseline days out of role (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [6] Sensitivity analysis using complete cases only with negative binomial regression adjusted for baseline days out of role (all models) and prognostic group (model with all participants only). [7] Same as 6 but adjusted for general practice treated as random intercept.

Two sets of supplementary analyses were conducted to describe the characteristics of the moderate prognostic group (see Appendix 11) and of participants followed for 18 months (see Appendix 12).

## 4.3. Interpreting the results

In this randomised controlled trial, we evaluated the effect of using a patient-completed DST to identify individual need and guide treatment pathways within a component of a stepped care framework. The treatment options available to each patient in the intervention arm differed according to the areas of need they identified, the services available in their area, and in the severe prognostic group, their discussions with their GP and care navigator. Ours was therefore a pragmatic trial, evaluating a targeted, complex intervention in the real-life setting of everyday primary care.

Our key finding is that those assessed and allocated to the Link-me intervention arm had lower psychological distress at six-month follow-up on average than those who received usual care. While the intervention did not appear to offer an improvement over usual care for the minimal/mild prognostic group, there was no evidence that it did harm either. The intervention appeared to offer improvement over usual care for the severe prognostic group. Importantly, the confidence bounds of the SMD for the severe prognostic group included the pre-specified, minimal clinically relevant difference of 0.26. This effect size is comparable to those previously associated with collaborative care for depression and anxiety [53, 54], the approach on which our intervention was based. Highlighting the challenge in engaging primary care attendees in collaborative care models, we detected this effect despite half of the participants allocated to the intervention arm not taking up the offer of care navigation. When we accounted for treatment received, the effect increased. Participants who accessed care package-funded services showed an average improvement in K10 scores of almost nine points more than their counterparts in the comparison arm would have, had they had the opportunity. Similar effects, albeit attenuated and statistically non-significant, were observed at 12-month follow-up for the K10. Although there is no assumption that all individuals allocated to the severe prognostic group require the full course of eight structured contacts or care package funding, further efforts to optimise this intervention, including improving uptake and engagement, appear warranted. The effect of the intervention on changes in depressive and anxiety symptoms was less conclusive. This may have been in part due to the heterogeneity of the sample which included a mix of participants with either or both depressive and anxiety symptoms, potentially attenuating the observed effect sizes on symptom-specific measures.

Trial strengths include a large and representative sample of patients drawn from the primary care population [51] and sufficient power to examine effectiveness both across and within the two prognostic groups, in line with calls for models of stepped care to be evaluated in their entirety rather than only at each step of care [10]. Another strength is that the sensitivity analyses did not substantially alter the interpretation of the findings. Limitations include the slight imbalance in attrition between arms (7.2 percentage points at 12-month follow-up) and fewer people predicted to have minimal/mild symptoms than anticipated reducing the study power to detect the nominated minimally important treatment effect in this group. Based on our previous trial [27], we had expected the minimal/mild prognostic group to comprise two thirds of all participants but instead it was about 40 percent.

Conversely, we identified proportionally more people predicted to have severe symptoms than we had expected (40% instead of 25%), which may have implications for generalisability of findings as well as the planning and delivery of primary and specialist mental health care. There could be several reasons that explain the higher representation of the severe prognostic group in the sample. It could be due to the DST algorithm and the thresholds used to classify prognostic groups. It may have reflected targeted recruitment of general practices in areas of high needs areas or potential selective recruitment of participant within practices. Another possibility is the inclusion of people taking antipsychotic medication (which may have skewed the sample towards poorer mental health overall). Finally it could be due to more frequent GP attendance by participants allocated to the severe prognostic group providing greater opportunity to be recruited to the trial [1, 3].

Among the severe prognostic group, we noted that males were more likely to participate in at least one care navigation contact than females. This may be consistent with other evidence that males may be more receptive to specialised care when their mental health problems are severe [55, 56].

To our knowledge, this is the largest randomised controlled trial of a treatment allocation tool for depression and anxiety in primary care. We applied minimal exclusion criteria and included general practice attendees with symptoms across the severity spectrum, thus enhancing generalisability to the broader primary care population.

## 4.4. Summary

In this chapter, we evaluated the outcomes of using a patient-completed DST to guide treatment allocation within a stepped care framework. The key finding from our analysis is that those allocated to the Link-me intervention arm showed more rapid reduction of psychological distress than those in usual GP care. It suggests that using prognostic tools to stratify and allocate people to an appropriate first step in a stepped care design is efficient as it allows general practice attendees — especially those with severe symptoms—to receive appropriate care sooner. Of course, appropriate treatment options need to be available, and our trial shows that when they are, psychological distress is reduced sooner than it would otherwise have been.

## 5. Process evaluation

I was seeing some doctors about pain 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 about problems with limbs, depression and so forth. I imagine a lot of people go and see GPs to get pills for depression and pain and things like that... I 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. (Intervention arm participant, Link-me trial)

## 5.1. Summary of approach

The process evaluation gathered additional information from participants in the Link-me trial as well as GPs, care navigators and others involved in the delivery of Link-me services using multiple methods (these data sources are described in section 3.4). This information was used, in combination with participant surveys and care navigation records from the trial, to address several aspects of the evaluation questions. Specifically, the process evaluation addressed how care navigation was implemented and the barriers and enablers to implementation (evaluation question 1), the experiences of care for people allocated to care navigation (evaluation question 2) or low intensity services (evaluation question 4), and factors that could impact on the feasibility of a wider roll-out of Link-me (evaluation question 5).

The analytical approach was as follows:

- (1) Implementation of care navigation and barriers and enablers. Qualitative data were collected from: notes taken at regular meetings, observations and outcomes of workshops; transcripts of telephone interviews with regional trial coordinators (n=3), care navigators (n=6), and GPs who had experience of one of their practice attendees in the care navigation intervention (n=14); feedback from GPs who participated in an RACGP quality improvement activity (n=6); and an 'implementation case study' (see Appendix 13) based on discussion with staff from practices in one PHN. These records were reviewed to identify individually important themes related to care navigation implementation using a thematic analysis method [57].
- (2) Experiences of care for people allocated to care navigation. Telephone interview data from a subset of participants allocated to care navigation (n=31) were used to explore the experiences of care; characteristics of these participants are shown in Appendix 14. Three patient journeys were re-constructed to demonstrate how care navigation took place over time (these are provided in Appendix 15).
- (3) Experiences of care for people allocated to low intensity services. Telephone interview data from a subset of participants allocated to low intensity services (n=32) were collated and analysed thematically. Characteristics of these participants are also shown in Appendix 14.
- (4) Feasibility of national implementation of Link-me. Normalisation process theory [58, 59] was used as an analytical framework to guide the synthesis of the themes emerging from the analysis of the various qualitative datasets. Normalisation process theory is a widely used

implementation theory which has been developed to help explain how interventions, technologies or processes become embedded into routine clinical practices. In brief, four areas for assessment were used to examine the feasibility of national implementation of the Link-me approach: *coherence* (how well was the Link-me approach understood by all stakeholders involved?), *cognitive participation* (how well did people engage with the Link-me approach?), *collective action* (how well did the Link-me approach fit into context, relationships, and workflows?), and *reflexive monitoring* (how was the DST and Link-me appraised?).

# 5.2. Care navigation – implementation and barriers and enablers

Our analysis of the various sources of qualitative data from people involved in the delivery of Linkme identified three common themes related to the implementation of care navigation:

- 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)

Within each of these themes, a range of barriers and enablers were identified. These are discussed below.

## **5.2.1.** Uptake

Regional trial coordinators 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. Most GPs welcomed the Link-me approach and found it beneficial to have a care navigator dedicate time to search for services for participants and support their attendance at various appointments. GPs acknowledged it would not be possible for them to research services in the area in as much depth as care navigators did. Care navigators provided practices with lists of local resources and services, which could benefit their patient cohort, and were seen as providing a level of independent review. One GP said:

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)

In some instances, care navigators perceived resistance to Link-me from GPs. Reasons for this resistance included: concern around the provision of a consulting room to a care navigator which for some practices represented a loss of income; concern about providing participants with a sense of privacy for completion of the DST prior to an appointment; uncertainty about having someone in their clinic who was not a member of the professional team; and questions about how risk would be managed for the participant who expressed thoughts of self-harm. Equally, however, care navigators raised concerns about being able to connect with GPs in a timely manner to discuss procedures for management of higher-risk participants. From their point of view, care navigators felt that if GPs had

not "bought into" the trial, this reduced participants' engagement in and uptake of Link-me. For example, one care navigator 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 I had 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.

An additional barrier to implementation of care navigation was related to PHN staff turnover. This resulted in some participants experiencing delays in commencing care navigation appointments and some staff in practices not being sure who the allocated PHN care navigator was.

### 5.2.2. Embedding

For those GPs interviewed, Link-me was largely described as a positive experience and they expressed disappointment when this support ended. They valued the extra time being given to participants with higher needs. Some GPs reported that they had worked with some participants for years and not made the levels of progress that were seen within the trial.

Most GPs agreed that working with the care navigator did not impact significantly on their workload, and said that they had received positive feedback from participants about the care navigator. There was a general impression that care navigation worked easily in the general practice setting, particularly in practices where there was already a multidisciplinary team. A few GPs expressed a level of frustration at the additional time required to write and approve referrals suggested by the care navigator. This was usually reported in situations where the care navigators found it difficult to access and engage the relevant GP.

The Link-me DST was seen as appropriate for the identification of the target populations and the GPs reported a good match between the results of the Link-me DST, the priorities that were set, and their clinical judgement. It provided reassurance for GPs that care navigation was appropriate for meeting participants' needs based on a validated support tool and person-centred approach. GPs noted the usefulness of the DST in identifying unmet mental health needs of participants 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 participants who might have been "stuck" a prompt to consider their mental health and provided them with a different professional to try and implement changes.

Several GPs indicated that they played a significant role in preparing the practice setting for the implementation of Link-me. This included reassuring participants about the use of the tablet-based survey and increasing awareness of the tablet-based survey through posters, with the aim that participants would not think it was "just another survey". There were some indications that GPs may have felt threatened by another professional taking over a component of their role or were not keen to engage in multi-professional care, or preferred a case-finding approach in preference to the whole-of-practice approach taken by Link-me. For example, some GPs noted a preference to refer

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participants to care navigation during a consultation rather than referral occurring via a tablet device in the waiting room. Privacy was also an issue for some GPs. There were mixed views from GPs on whether the waiting room was the best place to raise the topic of mental health issues and they indicated that this may have put some participants off being involved in Link-me.

There was some evidence of misalignment between GPs and care navigators in their view of Link-me and/or the care navigation role; a potentially important barrier to communication. For example, some GPs reported Link-me was for those with a high risk of suicide that may not otherwise have been identified. Some GPs thought the role of the care navigator was to be an advocate; others thought they were a psychologist or "coach" whose role was to provide counselling to participants.

Many of these themes are exemplified in the implementation case study shown in Appendix 13.

### 5.2.3. Engagement

Communication was considered critical to successful engagement between GPs and care navigators. Some GPs described communication with the care navigators as excellent, with joint meetings between the GP, care navigator and the participant occurring regularly to discuss priorities and develop an action plan. Other GPs said they could only allocate 10 to 15 minutes for joint appointments with the care navigators and participants. Some GPs and care navigators referred to regular informal discussions, often taking place in the tea-room. Still other GPs said there was no time allocated specifically for communication between themselves and the care navigator, and that dedicated time should be built into any future model to ensure GPs were 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".

Workplace practices and characteristics may have contributed to these different communication patterns. For example, one GP described the 'open door policy' in their practice that facilitated discussion of participants 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 care navigator and the extent of their communication being an initial letter to say their participant had been allocated to care navigation. In other cases, technological issues (e.g., the care navigator being unable to upload participant progress notes and reports on their electronic record system) impeded efficient communication about individual participants' progress.

Care navigators who worked with a higher number of general practices reported more difficulty in communicating with GPs about how participants in the trial were going and working collaboratively. For example, one care navigator 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.

Care navigators were able to work with many participants with complex and challenging needs to assist their engagement with general practice and the wider service sector. However, some participants could not be contacted despite multiple attempts - possible reasons for non-engagement included working in regional areas where anonymity may have been an issue; privacy concerns among participants with drug and alcohol issues; and anxiety 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 participants did not see that there were any benefits to seeing a care navigator.

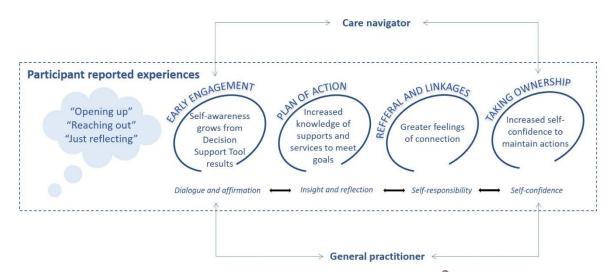
Once participants were engaged in care navigation, the care navigators reported little drop out. They considered that participants benefitted from the tailored information, the suggestions of apps for self-management and supported referrals to health professionals. They noted the importance of the motivational interviewing-inspired approach in working with participants who found it hard to set goals. They also noted their role in overcoming access to care issues (e.g., 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 participants not ready to re-engage, and social determinants of health such as transience, or work commitments and competing priorities).

# 5.3. Experiences of care for people allocated to care navigation

Based on various datasets (patient) ourneys (see Appendix 15), interview data, care navigator notes, and handover summaries provided to GPs) we developed an experiential model of care navigation which is shown in Figure 8 and explained further below.

In Figure 8, the component parts of care navigation are detailed in terms of: setting priorities (the DST), developing a plan of action (DST information and care navigator contact), the support for referrals and links (care navigator working in conjunction with GP). The figure shows the interrelation between these parts and how participant experiences of dialogue and affirmation, insight and reflection, self-responsibility and self-confidence appear to drive the success of care navigation.

Figure 8. An experiential model of care navigation based on participant-reported experience



#### 5.3.1.1. Early engagement

All participants first engaged with Link-me via the completion of the Link-me DST. Participants were positive about completing the tablet-based survey in the waiting room, commenting that it enabled them to open up, reach out or just reflect. As one participant said:

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.

The Link-me DST prompted participants to reflect on their current challenges and to set their own priorities ahead of their first goal-setting meeting with their care navigator. This provided a 'bridge' between them and their allocated care navigator, promoting a sense of continuity and affording care navigators insights into their needs ahead of the first meeting.

In Chapter 4 (section 4.2.2) we noted that the participants allocated to care navigation rated the importance of their priorities for care navigation more highly than their confidence to change. This mismatch between importance and confidence is a common barrier to behaviour change and required care navigators to implement the motivational interviewing approach covered in the Linkme training. The determining of priorities via the DST enabled a conversation to occur between care navigators and participants about the supports available that might help and to realise what action they needed to take to access those supports. As highlighted by this participant:

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.

In contrast, other participants reported that the identification of priorities ahead of meeting the care navigator prompted them to conduct their own research on anxiety prior to their appointment.

#### 5.3.1.2. Plan of action

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

Once participants were engaged and had affirmed their needs and potential supports, the care navigators worked with participants to formulate a plan of action. As part of this process, care navigators often conducted in-depth research into local services and supports that may help participants achieve their goals and provided this information back to the participant. From the participant journeys, we saw that the plan of action was also accompanied by many 'light touch' contacts that included emails and text messages in-between face to face contacts to engage and inform participants. Participants experienced the light touch contacts and updates positively and felt that phone contact was a good option when they were also managing work, family, study and other caring responsibilities. The process of developing an action plan also gave participants a sense that care navigators were going an extra step to address their needs.

Participants also said they valued having the care navigator there to listen, especially during stressful times and life events, something that was not usually possible in busy GP appointments. As one participant said:

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.

Care navigators were seen by some participants as a person to be accountable to, a motivator and "just sort of helping, supporting you, being there for you, trying to organise yourself." Many participants experienced this as a trusting relationship, they indicated that they "never pushed, [it was] always on my own terms".

Participants reported that the action plan process assisted them to build new skills, increase their self-confidence and take up new activities. One participant said that care navigation assisted them in learning how to live with their depression. Another described continuing with exercise routines (such as swimming and yoga) or appointments, even when care navigation in the trial had finished. One participant said:

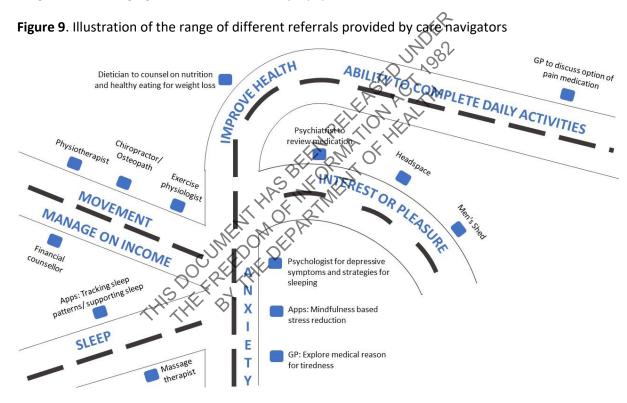
Just the fact that I was exercising more because the care navigator got me into the Pilates which I can do at home myself now, which is good. I mean I probably wouldn't have gone ahead and done that on my own at the time because of the cost of it and how things were going here, it was a bit difficult.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

#### 5.3.1.3. Referrals and linkages

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 care navigation was its holistic approach to care planning and referral. Participants were assisted to access a broad range of health and social services and they appreciated the tailored nature of the referrals provided by care navigators. As one participant 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".

Among the participants who were followed up after 18 months, referrals ranged from suggesting eHealth options, finding counsellors, to local social support groups and clubs, to psychological complementary therapies, dietitians, exercise groups, massage for pain management, psychological sessions, support groups for parents, financial and housing support, and specialist services also such as eating disorder services and pain specialists. This broad array is further illustrated in Figure 9. The priority areas are shown as the 'roads' and the referrals are points along on the road. For example, referrals made for participants reporting a desire to improve their interest and pleasure in life ranged from arranging a medication review by a psychiatrist to a referral to a Men's shed.



Participants reported that they valued the care package funding which increased their access to services and increased the frequency and duration with which they could attend.

Despite being provided with referrals, booking into services, particularly in regional areas, remained a problem for some participants. One participant noted, "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". There were also some difficulties reported about the procedures for invoicing for the care package payment.

#### 5.3.1.4. Taking ownership

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.

Care navigation provided the tools to support self-management and self-growth which participants reported as helpful, even if their symptom severity did not change.

Participants reported that being provided with a print-out of the action plan from the previous week to review was helpful. Tracking their own progress allowed them to gain insight into 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.

Some participants reported reading their action plan on a regular basis to remind themselves of what they had had agreed to do:

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

#### One participant noted:

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.

Most of the participants interviewed said that they had continued with the activities associated with their goals, even after care navigation was finished. Some of the continued activities included attending professional services, participating in local groups, continuing with their exercise or using new mobile phone apps and strategies.

Some participants mentioned that they later returned to the resources that care navigators had given them, particularly in the case of apps for finance and mindfulness to assist with sleep routines.

# 5.4. Experiences of care for people streamed to low intensity services

Participants allocated to the minimal/mild prognostic group were positive about Link-me being undertaken in general practice. They felt that it raised awareness of mental health issues and gave a sense that GPs would be open to addressing issues if required. They were positive about completing the tablet-based DST in the waiting room and found it easy to complete. There was variability in the extent to which participants in this group could recall receiving the email about the low intensity services that might benefit them. Some said that they did not feel they needed to follow up on any

of the priorities they had identified on the DST, so they intentionally did not use the resources provided to them via email. Others reported that, although they did not use the resources at the time they were provided, they had returned to use them at a later date. Many participants gave feedback that email may not be the best way to reach them and suggested they would have been more likely to use the resources if the information had been provided in hard copy format. One or two participants were disappointed not to have received more support, feeling that they could have benefited from an early intervention and prevention approach.

## 5.5. Feasibility of national implementation of Link-me

Using applied normalisation process theory, we synthesised the themes emerging from the analysis of the various qualitative datasets and suggest strategies, where applicable, to enabler the smooth implementation of Link-me on a wider scale.

## 5.5.1. Coherence – how well was the Link-me approach understood by all stakeholders involved?

The construct of 'coherence' focuses on determining the extent to which those involved in the Linkme trial had a shared understanding of the Link-me approach. We set out to examine: (a) how well the role of the decision support tool (DST) and the care navigator were understood by all involved; (b) how well those involved understood the potential benefits of using the DST and care navigation; and (c) what processes and work promoted or inhibited the routine embedding of the Link-me approach into the practice?

Overall, there was a good level of agreement about the role of the DST and the role of care navigator in the Link-me trial, yet this was not universal across or within practices. Participants triaged to the high and low intensity groups understood that the DST was being used to identify needs and priorities and to provide feedback that things were or were not going okay. The role of the DST was perceived positively, even though there was some feedback that technology might not suit all participant groups. The tool worked well in identifying high and low need participants and could be successfully implemented into the work-flow of busy general practices. GPs had few concerns with the DST itself apart from one or two mentioning the potential for duplication of effort (their practices were surveying participants at the same time) or some concern about the physical infrastructure and lack of privacy in their waiting rooms.

It should be noted that Link-me was offered to English-speaking primary care consumers. An assessment of the suitability of the current DST form and format for culturally and linguistically diverse, and, Aboriginal and Torres Strait Islander communities is also needed.

## 5.5.2. Cognitive participation-how well did people engage with the Link-me approach?

Cognitive participation refers to the extent to which people actively participated in Link-me and played their appropriate role.

The interview data confirm that most people knew their role and actively participated in Link-me accordingly. There were many examples of active buy-in to this new way of working and positive feedback about both the DST and the care navigation approach. There were numerous case studies

of positive impact on health outcomes and well-being. There were also times when this did not occur. There were examples where practices were unclear about the process for administering the DST and where care navigators found it difficult to engage with the appropriate GPs. There were a few GPs who did not value the support from a care navigator and saw it as an unnecessary intrusion. It was evident that where the regional trial co-ordinators had good relationships with practices this was less likely to occur. It was also noted that in practices where there were large numbers of staff, many part-time, it was more difficult to ensure that everyone was aware of what Link-me required of them. To assist practices, research staff supported the completion of the DST rather than imposing this task on busy reception staff. Large numbers of patients accepted the offer to complete the DST in the waiting room and engaged positively with it. Key to this was being provided with study information and the opportunity to ask any questions. Other evidence of the positive engagement with the Link-me approach was the finding that many participants engaged actively in researching information to bring to their care navigation appointment.

For any or future implementation it will be key to include strategies to generate awareness about the Link-me approach so that all practice staff and participants have a good understanding of the DST and the care navigator role.

## 5.5.3. Collective action—how well did the Link-me approach fit into context, relationships, and workflows

Collective action explores the roles, activities and skill sets required for successful uptake of an intervention and examines how well the intervention fits within overall goals and activities of an organisation and compatibility with existing work practices.

Link-me required practices to adopt a systematic approach to the administration of the DST in the waiting room, prior to a consultation and to integrate the role of the care navigator into the practice. It required practices to work out ways for the care navigator to communicate with GPs so they could complete the care planning work and patients could access new forms of support. We found that this worked well in practices that were open to new ways of working and where Link-me had support from senior practice staff. Care navigators requested that in any future role out it would be key for them to have access to the participant electronic medical record and be able to share progress efficiently with GPs. Participants liked the care navigator being available at the practice and GPs appreciated the time that care navigators could take with participants and the extra resourcing and links to services they provided.

Considerations for future implementation should include a pre-implementation assessment of workflow to allow for the necessary communications to take place.

### 5.5.4. Reflexive monitoring—how was the DST and Link-me appraised?

The construct of reflexive monitoring involves the engagement in activities to appraise and monitor the intervention and its outcomes by those who are using it. Reflexive monitoring includes informal and formal appraisal to assess advantages and disadvantages.

Several of the identified advantages and disadvantages to care navigation hinged on the need for clarity of roles and responsibilities, and communication of this role across practices. While care navigators did spend time formally appraising different aspects of care delivery in peer learning

groups and workshops, GPs only provided their perspectives during interview and practice meetings. Although there were examples of GPs and care navigators brainstorming together to find solutions this was not focused on monitoring the overall Link-me approach. Care navigators were involved in regular group sessions with a trained clinical psychologist to reflect upon and troubleshoot about cases they were managing. Care navigators were also asked to reflect and appraise the Link-me approach in workshops held at PHNs and through a peer learning group set up by the University. No practices reported assessing or appraising the outcomes of the DST or care navigation using formal assessments or audits of their own participant records.

In any future roll-out, a formal system to monitor in the uptake of the DST and progress of participants in care navigation would be useful.

## 5.6. Summary

This chapter reported on the process evaluation findings in relation to the implementation of the Link-me model, the barriers and enablers identified in this implementation and the experiences of those involved in care navigation and low intensity options. Synthesising these findings allowed us to identify several strategies that could improve the implementation of Link-me in future. These included further development of the Link-me DST to increase its acceptability and prepare it for use in new population groups; strategies to ensure that levels of awareness and information about Link-me are maximised in the practice setting and that workflows are optimised; and the development of systems to support monitoring individual's progress in tesponse to the Link-me intervention and to facilitate step up and step down processes in stepped care models.

## 6. Economic evaluation

## 6.1. Summary of approach

This chapter presents data relating to the costs of the Link-me trial for the people in the severe prognostic groups (evaluation question 3) and the minimal/mild prognostic group (evaluation question 4), and the broader cost implications of implementing Link-me through GPs across Australia (evaluation guestion 6). The overall framework for these analyses was a full economic evaluation using a within trial method as well as economic modelling to evaluate population level costs and effects. A health sector perspective was adopted as the primary perspective; this includes costs borne by the government as a third-party payer in addition to out of pocket costs incurred by participants when accessing health care. A partial societal perspective, which includes absenteeism and presenteeism effects on productivity for study participants, was undertaken as a secondary analysis [60]. For the within-trial analysis, cost data were collected from a variety of sources. Care package data provided by PHNs, University records, and data entered by care navigators in the Linkme 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 RUQ completed by participants as part of the six-month and 12-month follow-up surveys. To understand the broader societal implications of the Link-me approach to care, the RUQ 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). Standard Australian unit costs were applied to these resource use questions to calculate the cost of the services utilised by participants over the 12-month follow up period. For the economic modelling, the costs and outcomes data from the within trial evaluation were combined with estimates from published literature to estimate the broader cost implications of implementing Link-me through GPs across Australia under a 'most likely pathway' and a range of alternative pathways.

## 6.2. Descriptive analysis of resource use

#### 6.2.1. Adjusting for potential double-counting

Resource use included the use of care packages for care navigation and use of health and other services for all participants. In completing the RUQ, some participants in the severe prognostic 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 were unable to adjust for these potential sources of double counting.

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.

## 6.2.2. Use of care packages (care navigation participants)

A total of 112 (27%) participants allocated to care navigation received funding for care packages. The average spend was \$669 per person for the 112 participants who received a care package; this equated to \$178 per person when averaged out across the 420 people allocated to care navigation.

Psychologists were the most frequently funded service through care packages with 48 participants receiving funding for a total of 461 sessions (Table 15). 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). The observed pattern for use of psychology services is consistent with findings from evaluations of Australians programs providing government-subsidised psychological services [61, 62]. The low number of people using care package services for housing and finance reasons may reflect that most of the finance referrals were to free financial counselling services or Centerlink to apply for income support.

Table 15. Summary of care package services and use

Mental health Psychology Psychiatry Family therapy/counselling Mental health worker Allied health	Participants with approved	Participants using the service	Total sessions approved	Total sessions used
	Services	n (%)	n	n (%) [1]
CINE DO	n n			
Mental health				
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	2 (67)	12	7 (58)
Podiatry	3	3 (100)	7	7 (100)
Other allied health professional	1	1 (100)	10	10 (100)
Medical specialists				
Pain specialist	9	7 (78)	26	23 (88)
Rheumatology	3	3 (100)	4	3 (75)
Neurology	2	2 (100)	3	3 (100)

Service type	Participants with approved services	Participants using the service n (%)	Total sessions approved n	Total sessions used n (%) [1]
	n			
Gastroenterology	1	1 (100)	3	3 (100)
Vascular specialist	1	1 (100)	2	1 (50)
Orthopaedic surgeon	1	1 (100)	2	1 (50)
Dermatology	1	1 (100)	2	1 (50)
Metabolic specialist	1	1 (100)	1	1 (100)
Complementary therapies				
Massage	19	16 (84)	114	87 (76)
Exercise [2]	18	12 (67)	236	135 (57)
Yoga	13	10 (77)	154	106 (69)
Meditation, mindfulness and related training	8	5 (63)	28	8 (29)
Acupuncture	5	4 (80)	44	29 (66)
Other [3]	2	1 (50)	20	10 (50)
Support service	C			
Vocational service	2 4 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 (50)	6	3 (50)
Housing related service	24/	(100)	15	13.5 (90)
Other	CHINA	0 (0)	1	0 (0)

**Notes**: n = count. Some participants received funding for more than one service. [1] Percentage of sessions paid by PHN compared to the number of sessions approved for funding. [2] Includes Tai Chi, Qi Gong, pilates personal training, group fitness, and water or swimming activities. [3] Includes defence and music classes.

## 6.2.3. Use of health and other services (all participants)

Information from the RUQ was used to examine patterns of health and other service use across trial arms overall, and within the minimal/mild and severe prognostic groups (Table 16). Overall, participants in the intervention arm were more likely to report the use of services provided by mental health nurses (9.4% vs 5.4%) and psychologists (44.1% vs 35.5%) than those in the comparison arm. Participants in the intervention arm were also more likely to use <u>any</u> 'formal' health services (including health professional visits, medications, acute care and residential care) than those in the comparison arm (72.7% vs 67.1%). This difference was no longer present when the use of digital help and self-help were included (77.0% vs 73.9%).

Differences in service use varied across the two prognostic groups. In the minimal/mild prognostic group, participants in the intervention arm were more likely to use <u>any</u> 'formal' health services than those in the comparison arm (55.0% vs 45.4%). This difference was no longer present when digital help and self-help were included (62.3% vs 56.3%). There was a trend toward more participants in the intervention group reporting the use of psychologists (25.4% vs 18.9) and time off unpaid work (29.1% vs 22.1%), although these differences were not statistically significant. In the severe prognostic group, participants in the intervention arm were significantly more likely to report at least one visit to a GP (83.4% vs 75.8%), mental health nurse (18.1% vs 9.8%), or psychologist (62% vs 51.2%) in the 12 months since enrolling in the Link-me trial. Note that participants were asked to

indicate their use of services specifically for their mental health, so these figures may underestimate participants' total use of these services.

Table 17 reports the mean number of services reported by participants who endorsed each category of service use. The only statistically significant difference was between participants in the intervention and comparison arms overall, relating to the mean number of days off from unpaid work in the 12 months since trial enrolment (50 days in comparison arm vs. 39 days in the intervention arm). There were no significant differences between participants in the trial arms within the minimal/mild or severe prognostic groups.

Of note, we observed that more than one-quarter of the minimal/mild prognostic group reported use of psychotropic medications over the 12-month follow-up period (28% in the intervention arm and 26% in the comparison arm). One quarter (25%) of the intervention group and one-fifth (19%) of the comparison arm reported consulting a psychologist (Table 16). Of those who consulted a psychologist the average number of sessions was 5 (Table 17).

**Table 16.** Participants self-reporting any use of specific services and time off work in the 12 months since trial enrolment, by trial arm and prognostic group (N = 1,071)

Service type	All participants (comparison) n=549	All participants (intervention) n=522		Minimal/mild prognostic group (comparison) n=268	Minimal/mild prognostic group (intervention) n=256		Severe prognostic group (comparison) n=281	Severe prognostic group (intervention) n=266	
	n (%)	n (%)	p value	n (%)	n(%)	p value	n (%)	n (%)	p value
GP	317 (57.1)	334 (62.9)	.05	101 (37.4)	108 (41.5)	.33	216 (75.8)	226 (83.4)	.03
Nurse	37 (6.7)	47 (8.9)	.18	5 (1.9)	5 8 (1.2)	.51	32 (11.2)	44 (16.2)	.09
Mental health nurse	30 (5.4)	50 (9.4)	.01	2 (0.7)	1(0.4)	.59	28 (9.8)	49 (18.1)	<.01
Psychiatrist	103 (18.6)	121 (22.8)	.09	15 (5.6)	24 (9.2)	.11	88 (30.1)	97 (35.8)	.22
Psychologist	197 (35.5)	234 (44.1)	<.01	51 (18.9)	66 (25.4)	.07	146 (51.2)	168 (62.0)	.01
Allied health	74 (13.3)	84 (15.8)	.25	(7.0)	27 (10.4)	.17	55 (19.3)	57 (21.0)	.61
Other health professional	36 (6.5)	40 (7.6)	.49	9(3,3)	10 (3.8)	.75	27 (9.5)	30 (11.2)	.52
Medication	258 (46.6)	244 (46.2)	.91	69 (25.7)	73 (28.1)	.53	189 (66.3)	171 (63.8)	.54
Ambulance	15 (2.7)	23 (4.4)	.14	0 (0.0)	3 (1.2)	.08	15 (5.3)	20 (7.5)	.29
Emergency department	30 (5.4)	32 (6.1)	S (64)	1 (0.4)	4 (1.6)	.16	29 (10.2)	28 (10.4)	.93
Hospital	17 (3.1)	18 (3.4)		0 (0.0)	2 (0.8)	.15	17 (6.0)	16 (6.0)	1.0
Residential care	7 (1.3)	2 (0.4)	8.11	0 (0.0)	0 (0.0)	n/a	7 (2.5)	2 (0.8)	.11
Any service use [1]	373 (67.1)	386 (72.7)	.04	123 (45.4)	143 (55.0)	.03	250 (87.4)	243 (89.7)	.40
Online therapy	50 (9.0)	48 (9.1)	.96	17 (6.3)	17 (6.5)	.91	33 (11.6)	31 (11.6)	1.0
Smartphone apps	122 (22.1)	110 (21.0)	.66	44 (16.4)	43 (16.8)	.91	78 (27.5)	67 (25.0)	.51
Self-help (Books/DVDs)	149 (27.0)	150 (28.6)	.55	58 (21.6)	57 (22.3)	.86	91 (32.0)	93 (34.7)	.51
Any service use [2]	411 (73.9)	409 (77.0)	.24	152(56.3)	162 (62.3)	.16	259 (90.6)	247 (91.1)	.81
Time off paid work	236 (42.8)	215 (41.0)	.55	99 (37.1)	78 (30.2)	.10	137 (48.2)	137 (51.5)	.44
Time off unpaid work	215 (39.0)	215 (41.0)	.50	59 (22.1)	75 (29.1)	.07	156 (54.9)	140 (52.6)	.59

**Notes**: Participants were asked about their use of services specifically for their mental health. All p values calculated using Chi-square test. [1] Includes health professional visits, medications, acute care (ambulance, emergency department, hospital), residential care. [2] Includes health professional visits, medications, acute care, digital/self-help materials (online, apps, self-help).

Table 17. Mean number of self-reported visits to services and days off work in the 12 months since trial enrolment, by trial arm and prognostic group

All participants (comparison)	All participants (intervention)		Minimal/mild prognostic group (comparison)	Minimal/mild prognostic group (intervention)		Severe prognostic group (comparison)	Severe prognostic 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
6.36 (1,80)	5.56 (1,32)	.08	3.33 (1,34)	3.10 (1,27)	.56	7.79 (1,80)	6.74 (1,32)	.11
3.42 (1,24)	3.66 (1,20)	.74	1.60 (1,3)	1.67(1,2)	.94	3.71 (1,24)	3.80 (1,20)	.92
5.32 (1,37)	5.43 (1,49)	.93	1.50 (1,2)	1,00 (1,1)	.72	5.62 (1,37)	5.52 (1,49)	.94
5.04 (1,42)	4.62 (1,44)	.47	2.67 (1,8)	3.71(1,18)	.23	5.44 (1,42)	4.85 (1,44)	.39
7.31 (1,130)	7.98 (1,70)	.30	4.49 (1,23)	5,30 (1,18)	.24	8.31 (1,130)	9.04 (1,70)	.39
9.70 (1,90)	7.24 (1, 90)	.09	4.47 (1,21)	4.74 (1,30)	.83	11.51 (1,90)	8.54 (1,90)	.15
6.61 (1,54)	6.44 (1,52)	.92	8.78(1.54)	7.80 (1,52)	.84	5.89 (1,52)	5.97 (1,26)	.96
1.60 (1,6)	1.40 (1,3)	.63	no observations	1 (1,1)	n/a	1.60 (1,6)	1.44 (1,3)	.72
2.10 (1,10)	1.75 (1,8)	.38(2)	1(1,1)	1.25 (1,2)	.84	2.14 (1,10)	1.82 (1,8)	.46
41.47 (1,260)	41.66 (1,260)	(\\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\ \\	23.58 (1,260)	21.19 (1,260)	.58	54.41 (2,260)	53.48 (1,260)	.91
50.14 (1, 365)	38.77 (1, 260)	.02	21.34 (1,180)	20.19 (1,110)	.77	61.03 (1,365)	48.59 (2,260)	.08
18.12 (1,120)	45.64 (1,185)	.77	no observations	5.5 (1,10)	n/a	18.12 (1,120)	23.07 (1,185)	.64
24.57 (1,120)	no observations	n/a	no observations	no observations	n/a	24.57 (1,120)	no observations	n/a
	(comparison)  Mean (min, max) 6.36 (1,80) 3.42 (1,24) 5.32 (1,37)  5.04 (1,42) 7.31 (1,130) 9.70 (1,90) 6.61 (1,54)  1.60 (1,6) 2.10 (1,10)  41.47 (1,260)  50.14 (1, 365)  18.12 (1,120)	Mean (min, max)         Mean (min, max)           5.56 (1,32)         3.42 (1,24)           5.32 (1,37)         5.43 (1,49)           5.04 (1,42)         4.62 (1,44)           7.31 (1,130)         7.98 (1,70)           9.70 (1,90)         7.24 (1, 90)           6.61 (1,54)         6.44 (1,52)           1.60 (1,6)         1.40 (1,3)           2.10 (1,10)         1.75 (1,8)           41.47 (1,260)         41.66 (1,260)           50.14 (1,365)         38.77 (1,260)           18.12 (1,120)         45.64 (1,185)	Mean (min, max)         Mean (min, max)         p value           6.36 (1,80)         5.56 (1,32)         .08           3.42 (1,24)         3.66 (1,20)         .74           5.32 (1,37)         5.43 (1,49)         .93           5.04 (1,42)         4.62 (1,44)         .47           7.31 (1,130)         7.98 (1,70)         .30           9.70 (1,90)         7.24 (1,90)         .09           6.61 (1,54)         6.44 (1,52)         .92           1.60 (1,6)         1.40 (1,3)         .63           2.10 (1,10)         1.75 (1,8)         .38           41.47 (1,260)         41.66 (1,260)         .94           50.14 (1, 365)         38.77 (1,260)         .02           18.12 (1,120)         45.64 (1,185)         .77	Mean (min, max)         Mean (min, max)         p (min, max)         Mean (min, max)         Mean (min, max)         p (min, max)         Mean (min, max)         max)         Mean (min, max)	(comparison)         (intervention)         prognostic group (comparison)         prognostic group (intervention)           Mean (min, max)           6.36 (1,80)         5.56 (1,32)         .08         3.33 (1,34)         3.10 (1,27)           3.42 (1,24)         3.66 (1,20)         .74         1.60 (1,3)         1.67 (1,2)           5.32 (1,37)         5.43 (1,49)         .93         1.50 (1,2)         1.00 (1,1)           5.04 (1,42)         4.62 (1,44)         .47         2.67 (1,8)         3.71 (1,18)           7.31 (1,130)         7.98 (1,70)         .30         4.49 (1,23)         5.30 (1,18)           9.70 (1,90)         7.24 (1,90)         .09         4.47 (1,21)         4.74 (1,30)           6.61 (1,54)         6.44 (1,52)         .92         8.78 (1,54)         7.80 (1,52)           1.60 (1,6)         1.40 (1,3)         .63         no observations         1 (1,1)           2.10 (1,10)         1.75 (1,8)         .38         1 (1,1)         1.25 (1,2)           41.47 (1,260)         41.66 (1,260)         .97         23.58 (1,260)         21.19 (1,260)           50.14 (1, 365)         38.77 (1,260)         .02         21.34 (1,180)	(comparison)         (intervention)         prognostic group (comparison)         prognostic group (intervention)           Mean (min, max)         prognostic group (intervention)           6.36 (1,80)         5.56 (1,32)         .08         3.33 (1,34)         3.10 (1,27)         .56           3.42 (1,24)         3.66 (1,20)         .74         1.60 (1,3)         1.67 (1,2)         .94           5.32 (1,37)         5.43 (1,49)         .93         1.50 (1,2)         1.00 (1,1)         .72           5.04 (1,42)         4.62 (1,44)         .47         2.67 (1,8)         3.71 (1,48)         .23           7.31 (1,130)         7.98 (1,70)         .30         4.49 (1,23)         5.38 (1,18)         .24           9.70 (1,90)         7.24 (1,90)         .09         4.47 (1,21)         4.74 (1,30)         .83           6.61 (1,54)         6.44 (1,52)         .92         8.78 (1,54)         7.80 (1,52)         .84           1.60 (1,6)         1.40 (1,3)         .63         no observations         1 (1,1)         n/a           2.10 (1,10)         1.75 (1,8)         .38         23.58 (1,260)         21.19 (1,260)         .58	(comparison)         (intervention)         prognostic group (comparison)         prognostic group (intervention)         prognostic group (comparison)           Mean (min, max)         Mean (min, max)         p value (min, max)         Mean (min, max)         Mean (min, max)         p value (min, max)           6.36 (1,80)         5.56 (1,32)         .08         3.33 (1,34)         3.10 (1,27)         .56         7.79 (1,80)           3.42 (1,24)         3.66 (1,20)         .74         1.60 (1,3)         1.67 (1,2)         .94         3.71 (1,24)           5.32 (1,37)         5.43 (1,49)         .93         1.50 (1,2)         .00 (1,1)         .72         5.62 (1,37)           5.04 (1,42)         4.62 (1,44)         .47         2.67 (1,8)         3.71 (1,48)         .23         5.44 (1,42)           7.31 (1,130)         7.98 (1,70)         .30         4.49 (1,23)         5.30 (1,18)         .24         8.31 (1,130)           9.70 (1,90)         7.24 (1,90)         .09         4.47 (1,21)         4.74 (1,30)         .83         11.51 (1,90)           6.61 (1,54)         6.44 (1,52)         .92         8.78 (1,54)         7.80 (1,52)         .84         5.89 (1,52)           1.60 (1,6)         1.40 (1,3)         .63         no observations         1 (1,1)         n/	(comparison)         (intervention)         prognostic group (comparison)         prognostic group (intervention)         prognostic group (comparison)         prognostic group (intervention)         prognostic group (comparison)         group (intervention)           Mean (min, max)         3.71 (1,30)         3.71 (1,30)         3.72 (1,40)         3.80 (1,20)         3.72 (1,40)         3.72 (1,40)         3.72 (

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

## 6.3. Calculation of costs

### 6.3.1. 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 18). Screening phase costs included those associated with IT/communication systems required to triage and follow participants, and the purchase of tablet devices for participants 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. 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 costs of care navigation included the training sessions for care navigators and care navigator time spent undertaking clinical duties (i.e., working with participants, flaising 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 prognostic group and randomly allocated to the intervention arm (n = 420).

It is worth noting that in the trial, the Link-me intervention, 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 participants would be increased, learning effects finalised and therefore the average cost per person (as well as average cost per contact) would likely be reduced.

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<sup>&</sup>lt;sup>12</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 18. Intervention costing

Item	Unit cost	Unit	Quantity	Total cost	Reference/Assumptions
Screening phase (all participants)					
Survey/DST development				\$61,423	
Survey/DST implementation and maintenance				\$153,000	
iPads to undertake survey/DST	\$460.75	Each	39	\$17,969	Assumes outright purchase; no maintenance and working condition at end of 1 year with 5% discountrate on resale price
Receptionist time to approach participants in waiting room [1]	\$23.39	Hours	410	\$9,595	Assumes 1 minute of receptionist time per encounter; includes 25% on-costs
Subtotal without sunk costs			CLICA	\$180,564	
Subtotal with sunk costs			BALLO	\$241,987	
Average health sector cost/person invited to trial without sunk costs		G BEE	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)	4	Per person  Day	24,616	\$9.83	To be applied in a sensitivity analysis
Care navigation (severe symptom group only)	CUMP	30,0kx			
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	
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 prognostic group and intervention arm only

Item	Unit cost	Unit	Quantity	Total cost	Reference/Assumptions
Care packages	Specific to				Will be applied to individual participants
	individual				

Notes: DST = Decision support tool. [1] Hourly wage estimated using ABS Employee Earnings and Hours, Australia, May 2018; ANZSCO code 5421 Receptionist.

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#### 6.3.2. Total health sector costs

Health sector costs include those costs of health services, paid by participants 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. The results were reported separately over the six-month and 12-month follow-up. The 12-month costs are inclusive of the six-month costs.

#### 6.3.3. 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 16. Only participants who reported that they were actively working were included in the analysis of paid work productivity.

## 6.4. Within trial 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 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 [37], with all analyses The K10 psychological distress score, the primary outcome measure in this trial, was used to assess completed using Stata 15.0 [63].

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 (ICERs). 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 [64]. The utility values at baseline, 6 and 12 month follow-up were used to calculate total QALYs for each participant using the area under the curve method [65].

An analysis technique that accounts for the skewed nature of cost and QALY data (generalised linear models) was used to estimate the differences between the intervention and comparison arms at sixand 12-month follow-up with adjustment for prognostic 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 generalised linear models were used to estimate the difference in total health sector and societal costs as well as QALYs between the intervention and comparison arms.

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.

## 6.5. Within trial findings

#### 6.5.1. Health sector costs

Cost data was highly skewed with many participants reporting very low or no health sector costs. For all participants, the intervention arm was found to have significantly higher mean health sector costs than the comparison arm at both six- and 12-month follow-up. The mean difference at six-month follow-up was \$24 (95% CI \$9.3 to \$44.3) and increased to \$50 (95% CI \$10.0 to \$12.0; Table 19) at 12-month follow-up. The mean difference varied between the primary and sensitivity analyses but remained statistically significant at six and 12-month follow-up.

The intervention arm of the minimal/mild prognostic group had higher mean costs at both six and 12-month follow-up, but these differences were largely non-significant. Only the primary analysis using imputed data found that the intervention group had a statistically significant higher average mean cost of \$59 (95% CI 6.1 to 133.8) at 12-month follow-up.

For the severe prognostic group, the intervention arm had statistically significantly higher health sector costs at six-month follow-up (mean difference \$340). While the mean difference between groups was larger at 12-month follow-up, increasing to \$645 (95% CI -151.9 to 1817.8) it was statistically non-significant in the primary analysis. In the sensitivity analyses the mean differences were smaller but significantly different between groups. The sensitivity analysis using only complete cases found a mean difference of \$366 (95% CI 88.6 to 801.5). The sensitivity analysis using complete cases and adjusting for GP practice found a mean difference of \$492 (95% CI 142.6 to 1030.6).

# 6.5.2. Societal costs

There were no significant differences in mean societal costs between the intervention and comparison arms, overall or within prognostic groups at either six- or 12-month follow-up (Table 20). This pattern of results was observed in both the primary and sensitivity analyses.

### 6.5.3. 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 in either prognostic group, nor the sample overall.

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Table 19. Health sector costs, including intervention costs, according to trial arm, in total sample and stratified by prognostic group

	All participants	p value	Minimal/mild prognostic group	p value	Severe prognostic group	p value
Comparison, n	837		416		421	
Intervention, n	834		414		420	
			12			
Six-month follow-up			70r			
Mean cost (SD) [1]			714085			
Comparison	\$1,247 (4,473)		6204 M NATA		\$2,178 (6,057)	
Intervention	\$2,231 (6,716)		\$429 (1,150)		\$4,006 (8,984)	
			SEL OF LAV			
Mean difference, Coef. (95% CI)			HALL HI			
Primary analysis [2]	\$24 (9.3 to 44.3)	<0.0001	\$28 (-4.9 to 78.7)	0.106	\$340 (125.7 to 643.7)	<0.0001
Sensitivity analysis [3]	\$20 (6.1 to 40.0)	0.002	\$20 (-3.5 to 60.0)	0.108	\$227 (45.1 to 514.4)	.009
Sensitivity analysis [4]	\$24 (7.3 to 46.3)	0.002	\$17 (-2.2 to 49.6)	0.092	\$320 (93.8 to 668.8)	0.002
		12/1/20	PL			
12-month follow-up		14,000				
Mean cost (SD) [1]	-0					
Comparison	\$2,787 (9,879)	the de	\$640 (1,801)		\$4,908 (13,498)	
Intervention	\$3,871 (12,178)	♦,	\$991 (2,448)		\$6,710 (16,476)	
Mean difference, Coef. (95% CI)			\$28 (4.9 to 78.7) \$20 (-3.5 to 60.0) \$17 (-2.2 to 49.6) \$991 (2,448)			
Primary analysis [2]	\$50 (10.0 to 102.0)	0.011	\$59 (6.1 to 133.8)	0.025	\$645 (-151.9 to 1817.8)	0.128
Primary analysis [2]			· · · · · · · · · · · · · · · · · · ·			
Sensitivity analysis [3]	\$31 (8.7 to 63.8)	0.003	\$31 (-15.3 to 114.0)	0.108	\$366 (85.6 to 801.5)	.005
Sensitivity analysis [4]	\$31 (8.4 to 62.3)	0.003	\$23 (-9.9 to 82.4)	0.214	\$492 (142.6 to 1030.6)	.002

Notes: SD = Standard deviation; Coef. = Estimated coefficient; CI = Confidence interval. [1] Estimated using multiple imputation. [2] Mean for intervention arm minus mean for control arm estimated using generalized linear models (gamma family, log link) adjusted for baseline K10 (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [3] Sensitivity analysis using complete cases only using generalized linear models (gamma family, log link) adjusted for baseline K10 (all models) and prognostic group (model with all participants only). [4] Same as [3] but adjusted for general practice.

Table 20. Societal costs, including intervention and lost productivity costs, according to trial arm, in total sample and stratified by prognostic group

	All participants	p value	Minimal/mild prognostic group	p value	Severe prognostic group	p value
Comparison, n	837		416		421	
Intervention, n	834		414		420	
Circ magnetic fallows we						
Six-month follow-up						
Mean cost (SD) [1]			70.5			
Comparison	\$5,575 (12,302)		\$2,647 (7,378)		\$8,469 (14,906)	
Intervention	\$6,529 (13,315)		\$2,619 (7,111)		\$10,383 (16,354)	
			L.R. PO KIY			
Mean difference, Coef. (95% CI)			OF TONER			
Primary analysis [2]	\$97 (-64.3 to 298.1)	0.261	\$55 (-144,6 to 351.0)	0.642	\$678 (-72.2 to 1624.2)	0.080
Sensitivity analysis [3]	\$109 (-64.1 to 333.2)	0.241	\$78.4-98.8 to 368.7)	0.456	\$443 (-158.9 to 1280.0)	0.164
Sensitivity analysis [4]	\$144 (-72.8 to 423.6)	0.213	\$77 (-176.4 to 482.4)	0.615	\$546 (-132.9 to 1431.4)	0.125
		14/1/	\$55 (144,6 to 351.0) \$78 (-98.8 to 368.7) \$77 (-176.4 to 482.4) \$4,749 (11,190) \$5,136 (12,390)			
12-month follow-up		Wall.	OR			
Mean cost (SD) [1]	ال	1,00,0				
Comparison	\$11,022 (21,538)		\$4,749 (11,190)		\$17,221 (26,903)	
Intervention	\$11,553 (23,787)	7/	\$5,136 (12,390)		\$17,878 (28,856)	
	(HI/HE)	\$				
Mean difference, Coef. (95% CI)						
Primary analysis [2]	\$115 (-203.1 to 504.7)	0.505	\$179 (-162.1 to 658.9)	0.344	\$344(-1835.1 to 3057.2)	0.778
Sensitivity analysis [3]	-\$9 (-223.2 to 271.5)	0.946	-\$93 (-233.7 to 124.7)	0.345	-\$111 (-2480.6 to 2480.6)	0.937
Sensitivity analysis [4]	\$1 (-243.3 to 319.7)	0.993	-\$91 (-224.3 to 117.9)	0.336	-\$24 (-2619.6 to 3468.6)	0.998

Notes: SD = Standard deviation; Coef. = Estimated coefficient; CI = Confidence interval. [1] Estimated using multiple imputation. [2] Mean for intervention arm minus mean for control arm estimated using generalized linear models (gamma family, log link) adjusted for baseline K10 (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [3] Sensitivity analysis using complete cases only using generalized linear models (gamma family, log link) adjusted for baseline K10 (all models) and prognostic group (model with all participants only). [4] Same as [3] but adjusted for general practice.

#### 6.5.4. Incremental cost-effectiveness ratios

The differences in costs, outcome measures and ICERs using the 12-month follow up data are reported in Table 21. The incremental cost per point change in the K10 score across all participants from the health sector perspective was \$2,371 (95% CI 1963 to Dominated). Figure 10 displays the 1000 bootstrap iterations used to estimate the confidence intervals for the ratio of cost per point change in K10 score across all participants from the health sector perspective. Note that the direction of the change in K10 score has been reversed so that improvement is reflected by positive change scores. The majority of iterations (92.5%) fall within the northeast quadrant of the cost-effectiveness plane, demonstrating that higher health sector costs for Link-me compared to the comparison group were associated with improvement in K10 scores. Only 6.7% of iterations were found in the northwest quadrant where higher health sector costs were associated with worse K10 scores.

From the societal perspective the cost per point decrease in the K10 was estimated at \$1,217 (95% CI Dominant to Dominated). Viewing the 1000 bootstrap iterations used to estimate the confidence intervals for the ratio of cost per point change in K10 score across all participants from the societal perspective in Figure 11, the majority of points (66.8%) reside in the northeast quadrant indicating higher societal costs for Link-me compared to the comparison group were associated with higher K10 scores. Nearly one quarter of the iterations fall within the southeast quadrant, indicating that Link-me was dominant (lower societal costs and improved K10 scores) compared to the comparison group.

In the minimal/mild prognostic group the cost per point change in K10 ICER indicated that the intervention was dominated by the comparison group from both the health sector and societal perspectives. This means that the costs were higher and the mean difference in K10 score was higher (indicating worse symptoms) in the intervention arm compared to the comparison arm.

For the severe prognostic group, the incremental cost per point decrease in K10 score was \$1326 (95% CI 28 to 8361) from the health sector perspective and \$479 (Dominant to 1593) 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.

Table 21. Incremental cost-effectiveness ratios at 12-month follow-up (based on unadjusted cost differences)

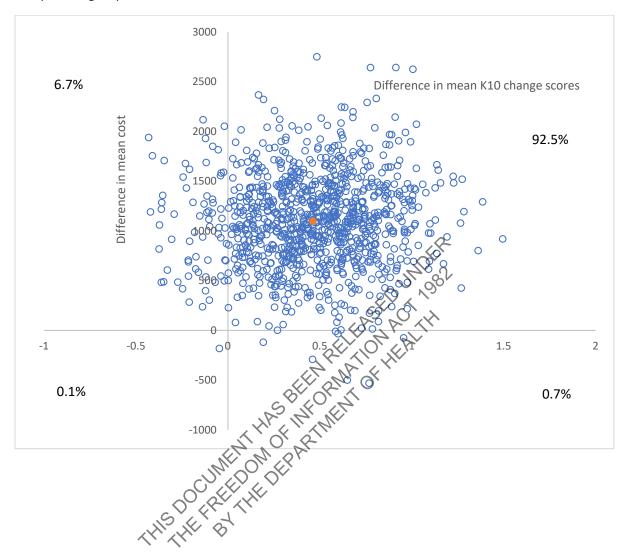
	Difference in mean costs (95% CI)	Difference in mean effects (95% CI)	ICER (95% CI)
All participants	(3370 Ci)	(55% Ci)	
Health sector cost/change in K10 score	1096 (198 to 2036)	-0.46 (-1.04 to 0.21)	2,371 (1963 to Dominated)
Societal cost/change in K10 score	526 (-1138 to 2159)	-0.43 (-1.11 to 0.20)	1,217 (Dominant to Dominated)
Minimal/mild prognostic group		WE.	
Health sector cost/change in K10 score	346 (142 to 555)	0.45 (-0.20 to 2011)	Dominated (712 to Dominated)
Societal cost/change in K10 score	396 (-675 to 1553)	0.49 (-0.15 to 1.16)	Dominated (579 to Dominated)
Severe prognostic group		UPS PO TH	
Health sector cost/change in K10 score	1781 (63 to 3794)	-134 (-2.23 to -0.45)	1326 (28 to 8361)
Societal cost/change in K10 score	642 (-2328 to 3548)	1.34 (2.23 to -0.42)	479 (Dominant to 1593)

Societal cost/change in K10 score 642 (-2328 to 3548) 1.34 (2.23 to -0.42) 479 (Dominant to 1593)

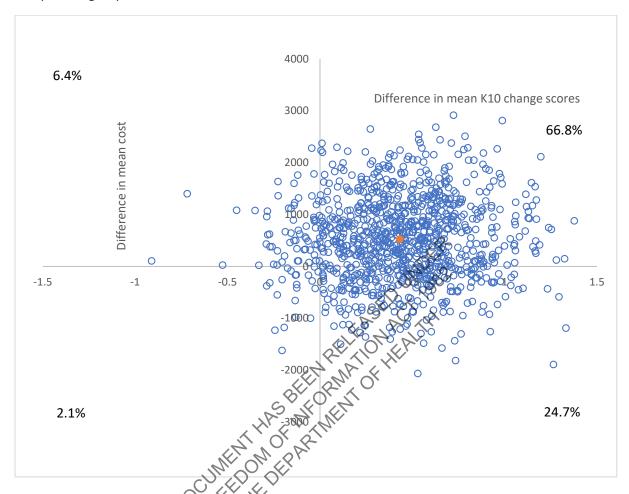
Notes: CI = Confidence interval; ICER = Incremental cost-effectiveness ratio, based on bootstrap simulation Dominated = Greater costs and less benefit than the comparator; Dominant = Less costs and greater benefits than the comparator.

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**Figure 10.** Cost effectiveness plane of 1000 incremental cost effectiveness ratios of the difference in mean health sector costs and the difference in mean K10 scores between the intervention and comparison groups



**Figure 11.** Cost effectiveness plane of 1000 incremental cost effectiveness ratios of the difference in mean societal costs and the difference in mean K10 scores between the intervention and comparison groups



# 6.6. National implementation analysis

The likely cost of scaling up Link-me to be delivered across Australia is dependent on a number of data sources and assumptions. Here, we describe the likely pathway for the Australian population to participate in the screening and care navigation provided through Link-me. We also estimate costs of implementation under a set of base case assumptions and a range of alternative assumptions in which key parameters are varied (sensitivity analyses).

Under base case assumptions, we estimated the number of people likely to receive Link-me when implemented within the Australian population using assumptions based on the published literature and estimates from the trial. The intervention pathway starts with Australian adults aged over 18 years based on the Australian Bureau of Statistics population data from 2018 [66], as shown in Figure 12. Based on information from a recent report of the Royal Australian College of General Practitioners, 87.8% of Australians visit their GP each year [67]. From those adults attending GPs, 37.1% of people attending GP practices in the Link-me trial refused screening, leaving 62.9% likely to complete the DST in a GP waiting room at least once during a year.

From there it was estimated that 11.9% of individuals screened in GP waiting rooms would fall into the severe category, making them eligible for care navigation [68]. Of those eligible for care navigation within the Link-me trial, 51% received at least one care navigation contact, and of those, just over half (54%) received care package funding through PHNs. Of those eligible for care navigation within the Link-me trial, 51% received at least one care navigation session, and of those, just over half (54%) received care package funding through PHNs.

The initial cost of screening was based on the DST being completed in GP waiting rooms using a similar method to that used within the trial. This would require one iPad being purchased (\$529) [69] by each of the estimated 6300 GP practices across Australia [67]. It was also estimated that one minute of receptionist time was needed to introduce the DST. Implementation and maintenance costs for the DST were estimated at \$153,000 annually based on information from the trial.

The cost of treatments once people have been stratified into prognostic group was based on findings from the Link-me trial. People who were stratified into the minimal/mild prognostic group were not assigned any additional treatment costs since there were no differences in health care resource use found in the trial. For those stratified into the severe prognostic group, it was assumed that 51% received five one-hour care navigation contacts. From the number of total estimated contacts, the number of full-time equivalent care navigators needed each year was calculated. The calculations assumed that care navigator time was spent exclusively working with clients. The cost of a one-day training session for care navigators was based on 20 care navigators per live session with a dedicated trainer (daily cost of \$1278). Care navigator wages were based on the hourly rate paid to care navigators in the trial (\$49.34). The cost of a care package was estimated at \$669 based on the packages provided within the trial.

Due to the uncertainty with assumptions and cost estimates used in the calculations, sensitivity analyses were conducted by varying individual inputs. The values varied included the percentage screened as severe, percentage attending care navigation, and the number of contacts provided.

It was also identified that the delivery of screening may be undertaken online using mobile phones, laptops or home computers. Similarly, the care navigator training may be implemented in an online format. The effect of these alternate scenarios on costs were also calculated.

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<sup>&</sup>lt;sup>13</sup> We based this estimate on data from modelling of data from the Target-D trial which used the precursor *diamond* algorithm for predicting future depression severity.

19,395,635 2018 Australian adults (aged 18-100 yrs)

2,366,268 Not attending general practices

17,029,367 (87.7%) Attending general practices

6,317,895 Decline to Complete Decision Support Tool

49,436,807 Minimal/mild or moderate prognostic group

1,274,665 (11.9%) Severe prognostic group

624,586 Refuse care navigation

304,919 No care package

344,160 (53%) Access care package funding

Figure 12. Estimated population figures for *Link-me* implementation

# 6.7. National implementation findings

The total annual cost of implementing Link-me nationally under the base case assumptions was estimated at \$414 million, or \$637 per year per person attending care navigation as shown in Table 22. Screening in the base case is estimated to cost \$10,124,315 which includes the purchase of equipment (one iPad per GP practice), receptionist time to introduce the survey (one minute per person), and annual maintenance costs for the DST

The cost of care navigation depends on the number of care navigators. The base case estimated that a total of 1782 care navigators would be required. This was based on the 51% of the people in the severe prognostic group receiving five hours of care navigation each. This assumed that care navigators spent all of their time on care navigation (i.e., no additional time was included for administrative tasks or professional development), either in direct patient contact or out-of-session tasks including research and communication with other services involved in the patients care.

Total care navigator training costs were estimated at \$113,839. Care navigator wages over a year totalled nearly \$174 million. The cost of care packages was the largest cost category estimated at over \$230 million.

Due to the uncertainty in the base case assumptions, sensitivity analysis varied key assumptions. Increasing the percentage of people who would attend care navigation contacts to 75%, increased total annual costs to just under \$605 million dollars or \$633 per year per person attending care navigation. Increasing the number of care navigation contacts attended to the full eight contacts available in the Link-me trial would lead to total costs of approximately \$519 million dollars and \$798 per year per person attending care navigation. Increasing the percentage of people in the severe prognostic group to 20% (the percentage of people with severe symptoms from the 2007 National Survey of Mental Health and Wellbeing [50]), resulted in a total cost of \$689 million. Because this increase was driven by greater volume of people eligible for care navigation rather than a change in the cost of care navigation itself, the cost per person per year remained relatively stable at \$631.

An alternative scenario where the DST was implemented on general practice attenders' own device would decrease the cost of screening by approximately \$10 million. The resulting estimated total implementation cost would be \$404 million or \$622 per year per person attending care navigation. Delivering the care navigator training online was estimated to decrease training costs by \$100,000 and therefore had little effect on the overall total cost or per person costs.

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**Table 22.** National implementation cost estimates

					Screening on	
	Base case	75% attending	8 care navigation	20% screened	person's own	Care navigator
	assumptions	care navigation	contacts	severe	device	training online
Component costs						
Screening	\$10,124,315	\$10,124,315	\$10,124,315	\$10,124,315	\$153,000	\$10,124,315
Care navigator training	\$113,839	\$167,410	\$182,142	\$191,326	\$113,839	\$12,776
Care navigator wages	\$173,739,092	\$255,498,665	\$277,982,548	\$291,998,475	\$173,739,092	\$173,739,092
Care package costs	\$230,242,768	\$338,968,520	\$230,242,768	\$386,962,636	\$230,242,768	\$230,242,768
Total	\$414,220,014	\$604,758,910	\$518,531,773	\$689,276,751	\$404,248,699	\$414,118,952
Cost per person attending care navigation	\$637	\$633	\$798	\$631	\$622	\$637

### 6.8. 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 from the trial. Overall, the results suggest that the average cost to the health sector of screening general practice attendees in GP waiting rooms was \$7.34 per person. Health sector costs were \$50 per person higher in the intervention arm than the comparison arm, with a 1-point improvement on the K10 coming at a cost of \$2,371 in addition to costs associated with usual care. The cost per point decrease in the K10 was slightly lower from a societal perspective, at \$1,217 overall. There was a 25 percent probability that Link-me was dominant (lower cost and improved K10 scores) over the comparison condition from the societal perspective.

The health sector cost of delivering care navigation to people with severe and complex mental illness was estimated at \$1144 per person, with an incremental cost per point improvement on the K10 of \$1326 from a health sector perspective and \$479 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 the service recipient. We are awaiting Medicare claims data to validate the self-reported health care costs (consent to access this data was provided by 36% of the trial participants). Due to the time required to extract the Medicare data it was not able to be included in this report.

The trial data suggest that triaging participants in the minimal/mild prognostic 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 prognostic 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.

An interesting, related finding was that those in the minimal/mild prognostic group who were offered low intensity services were significantly more likely to use formal health services and had a significantly higher average mean health sector cost at 12-month follow-up than their usual care counterparts, possibly (at least in part) due to their greater use of psychology services. Given that the trial did not restrict access for this group to more intensive forms of care, such as psychology services, one possible explanation is that exposure to the Link-me DST and associated processes prompted them to use services, but they used formal services in preference to low intensity services.

The trial data did not demonstrate significant differences between groups on the EQ-5D-5L and therefore there were no significant differences in QALYs. It may be that this very brief generic quality of life measure could not detect improvements in specific quality of life domains that were relevant to participants but not measured by the EQ-5D-5L (e.g., self-esteem). While a published transformation algorithm from the K10 to other utility values could have been used to estimate potential QALY improvements [70], the difference in K10 at 12-month follow-up was not statistically significantly different between groups so we did not undertake this analysis.

This chapter also provided estimates for the cost of implementing Link-me across Australian general practitioners. The total cost for the first year of implementing Link-me nationally was estimated at

\$414 million. This cost would increase to as high as \$604 million if a greater proportion of people were to utilise care navigation or participate in more care navigation contacts. The main factor increasing costs appeared to be the proportion of people stratified into the severe prognostic group by the DST. If this were to increase to 20%, the cost of implementing Link-me would potentially exceed \$689 million in the first year. However, the cost of national implementation was estimated to decrease to \$404 million if the DST was completed using participants' own devices. Evaluating the implementation costs based on the projected number of people accessing care navigation services provided an estimate of \$637 per person per year. This is considerably lower than the ongoing annual cost of \$13,434 per person calculated for people with severe and persistent mental illness participating in the Partners in Recovery initiative in Australia [71].

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## 7. Conclusions

A key feature of Link-me was its integrated approach to assessment and intervention, using digital and human modes to link individuals at both ends of the symptom severity spectrum with service options within and outside of the mental health system. The need to improve integration of primary, specialist, and ancillary services to support whole-of-person care is recognised internationally [19, 72-74].

## 7.1. Key findings

# 7.1.1. How was the clinical care coordination model for people with severe and complex mental illness implemented and what were the barriers and enablers?

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

We sought to address this question by implementing care navigation of model of clinical care coordination) 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 general practice attendees and GPs to develop and implement a structured care plan designed to meet self-identified priorities. A key feature of the Link-me approach was a focus on improving mental health through addressing both mental, physical and social needs. Our intention was that care navigators would not require specialist mental health training but that they could work across the mental-physical-social service sectors. We also expected the care navigator to become an integral part of the general practice who would feel comfortable in the practice and would see general practice attendees within the practice location. To support a generalist model of health care, we designed a position description which outlined the skill set that a care navigator 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 individual's self-identified priorities. We were explicit in the care navigator 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 individuals to address long term physical or social problems could have a major impact on mental health outcomes.

#### 7.1.1.2. 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 general practice attendees (with mixed views on exactly when and where the tool should be completed for example, in a private room, or during a consultation, or on an ad hoc basis in the waiting room). Our interview data showed 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. 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. There were some barriers identified, including variable buy-in from GPs (which may have impacted completion of the DST and participant engagement in Link-me), and processes to be smoothed out (e.g., ensuring timely opportunity for communication between the care navigator and GP re participant progress and risk issues).

# 7.1.2. 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?

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

We sought to develop and apply a systematic approach to identifying individuals who might benefit from care navigation, a model of clinical care coordination. This began by asking general practice attendees to complete the Link-me DST on a tablet-device. The Link-me DST is underpinned by a population health approach to primary care which identifies individuals likely to have mild, moderate, or severe symptoms of depression or anxiety in three months' time. Among those in the severe prognostic group, half were randomly assigned to receive care navigation and the other half to receive usual care. We surveyed both groups six and 12 months later to determine their mental health outcomes, in terms of psychological distress, depression, anxiety, days out of role, and quality of life. In addition, we sought 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.

#### **7.1.2.2.** What we found

In the Link-me trial, 420 participants in the severe prognostic group were allocated to receive care navigation, of whom 216 (51%) had at least one structured care planning contact with a care navigator over a median duration of 4 months. The trial showed that care navigation was effective in reducing psychological distress among people with an expected severe symptom trajectory over the next three months. At six-month follow-up, care navigation participants reported greater reductions in psychological distress at 6 months than those who received usual care, with a standardised mean difference of -0.09 (95% CI: -0.17 to -0.01). This corresponds to an effect size estimate of 0.26 which is considered clinically meaningfully different and is similar to the small-to-moderate effects typically observed in other collaborative care studies [6, 75]. At 12-month follow-up, the average psychological distress score for the intervention group was similar to that at six-month follow-up, however the magnitude of the difference between groups had attenuated. This indicates that care navigation resulted in more rapid reductions in psychological distress than usual care, and that the improvement was maintained beyond the duration of the intervention.

Importantly, these results were observed despite only half of those allocated to care navigation receiving one or more structured care navigation contacts. When we accounted for the intensity of care navigation received, we found that the greater the number of elements of care navigation received, the greater the effect on psychological distress compared to usual care: at six-months, this equated to a 4-point improvement for people who also had an action plan developed relevant to

their needs; a 5-point improvement for people who received a referral to other services; a 7-point improvement for those who were approved for care package funding; and an 8-point improvement for people who also accessed a care package-funded service. Although there is no assumption that all individuals in the severe prognostic 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.

Contrary to expectations, we found no significant effects of care navigation on the secondary outcomes of depression, anxiety, days out of role, and quality of life. This may have been, in part, due to the use of measures that were either too specific for a symptomatically heterogeneous group (e.g., measures of depressive or anxiety symptoms) or too generic (e.g., quality of life) to take into account domains of relevance to people with mental health problems.

Link-me participants who utilised care navigation mostly reported positive experience of care. They appreciated the increased self-awareness of mental health issues from completing the Link-me DST which was carried forward in their contacts with the care navigators. They also reported that having an action plan tailored to their needs increased their knowledge of supports and services and helped to developed greater insight and the opportunity for self-reflection. Participants 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. Some participants reported negative experiences caused by structural issues at a local level (e.g., long wait lists, staff turnover at PHNs, and transport difficulties).

Link-me fills an important gap in evidence regarding the effectiveness of stepped care across different segments of the severity spectrum. This evaluation shows that using a prognostic tool to allocate people with severe symptoms to an appropriate first step in a stepped care framework (in this case, care navigation) is efficient (as it allows them to receive appropriate care in a timely manner), effective (as it resulted in more rapid improvement in mental health outcomes than would be experienced with usual care), and acceptable (as participants reported multiple benefits from different elements of the care navigation process).

# 7.1.3. 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?

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

To understand the costs associated with delivering care navigation, we first examined the components of care packages approved and used by participants, as well as health and other resource use more broadly. We estimated 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.

#### 7.1.3.2. What we found

Over 12 months, the health sector cost of delivering care navigation to people with severe and complex mental illness was estimated at \$1144 per recipient. This cost of delivering Link-me within the trial is comparable to the average costs of collaborative care interventions for treatment of people with depression in primary care ranging from approximately \$AUD 135 to 1900 [76].

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 individuals 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 visiting a GP, mental health nurse, or psychologist in the 12 months since enrolling in Link-me.

The full economic evaluation, including additional health care resource costs found that, from the health sector perspective, the total cost of delivering care navigation for people in the severe prognostic group was estimated at an additional \$340 per person after six months (a statistically significant increase over usual care), rising to \$645 after 12 months (no longer statistically different from usual care). This incremental cost of Link-me compared to usual care is towards the lower end of the range of estimates from other economic analyses of collaborative care interventions for people with depression treated in primary care (range \$69 - \$5642) [76]. 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 \$1326 from the health sector perspective and \$479 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. This has been found in other trials of collaborative care models. Presently, we are unaware of other cost per point improvement data for the K10 from similar programs to enable comparison.

# 7.1.4. 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?

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

Using the Link-me DST completed by general practice attendees 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 prognostic group.

#### 7.1.4.2. What we found

The average health sector costs of Link-me (including the cost of the intervention) for people in the minimal/mild prognostic group were \$429 (SD 1150) per person after 6 months and \$991 (SD 2448) per person after 12 months. This amounted to a significantly higher average mean cost of \$59 (95% CI 6.1 to 133.8) after 12-months when compared to usual care. This may indicate greater overall service use for this group although we did not observe increased use of low intensity service types (e.g., online therapy, smartphone apps, or self-help). In the minimal/mild prognostic group, the intervention was associated with higher incremental costs and lower scores on the K10 from both health sector and societal perspectives. Thus, we did not find that triaging participants in the minimal/mild prognostic group to low intensity services led to a cost-saving that could offset the costs of intervention in the severe prognostic group. Nor did we find that providing treatment pathways for people with mild/minimal problems led to a level of demand for services that the health system could not accommodate.

As noted above, the group offered low intensity services were more likely to use formal health services and had a significantly higher average mean health sector cost at 12-month follow-up, possibly tied to higher use of psychology services. However, they were no more likely to use digital help or self-help. It is important to note that people in the minimal mild prognostic groups were not limited to taking up the low intensity options and had the same access to more intensive forms of care (e.g., face-to-face psychology services) as they would usually have. Our findings suggest that the Link-me intervention raised their awareness of their issue and they responded by accessing this more traditional form of care if it was available to them.

People in the minimal/mild prognostic group also had positive feedback about completing the Linkme 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 immediately but could be referred back to at a later date if needed.

In contrast to the positive effects on outcomes of Link-me for people in the severe prognostic group, the intervention did not appear to offer an improvement over usual care for the minimal/mild prognostic group.

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. One is that it is difficult to ensure that people with lower levels of need utilise appropriate services, and this may contribute to a greater focus within PHNs on people at the more severe end of the spectrum who may be easier to identify and present more frequently. Continually updating treatment options for this group as newly commissioned services are established and monitoring their uptake and may provide insight into which services are more acceptable or relevant to an individual's needs.

# 7.1.5. 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?

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

To address this question, we considered evidence from the process evaluation which examined the implementation of Link-me, barriers and enablers of implementation, and the experiences reported by those who participated in Link-me.

#### 7.1.5.2. What we found

The process evaluation indicated that the Link-me DST can be routinely implemented and that care navigation is an acceptable and feasible model of clinical care coordination. Some impediments to smooth implementation were identified, but these could be readily addressed. Using the normalisation process theory framework, we examined feasibility issues in terms of four guiding concepts, summarised below:

Coherence (how well was the Link-me approach understood by all stakeholders involved?): Overall, there was a good level of agreement about the role of the DST and the role of care navigator in the Link-me trial, yet this was not universal across or within practices. The tool worked well in identifying high and low need participants and could be successfully implemented into the work-flow of busy general practices. Options for the DST to be completed securely prior to the GP appointment (e.g., via mobile phone app) may be preferable for some people and may reduce demands on practice staff. There is a need to modify and validate the DST for specific populations including culturally and linguistically diverse people, and Aboriginal and Torres Strait Islander people.

Cognitive participation (how well did people engage with the Link-me approach?): There were many examples of active buy-in to this new way of working and positive feedback about both the DST and the care navigation approach. There were also times when this did not occur (e.g., in practices with large numbers of part-time staff). Targeted strategies are needed to generate awareness about the Link-me and clarify the purpose and role and potential benefits of the DST and care navigation.

Collective action (how well did the Link-me approach fit into context, relationships, and workflows?): The care navigator role was perceived as having a good skillset fit to the general practice setting and as addressing a known gap in GPs' capacity. Some workflow issues were identified (e.g., the increased workload of GPs in preparing written referrals to services identified by care navigators, and difficulties in timely sharing of information about recipients' progress and risk management issues). Future implementation could include a pre-implementation assessment of workflow to plan for the necessary communications to take place.

Reflexive monitoring (how was the DST and Link-me appraised?): No practices involved in the Link-me trial reported evaluating the outcomes of the DST or care navigation using formal assessments or audits of their own records. That may be because they implemented Link-me in the context of an evaluation. In any future roll-out, a formal system to monitor in the uptake of the DST and progress of participants in care navigation would be useful.

# 7.1.6. What are the financial implications of the trial if a similar approach was implemented nationally?

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

We sought to identify the service delivery and economic implications of a national roll-out of the clinical care coordination model for future national policy directions in primary mental health care. We reviewed evidence from the Link-me trial overall, as this represents the outcomes and costs for Link-me as a system of care taking into account each end of the spectrum of severity of mental health needs and the spectrum of treatment intensity. We then estimated the likely cost of scaling up Link-me to be delivered across Australia, based on information from the trial and other published data.

#### 7.1.6.2. What we found

Together, participants in the minimal/mild and severe prognostic groups who were allocated to Linkme experienced a more rapid reduction in psychological distress, with a standardised mean difference (effect size) at six-month follow-up of -0.09 (95% CI -0.17 to -0.01). At 12-month follow-up the improvements in the intervention group were maintained but the difference between groups was no longer statistically significant. A trial in the Netherlands also found that those who received stepped collaborative care improved more quickly than did the usual care group, with significant differences at 4 months but not at 8 or 12 months [77].

With respect to costs, the trial results including all participants showed that health sector costs were \$50 per person higher in the intervention arm than the comparison arm, with a 1-point improvement on the K10 coming at a cost of \$2,371 in addition to costs associated with usual care. The cost per point decrease in the K10 was slightly lower from a societal perspective, at \$1,217 overall. That is, improvements in outcome were observed in the context of higher costs. As noted earlier (section 7.1.4.2), the likelihood of using formal health services and the average health sector cost at 12 months was higher among those allocated to Link-me in the minimal/mild prognostic group than those allocated to usual care, possibly reflecting their greater use of psychology services. Thus, we did not find that triaging the minimal/mild group to low intensity options was associated with lower costs that could be considered an offset to the increased costs of care in the severe prognostic group. The possibility that completing the DST and identifying priorities for action, prompted people in this group to use government-funded psychological care (where that was available to them) in preference to the low intensity options, could be investigated in future.

The total annual cost of implementing Link-me nationally was estimated at \$414 million. This mostly comprised 'core' care navigation costs, specifically the cost of wages for the estimated number of care navigators required (\$174 million in wages for 1,782 care navigators) and care package costs of \$230 million. The remainder comprised \$10 million for screening, including the purchase of equipment, receptionist time to introduce the survey, and annual maintenance costs for the DST and \$114,000 for care navigator training.

Available evidence suggests that Link-me offers clinical benefits at an affordable cost. For example, the total cost of providing care navigation (between \$622 and \$798 per person per year) compares favourably with the costs of the Partners in Recovery model which were estimated to be \$15,755 per person in the initial year, and \$13,434 thereafter [75]. Notwithstanding likely differences in the

target population between the two programs, the Link-me approach likely limits costs by using an assessment model implemented in general practice as a gateway to the more expensive care navigation model.

We investigated the impact of providing screening and care navigation training via online modalities; each resulted in negligible cost reductions. We do not have any evidence of how acceptable and effective online provision of these Link-me functions would be, but in light of increased availability of telehealth services introduced in response to the ongoing COVID-19 pandemic, it may be important to consider the pros and cons of these options and subject them to rigorous evaluation. Shifting to online care provision (e.g., care navigation sessions) is a further possibility, and would likely have effects that have not been taken into account and could have implications for the way services are organised and delivered. For example, online services would not necessarily need to be organised on a regional basis and this could affect the role and resourcing requirements for both care navigators and PHNs. We also explored the impact of other scenarios (increasing the engagement with care navigation, number of care navigation contacts attended, and the number of people meeting criteria for care navigation); each of these substantially increased costs. If Link me were to be rolled out nationally, a staged implementation would provide an opportunity to refine the precision of these parameters.

# 7.2. Strengths and limitations of the evaluation

Between August 2017 and September 2018, three regional trial coordinators successfully recruited 23 general practices, and over 15,000 adults in these practices completed a brief 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 controlled 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- and 12-month outcomes of 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. Dissemination efforts to date have sought to engage a broad range of stakeholders with an interest in the results of the Link me evaluation (see Appendix 17).

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. It required additional effort from all involved, including regional trial coordinators, care navigators, GPs, and participants, to collect the information required to provide high level evidence and adhere to the national guidelines on conducting ethical research. While extremely important to the successful conduct of the trial, this additional work is not relevant to the outcomes, experiences, and costs associated with the Link-me model of care, so has not been discussed in this report.

The onset of the COVID-19 pandemic has dramatically altered the primary care and mental health service landscapes. The uptake of new telehealth mental health services has been substantial and

there have been calls to continue the newly introduced telehealth services even after the pandemic has resolved [78, 79]. To some extent, we were able to take these issues into account in the modelling of national Link-me implementation costs, which included alternative assumptions based on online provision of the DST/screening procedure and delivery of care navigation training. As this situation could not have been predicted at the outset of the evaluation, we do not have data about the acceptability and uptake of these options among general practice attendees.

We had planned to incorporate MBS and PBS data from consenting participants, but data were pending at the time of preparing this report. Because the RUQ captured service encounters and medication use generally, this did not affect our ability to capture resource use and associated costs for the within-trial economic analyses. However, it did mean we were not able to use these data to corroborate self-reported service use data among the 36% of trial participants who consented for this data to be provided. It also meant that we were unable to examine patterns of use of specific government-subsidised mental health interventions (e.g., psychological therapies delivered under the 'Better Access' program, and antidepressant medication prescribing). For example, as the Better Access program is intended for use by people with more moderate levels of mental disorder, its utilisation by Link-me participants with minimal/mild and severe mental health problems could offer some insights into how the program might be refined to better reach its target population. Similarly given concerns about the overuse of psychotropic medications, particularly antidepressants, examining the use of these medications among Link-me participants with minimal or mild problems (and the extent to which they are used in combination with other service types) could offer similar insights. That said, the data provided by the RUQ suggest that a substantial minority of participants in the minimal/mild prognostic group may be using these services (see section 6.2.3).

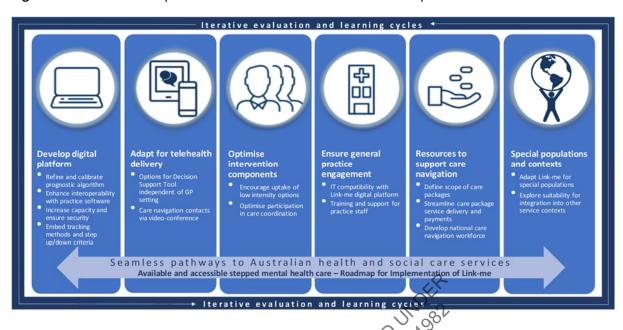
## 7.3. Actions

This Australian-first individually randomised controlled trial, conducted across three states in Australia, provided gold-standard evidence to support the Link-me approach to system design. We found that Link-me was well-received by GPs, resulted in positive experiences of care to participants, and led to improved mental health outcomes at reasonable additional cost, particularly for those with severe and complex needs. Together, these findings indicate that Link-me can successfully organise mental health care at scale for the general practice population and tailor treatment to individual need across the symptom severity spectrum.

Building on these findings, Figure 13 depicts six high-level actions that provide a 'roadmap' to optimise Link-me in readiness for routine implementation:

- 1. Develop digital platform;
- 2. Adapt for telehealth delivery;
- 3. Optimise intervention components;
- 4. Ensure general practice engagement;
- 5. Resources to support care navigation; and
- 6. Special populations and contexts.

Figure 13. Six actions to optimise Link-me in readiness for routine implementation



Issues to consider in relation to each of these actions are discussed in the sections that follow.

Crucially, each of these actions fits with the goal of enabling seamlessly pathways for consumers across existing health and care systems, taking into account the availability and accessibility of services across all levels of care, existing referral pathways, and payment mechanisms.

We recommend that the developments and enhancements described in each action be subject to an iterative cycle of evaluation and the learnings from those evaluations be disseminated to inform further refinements. Some enhancements could be evaluated in priority practices or PHNs. For example, PHNs could be resourced to identify general practices that would benefit most from implementing the Link-me approach. These might include practices serving socio-economically disadvantaged areas — where the assistance afforded through care packages is most needed — and/or practices with high proportions of attenders with more severe mental health problems.

#### 7.3.1.1.1. Develop digital platform

Through the trial we found that the Link-me DST interface was generally fit-for-purpose. That said, it was developed specifically for this evaluation; we did not work with a commercial partner to develop it. Further enhancements could be made to improve engagement with the tool and the treatment recommendations it provides. For example, user-testing could be undertaken to inform improvements to the functionality and look and feel of the care navigator portal. 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.

The implementation and sustainability of Link-me 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 Primary Mental Health Care Minimum Data Set (PMHC MDS), and potentially other practice-based screening tools would substantially reduce the administrative burden on care navigators, ensure GPs were kept informed of the progress of general practice attendees using Link-me, and reinforce the role of the care navigator as

a clinical companion to the GP. Interoperability is also an important consideration in thinking about the development of protocols for stepping up and down care.

The web platform would also need to be optimised for increased numbers of general practice attendees and care navigators using Link-me 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 could 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.

Link-me is a model of stepped care that stratifies general practice attenders according to their level of need (or severity) and matches them with the least intensive treatment appropriate to their needs. In this way, Link-me focuses on the initial 'step' in a full stepped care model. As an individuals' treatment progresses over time, stepped care models should be 'self-correcting', that is, the individuals' response to treatment is systematically monitored and treatment intensity is stepped up or down, ideally based on pre-determined eligibility criteria. There is a lack of monitoring of mental health in general practice compared with other conditions, such as diabetes. Monitoring systems are needed to ensure that people do not get stuck in a cycle of visits to a therapy/service that may not be addressing their need when perhaps what they need is a referral to another type of service or a specialist. A next logical step is to optimise the Link-me model by developing and embedding systematic tracking methods and criteria to inform decisions about 'stepping up' and 'stepping down' treatment intensity in response to changes in an individual's need. These enhancements should be evaluated in routine practice.

## 7.3.1.1.2. Adapt for telehealth delivery

Recent events (e.g., bushfires, the onset of the COVID-19 pandemic) have increased the need to consider alternative forms of service delivery for Link-me. For example, the Link-me DST could be made available independently of the general practice setting (e.g., via a mobile phone app), or care navigator sessions could be adapted for delivery via video-conference. On the face of it, these options may seem reasonable. However, potential risks and medicolegal implications would need to be explored.

Making access to the Link-me DST widely available does run 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 prognostic group for further support to connect and engage with their care navigator. Therefore, options for restricted access to the DST might be more appropriate (for example, individuals with a GP appointment could be provided with a single-use password to enable them to access and complete the DST prior to their appointment). Likely too, if the DST was made available as a standalone tool, it would need Therapeutic Goods Administration approval.

Similarly, unrestricted access to care navigators would not address the need for more efficient allocation to effective care in general practice and has the potential to result in much higher costs. Systems for providing supervision, ongoing training and monitoring of standards would need to be developed. Secure methods of video service delivery would need to be identified.

#### 7.3.1.1.3. Optimise intervention components

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. However, there is a clear need for further work to address treatment uptake and engagement in relation to both low and high intensity services.

In the minimal/mild prognostic group, we found that those offered low intensity services via Link-me were more likely to use formal health services but were no more likely to use digital help or self-help. Link-me could be further optimised by exploring ways in which people with minimal/mild symptoms might be encouraged to use low intensity services.

In the severe prognostic group, we found that additional clinical benefits accrued to participants who received a greater number of care navigation elements, but only half of those allocated to care navigation participated in any care navigation contacts. Strategies to optimise uptake of and adherence to care navigation elements should be developed and evaluated.

#### 7.3.1.1.4. Ensure general practice engagement

We found that ensuring practice engagement in Link me was most successful when care navigators developed effective working relationships with practice staff (including GPs, practice manager, receptionists and others), and felt welk 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 general practice attendee population (e.g., pain clinics, financial planning services).

Within practices implementing the Link-me approach to stepped care, identifying mental health need and triaging into appropriate care requires general practice attendees 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.

Further work to develop the Link-me digital platform to enable seamless inter-operability with the electronic medical record is also indicated. This would ensure that all the information that care navigators record would be available to the GP, thereby improving inter-professional communication and GP involvement.

To support general practice engagement, we developed an implementation checklist, shown at Appendix 18. By using it to develop and track their implementation strategy, organisations can support continued evaluation and improvement of the Link-me approach.

#### 7.3.1.1.5. Resources to support care navigation

It is important to remember that, while Link-me starts with a practice willing to be engaged and use a DST, it does not end there. It is widely accepted that screening alone is insufficient and this approach is not recommended [80, 81]; critical is the next step, in which people are supported to access appropriate care. For people in the severe prognostic group, resources to support the delivery of care navigation could be enhanced.

Some of these resources relate to the care packages. In the Link-me trial, we found that care navigators were judicious in their use of this funding and proactive in identifying and linking general practice attendees in with appropriate care package-funded services. The guidance document provided by the Department of Health appears to have achieved sufficient clarity regarding 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 the needs to general practice attendees where care package funds are out of scope <sup>1</sup>, and providing resources to support clear communication to both general practice attendees and providers around the approval of services. Some of the more frequently identified '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 implement a preferred provider type model nationally, whereby service organisations or individual 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 general practice attendees to access non-preferred providers where appropriate (e.g., due to preference for a particular provider or novel uses of care package funding not

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<sup>&</sup>lt;sup>1</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.

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.

Other resources relate to the development and governance of a 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 service recipient and a clinical companion to the GP. This role requires a person with excellent self-awareness, openmindedness 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 19).

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.

#### 7.3.1.1.6. Special populations and contexts

The Link-me trial findings are generalisable to the Australian general practice population, for several reasons. The trial was conducted in a large number of real-world, general practice settings. With few exclusions (none of which related to clinical presentation), all adults attending the participating practices for any reason were eligible to be invited to complete the DST. Further, other than offering a new model of care coordination to people in the severe prognostic group, the referral pathways offered to participants in the intervention group were based on existing services in the participants' community. That said, the Link-me model was not specifically tailored for special population groups (e.g., people in remote communities, people with living with particular types of disability, people who speak a language other than English, people in communities affected by natural disasters, to name a few).

One potential future direction is to adapt or refine the Link-me for use with other population groups. Implementation in other communities could be evaluated to determine if the costs stay the same or increase, whether those who receive Link-me find the model of care acceptable and whether they adhere to it. Another option may be to explore the value of Link-me in other service contexts, and whether consumers and providers would engage with it. Relevant service contexts may include: public sector mental health services, where Link-me might be a useful adjunct to clinical case

management, or in Aboriginal controlled mental health services (noting, however, that a holistic approach to care is the norm in these services).

## 7.4. Summary

Effective primary mental healthcare depends on creating a system that general practice attendees can easily navigate and that is flexible to the way that symptoms and needs fluctuate. Effective referral management, which focusses on mechanisms for facilitating access to the most appropriate treatment, will likely be critical to achieving better system integration and continuity of care [82]. 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' which enabled access to services to addressed their mental, physical and social needs. The gold-standard evidence generated by the trial provides reassurance that the Link-me model is effective and acceptable. Importantly, the trial also afforded an opportunity to learn what worked well and what could be improved to optimise Link-me in readness for routine implementation.

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# **Appendix 1. Work informing Link-me**

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, participants, 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 ma
	and the continue of the contin

*Objective:* Sought to describe depression management in general practice, in particular the relationship between medication use and focussed psychological strategies.

Participants: 153 Victorian GPs.

Key reference: McGarry H, Hegarty K, Gunn J. How do Victorian GPs manage patients with depression? Australian Family Physician 2005; 34: 603.

https://www.ncbi.nlm.nih.gov/pubmed/15999175

2003-2005 diamond pilot study

Objective: To explore the patient, practitioner and systems factors affecting the diagnosis, management and outcomes of depression in the primary care setting.

Participants: 646 GP patients and 2 GPs from 2 regional general practices.

Study overview: http://bit.ly/2pAm20d

2005 diamond consortium

Objective: Establishment of a depression research network.

Participants: A multidisciplinary team consisting of 92 members.

Study overview: http://kit.ly/2qHaJkS

2005-2015 diamond cohort study

*Objective*: 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. *Medical Journal of Australia* 2008; 188: S119-125. <a href="https://www.ncbi.nlm.nih.gov/pubmed/18558911">https://www.ncbi.nlm.nih.gov/pubmed/18558911</a>

Gunn J, et al. The association between chronic illness, multimorbidity and depressive symptoms in an Australian primary care cohort. *Social Psychiatry and Psychiatric Epidemiology* 2012; 47: 175-184. <a href="http://bit.ly/2q0BHY4">http://bit.ly/2q0BHY4</a>

Gunn J, et al. A trajectory-based approach to understand the factors associated with persistent depressive symptoms in primary care. *Journal of Affective Disorders* 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. *Journal of Affective Disorders* 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. *Journal of Affective Disorders* 2015; 177: 65-73. https://www.ncbi.nlm.nih.gov/pubmed/25745837

#### 2006 **MoD 2 study**

*Objective:* 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.

#### 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. *Mental Health in Family Medicine* 2009; 6: 75-83. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC27778855/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC27778855/</a>

#### 2006 **RE-ORDER phase 1**

Objective: To re-examine 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. https://www.ncb.nlm.nih.gov/pubmed/18818274

Boardman F, et al. Resillence as a response to the stigma of depression: A mixed methods analysis. *Journal of Affective Disorders* 2001; 135: 267-276. http://bit.lv/2p8-xvit

Kokanovic R, et al Maps, models, and narratives: The ways people talk about depression. *Qualitative Health Research* 2013; 23: 114-125. http://bit.ly/2gH151t

#### 2006 RE-ORDER phase 2

Objective: 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.

*Participants:* 586 stakeholders from the government, non-government (included consumer and carer organisations, education, emergency services), allied health and health sectors and academics.

*Key reference:* Palmer V et al. Diverse voices, simple desires: A conceptual design for primary care to respond to depression and related disorders. *Family Practice* 2010; 27: 447-458. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2908158/

#### 2006 **RE-ORDER phase 3**

*Objective:* To develop practice level improvements informed by the theoretical framework of complexity theory.

Participants: 4 privately owned GP clinics, 1 corporate GP clinic, 1 community health centre.

Key references: Gunn J et al. Embedding effective depression care: using theory for primary care organisational and systems change. *Implementation Science* 2010; 5: 62-76. <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2925331/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2925331/</a>

Gunn J, 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.au/research/full report 13593.pdf

#### 2010 i-CCaAN

*Objective:* To develop and pilot a social prescription tailored treatment plan for patients with depression and anxiety and comorbid chronic physical illness.

Participants: 2 Victorian GP clinics & 19 patients with depression and anxiety.

Study overview: http://bit.ly/2q0UGIh

#### 2013 Emotional goal modelling for the development of a clinical prediction tool

Objective: 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 E, Mendoza A, Willer T. Rsychologically-driven requirements engineering: A case study in depression care. 25<sup>th</sup> Australasian Software Engineering Conference (ASWEC), pp 44-50. https://bit.ly/2K2sRRg

#### 2014 Development of the diamond clinical prediction tool

Objective: Develop a prognostic tool to predict future depression severity among primary care patients with current depressive symptoms at three months.

Participants 593 diamond participants

Reference: 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. *Journal of Affective Disorders* 2017; 227: 854-860. 10.1016/j.jad.2017

#### 2014 Development of a clinical predication tool online platform

*Objective:* Employ a user-centred design approach to a developing a digital platform through which to deliver the *diamond* clinical prediction tool, ensuring it is engaging and meets patient need.

*Participants:* 16 healthy participants and 8 patients with current depressive symptoms.

Reference: Wachtler et al. Development of a mobile clinical prediction tool to estimate future depression severity and guide treatment in primary care: User-centered design. JMIR mHealth and uHealth 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 severity 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 J et 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. *Trials* 2017; 18: 342. https://doi.org/10.1186/s13063-017-2089-y

#### 2015

#### Depression monitoring in the general practice setting

*Objectives:* Investigate the concept of recovery from depression from the patient perspective.

Participants: 576 RE-ORDER patients and 8 case studies with patients, GPs and carers.

Key references: 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'. *Mental Health in Family Medicine* 2009; 6: 49-55.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2777597/

Johnson C. An exploration of monitoring people with depression in the general practice setting (PhD Thesis).

https://minerva-access.unimeth.edu.au/kandle/11343/55698

#### 2015 -

# Development of a motivational interviewing-inspired approach to working with patients with multimorbidity

Objectives: 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

#### Key references:

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. *Journal of Comorbidity* 2015; 5: 162-174. 10.15256/joc.2015.5.55

McKenzie K, Pierce D, Gunn J. Guiding patients through complexity: Motivational interviewing for patients with multimorbidity. *Australian Journal of General Practice* 2018; 47: 8. <a href="https://bit.ly/2JSJUX9">https://bit.ly/2JSJUX9</a>

McKenzie K et al. Moving from "let's fix them" to "actually listen": the development of a primary care intervention for mental-physical multimorbidity. Manuscript submitted July 2020 to *International Journal of Behavioral Medicine*.

#### 2016

#### Patient perspectives of nurse-delivered collaborative care for depression

*Objective:* To investigate how collaborative care for the management of depression is understood by primary care patients at high risk of chronic depressive symptoms.

*Participants:* 12 GP patients with severe depressive symptoms; reported in unpublished student thesis.

2016 2010	Take the second of the second
2016 – 2018	Antidepressant management in general practice
	Objectives: Explore how patients and GPs understand antidepressant medication management of depression, and how to support appropriate use and cessation.
	management of depression, and now to support appropriate use and cessation.
	Participants: A summary report of this pilot work was submitted to the funder.
	Research continues with an NHMRC funded Project Grant to test in a large-scale
	primary care trial: WiseAD NHMRC: IDGNT1157337 [2019-2023]
2016 – 2018	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.
	Participants: 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 treatment for
	subthreshold depressive symptoms, particularly focusing on non-pharmacological and
	self-help strategies.
	Participants: 14 GP nationts with subthreshold debressive symptoms: manuscript
	under review.
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	Participants: 14 GP patients with subthreshold depressive symptoms; manuscript under review.
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# Appendix 2. Example Link-me DST screenshots

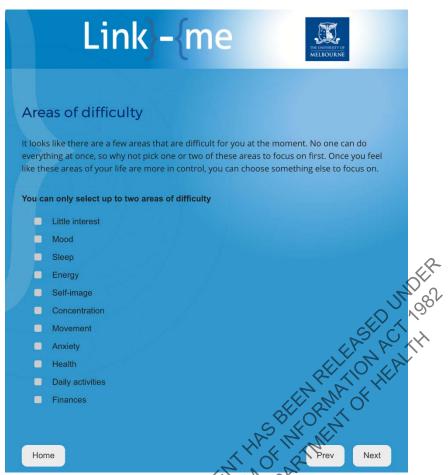
### **Question pages**



## Symptom feedback



### **Priority setting**



Importance and confidence scaling



#### **Treatment recommendations**

#### Severe prognostic group



bookings are required. There is a small (\$5) attendance

# Appendix 3. The Link-me Decision Support Tool

The two prognostic algorithms embedded within the Link-me DST draw on an individual's responses to 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 (see Table A3-1).

**Table A3-1.** Items included in the algorithms used to predict depressive and anxiety symptoms at 3 months

Predictive factors	Items	Included in algorithm for predicted depressive symptoms	Included in algorithm for predicted anxiety symptoms
Sex	Are you male or female? (Male / Female Other)	Yes	Yes
Current depressive symptoms	Are you male or female? (Male / Female / Other)  Depressive symptoms over past 2 weeks calculated using the sum of the 9 PHQ items [42] (Range: 0 to 27)  Anxiety symptoms over the past two weeks	KAT Yes	Yes
Current anxiety symptom	Anxiety symptoms over the past two weeks calculated using the sum of the AGAD items [43] (Range: 0 to 21)	First two items of the GAD-7 (GAD- 2; Range: 0-6)	Yes
Ever had depression and no interest for greater than two weeks (if Yes to both items)	Have you ever been bothered by feeling down, depressed or hopeless for longer than 2 weeks? (Yes/No)  Have you ever been bothered by little interest or pleasure in doing things for longer than 2 weeks? (Yes / No)	Yes	Yes
Live alone	Do you live alone? (Yes/No)	Yes	Yes
Self-rated health	In general, would you say your health is (Excellent / Very good / Good / Fair / Poor)	Yes	No
Long-term illness	Do you have any long-term illness, health problem, which limits your daily activities or the work you can do (including problems that are due to old age)? (Yes / No)	Yes	No
Managing on available income	How do you manage on your available income? (Easily / Not too bad / Difficult some of the time / Difficult all the time / Impossible)	Yes	No

<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.

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As described in section 2.2, based on their responses to these 23 items, individuals were then classified into three prognostic groups (minimal/mild, moderate and severe), reflecting their predicted symptom severity in three months' time. As an individual may be classified into different prognostic groups for anxiety and depression, a hierarchy was developed for the combined group which favours the more severe of the two (see Table 2). For example, an individual who is female, with a PHQ-9 score of 8, self-rated health is fair, does not have a long-term illness, manages not too bad on available income and is not living alone would be classified to the mild/minimal prognostic group for depressive symptoms. If the same individual however scores 18 for current anxiety symptoms on the GAD-7, they would be classified as moderate group for anxiety. Overall, the individual would be classified into the moderate prognostic group.

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# **Appendix 4. Low intensity options**

## **Template**

Trial participants identified by the Decision Support Tool as being good candidates for low intensity services will be provided a short list of service options matched to the areas they are facing difficulties in.

Please complete the table below to suggest low intensity services relevant to each of the 14 potential areas of difficulty. Note that one service may be relevant for several areas. If there are services that are relevant to all 14 areas or that you are unsure about what to map against, please enter them in the last row of the table.

Area of difficulty	Services available / commissioned
Having little interest or pleasure in doing things	10 1NDEX
Feeling down, depressed, or hopeless	
Trouble falling or staying asleep, or sleeping too much	
Feeling tired or having little energy	
Poor appetite or overeating	
Feeling bad about yourself, or that you are a failure, or have let yourself or your family down	OF ETHE
a failure, or have let yourself or your family down  Trouble concentrating on things, such as reading the newspaper or watching television  Moving or speaking so slowly that other people could have noticed. Or the	
Moving or speaking so slowly that other people could have noticed. Or the opposite-being so fidgety or restless that you have been moving around a lot more than usual	
Thoughts that you would be better off dead, or of hurting yourself in some way	
Feeling nervous, anxious, on edge	
Not being able to stop or control worrying	
General health	
Long-term illness, health problem, which limits your daily activities or the work you can do (including problems that are due to old age)	
Ability to manage on available income	
SERVICES RELEVANT TO ALL AREAS OR	
UNABLE TO BE MATCHED	

## List of apps supplied by PHNs

#### **North Western Melbourne**

Priority	Type of support	Name	Details	Resource name links to
Little interest or pleasure in doing things	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Little interest or pleasure in doing things	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Little interest or pleasure in doing things	Mobile app	MoodMission	Sets simple and effective missions to help you achieve better mental health.	http://moodmission.com/
Little interest or pleasure in doing things	Near me	MeetUp	Meet people with similar interests or get inspired to try something new.  Provides free online assessment and treatment for	https://www.meetup.com/en- AU/find/?allMeetups=true&radius=3&userFreefor m=me&mcld=c1000654&change=yes&sort=default
Mood	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems	https://mindspot.org.au/
Mood	Telephone	CAREinMIND Wellbeing Support Service	Provides free courselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Mood	Mobile app	Smiling mind	Build mental health and wellbeing through mindfulness- based tools.	https://smilingmind.com.au/smiling-mind-app/
Mood	Near me	Anxiety Disorders Association of Victoria (ADAVIC) support group	Provides support for people experiencing symptoms of anxiety or depression. Meetings are held on weeknights in Altona, Camberwell, Coburg, and Cranbourne. No bookings are required. There is a small (\$5) attendance fee.	https://www.adavic.org.au/PG-social-support-support-groups.aspx
Sleep	Online	This Way Up	In this free course, learn cognitive behavioural therapy (CBT) skills to help improve your sleep.	https://thiswayup.org.au/how-we-can-help/courses/managing-insomnia/
Sleep	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au

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Priority	Type of support	Name	Details	Resource name links to
Sleep	Mobile app	Smiling mind	Mindfulness training with a sleep-specific module as well as others that may assist in improving sleep (e.g., stress).	https://smilingmind.com.au/smiling-mind-app/
Sleep	Near me	Sahaja yoga	Learn to unwind at a free meditation class, available at several locations across Melbourne.	http://www.sahajayogavic.com/classes/
Energy	Online	MindSpot	Provides free online assessment and treatment for people troubled by problems with energy and other symptoms of anxiety or depression.	https://mindspot.org.au/
Energy	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Energy	Mobile app	Recharge	Assists you to improve energy by establishing a good sleep/wake routine that includes regular exercise and exposure to daylight.	https://au.reachout.com/tools-and-apps/recharge
Energy	Near me	Heart Foundation	Improve your energy levels with regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live near a group or prefer to walk on your own, you can join as a 'Virtual Walker' and track your progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Appetite	Online	MindSpot	Provides free online assessment and treatment for people troubled by problems with appetite and other symptoms of anxiety or depression.	https://mindspot.org.au/
Appetite	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Appetite	Mobile app	Smiling mind	Provides guidance on mindful eating which may have benefits whether you are eating too much or too little.	https://smilingmind.com.au/smiling-mind-app/
Appetite	Near me	RMIT Health Sciences Clinic	A teaching clinic which offers a range of services including Chinese medicine, osteopathy, chiropractic, and psychology.	https://www.rmit.edu.au/about/our-locations- and-facilities/services/health-clinics/health- sciences-clinic
Self-image	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/

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Priority	Type of support	Name	Details	Resource name links to
Self-image	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Self-image	Mobile app	Good Blocks	Assists to improve self-esteem, body image, anxiety and mood through game-based training.	http://samuramu.com/goodblocks/
Self-image	Near me	Anxiety Disorders Association of Victoria (ADAVIC) support group	Provides support for people experiencing symptoms of anxiety or depression. Meetings are held on weeknights in Altona, Camberwell, Coburg, and Cranbourne. No bookings are required. There is a small (\$5) attendance fee.	https://www.adavic.org.au/PG-social-support-support-groups.aspx
Concentration / attention	Online	MindSpot	Provides free online assessment and treatment for people troubled by problems with concentration and other symptoms of anxiety or depression.	https://mindspot.org.au/
Concentration / attention	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Concentration / attention	Mobile app	Smiling mind	Learn to focus your mine through short mindfulness training exercises.	https://smilingmind.com.au/smiling-mind-app/
Concentration / attention	Near me	Anxiety Disorders Association of Victoria (ADAVIC) support group	Provides support for people experiencing symptoms of anxiety or depression. Meetings are held on weeknights in Altona, Camberwell, Coburg, and Cranbourne. No bookings are required. There is a small (\$5) attendance fee.	https://www.adavic.org.au/PG-social-support-support-groups.aspx
Motor activity / movement	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Motor activity / movement	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Motor activity / movement	Mobile app	MoodMission	Tell the app how you're feeling to receive a selection of simple and effective missions that will help boost your activity levels.	http://moodmission.com/
Motor activity / movement	Near me	Anxiety Disorders Association of	Provides support for people experiencing symptoms of anxiety or depression. Meetings are held on weeknights	https://www.adavic.org.au/PG-social-support- support-groups.aspx

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Priority	Type of support	Name	Details	Resource name links to
	••	Victoria (ADAVIC) support group	in Altona, Camberwell, Coburg, and Cranbourne. No bookings are required. There is a small (\$5) attendance fee.	
Thoughts of death	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Thoughts of death	Telephone	Suicide Call Back Service	Provides immediate support to anyone feeling suicidal, and longer term support through up to six free telephone counselling sessions. Call 1300 658 467.	https://www.suicidecallbackservice.org.au/
Thoughts of death	Mobile app	BeyondNow	Allows you to create a safety plan that you can work through when you're experiencing suicidal thoughts.	https://www.beyondblue.org.au/get- support/beyondnow-suicide-safety-planning/
Thoughts of death	Near me	GP	Talk to a trusted GP about ways to manage thoughts of death or self harm.	https://healthengine.com.au/
Anxiety / worry	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Anxiety / worry	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Anxiety / worry	Mobile app	Smiling mind	Learn to calm your mind and build mental health and wellbeing through mindfulness-based tools.	https://smilingmind.com.au/smiling-mind-app/
Anxiety / worry	Near me	Anxiety Disorders Association of Victoria (ADAVIC) support group	Provides support for people experiencing symptoms of anxiety or depression. Meetings are held on weeknights in Altona, Camberwell, Coburg, and Cranbourne. No bookings are required. There is a small (\$5) attendance fee.	https://www.adavic.org.au/PG-social-support-support-groups.aspx
Health	Online	iChooseWell	A comprehensive program that provides instructions and tools to help you learn new wellness strategies and put them into practice.	https://www.mydigitalhealth.org.au/programs-available/
Health	Telephone	NURSE-ON-CALL	provides immediate, expert health advice from a registered nurse. Call 1300 60 60 24, available 24 hours a day.	https://www2.health.vic.gov.au/primary-and-community-health/primary-care/nurse-on-call

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Priority	Type of support	Name	Details	Resource name links to
Health	Mobile app	healthdirect	Provides tools to help you manage your health. Check your symptoms, find a health service, and get trusted health information.	https://www.healthdirect.gov.au/health-app
Health	Near me	GP	Talk to a GP you trust about the areas of health and wellbeing you would like to improve.	https://healthengine.com.au/
Activities of daily life	Online	iChooseWell	A comprehensive program that provides instructions and tools to help you learn new wellness strategies and put them into practice.	https://www.mydigitalhealth.org.au/programs-available/
Activities of daily life	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north central, or western suburbs of Melbourne. Call 1300 096	https://www.careinmind.com.au
Activities of daily life	Mobile app	Flaredown	Track symptoms, treatments, triggers, and connect with the online community.	http://flaredown.com/
Activities of daily life	Near me	Victoria University Clinical Exercise & Rehabilitation Clinic	Located in Footscray, this clinic provides individualised programs for the management of chronic diseases and injuries. If you have a chronic medical condition you may be eligible for Medicare funding.	https://www.vu.edu.au/about-vu/facilities- services/our-services/health-wellbeing- clinics/clinical-exercise-rehabilitation
Household economy	Online	MoneySmart	Provides financial guidance, tools, and resources.	https://www.moneysmart.gov.au/
Household economy	Telephone	National Debt Helpline	Provides free financial counselling. Call 1800 007 007 between 9:30am and 4:30pm, Monday to Friday.	http://www.ndh.org.au/
Household economy	Mobile app	Pocketbook	Includes a budget planner and personal finance software.	https://getpocketbook.com/
Household economy	Near me	Anglicare	Provides free financial counselling at several locations across Melbourne. Call 9731 2500 for an appointment near you.	https://www.anglicarevic.org.au/what-we-do/strengthening-communities/
Generic	Online	MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Generic	Telephone	CAREinMIND Wellbeing Support Service	Provides free counselling for people in the north, central, or western suburbs of Melbourne. Call 1300 096 269, available 24 hours a day.	https://www.careinmind.com.au
Generic	Mobile app	Smiling mind	Build mental health and wellbeing through mindfulness-based tools.	https://smilingmind.com.au/smiling-mind-app/

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Priority	Type of support	Name	Details	Resource name links to
Generic	Near me	GP	Maintain good mental health and wellbeing with the help of a trusted GP.	https://healthengine.com.au/

#### **North Coast PHN**

Priority	Type of support	Location	Name	Details	Resource name links to
Little interest or pleasure in doing things	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Little interest or pleasure in doing things	Telephone		New Access	Provides free support from a trained coach; call 1800 010 630.	https://www.beyondblue.org.au/get- support/newaccess
Little interest or pleasure in doing things	Mobile app		MoodMission	Sets simple and effective missions to help you achieve bettermental health.	http://moodmission.com/
Little interest or pleasure in doing things	Near me	Coffs Harbour	CoffsConnect	Meet people with similar interests or get inspired to try something new.	http://coffsconnect.com.au/community-groups
Little interest or pleasure in doing things	Near me	Port Macquarie	Port Macquarie community groups	Meet people with similar interests or get inspired to try something new.	http://www.pmncinfo.org.au/images/CSD/Special%20Interest%20Groups.pdf
Mood	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Mood	Telephone		New Access	Provides free support from a trained coach; call 1800 010 630.	https://www.beyondblue.org.au/get- support/newaccess
Mood	Mobile app		Smiling mind	Build mental health and wellbeing through mindfulness-based tools.	https://smilingmind.com.au/smiling-mind-app/
Mood	Near me	Coffs Harbour	Coffs Harbour Mental Health and Wellbeing Support Group	Provides support for people experiencing difficulties with their mental health and wellbeing. This group meets at 11am on the first Thursday of each month.	http://coffsconnect.com.au/coffs-harbour- mental-health-and-wellbeing-support-group

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Priority	Type of support	Location	Name	Details	Resource name links to
Mood	Near me	Port Macquarie	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/nsw/
Sleep	Online		This Way Up	In this free course, learn cognitive behavioural therapy (CBT) skills to help improve your sleep.	https://thiswayup.org.au/how-we-can-help/courses/managing-insomnia/
Sleep	Telephone		New Access	Provides free support from a trained coach; call 1800 010 630.	https://www.beyondblue.org.au/get- support/newaccess
Sleep	Mobile app		Smiling mind	Mindfulness training with a sleep specific module as well as others that may assist in improving sleep (e.g., stress).	https://smilingmind.com.au/smiling-mind- app/
Sleep	Near me	Coffs Harbour	Coffs Harbour Mental Health and Wellbeing Support Group	Provides support for people experiencing difficulties with their mental health and wellbeing. This group meets at 11am on the first Thursday of each month.	http://coffsconnect.com.au/coffs-harbour- mental-health-and-wellbeing-support-group
Sleep	Near me	Port Macquarie	Sahaja yoga	Learn to unwind at a free meditation class. Both evening and weekend classes available.	http://www.sahajayoga.com.au/class workshops/nsw/#port macquarie
Energy	Online		MindSpot	Provides free online assessment and treatment for people troubled by problems with energy and other symptoms of anxiety or depression.	https://mindspot.org.au/
Energy	Telephone		Get healthy	Free confidential telephone based expert advice	http://www.gethealthynsw.com.au/
Energy	Mobile app		Recharge C	Assists you to improve energy by establishing a good sleep/wake routine that includes regular exercise and exposure to daylight.	https://au.reachout.com/tools-and- apps/recharge
Energy	Near me	Coffs Harbour	Heart Foundation	Improve your energy levels with regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live near a group or prefer to walk on your own, you can join as a 'Virtual Walker' and track your progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Energy	Near me	Port Macquarie	Heart Foundation	Improve your energy levels with regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different	http://walking.heartfoundation.org.au/walking/find-walk

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Priority	Type of support	Location	Name	Details	Resource name links to
				groups to suit most abilities. If you do not live	
				near a group or prefer to walk on your own, you	
				can join as a 'Virtual Walker' and track your	
				progress online.	
Appetite	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
				for people troubled by problems with appetite	
				and other symptoms of anxiety or depression.	
Appetite	Telephone		Get healthy	Free confidential telephone based expert advice	http://www.gethealthynsw.com.au/
				to find a healthier, happier you	
Appetite	Mobile app		Smiling mind	Provides guidance on mindful eating which may	https://smilingmind.com.au/smiling-mind-
				have benefits whether you are eating too much	app/
				or too little.	
Appetite	Near me	Coffs	Coffs Harbour	Provides support for people experiencing	http://coffsconnect.com.au/coffs-harbour-
		Harbour	Mental Health	difficulties with their mental health and	mental-health-and-wellbeing-support-group
			and Wellbeing	wellbeing. This group meets at 11am on the first	
			Support Group	Thursday of each month.	
Appetite	Near me	Port	Healthier You	This multi-site clinic provides nutrition advice to	http://healthieryou.net.au/
		Macquarie		help people live healthier, happier lives.	
			A.	Medicare and private health insurance rebates	
			18	are available.	
Self-image	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
			0,6	for people troubled by symptoms of anxiety,	
			5/1	depression, and related problems.	
Self-image	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
				1800 010 630.	support/newaccess
Self-image	Mobile app		Good Blocks	Assists to improve self-esteem, body image,	http://samuramu.com/goodblocks/
		- "		anxiety and mood through game-based training.	
Self-image	Near me	Coffs	Coffs Harbour	Provides support for people experiencing	http://coffsconnect.com.au/coffs-harbour-
		Harbour	Mental Health	difficulties with their mental health and	mental-health-and-wellbeing-support-group
			and Wellbeing	wellbeing. This group meets at 11am on the first	
6 IC:			Support Group	Thursday of each month.	
Self-image	Near me	Port	Grow	Provides a chance to talk with others about	https://www.grow.org.au/nsw/
		Macquarie		mental health and wellbeing, share experiences,	
				and support each other.	

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Priority	Type of support	Location	Name	Details	Resource name links to
Concentration / attention	Online		MindSpot	Provides free online assessment and treatment for people troubled by problems with concentration and other symptoms of anxiety or depression.	https://mindspot.org.au/
Concentration / attention	Telephone		New Access	Provides free support from a trained coach; call 1800 010 630.	https://www.beyondblue.org.au/get- support/newaccess
Concentration / attention	Mobile app		Smiling mind	Learn to focus your mind through short mindfulness training exercises.	https://smilingmind.com.au/smiling-mind-app/
Concentration / attention	Near me	Coffs Harbour	Coffs Harbour Mental Health and Wellbeing Support Group	Provides support for people experiencing difficulties with their mental health and wellbeing. This group meets at 11am on the first Thursday of each month.	http://coffsconnect.com.au/coffs-harbour- mental-health-and-wellbeing-support-group
Concentration / attention	Near me	Port Macquarie	Port Macquarie community groups	Build concentration by focusing on something you enjoy; join a group to find a new hobby or meet people with similar interests.	http://www.pmncinfo.org.au/images/CSD/Special%20Interest%20Groups.pdf
Motor activity / movement	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Motor activity / movement	Telephone		New Access	Provides free support from a trained coach; call 1800 010 630.	https://www.beyondblue.org.au/get- support/newaccess
Motor activity / movement	Mobile app		MoodMission  Heart  Foundation	Tell the app how you're feeling to receive a selection of simple and effective missions that will help boost your activity levels.	http://moodmission.com/
Motor activity / movement	Near me	Coffs Harbour	Heart Foundation	Manage your movement through regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live near a group or prefer to walk on your own, you can join as a 'Virtual Walker' and track your progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Motor activity / movement	Near me	Port Macquarie	Heart Foundation	Manage your movement through regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live	http://walking.heartfoundation.org.au/walking/find-walk

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Priority	Type of support	Location	Name	Details	Resource name links to
				near a group or prefer to walk on your own, you	
				can join as a 'Virtual Walker' and track your	
				progress online.	
Thoughts of	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
death				for people troubled by symptoms of anxiety,	
				depression, and related problems.	
Thoughts of	Telephone		Suicide Call Back	Provides immediate support to anyone feeling	https://www.suicidecallbackservice.org.au/
death			Service	suicidal, and longer term support through up to	
				six free telephone counselling sessions. Call 1300	
				658 467.	
Thoughts of	Mobile app		BeyondNow	Allows you to create a safety plan that you can	https://www.beyondblue.org.au/get-
death				work through when you're experiencing suicidal	support/beyondnow-suicide-safety-planning/
				thoughts.	
Thoughts of	Near me	Coffs	GP	Talk to a trusted GP about ways to manage	https://healthengine.com.au/
death		Harbour		thoughts of death or self harm.	
Thoughts of	Near me	Port	GP	Talk to a trusted GP about ways to manage	https://healthengine.com.au/
death		Macquarie		thoughts of death or self harm.	
Anxiety /	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
worry				for people troubled by symptoms of anxiety,	
				depression, and related problems.	
Anxiety /	Telephone		New Access	Rroyides free support from a trained coach; call	https://www.beyondblue.org.au/get-
worry			0,67	1800 010 630.	support/newaccess
Anxiety /	Mobile app		Smiling mind	Learn to calm your mind and build mental health	https://smilingmind.com.au/smiling-mind-
worry		0 "	ZHIZHV &	and wellbeing through mindfulness-based tools.	app/
Anxiety /	Near me	Coffs	Coffs Harbour	Meet others struggling with anxiety; share	http://coffsconnect.com.au/coffs-harbour-
worry		Harbour	Anxiety Support	experiences and solutions. The group meets at	anxiety-support-group
			Group	11am on the second and fourth Tuesdays of the	
/		5 .	6	month.	1
Anxiety /	Near me	Port	Grow	Provides a chance to talk with others about	https://www.grow.org.au/nsw/
worry		Macquarie		mental health and wellbeing, share experiences,	
l loolah	Online		:Chanas Mall	and support each other.	hating of the second site is a label and a second
Health	Online		iChooseWell	A comprehensive program that provides	https://www.mydigitalhealth.org.au/program
				instructions and tools to help you learn new	-available/
				wellness strategies and put them into practice.	

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Priority	Type of support	Location	Name	Details	Resource name links to
Health	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
				1800 010 630.	support/newaccess
Health	Mobile app		healthdirect	Provides tools to help you manage your health.	https://www.healthdirect.gov.au/health-app
				Check your symptoms, find a health service, and get trusted health information.	
Health	Near me	Coffs	Heart	Improve your general health with regular	http://walking.heartfoundation.org.au/walkin
		Harbour	Foundation	physical activity. The Heart Foundation walking	g/find-walk
				groups make this enjoyable, and there are	
				different groups to suit most abilities. If you do	
				not live near a group or prefer to walk on your	
				own, you can join as a 'Virtual Walker' and track	
				your progress online.	
Health	Near me	Port	GP	Talk to a GP you trust about the areas of health	https://healthengine.com.au/
		Macquarie		and wellbeing you would like to improve.	
Activities of	Online		iChooseWell	A comprehensive program that provides	https://www.mydigitalhealth.org.au/programs
daily life				instructions and tools to help you learn new wellness strategies and put them into practice.	<u>-available/</u>
Activities of	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
daily life			_	1800,010 630.	support/newaccess
Activities of	Mobile app		Flaredown	Track symptoms, treatments, triggers, and	http://flaredown.com/
daily life				connect with the online community.	
Activities of	Near me	Coffs	New Horizons	Provides personalised plans to support you to	http://newhorizons.org.au/expertise/mental-
daily life		Harbour	5/14	reach your goals.	health/
Activities of	Near me	Port	Neighborhood		http://www.pmncinfo.org.au/images/CSD/Sup
daily life		Macquarie	Centre	assist people to get the most out of life.	port%20Groups.pdf
			Community		
11	0-1:		Directory	Duraidas financial acidenas table and user man	h.t
Household economy	Online		MoneySmart	Provides financial guidance, tools, and resources.	https://www.moneysmart.gov.au/
Household	Telephone		National Debt	Provides free financial counselling. Call 1800 007	http://www.ndh.org.au/
economy			Helpline	007 between 9:30am and 4:30pm, Monday to Friday.	
Household	Mobile app		Pocketbook	Includes a budget planner and personal finance	https://getpocketbook.com/
economy				software.	

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Priority	Type of support	Location	Name	Details	Resource name links to
Household	Near me	Coffs	Lifeline	Provides free face-to-face financial counselling	https://www.lifeline.org.au/north-coast-
economy		Harbour		for anyone who feels overwhelmed with money	nsw/counselling-services
				problems. Call 02 6651 4093 to make an	
				appointment.	
Household	Near me	Port	Neighborhood	Offers free financial advice, tenants advice, tax	http://www.pmncinfo.org.au/pages/servicespr
economy		Macquarie	Centre	help and free food and produce.	ogramswhats-on/whats-on-at-the-nc.php
Generic	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
				for people troubled by symptoms of anxiety,	
				depression, and related problems.	
Generic	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
				1800 010 630.	support/newaccess
Generic	Mobile app		Smiling mind	Build mental health and wellbeing through	https://smilingmind.com.au/smiling-mind-
				mindfulness-based tools	app/
Generic	Near me	Coffs	GP	Maintain good mental health and wellbeing with	https://healthengine.com.au/
		Harbour		the help of a trusted GP.	
Generic	Near me	Port	Neighborhood	Provides a range of services and activities to	http://www.pmncinfo.org.au/
		Macquarie	Centre	assist people to get the most out of life.	

#### **Brisbane North PHN**

Priority	Type of support	Location	Name	Details	Resource name links to
Little interest or pleasure in doing things	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Little interest or pleasure in doing things	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Little interest or pleasure in doing things	Mobile app		MoodMission	Sets simple and effective missions to help you achieve better mental health.	http://moodmission.com/
Little interest or pleasure in doing things	Near me	North	MeetUp	Meet people with similar interests or get inspired to try something new.	https://www.meetup.com/en- AU/find/?allMeetups=true&radius=3&userFreef

Priority	Type of support	Location	Name	Details	Resource name links to
					orm=Brisbane%2C+Australia&mcId=c1000655&c hange=yes&sort=default
Little interest	Near me	South	MeetUp	Meet people with similar interests or get inspired	https://www.meetup.com/en-
or pleasure in			•	to try something new.	AU/find/?allMeetups=true&radius=3&userFreef
doing things				,	orm=Brisbane%2C+Australia&mcId=c1000655&c
				Δ.	hange=yes&sort=default
Mood	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
				for people troubled by symptoms of anxiety,	
				depression, and related problems	
Mood	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
				07 3358 4424.	<u>support/newaccess</u>
Mood	Mobile app		Smiling mind	Build mental health and wellbeing through	https://smilingmind.com.au/smiling-mind-app/
			_	mindfulness-based tools.	
Mood	Near me	North	Grow	Provides a chance to talk with others about	https://www.grow.org.au/qld/
				mental health and wellbeing, share experiences,	
Mood	Noor mo	Courth	Crow	and support each other.  Provides a chance to talk with others about	https://www.grow.org.au/qld/
Mood	Near me	South	Grow	mental health and wellbeing, share experiences,	ittps://www.grow.org.au/qiu/
				and support each other.	
Sleep	Online		This Way Up	In this free course, learn cognitive behavioural	https://thiswayup.org.au/how-we-can-
эгсер	Omme		Tills Way op	therapy (CBT) skills to help improve your sleep.	help/courses/managing-insomnia/
Sleep	Telephone		New Access	Provides free support from a trained coach; call	https://www.beyondblue.org.au/get-
				07 3358 4424.	support/newaccess
Sleep	Mobile app		Smiling mind	Mindfulness training with a sleep-specific module	https://smilingmind.com.au/smiling-mind-app/
·			4 4.	as well as others that may assist in improving	
				sleep (e.g., stress).	
Sleep	Near me	North	Relaxation	Offers talks, classes, and courses to help with	http://www.relaxationcentreqld.org/
			Centre	insomnia, depression, anxiety, stress and more.	
Sleep	Near me	South	Sahaja yoga	Learn to unwind at a free meditation class,	https://www.sahajayogaqld.com/classes-and-
				available at several locations across Brisbane and	events/#new-page
				surrounds.	
Energy	Online		MindSpot	Provides free online assessment and treatment	https://mindspot.org.au/
				for people troubled by problems with energy and	
				other symptoms of anxiety or depression.	

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Priority	Type of support	Location	Name	Details	Resource name links to
Energy	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Energy	Mobile app		Recharge	Assists you to improve energy by establishing a good sleep/wake routine that includes regular exercise and exposure to daylight.	https://au.reachout.com/tools-and-apps/recharge
Energy	Near me	North	Moreton Bay Regional Council	Improve your mental and physical health with free or low cost fitness, sport and recreation activities.	https://www.moretonbay.qld.gov.au/sport- recreation/
Energy	Near me	South	Heart Foundation	Improve your energy levels with regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live near a group or prefer to walk on your own, you can join as a 'Virtual Walker' and track your progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Appetite	Online		MindSpot	Provides free online assessment and treatment for people troubled by problems with appetite and other symptoms of anxiety or depression.	https://mindspot.org.au/
Appetite	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Appetite	Mobile app		Smiling mind	Provides guidance on mindful eating which may have benefits whether you are eating too much or too little.	https://smilingmind.com.au/smiling-mind-app/
Appetite	Near me	North	Wellnation Clinic (Endeavour College Student clinic)	offers a whole system approach to nutrition, with consultations ranging from \$12-\$20.	https://www.wellnationclinics.com.au/treatments/nutritional-medicine
Appetite	Near me	South	Wellnation Clinic (Endeavour College Student clinic)	Offers a whole system approach to nutrition, with consultations ranging from \$12-\$20.	https://www.wellnationclinics.com.au/treatments/nutritional-medicine
Self-image	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/

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Priority	Type of support	Location	Name	Details	Resource name links to
Self-image	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Self-image	Mobile app		Good Blocks	Assists to improve self-esteem, body image, anxiety and mood through game-based training.	http://samuramu.com/goodblocks/
Self-image	Near me	North	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Self-image	Near me	South	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Concentration / attention	Online		MindSpot	Provides free online assessment and treatment for people troubled by problems with concentration and other symptoms of anxiety or depression.	https://mindspot.org.au/
Concentration / attention	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424	https://www.beyondblue.org.au/get- support/newaccess
Concentration / attention	Mobile app		Smiling mind	Learn to focus your mind through short mindfulness training exercises.	https://smilingmind.com.au/smiling-mind-app/
Concentration / attention	Near me	North	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Concentration / attention	Near me	South	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Motor activity / movement	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Motor activity / movement	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Motor activity / movement	Mobile app		MoodMission	Tell the app how you're feeling to receive a selection of simple and effective missions that will help boost your activity levels.	http://moodmission.com/

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Priority	Type of support	Location	Name	Details	Resource name links to
Motor activity / movement	Near me	North	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Motor activity / movement	Near me	South	Heart Foundation	Manage your movement through regular physical activity. The Heart Foundation walking groups make this enjoyable, and there are different groups to suit most abilities. If you do not live near a group or prefer to walk on your own, you can join as a 'Virtual Walker' and trackyour progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Thoughts of death	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Thoughts of death	Telephone		Suicide Call Back Service	Provides immediate support to anyone feeling suicidal, and longer term support through up to six free telephone counselling sessions. Call 1300 658 467.	https://www.suicidecallbackservice.org.au/
Thoughts of death	Mobile app		BeyondNow	Allows you to create a safety plan that you can work through when you're experiencing suicidal thoughts.	https://www.beyondblue.org.au/get- support/beyondnow-suicide-safety-planning/
Thoughts of death	Near me	North	GP C	Talk to a trusted GP about ways to manage thoughts of death or self harm.	https://healthengine.com.au/
Thoughts of death	Near me	South	GP CHISTIP	Talk to a trusted GP about ways to manage thoughts of death or self harm.	https://healthengine.com.au/
Anxiety / worry	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Anxiety / worry	Telephone		New Access	Provides free support from a trained coach; call 07 3358 442.	https://www.beyondblue.org.au/get- support/newaccess
Anxiety / worry	Mobile app		Smiling mind	Learn to calm your mind and build mental health and wellbeing through mindfulness-based tools.	https://smilingmind.com.au/smiling-mind-app/
Anxiety / worry	Near me	North	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/

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Priority	Type of support	Location	Name	Details	Resource name links to
Anxiety / worry	Near me	South	Grow	Provides a chance to talk with others about mental health and wellbeing, share experiences, and support each other.	https://www.grow.org.au/qld/
Health	Online		iChooseWell	A comprehensive program that provides instructions and tools to help you learn new wellness strategies and put them into practice.	https://www.mydigitalhealth.org.au/programs-available/
Health	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Health	Mobile app		healthdirect	Provides tools to help you manage your health. Check your symptoms, find a health service, and get trusted health information.	https://www.healthdirect.gov.au/health-app
Health	Near me	North	Moreton Bay Regional Council	Improve your mental and physical health with free or low cost fitness, sport and recreation activities	https://www.moretonbay.qld.gov.au/sport-recreation/
Health	Near me	South	Heart Foundation	Join a walking group for an enjoyable way to improve your general health. The Heart Foundation makes it easy to find a group that suits your abilities. If you do not live near a group or prefer to walk on your own, you can join as a Virtual Walker' and track your progress online.	http://walking.heartfoundation.org.au/walking/find-walk
Activities of daily life	Online		iChooseWell	A comprehensive program that provides instructions and tools to help you learn new wellness strategies and put them into practice.	https://www.mydigitalhealth.org.au/programs-available/
Activities of daily life	Telephone		New Access	Provides free support from a trained coach; call 07 3358 4424.	https://www.beyondblue.org.au/get- support/newaccess
Activities of daily life	Mobile app		Flaredown	Track symptoms, treatments, triggers, and connect with the online community.	http://flaredown.com/
Activities of daily life	Near me	North	Moreton Bay Regional Council	Improve your mental and physical health with free or low cost fitness, sport and recreation activities.	https://www.moretonbay.qld.gov.au/sport-recreation/
Activities of daily life	Near me	South	Anglicare Southern Queensland	Provides a range of lifestyle and wellbeing programs to support all aspects of wellbeing, with programs tailored to suit your interests and abilities.	https://anglicaresq.org.au/your-well-being/lifestyle-wellbeing-programs/

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Priority	Type of support	Location	Name	Details	Resource name links to
Household economy	Online		MoneySmart	Provides financial guidance, tools, and resources.	https://www.moneysmart.gov.au/
Household economy	Telephone		National Debt Helpline	Provides free financial counselling. Call 1800 007 007 between 9:30am and 4:30pm, Monday to Friday.	http://www.ndh.org.au/
Household economy	Mobile app		Pocketbook	Includes a budget planner and personal finance software.	https://getpocketbook.com/
Household economy	Near me	North	MoneyCare	Provides free and confidential financial counselling for people facing financial difficulties or wanting to avoid financial difficulties in the future.	https://salvos.org.au/need-help/financial-assistance/financial-counselling/
Household economy	Near me	South	MoneyCare	Provides free and confidential financial counselling for people facing financial difficulties or wanting to avoid financial difficulties in the future.	https://salvos.org.au/need-help/financial-assistance/financial-counselling/
Generic	Online		MindSpot	Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems.	https://mindspot.org.au/
Generic	Telephone		beyondblue	Provides free information and advice from a trained mental health professional. Call 1300 22 4636, available 24 hours a day.	https://www.beyondblue.org.au/
Generic	Mobile app		Smiling mind	Build mental health and wellbeing through mindfulness-based tools.	https://smilingmind.com.au/smiling-mind-app/
Generic	Near me	North	GP THISTIE	Maintain good mental health and wellbeing with the help of a trusted GP.	https://healthengine.com.au/
Generic	Near me	South	GP	Maintain good mental health and wellbeing with the help of a trusted GP.	https://healthengine.com.au/

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## Appendix 5. 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. General Practice attendees 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 patients 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**.
- 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 gains in the

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

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 RHN 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.

Ser	<b>J</b> ,	How data will be collected for the evaluation	Implications for Care Navigators and Trial Coordinators
A.		Data will be recorded and stored in the Link-me data capture system	Contacts with Navigators will need to be recorded on an occasion of service basis.
В.	purchased from the special Link-me Trial funding managed by PHNs	Services need to be recorded using the agreed system for classifying and capturing data (see below).  Data will be recorded and stored in the Link-me data capture system.  Services provided by PHN	A process for recording and coding additional services will need to be implemented within each PHN region. Options include using invoices submitted by additional service providers as triggers for data recording either by the Care Navigator or Regional Trial Coordinator.
C.	commissioned organisations that are inscope for PMHC MDS reporting	Services provided by PHN-commissioned providers will be collected in the PMHC Minimum Data Set and is the responsibility of those providers. PMHC MDS data will be provided to the evaluators and linkage will be via the SLK-581 statistical linkage key.	Nil.  But the national evaluators will need to ensure capacity for generating SLK-581 keys within the Link-me specific data collection.
D.	services plus PBS	From Medicare records of actual use, provided at study end by the Department of Human Services for consenting patients.	Regional Trial Coordinators will be required to assist in following up patients to return Medicare consent forms via the Link- me portal.
E.	provided by state and territory government- funded agencies including	Service utilisation for these types of services will be captured by a specific service history survey of all trial patients conducted at the conclusion of their involvement.	Regional Trial Coordinators will be required to follow-up patients to prompt their completion of service utilisation surveys via the 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 patients 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	Respon	se options	Details
PHN Code	PHN201	l.	North Western Melbourne
	PHN109		North Coast
	PHN301	ı	Brisbane North
Patient ID	The uni	que identifier assigned to the patient	Each patient in the study will
	at regist	TYYY  Support service - Vocational	have a trial-specific unique ID.
Date of service	DDMM	MYYY LP P	For Date fields, data must be
		CIT OF A	recorded in compliance with the
		LANCE THE	standard format used across the
		CEL MILOR	National Health Data Dictionary;
		8,02	specifically, dates must be of
		AS AY NEW	fixed 8 column width in the
		Y Charles	format DDMMYYYY, with
		ALT AL OP	leading zeros used when
	1	Wir O. Of.	necessary to pad out a value.
	0	4,4,4,	For instance, 13th March 2008
	0 4	ST.	would appear as 13032008
Service type <sup>18</sup>	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.
	4.	Support service – Other	Services to provide other
		•	personal support
	5.	Family therapy/counselling	Services to assist the patient and their family.
	1		1

<sup>&</sup>lt;sup>18</sup> The proposed code list aims to classify additional services to meaningful groups.

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	6. Me	editation, Mindfulness and	Structured training programs to
	rel		assist the person in dealing with
		<del>-</del>	stress.
	7. Nu	trition/Dietary services	Services to assist the person
			with dietary or nutrition
			management
	8. Ex	· · · =	Engagement of recognised
			exercise physiology practitioner
			to assist the person in
			establishing a physical exercise
			program.
	0 0	us and alaskal as usedline	Compiess to essist the manage
	9. Dr	=	Services to assist the person
			manage a substance abuse
			problem.
	10. Ot	her allied health service	Services delivered by another
		10.	allied health practitioner not
		V * X	described elsewhere in this list.
	11. MI	BS gap payment – Psychiatrist	
	12. Mi	BS gap payment – Rsychologist	
	13. MI	BS gap payment – Other allied	
		alth	
	14. Ot	her additional service	
Cost to PHN	Enter in wh	ole dollars	This is the amount paid by the
.0	00585	·	PHN for the service

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 general practice attendees 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 PHN-commissioned 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 6. Interview questions and sampling

### Care navigator and regional trial coordinator **Interviews**

Regional trial coordinators and care navigators 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 participants, 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 participants. Information was shared about the kinds of care packages that were developed and how care navigators identified services for participants 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 participants and delivering care?
  - Prompt: what other activities are you involved in within the PHN?
- 3. How did you coordinate care for participants 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?

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- 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

- 1. 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 six-month survey but not yet reached the 12 month timepoint. This window was selected so as to avoid contaminating the primary outcome assessment at six-month follow-up, 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 prognostic group: Triaged to low intensity services

- 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 prognostic 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 navigator was like?
- 3. What was your experience of completing the plan with the care navigators? Were there any 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?
- 6. Are there any other comments you would like to make about Link-me?

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## Appendix 7. GP approach to mental health care

**Table A7-1.** Scheduled GP follow-up and after hours care for general practice attendees with mental health problems (N = 167)

	n	(%)
First follow up appointment for general practice attendees 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	14	(8.5)
Within 3 months	1	(0.6)
Varies depending on severity	17	(10.4)
I would not schedule a follow up appointment	0	(0.0)
After hours care arrangements		
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 Lifeline	9	(5.4)
CAT team	8	(4.8)
Provide own	5	(3.0)
Share with other practices	4	(2.4)
Within a fortnight Within a month Within 3 months Varies depending on severity I would not schedule a follow up appointment  After hours care arrangements Share with GPs in practice Deputising locum service Collaboration with local hospital None Lifeline CAT team Provide own Share with other practices Other	10	(6.0)

Table A7-2. Strategies used by general practitioners when seeing adults with mental health problems in the past 12 months (N = 167)

Strategy	Used with no patients n (%)	Used with very few patients n (%)	Used with about one quarter of patients n (%)	Used with about half of patients n (%)	Used with about three quarters of patients n (%)	Used with almost all patients n (%)
Assess			0			
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)	10 (6.2)	27 (16.7)	115 (71.0)
Advise			SCIN			
Provide psychoeducation	7 (4.4)	6 (3.8)	18 (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)	15 (9.3)	24 (14.8)	28 (17.3)	77 (47.5)
Provide advice on getting a good night's sleep	1 (0.6)	13 (1.9)	20 (12.3)	21 (13.0)	35 (21.6)	82 (50.6)
Teach mediation and/or relaxation	41 (25.6)	3 (1.9) 33 (20.6) 50 (31.1)	33 (20.6)	14 (8.8)	17 (10.6)	22 (13.8)
techniques	M.	ONFLY				
Recommend	CO.					
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	Used with no patients n (%)	Used with very few patients n (%)	Used with about one quarter of patients n (%)	Used with about half of patients n (%)	Used with about three quarters of patients n (%)	Used 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 (11.30	3 (1.9)	3 (1.9)	0 (0.0)
Refer			711,081			
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)	52 (33.5)	16 (10.3)	4 (2.6)	1 (0.6)
Other strategies	4 (33.3)	5(41,7) <	2 (16.7)	0 (0.0)	0 (0.0)	1 (8.3)

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## Appendix 8. Detailed description of the Link-me intervention

The Link-me intervention is described in detail here, organised according to the Template for Intervention Description and Replication (TIDieR) checklist. The TIDieR checklist [83] is intended to provide complete reporting of an intervention and in sufficient detail that it can be replicated elsewhere. The elements of the checklist are: name, why, what (materials), what (procedure), who provided, how, where, when and how much, tailoring, modifications, how well (planned), how well (actual). Because people classified into the minimal/mild prognostic group were assigned to low intensity services and those in the severe prognostic group were assigned to care navigation (high intensity services), we describe each separately (see Table A9-1 and Table A8-2).

Table A8-1. Essential elements of low intensity services

NAME	LOW INTENSITY SERVICES
WHY	Mental health interventions that minimise of eliminate specialist therapist contact time are a focus of current policy direction[20] and recommended in clinical practice guidelines[84] as a first line of treatment for people with minimal or mild anxiety or depression.
WHAT	C BEE PRINT OF
Materials	We developed an Excel spreadsheet of low intensity service options across four modalities, which sat behind the Link-me digital support platform. Information from this spreadsheet fed into the treatment recommendations presented to participants on the tablet device (see example screenshot below; further recommended service options available on request). Participants also received a PDF copy of the recommendation via email, with links to the relevant services.

#### Link - me THE UNIVERSITY OF MELBOURNE You might be interested in accessing some information or support to improve your self-When you are ready, please click 'finish' and we will send you an email with a link to find out more about these options and decide which one might be right for you. You might also like to discuss these options with your GP. Resources To improve self-image Mode Details Name Provides free online assessment and treatment for people troubled by symptoms of anxiety, depression, and related problems beyondblue Telephone mental health professional. Ca 24 hours a day. Mobile app Disorders are held on weeknights Association of Near me el Coburg, and Cranbourne. No here is a small (\$5) attendance Participants viewed their recommended service options on the tablet device in their GP **Procedures** waiting room immediately after completing the Link-me DST assessment and priority setting. Clicking finish on the tablet device triggered the automated email with service recommendations attached for participants to refer back to as needed. WHO PROVIDED Service options were provided electronically; no provider involvement. Recommended services were external, publicly available, and delivered by a range of provider types. HOW Service options were delivered electronically via tablet device and email. For each identified focus area participants received four service options: online, telephone, mobile phone app, and a service available in the local community. In person services could be either individual (e.g., dietitian) and group (e.g., support group) format, depending on the focus area and services available. WHERE As above, service options delivered electronically via tablet device in the GP waiting room and to the participant's nominated email address. Settings and infrastructure for recommended services varied and were outside of the control of the trial. WHEN and HOW Service options were provided immediately after completion of the Link-me DST. **MUCH** Participants were free to follow the recommendation or not, and to use as many or as few of the services as they wished as often as they wished. TAILORING Suggested service options were tailored a) to the participant's identified areas of difficulty or those they prioritised (where more than 2 areas of difficulty were identified), and b) the participant's geographic area. **MODIFICATIONS** No modifications to the intervention were made during the trial.

HOW WELL	No measures to encourage fidelity were planned or taken.

 Table A8-2. Essential elements of care navigation

NAME	CARE NAVIGATION
WHY	Collaborative care is an augmented form of care first developed by Katon and colleagues in the United States [32] and is a regular feature in stepped care models.[6] It comprises four core components: a) a multi-professional approach, b) a structured management plan, c) scheduled follow-ups to foster uptake and engagement and provide opportunity for monitoring and review, and d) enhanced interprofessional communication [31]. Collaborative care has demonstrated effectiveness in improving mental health outcomes in primary care,[33] but tends to target medication adherence rather than addressing an individual's broader psychosocial needs and to date has not been successfully implemented in routine care.
	Link-me care navigation sought to overcome these limitations in a number of ways. It was designed for delivery by a registered health professional such as a registered nurse, embedded in the general practice and acting as a chilical companion to the GP. A key feature of Link-me was the addition of a digital support platform as a fifth key component of collaborative care. This platform supported 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. Link-me care navigation was 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. [34, 35] The intervention was therefore 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 affecting the person's mental health. Finally, Link-me care navigators had access to 'care package' funding to assist participants to access services that were identified as necessary to improve the participant's mental health outcomes but were not accessible due to out of pocket costs. Care packages were designed primarily to fund services delivered by a clinical health professional, but could also support access to services delivered by others as ancillary to formal health care (e.g., 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).
WHAT	
Materials	Participant materials: Recommendation presented on tablet device (see screenshot below) and emailed to participants for their reference. PDF of care plans downloaded by care navigator from online portal.

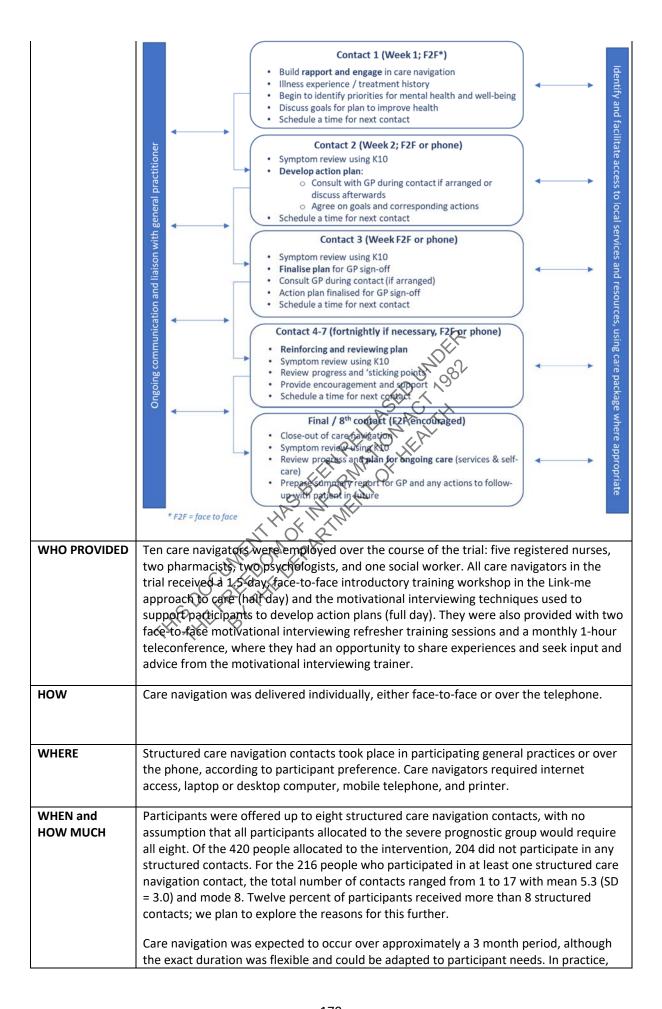


Care navigator materials: Structured care planning templates embedded in online portal; intervention manual (available on request) outlining background to Link-me, care navigator role, care package guidance, daily task list, and step-by-step instructions for portal use; motivational interviewing resources.

#### **Procedures**

Following a participant's completion of the Link-me D8T and allocation to care navigation, the online care navigator portal auto-populated with Link-me DST results and contact details. Within one working day, care navigators attempted to contact participants (via phone, email, and/or SMS) to introduce themselves and the care navigation approach and to schedule a structured contact. Through up to 8 structured contacts, care navigators used the online portal to step through the process of developing a structured care plan with the participant. They could download the plan as a PDF and provide to participants in hard copy or via email, and share the plan with the GP and other health professionals involved in the participant's care as necessary. The general structure of care navigation is presented below, noting that the intervention was flexible and could be modified to respond to a participant's crisis or other issues as required.

Where there was the potential to use care package funding, care navigators sought agreement from the GP that the nominated service may improve the participant's mental health. Care navigators then submitted requests to access funding to their Primary Health Network (PHN). The procedure for payment of funding was developed by each individual PHN but generally required submission of invoices from service providers following the delivery of approved services.



the median duration between randomization and first structured contact was 21 days (range 1-211), while the mean duration between randomization and last structured contact was 123 days (range 6-348).

For each participant, early structured contacts were expected be longer, while the care plan was developed; later contacts which focused on reviewing progress and modifying the plan where required were anticipated to be briefer. Again, the exact duration of each contact was flexible and could be adapted to participant need and care navigator availability. Care navigators recorded the duration of each contact and we are currently analyzing this data.

#### **TAILORING**

Care navigation was designed to be tailored to suit individual participant needs, GPs, and the local service landscape. Participants and care navigators, in collaboration with the treating GP, worked to design and implement a tailored treatment plan specific to the participant's own goals.

### **MODIFICATION**

No modifications to the intervention were made during the trial.

#### **HOW WELL**

#### **Planned**

Receipt of core elements of the intervention: We identified four key elements of care navigation:

- Participation in at least one structured contact with a care navigator and a match between the participant's priorities and the treatment plan they developed.
- The care navigator recommended a specific and new referral or resource to the participant.

  The participant was approved for care package funding.
- The approved funding was spent.

Information relevant to elements 1 and 2 were recorded by care navigators in the online portal. Attendance was encouraged through reminder texts, emails, and phone calls from care navigators. Where possible, care navigators also sought the support of GPs in encouraging attendance. Information relevant to elements 3 and 4 was recorded in an Excel spreadsheet by trial staff at each participating PHN. As above, there was no assumption made that all participants allocated to the severe prognostic group would require all four elements of care navigation, or the full course of 8 structured contacts.

Delivery of intervention: 6 active care navigators were asked to audio-record at least one structured contact for 20% of their active participants in Nov – Dec 2018; a total target of 41 recordings. Strategies to improve fidelity to the intervention throughout the trial included regular teleconferences and face-to-face workshops as described in 'who provided' above.

#### **Actual**

As described above, half of those allocated to the intervention had at least one structured contact with a care navigator. The majority of those were able to develop a plan relevant to their Link-me DST priority areas (see table below). 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., psychologist, meditation group, 'Calm' mobile phone app) as a result of their Link-me action plan. Care package funding was used to access a range of services including mental health, allied health, medical specialists, social services, and complementary therapies.

Care navigation element	n (%)
There was a match between the participant's priorities and the treatment plan they developed.	188 (87.0)
As above and the care navigator recommended a specific and new referral or resource	153 (70.8)
As above and the participant was approved for care package funding	112 (51.9)
As above and the approved funding was spent.	95 (44.0)

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## Appendix 9. Missing data and multiple imputation

#### Overview

Our examination of the pattern of missing data suggested that the missingness was likely missing at random (MAR), supporting the use of multiple imputation for the primary analysis. We therefore used multiple imputation to estimate differences in mean outcomes between trial arms in our primary and secondary analyses. We did this by generating 50 imputation samples, with the samples generated separately in each trial arm and each prognostic group. Imputation samples were generated using chained equations. Linear regression was used for imputing all variables except days out of role, which was imputed using predictive mean matching and choosing the nearest neighbour. Missing baseline, six-month and 12-month data were all generated simultaneously. We imputed 6and 12-month data for the K10, PHQ-9, GAD-7, EQ-5D-5L utility scores, EQ-5D-5L VAS scores and days out of role (the sum of the K11 and K12 questions, set to a maximum of 28 days). We also imputed baseline EQ-5D-5L Utility scores and EQ-5D-5L VAS scores because there was some missing data at this time point. Variables used in the prediction were all imputed variables plus baseline K10, PHQ-9 and GAD-7 scores, age in years, gender and GP practice. For participants in the severe prognostic group we also used the four CACE variables for prediction (see Chapter 4). We report details of the multiple imputation procedure below using guidelines for the reporting of missing data [85].

## Missing values

Overall, 1,016 observations (60.8%) out of 1,671 observations had complete data on all primary and secondary outcome variables at all timepoints (Table A9-1). For the primary outcome, K10 scores at six-month follow-up, 1,111 (66.5%) observations had complete data. The amount of missing data was greater for secondary outcome variables.

**Table A9-1.** Number of complete and missing values for primary and secondary outcomes (total sample is 1671 participants)

Ressler Psychological Distress scale (K10)  Baseline 1671 0 Six-month follow-up (primary outcome) 1111 560 12-month follow-up (secondary outcome) 992 679 Patient Health Questionnaire (PHQ-9)  Baseline 1671 0 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 825 846	Variable	Complete, n	Incomplete, n
Baseline 1671 0 Six-month follow-up (primary outcome) 1111 560 12-month follow-up (secondary outcome) 992 679 Patient Health Questionnaire (PHQ-9) Baseline 1671 0 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 825 846 Generalized Anxiety Disorder scale (GAD-7)	All variables, across all time points	1016	655
Six-month follow-up (primary outcome)  1111  560  12-month follow-up (secondary outcome)  Patient Health Questionnaire (PHQ-9)  Baseline  1671  0  Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  825  846  Generalized Anxiety Disorder scale (GAD-7)	Kessler Psychological Distress scale (K10)		
12-month follow-up (secondary outcome)  Patient Health Questionnaire (PHQ-9)  Baseline  1671  Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  32 month follow-up (secondary outcome)  34 Generalized Anxiety Disorder scale (GAD-7)	Baseline	1671	0
Patient Health Questionnaire (PHQ-9)  Baseline 1671 0  Six-month follow-up (secondary outcome) 939 732  12 month follow-up (secondary outcome) 825 846  Generalized Anxiety Disorder scale (GAD-7)	Six-month follow-up (primary outcome)	1111	560
Baseline 1671 0 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 825 846 Generalized Anxiety Disorder scale (GAD-7)	12-month follow-up (secondary outcome)	992	679
Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  825  846  Generalized Anxiety Disorder scale (GAD-7)	Patient Health Questionnaire (PHQ-9)		
12 month follow-up (secondary outcome) 825 846  Generalized Anxiety Disorder scale (GAD-7)	Baseline	1671	0
Generalized Anxiety Disorder scale (GAD-7)	Six-month follow-up (secondary outcome)	939	732
	12 month follow-up (secondary outcome)	825	846
Baseline 1671 0 Six-month follow-up (secondary outcome) 937 734 12 month follow-up (secondary outcome) 825 846 EuroQol 5-dimension quality of life (EQ-5D-5L VAS)  Baseline 1669 2 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 EuroQol 5-dimension quality of life (EQ-5D-5L Utility)  Baseline 1652 19 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 Days out of role (K10+)  Baseline 1671 0 Six-month follow-up (secondary outcome) 1095 576 12 month follow-up (secondary outcome) 978 693	Generalized Anxiety Disorder scale (GAD-7)		
Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  825 846  EuroQol 5-dimension quality of life (EQ-5D-5L VAS)  Baseline 1669 2 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848  EuroQol 5-dimension quality of life (EQ-5D-5L Utility)  Baseline 1652 19 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 939 730  Six-month follow-up (secondary outcome) 939 939 930 930 930 930 930 930 930 930	Baseline	<b>1</b> 671	0
12 month follow-up (secondary outcome)  Baseline  Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  13 month follow-up (secondary outcome)  14 month follow-up (secondary outcome)  15 month follow-up (secondary outcome)  1652  19 month follow-up (secondary outcome)  17 month follow-up (secondary outcome)  18 month follow-up (secondary outcome)	Six-month follow-up (secondary outcome)	937	734
Baseline 1669 2 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 EuroQol 5-dimension quality of life (EQ-5D-5L Utility) Baseline 1652 19 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 Days out of role (K10+)  Baseline 1671 0 Six-month follow-up (secondary outcome) 1095 576 12 month follow-up (secondary outcome) 978 693	12 month follow-up (secondary outcome)	0825	846
Baseline 1669 2 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 EuroQol 5-dimension quality of life (EQ-5D-5L Utility)  Baseline 1652 19 Six-month follow-up (secondary outcome) 939 732 12 month follow-up (secondary outcome) 823 848 Days out of role (K10+)  Baseline 1671 0 Six-month follow-up (secondary outcome) 1095 576 12 month follow-up (secondary outcome) 978 693	EuroQol 5-dimension quality of life (EQ-5D-5L VAS)		
Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  823  848  EuroQol 5-dimension quality of life (EQ-5D-5L Utility)  Baseline  1652  19  Six-month follow-up (secondary outcome)  939  732  12 month follow-up (secondary outcome)  823  848  Days out of role (K10+)  Baseline  1671  0  Six-month follow-up (secondary outcome)  1095  576  12 month follow-up (secondary outcome)  939  732  105  105  107  107  108  1095  1095  1095	Baseline	1669	2
12 month follow-up (secondary outcome)  Baseline  Six-month follow-up (secondary outcome)  12 month follow-up (secondary outcome)  13 month follow-up (secondary outcome)  14 month follow-up (secondary outcome)  15 month follow-up (secondary outcome)  1671  17 month follow-up (secondary outcome)  18 month follow-up (secondary outcome)	Six-month follow-up (secondary outcome)	939	732
Baseline 1652 19 Six-month follow-up (secondary outcome) 939 732  12 month follow-up (secondary outcome) 823 848  Days out of role (K10+)  Baseline 1671 0  Six-month follow-up (secondary outcome) 1095 576  12 month follow-up (secondary outcome) 978 693	12 month follow-up (secondary outcome)	823	848
Baseline       1652       19         Six-month follow-up (secondary outcome)       939       732         12 month follow-up (secondary outcome)       823       848         Days out of role (K10+)       50       1671       0         Six-month follow-up (secondary outcome)       1095       576         12 month follow-up (secondary outcome)       978       693	EuroQol 5-dimension quality of life (EQ-5D-5L Utility)		
Six-month follow-up (secondary outcome) 939 732  12 month follow-up (secondary outcome) 823 848  Days out of role (K10+)  Baseline 1671 0  Six-month follow-up (secondary outcome) 1095 576  12 month follow-up (secondary outcome) 978 693	Baseline	1652	19
12 month follow-up (secondary outcome) 823 848  Days out of role (K10+)  Baseline 1671 0  Six-month follow-up (secondary outcome) 1095 576  12 month follow-up (secondary outcome) 978 693	Six-month follow-up (secondary outcome)	939	732
Days out of role (K10+)  Baseline 1671 0  Six-month follow-up (secondary outcome) 1095 576  12 month follow-up (secondary outcome) 978 693	12 month follow-up (secondary outcome)	823	848
Baseline 1671 0 Six-month follow-up (secondary outcome) 1095 576 12 month follow-up (secondary outcome) 978 693	Days out of role (K10+)		
Six-month follow-up (secondary outcome) 1095 576 12 month follow-up (secondary outcome) 978 693	Baseline	1671	0
12 month follow-up (secondary outcome) 978 693	Six-month follow-up (secondary outtome)	1095	576
	12 month follow-up (secondary outcome)	978	693

# Factors associated with complete versus incomplete primary outcome data and testing the MAR assumption

Using logistic regression analysis, we examined the baseline variables associated with missing data on the K10 primary outcome variable (complete vs. incomplete). The baseline predictor variables we included were trial arm and prognostic group and most of the baseline variables listed in Table 9 in Chapter 4. The variables we did not include were EQ-5D-5L, because it had some missing baseline data, and main activity for those not in the labour force, because this question was only asked of a subset of the sample. We found no evidence that the presence of incomplete outcome data was related to trial arm or prognostic group (Table A9-2). We did find evidence that age, Indigenous status and level of education were associated with missing data. The odds of having missing data appeared to decline with age, with the

odds decreasing by a factor of 0.98 for every 1-year increase in age. People who were Indigenous had higher odds of having missing primary outcome data than non-Indigenous people (OR = 1.84). The odds of having missing data appeared to decline as level of education increased. Compared to people with education below Year 10, the odds of having missing data 0.45 times lower for people with a diploma and 0.38 for people with a bachelor degree. All other variables (gender, language spoken at home, employment status, health care card holder status, use of mental health medications, history of depression, reasons for GP visit, self-rated health, a long-term health condition that limits daily activities, living alone, managing on available income, and baseline K10, PHQ-9 and GAD-7) were unrelated to missing primary outcome data.

**Table A9-2**. Number and percentage of incomplete data for the primary outcome variable, and adjusted odds of having missing primary outcome data (n = 1,671)

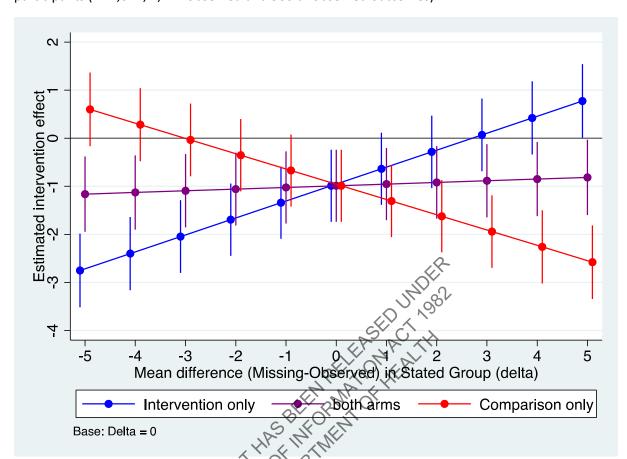
Variable	Complete, n (%)	Incomplete, n (%)	Odds Ratio	95% Confidence Interval	p-value
Trial arm			18	-	0.100
Comparison	571 (68.2)	266 (31.8)	1.00		
Intervention	540 (64.8)	294 (35.2)	1.1900	0.97 to 1.48	
Prognostic group		S			0.790
Minimal/mild	556 (67.0)	274 (33.0)	1.00		
Severe	555 (66.0)	286 (34.0)	1.06	0.68 to 1.65	
Gender		CH MACE	Κ,		0.186
Male	295 (64.6)	162 (35.4)	1.00		
Female	815 (67.4)	394 (32.6)	0.90	0.71 to 1.15	
Other  Age per year Indigenous No Yes Language mainly spoken at home	1 (20.0)	4 (80.0)	6.33	0.63 to 63.2	
Age	ELW B	X			<0.001
per year	50-0K		0.98	0.97 to 0.98	
Indigenous	1,080 (67.2) 31 (49.2)				0.028
No S	1,080 (67.2)	528 (32.8)	1.00		
Yes	31 (49.2)	32 (50.1)	1.84	1.07 to 3.16	
Language mainly spoken at home					0.082
English	1,077 (66.9)	532 (33.1)	1.00		
Other	34 (54.8)	28 (45.2)	1.64	0.94 to 2.85	
Highest level of education attained					<0.001
Below Year 10	43 (58.1)	31 (41.9)	1.00		
Year 10	95 (61.7)	59 (38.3)	0.86	0.47 to 1.56	
Year 11	36 (53.7)	31 (46.3)	0.82	0.40 to 1.67	
Year 12 or equivalent	207 (66.3)	105 (33.7)	0.39	0.22 to 0.69	
Certificate III/IV	215 (64.8)	117 (35.2)	0.53	0.30 to 0.93	
Advanced diploma / Diploma	151 (69.9)	65 (30.1)	0.45	0.25 to 0.81	
Bachelor degree	223 (70.1)	95 (29.9)	0.38	0.21 to 0.68	
Graduate diploma/Certificate	51 (69.9)	22 (30.1)	0.54	0.26 to 1.13	
Postgraduate degree	90 (72.0)	35 (28.0)	0.38	0.19 to 0.73	
Current employment status					0.062
Employed	707 (64.5)	389 (35.5)	1.00		

Variable	Complete, n (%)	Incomplete, n (%)	Odds Ratio	95% Confidence Interval	p-value
Unemployed, looking for and available to start work	109 (66.9)	54 (33.1)	0.69	0.47 to 1.03	
Not in labour force	295 (71.6)	117 (28.4)	0.74	0.54 to 1.00	
Health care card holder					0.137
No	658 (67.7)	314 (32.3)	1.00		
Yes	453 (64.8)	246 (35.2)	1.21	0.94 to 1.56	
Currently taking medication for mental health					0.083
No	630 (64.0)	354 (36.0)	1.00		
Yes	481 (70.0)	206 (30.0)	0.80	0.62 to 1.03	
History of depression					
No	422 (66.5)	213 (33.5)	1.00		0.719
Yes	689 (66.5)	347 (33.5)	1.05	0.79 to 1.40	
Reason for visit to GP			COLD,	,	0.915
Physical health	562 (66.0)	289 (34.0)	1.00		
Mental health and wellbeing	157 (66.2)	80 (33.8)	0,97	0.68 to 1.38	
Both physical and mental health	289 (69.1)	129 (30.9)	0.90	0.68 to 1.21	
None of these	103 (62.4)	62 (37.6)	1.02	0.71 to 1.47	
Self-rated health	¢.	ST SELLO			0.777
Excellent	45 (58.4)	32 (41.6)	1.00		
Very good	265 (67.8)	126 (32.2)	0.81	0.48 to 1.36	
Good	416 (66.8)	207 (33.2)	0.86	0.52 to 1.44	
Fair	276 (66.8)	137 (33.2)	0.91	0.52 to 1.58	
Poor	109 (65.3)	58 (34.7)	1.07	0.56 to 2.02	
Long-term illness which limits daily activities	7				0.058
No	643 (64.2)	359 (35.8)	1.00		
Yes	468 (70.0)	201 (30.0)	0.77	0.59 to 1.01	
Living alone					0.128
No	937 (66.6)	471 (33.4)	1.00		
Yes	174 (66.2)	89 (33.8)	1.26	0.93 to 1.71	
Managing on your available income					0.561
Easily	182 (67.2)	89 (32.8)	1.00		
Not too bad	417 (68.6)	191 (31.4)	0.90	0.66 to 1.24	
Difficult some of the time	321 (63.4)	185 (36.6)	1.10	0.78 to 1.54	
Difficult all of the time	172 (67.7)	82 (32.3)	0.92	0.61 to 1.40	
Impossible	19 (59.4)	13 (40.6)	1.37	0.60 to 3.12	
Baseline K10 (range: 10 to 50)					
Per unit increase			1.00	0.97 to 1.03	0.939
Baseline PHQ-9 (range: 0 to 27)					

Variable	Complete, n (%)	Incomplete, n (%)	Odds Ratio	95% Confidence Interval	p-value
Per unit increase)			1.00	0.96 to 1.04	0.874
Baseline GAD-7 (range: 0 to 27)					
Per unit increase			0.99	0.95 to 1.03	0.668

In separate analyses, we also examined a potential interaction between trial arm and prognostic group on missing outcome data but found no evidence of this (p = 0.651), and we examined potential interactions between trial arm and the variables we identified as related to missing outcome data. None of these variables differed by trial arm – trial arm by age interaction (p = 0.255); trial arm by Indigenous status (p = 0.744); trial arm by education (p = 0.481). This suggests that while there were some systematic differences between completers and non-completers, their distribution was evenly spread across trial arms, minimising any potential bias, and providing some evidence that the data are consistent with a pattern of being MAR.

To further test this assumption, we undertook an analysis to determine how sensitive the results are to plausible departures from MAR [86]. We used a pattern mixture model to assess departures from MAR by adding the quantity  $\Delta = p_1 \delta_1 + p_0 \delta_0$  to the estimated difference between trial arms, where  $\delta_1$  and  $\delta_0$  represent the difference in mean K10 scores with missing responses (unobserved) and those that provided a response (observed) for the intervention and comparison arms, respectively.  $p_1 = 64.8\%$  and  $p_0 = 68.2\%$  represent the percentage of cases with complete data in the intervention and comparison arms, respectively. The values of  $\delta_1$  and  $\delta_0$  were varied between -5 and 5 (in increments of 1) in the same way for both arms, e.g., varying  $\delta_1$  in the intervention arm only and fixing  $\delta_0$  to zero, and varying  $\delta_0$  in the control arm only and fixing  $\delta_1$  to zero.



**Figure A9-1.** Sensitivity analysis for departures from MAR for K10 at six-month follow-up for all participants (N=1,671; 1,111 observed and 560 unobserved outcomes).

Figure A9-1 shows how the estimated intervention effect for all participants varied according to the different assumptions about the departures from the MAR assumption. The departures were slightly greater in the intervention arm because a higher proportion of participants had missing outcomes at 3 months compared to the comparison arm (35.2% vs 31.8%). By way of orientation to the results, the findings from the complete case analysis show that there was a mean difference of approximately -1 point on the K10 at six-month follow-up, favouring the intervention arm for all participants. This analysis assumes any missing data were MAR. This analysis shows that for this conclusion to change there would need to be at a least two-point difference in the mean K10 scores between the participants who had missing responses and those observed in both arms. Such a difference in means would be unlikely given that the size of the overall difference we observed between trial arms. As such, the assumption that data is MAR appears to be reasonable, supporting the use of multiple imputation for the primary analysis.

### **Generation of imputation datasets**

As per our statistical analysis plan, the following variables were included in the generation of the imputation data. For all observations: primary and secondary outcome data measured at each assessment time (baseline, six-month follow-up and 12-month follow-up), age (in years), gender (males, female, other) and GP practice. Trial arm and prognostic group was used as a stratification variable as we powered our study to examine subgroup differences on these two variables [38, 87]. For those participants in the severe prognostic group, we also included the four CACE variables for prediction (that

is, the four variables that measured aspects of care received). We generated 50 imputed datasets. All imputed values at all time points were generated simultaneously using chained equations after an initial burnin on 100 iterations [88]. All imputations were generated using Stata 16.1 [49] using built-in commands. The following methods were used to generate the specific outcome variables:

Table A9-3. Methods used to simulate outcome variables

Variable	Method
K10	Linear regression
PHQ-9	Linear regression
GAD-7	Linear regression
EQ-5D-5L VAS	Linear regression
EQ-5D-5L Utility	Linear regression
Days out of role	Predictive mean matching and choosing the nearest neighbour

The variables included into each equation to generate the simulations were entered as follows:

Table A9-4. Specification of each predictor variable in the simulation of missing data

Variable	Method
K10	Continuous variable
PHQ-9	Continuous variable
GAD-7	Continuous variable
EQ-5D-5L VAS	Continuous variable
EQ-5D-5L Utility	Continuous variable
Days out of role	Continuous variable
Gender	Indicator variable with one group omitted
Age	Continuous variable
GP practice	Indicator variable with one group omitted

## Comparison between observed and imputed data

The multiple imputation procedure does not result in substantial differences from the observed data when estimating the means of each outcome variable. Table A9-5 shows these means stratified by the four combinations of trial arm and prognostic group. Groups 1 and 3 are the comparison arms and 2 and 4 are the intervention arms. Similarly, 1 and 2 are the minimal/mild prognostic group and 3 and 4 are the severe prognostic group. When reading across, the table shows that the means between the two sets of data were similar with mean values from the multiple imputation data falling within the 95% confidence intervals of the observed data (and vice versa). To illustrate, using the multiple imputation dataset, the mean K10 score at six-month follow-up was 19.5 for the comparison arm (95% CI 18.8 to 20.2) in the minimal/mild prognostic group. The equivalent value for the observed data was 19.4 (95% CI 18.7 to 20.1). Note that the Ns in the observed data vary across the same trial arm and prognostic group because of item non-response, and that therefore these Ns are slightly different from the overall number of participants completing each follow-up survey and reported in Figure 5 in Chapter 4.

**Table A9-5.** Comparison between mean estimates of outcome data derived from multiple imputation data and the observed data, stratified by trial arm and prognostic group

Outcome variable	Trial arm and prognostic group <sup>1</sup>		Multiple imputation data		Observed data
		N <sup>2</sup>	Mean (95% CI)	N²	Mean (95% CI)
K10, six-month follow-up	1	416	19.5 (18.8 to 20.2)	288	19.4 (18.7 to 20.1)
	2	414	19.4 (18.7 to 20.1)	268	19.2 (18.5 to 19.9)
	3	421	29.1 (28.2 to 30.0)	283	28.9 (28.1 to 29.8)
	4	420	27.4 (26.3 to 28.4)	272	27.0 (25.9 to 28.1)
K10, 12-month follow-up	1	416	19.0 (18.3 to 19.7)	254	18.8 (18.0 to 19.5)
	2	414	18.9 (18.1 to 19.7)	235	18.7 (18.0 to 19.4)
	3	421	28.5 (27.6 to 29.4)	272	28.1 (27.2 to 29.1)
	4	420	27.4 (26.3 to 28.5)	231	27.0 (25.9 to 28.1)
PHQ-9, six-month follow-up	1	416	6.1 (5.5 to 6.7)	235	6.2 (5.6 to 6.7)
	2	414	28.5 (27.6 to 29.4) 27.4 (26.3 to 28.5) 6.1 (5.5 to 6.7) 5.9 (5.3 to 6.5) 13.8 (13.1 to 14.6) 13.4 (12.6 to 14.2) 5.5 (5.0 to 6.1)	222	6.0 (5.4 to 6.6)
	3	421	13.8 (13.1 to 14.6)	245	13.5 (12.8 to 14.3)
	4	420	13.4 (12.6 to 14.2)	237	13.3 (12.5 to 14.2)
PHQ-9, 12-month follow-up	1 5	406	5.5 (5.0 to 6.1)	208	5.5 (4.9 to 6.0)
	2	414	5.6 (5.0 to 6.2)	196	5.4 (4.8 to 6.0)
	35	421	13.7 (12.9 to 14.5)	230	13.6 (12.8 to 14.5)
		420	13.2 (12.3 to 14.0)	191	13.3 (12.5 to 14.2)
GAD-7, six-month follow-up	1	416	4.8 (4.2 to 5.3)	234	4.9 (4.3 to 5.4)
	2	414	4.7 (4.2 to 5.2)	222	4.8 (4.3 to 5.3)
	3	421	10.4 (9.8 to 11.1)	244	10.1 (9.5 to 10.8)
	4	420	9.7 (9.0 to 10.4)	237	9.5 (8.8 to 10.2)
GAD-7, 12-month follow-up	1	416	4.4 (3.9 to 4.9)	208	4.3 (3.8 to 4.8)
	2	414	4.5 (4.0 to 5.0)	196	4.3 (3.8 to 4.8)
	3	421	9.9 (9.2 to 10.7)	230	9.8 (9.1 to 10.6)
	4	420	9.5 (8.8 to 10.3)	191	9.3 (8.5 to 10.1)

Outcome variable	Trial arm and prognostic group <sup>1</sup>	N	Aultiple imputation data		Observed data
		N <sup>2</sup>	Mean (95% CI)	N <sup>2</sup>	Mean (95% CI)
EQ-5D-5L VAS, six-month follow-up	1	416	0.7 (-2.3 to 3.8)	208	-0.6 (-3.4 to 2.3)
	2	414	1.2 (-1.8 to 4.3)	197	0.8 (-2.1 to 3.7)
	4	420	10 7 /7 2 to 14 0\	189	0.6/6.2 to 12.0\
	4	420	10.7 (7.3 to 14.0)	109	9.6 (6.2 to 12.9)
	2	414	3.8 (1.3 to 6.2)	222	3.0 (0.5 to 5.5)
	4	420	7.4 (4.4 to 10.4)	235	7.8 (4.9 to 10.8)
			OFIL OR LAL		
	2	414	-0.019 (-0.045 to 0.007)	195	-0.015 (-0.041 to 0.011)
	3	421	0:064 (0.032 to 0.097)	227	0.064 (0.029 to 0.099)
		420	0.064 (0.021 to 0.106)	190	0.050 (0.011 to 0.088)
EQ-5D-5L Utility, 12-month follow-up	1	420	-0.004 (-0.028 to 0.021)	231	0.004 (-0.021 to 0.029)
	2	414	-0.004 (-0.030 to 0.022)	219	-0.003 (-0.029 to 0.023)
	3	K421 N	0.049 (0.015 to 0.083)	243	0.061 (0.028 to 0.093)
	(ب) 4	420	0.071 (0.035 to 0.107)	236	0.073 (0.041 to 0.105)
Days out of role, six-month follow-up	1 000	416	4.8 (3.8 to 5.7)	251	4.5 (3.5 to 5.4)
	25,4,4	414	4.9 (3.9 to 5.8)	232	4.6 (3.6 to 5.6)
	\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	421	14.0 (12.8 to 15.2)	268	13.9 (12.6 to 15.1)
	4	420	12.6 (11.3 to 14.0)	227	12.6 (11.2 to 14.0)
Days out of role, 12-month follow-up	1	416	5.1 (4.1 to 6.1)	286	4.9 (4.0 to 5.9)
	2	414	4.5 (3.5 to 5.4)	263	4.3 (3.4 to 5.2)
	3	421	14.0 (12.9 to 15.1)	278	13.9 (12.6 to 15.1)
	4	420	13.2 (11.9 to 14.4)	268	13.4 (12.1 to 14.6)

**Notes:** [1] 1 = Comparison arm, minimal/mild prognostic group, 2 = Intervention arm, minimal/mild prognostic group, 3 = Comparison arm, severe prognostic group, 4 = Intervention arm, severe prognostic group. [2] Differences between Ns in this table and in Figure 5 in Chapter 4 are due to *item* non-response being measured here whereas Figure 5 shows follow-up *survey* non-response.

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## Appendix 10. Characteristics of participants screened

Of the 15,474 participants 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 A10-1 below.

**Table A10-1.** Characteristics of participants who completed the eligibility screening survey: Ineligible vs eligible (N = 13,974)

Age (years)  Depressive symptoms (PHQ-2)  Anxiety symptoms (GAD-2)  Gender  Male  Female Other  Indigenous status  Aboriginal  Torres Strait Islander  Aboriginal and Torres Strait Islander  None of the above  Language mainly spoken at home  English Other  Highest level of education attained	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)
	n (%)	n (%)
Gender	E DIN OK	
Male	2394 (40.0)	2629 (32.9)
Female	3591 (60.0)	5343 (66.9)
Other	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		
	n (%)	n (%)

	Ineligible (N = 5989)	Eligible (N = 7985)
Employed	4181 (69.8)	5290 (66.2)
Unemployed, looking for and available to start work	184 (3.1)	667 (8.4)
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 participants 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 A10-2.

**Table A10-2.** Characteristics of participants who completed the eligibility screening survey and were eligible for the trial: Not consented vs consented (N = 7985)

Age (years) Depressive symptoms (PHQ-2) Anxiety symptoms (GAD-2) Gender Male Female	Not consented Consent		
AP AF ON	(N = 5681)	(N = 2304)	
Thick The	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)	
18,4,21	n (%)	n (%)	
Gender			
Male	1983 (34.9)	646 (28.0)	
Female	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)	

	Not consented (N = 5681)	Consented (N = 2304)
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)
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	(7.3)	57 (9.6)
Unable to work due to own illness, injury, or disability	311 (21.4)	179 (30.0)
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 LET 211	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)
Caring for children Studying Unable to work due to own illness, injury, or disability Caring for an ill or disabled person Working in an unpaid voluntary job Other Health care card holder Currently taking medication for mental health		

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## Appendix 11. Characteristics of the moderate prognostic 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. This group was not included in the main trial, but these individuals did receive the same information and completed the same baseline 6- and 12-month measures as those in the minimal/mild and severe prognostic groups who were randomly allocated to the comparison arm of the trial.

Information on baseline characteristics of the moderate prognostic group is presented in Table A11.1, along with the comparison arm participants in each of the other two prognostic groups. (A comparison with the intervention arm is inappropriate because there was no intervention arm for the moderate group). As 6- and 12-month outcome data was gathered from this group, we compare primary and secondary outcome data for all three prognostic groups at the two time points. This information is presented in Table A11-2. We also show change in the primary outcome (from baseline) for the total sample and for the three groups in Figure A11-1. We present means and standard deviations calculated using the same methods as the equivalent analysis in the main report.

The results for the moderate group are most clearly illustrated in Figure A11-1. The figure shows the change in K10 scores from baseline. The square is the mean change, and the vertical lines surrounding each square is the 95% confidence intervals for the mean (i.e., we are 95% confident that the true value of the mean is between these two values). The dashed line at y = 0 indicates no change from baseline. Thus, when the confidence interval is above this line, this indicates increased psychological distress. When it is below this line, it indicates reduced distress. Confidence intervals that include this line signify no change from baseline.

In the absence of the Link me intervention, psychological distress increased in the minimal/mild prognostic group by 2.2 points at six-month follow-up and remained at a similar value at 12-month follow-up. Distress remained stable over time in the moderate group, with no evidence of change from baseline. In contrast, in the severe prognostic group, participants improve by 2.8 points at six-month follow-up with some evidence of a slight improvement beyond this at 12-month follow-up. A similar pattern was observed for the depression and anxiety outcomes. The minimal/mild and the moderate had a similar number of days out of work at both time points (5 to 6 days) whereas the severe prognostic group had nearly 14 days off work at 6- and 12-months.

Table A11.1. Baseline characteristics of Link-me participants in the comparison arm for all participants and stratified by prognostic group (N=2098)

	All participants (n=1264)	Minimal/mild prognostic group (n=416)	Moderate prognostic group (n=427)	Severe prognostic group (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) 5.24 (2.81) 72 98 (16 674)	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) 0 (0 to 4) 1 (0 to 4) 119 (28.6) 297 (71.4) 0 (0.0)	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	10 to 4)	3 (0 to 7)	8 (3 to 15)
	n (%)	S (n)(%)	n (%)	n (%)
Gender	Α,	HILL II LAND		
Male	353 (27.9)	119 (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	SOFFI			
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 (0.0)
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)

	All participants (n=1264)	Minimal/mild prognostic group (n=416)	Moderate prognostic group (n=427)	Severe prognostic group (N=421)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
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)
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) 22 (5.3) 34 (82)	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)	34 (8.0)	25 (5.9)
Current employment status		22 (5.3) 34 (82)		
Employed	855 (67.6)	332 779,8	281 (65.8)	242 (57.5)
Unemployed, looking for and available to start work	112 (8.9)	332 (5.5) 23 (5.5) 61 (14.7) 25 (40.3) 7 (11.3) 5 (8.1)	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	AKE C	W. PA		
Retired or voluntarily inactive	88 (29.0)	25 (40.3)	50 (43.1)	13 (10.4)
Home duties	37 (12.2)	7 (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)
lealth care card holder	496 (39.2)	115 (27.6)	167 (39.1)	214 (50.8)
Managing on your available income				

	All participants (n=1264)	Minimal/mild prognostic group (n=416)	Moderate prognostic group (n=427)	Severe prognostic group (N=421)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
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)
Living alone	212 (16.8)	0 (0.0) 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.S)	112 (26.2)	47 (11.2)
Good	489 (38.7)	160 (38.5) 175 (42.4) 50 (12.0) 87 (0.7) 81 (19.5) 285 (68.5)	187 (43.8)	127 (30.2)
Fair	299 (23.7)	(12.0)	89 (20.8)	160 (38.0)
Poor	96 (7.6)	A (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	alki	WIPA		
Physical health	664 (52,5)	285 (68.5)	226 (52.9)	153 (36.3)
Mental health and wellbeing	168 (13.3)	285 (68.5) 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)

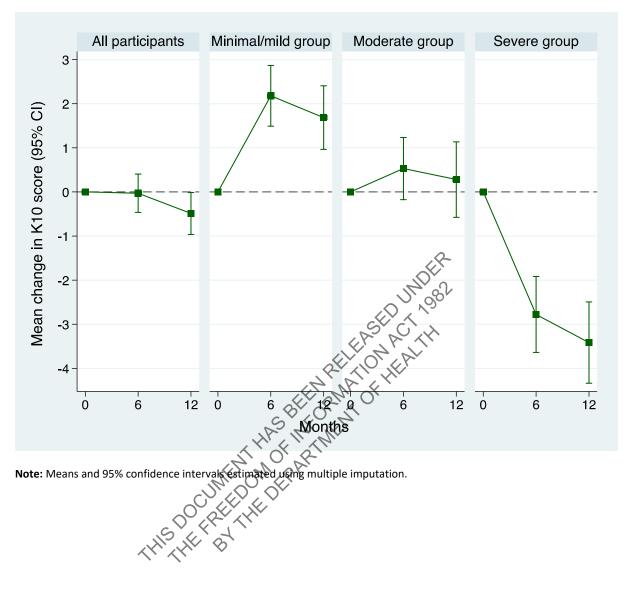
**Notes:** SD = standard deviation, n = count, IQR = Inter quartile range. Variables contributing to the Link-me DST include: Depressive symptom severity, anxiety symptom severity, gender, managing on your available income, living alone, self-rated health, long-term illness which limits daily activities,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

Table A11-2. Mean change in outcome scores in comparison group, in total sample and stratified by prognostic group at six and 12-month follow-up

	All participants	Minimal/mild prognostic group	Moderate prognostic group	Severe prognostic group
Number in each group				
N	1,264	416	427	421
Psychological distress (K10)		R		
Six-month follow-up, mean (95% CI)	-0.03 (-0.46 to 0.40)	2.18 (1.49 to 2.87)	0.53 (-0.17 to 1.23)	-2.78 (-3.64 to -1.92)
12 months, mean (95% CI)	-0.49 (-0.96 to -0.01)	1.68 (0.96 to 2.41)	0.28 (-0.58 to 1.14)	-3.42 (-4.34 to -2.49)
Depressive symptom severity (PHQ 9)		CELCY		
Six-month follow-up, mean (95% CI)	-1.32 (-1.67 to -0.97)	0.25 (-0.31 to 0.82)	-0.59 (-1.13 to -0.05)	-3.61 (-4.33 to -2.89)
12 months, mean (95% CI)	-1.50 (-1.91 to -1.09)	(-0.30 (\0.86\to 0.25)	-0.49 (-1.16 to 0.18)	-3.71 (-4.48 to -2.94)
Anxiety symptom severity (GAD 7)		4 Chickle		
Six-month follow-up, mean (95% CI)	-1.48 (-1.80 to -1.16)	-0.47 (-0.97 to 0.03)	-0.97 (-1.51 to -0.43)	-2.99 (-3.63 to -2.36)
12 months, mean (95% CI)	-1.79 (-2.15 to -1.44)	-0.83 (-1.30 to -0.35)	-1.05 (-1.65 to -0.44)	-3.50 (-4.21 to -2.79)
Quality of life - VAS (EQ-5D-5L)	H	KNIL		
Six-month follow-up, mean (95% CI)	4.28 (2.69 to 5.87)	2.12 (-0.57 to 4.82)	4.93 (2.40 to 7.45)	5.74 (2.76 to 8.73)
12 months, mean (95% CI)	3.38 (1.60 to 5.16)	0.73 (-2.35 to 3.81)	2.65 (-0.63 to 5.93)	6.73 (3.33 to 10.13)
Quality of life - Utility (EQ-5D-5L)	000			
Six-month follow-up, mean (95% CI)	0.03 (0.01 to 0.04)	-0.00 (-0.03 to 0.02)	0.03 (0.01 to 0.06)	0.05 (0.01 to 0.08)
12 months, mean (95% CI)	0.03 (0.02 to 0.05)	0.02 (-0.01 to 0.04)	0.02 (-0.01 to 0.05)	0.06 (0.03 to 0.10)
Days out of role (K10+)				
Six-month follow-up, mean (95% CI)	8.17 (7.53 to 8.81)	5.13 (4.15 to 6.11)	5.40 (4.53 to 6.27)	13.99 (12.86 to 15.13)
12 months, mean (95% CI)	8.27 (7.61 to 8.94)	4.77 (3.81 to 5.72)	6.06 (5.04 to 7.09)	13.98 (12.79 to 15.18)

Notes: All values estimated using multiple imputation. CI -Confidence interval. Mean scores represent mean change from baseline.

Figure A11-1. Mean change in K10 psychological distress scores at 6 and 12 months from baseline in comparision group, for all participants and stratified by prognostic group



# Appendix 12. Characteristics of participants followed for 18 months

While the main trial followed a sample of 1671 participants up to 12 months after randomisation, for participants who entered the study between 21 November 2017 and 30 April 2018, we were able to collect an additional wave of data at 18-month follow-up. This allows us to be able to examine medium-term effectiveness of the Link-me intervention, although there are important caveats on this analysis.

- 1. Only participants who completed the DST before 30 April 2018 were eligible to be included in this analysis. This means that only a sub-sample of participants (n = 527) were eligible to be included in an analysis that examined 6-, 12- and 18-months outcomes.
- 2. This study was not powered to detect differences between treatment arms overall or within prognostic groups. The sample is much smaller than is required to be able to do this with certainty. Even differences of the same magnitude as the main analysis may not be significant because there is a smaller sample size, and therefore greater variation, between treatment arms.
- 3. An implication of including only those who enrolled early in the study is that the sub-sample may not be representative of the sample as a whole. There may have been systematic differences between those enrolled early in the study and those enrolled later. Once example of this would be if the delivery if care navigation changed over time.
- 4. Because the sub-sample is not a random sample of all participants, and because the sample size is smaller than the main analysis and with reduced statistical power, any differences observed with the main analysis are difficult to interpret. Our view is that it is the general trends over time that should be of most interest because of the difficulty distinguishing the signal from the noise.

Nonetheless, the ability to track symptom severity in the two trial arms up to 18 months provides an opportunity to gauge the effectiveness of the Link-me intervention over the medium term.

### **Methods**

The methodology for the analysis of the 18-months outcome is the same as that used for the main trial. The major difference is that analysis was restricted to those participants who entered the study between 21 November 2017 and 30 April 2018. Participants recruited after this date were excluded from the analysis.

### **Results**

Figure A12-1 shows the flow of these participants through the trial. 650 people completed the decision support tool (DST). 123 of these were classified as having moderate symptoms and were excluded from the trial, leaving 527 who were randomly allocated to the comparison (n = 265, 50.3%) or intervention arms (n = 262, 49.7%). six-month outcome data was available 390

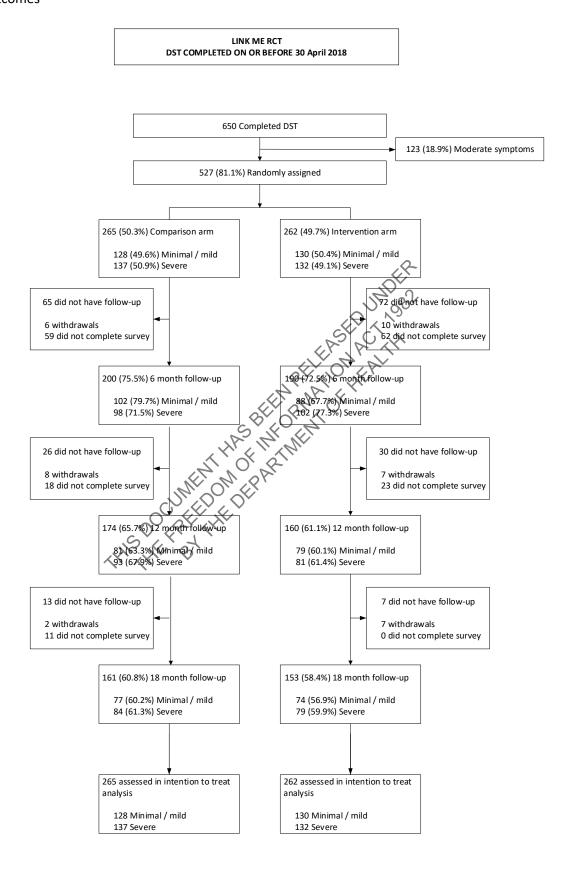
participants (n = 200 in the comparison arm, or 75.5% and n = 190 in the intervention arm, or 72.5%). At 12-months, outcome data was available for 334 participants (n = 174 in the comparison arm, or 65.7% and n = 160 in the intervention arm, or 61.1%). At 18-months, data was available for 314 participants (n = 161 in the comparison arm, or 60.8% and n = 153 in the intervention arm, or 58.4%). The sample available for the intention to treat analysis was n = 265 in the comparison arm (n = 128 in the minimal/mild prognostic group and n = 137 in the severe prognostic group) and 262 in the intervention arm (130 in the minimal/mild prognostic group and 132 in the severe prognostic group).

Baseline characteristics and subgroup analysis results for the 18-month follow-up group are shown in Table A12-1 through Table A12-3, The results for psychological distress are most clearly seen in Figure A12-2. The figure shows the change in K10 scores from baseline for the two treatment arms. The green square is the mean change for the comparison group and the orange square represents the mean change for the intervention group. The vertical lines surrounding each square is the 95% confidence intervals for the mean (i.e., we are 95% confident that the true value of the mean is between these two values). The dashed line at y = 0 indicates no change from baseline. We are most interested in differences between the two treatment groups. Where the confidence intervals for the two groups overlap, this suggests that the mean differences from baseline are similar.

For all eligible participants, both treatment arms showed some evidence of a decline in psychological distress over time. At 12 and 18 months, the comparison group showed a significant improvement from baseline of approximately 0.7 points on the \$10. The change was similar for the intervention group, although it was not significantly different from zero (indicating no change from baseline), and there was no evidence of a significant difference between the two trial arms. There was evidence of increased psychological distress in the minimal/mild prognostic group at six-months of approximately 3 points in both arms. This persisted for the intervention arm and returned to zero in the comparison arm at 12 months. The differences between the trial arms, however, were not significant. In the severe prognostic group, both arms had a reduction in psychological distress scores at six-month follow-up of approximately 3 points that persisted at 12 and 18 months. However, there was no evidence that any differences between arms were significant. A similar pattern was observed for the other outcomes.

As noted above, these results are difficult to interpret for a variety of reasons. It uses a subsample of the total sample that may not be representative of the sample as a whole, the intervention this subsample received may have been different to that offered to participants later on, and the size of the sample was insufficient to reliably detect effects. One possibility, although speculative, is that findings observed at 12 months probably carry over to the 18-month period. Thus, in the main analysis, there were some differences between trial arms at 12 months. If the findings observed in this subsample were replicated on the whole sample, these differences might therefore persist at 18-months.

**Figure A12-1.** Participant flow for subgroup eligible for inclusion in the analysis of the 18-month outcomes



**Table A12-1.** Baseline characteristics of Link-me participants according to trial arm, in total and stratified by prognostic group (18-month follow-up subsample, N = 527)

	All part	icipants	Minimal/mild pro	gnostic group	Severe prog	gnostic group
	Comparison (n=265)	Intervention (n=262)	Comparison (n=128)	Intervention (n=130)	Comparison (n=137)	Intervention (n=132)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	39.69 (15.18)	39.23 (14.20)	41.52 (15.46)	40.34 (14.32)	37.99 (14.76)	38.14 (14.05)
Psychological distress (K10)	24.73 (9.59)	24.47 (9.70)	17.26 (4.52)	16.74 (4.10)	31.71 (7.61)	32.08 (7.31)
Depressive symptom severity (PHQ-9)	11.90 (6.72)	11.75 (6.86)	5,99 (2,43)	5.92 (2.52)	17.42 (4.31)	17.50 (4.52)
Anxiety symptom severity (GAD-7)	9.18 (5.79)	9.44 (5.70)	5.13 (3.01)	5.25 (2.80)	12.96 (5.16)	13.56 (4.75)
Overall health (EQ-5D-5L VAS)	58.66 (22.47)	60.49 (22.70)	70 99 (19 12)	71.87 (17.63)	47.26 (20.05)	49.20 (21.54)
Quality of life (EQ-5D-5L utility weights)	0.58 (0.30)	0.59 (0.30)	0.77 (0.17)	0.78 (0.19)	0.39 (0.29)	0.41 (0.28)
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
Days totally out of role (K10+)	1.00 (5.00)	0.50 (5.00) 3,50 (10.00)	0.00 (2.00)	0.00 (0.00)	4.00 (10.00)	5.00 (13.00)
Days partially out of role (K10+)	4.00 (14.00)	3.50 (10.00)	0.00 (5.00)	0.50 (5.00)	10.00 (16.00)	7.00 (14.00)
	n (%)		n (%)	n (%)	n (%)	n (%)
Sex	IM	3.50 (10.00) hr (%) 67 (25.6) 195 (74.4)				
Male	74 (27.9)	67 (25.6)	36 (28.1)	32 (24.6)	38 (27.7)	35 (26.5)
Female	190 (71.7)	195 (74.4)	92 (71.9)	98 (75.4)	98 (71.5)	97 (73.5)
Other	(0,4)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	0 (0.0)
Indigenous status						
Aboriginal	7 (2.6)	6 (2.3)	3 (2.3)	2 (1.5)	4 (2.9)	4 (3.0)
Torres Strait Islander	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Aboriginal and Torres Strait Islander	1 (0.4)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.8)
None of the above	257 (97.0)	255 (97.3)	125 (97.7)	128 (98.5)	132 (96.4)	127 (96.2)
Language mainly spoken at home						
English	254 (95.8)	243 (92.7)	120 (93.8)	115 (88.5)	134 (97.8)	128 (97.0)
Other	11 (4.2)	19 (7.3)	8 (6.3)	15 (11.5)	3 (2.2)	4 (3.0)

	All participants		Minimal/mild pro	Minimal/mild prognostic group		Severe prognostic group	
	Comparison (n=265)	Intervention (n=262)	Comparison (n=128)	Intervention (n=130)	Comparison (n=137)	Intervention (n=132)	
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Highest level of education attained							
Below Year 10	17 (6.4)	8 (3.1)	6 (4.7)	2 (1.5)	11 (8.0)	6 (4.5)	
Year 10	20 (7.5)	27 (10.3)	9 (7.0)	9 (6.9)	11 (8.0)	18 (13.6)	
Year 11	17 (6.4)	9 (3.4)	6 (4.7)	1 (0.8)	11 (8.0)	8 (6.1)	
Year 12 or equivalent	50 (18.9)	52 (19.8)	23 (18.0)	22 (16.9)	27 (19.7)	30 (22.7)	
Certificate III/IV	51 (19.2)	43 (16.4)	26 (20.3)	23 (17.7)	25 (18.2)	20 (15.2)	
Advanced Diploma / Diploma	30 (11.3)	38 (14.5)	14 (10.9)	16 (12.3)	16 (11.7)	22 (16.7)	
Bachelor Degree	45 (17.0)	45 (17.2)	26 (20.3)	26 (20.0)	19 (13.9)	19 (14.4)	
Graduate Diploma/Certificate	12 (4.5)	15 (5.7)	5 (3.9)	11 (8.5)	7 (5.1)	4 (3.0)	
Postgraduate Degree	23 (8.7)	25 (9.5)	13 (10.2)	20 (15.4)	10 (7.3)	5 (3.8)	
Current employment status		JAS 17 M					
Employed	173 (65.3)	25 (9.5) 166 (63.4)	103 (80.5)	99 (76.2)	70 (51.1)	67 (50.8)	
Unemployed, looking for and available to start work	26 (9.8)	22(8.4)	3 (2.3)	8 (6.2)	23 (16.8)	14 (10.6)	
Not in labour force	66 (24.9)	74 (28.2)	22 (17.2)	23 (17.7)	44 (32.1)	51 (38.6)	
Main activity for those not in labour force	115 14 0						
Retired or voluntarily inactive	9 (13.6)	11 (14.9)	7 (31.8)	9 (39.1)	2 (4.5)	2 (3.9)	
Home duties	10 (15.2)	6 (8.1)	2 (9.1)	2 (8.7)	8 (18.2)	4 (7.8)	
Caring for children	6 (9.1)	16 (21.6)	2 (9.1)	4 (17.4)	4 (9.1)	12 (23.5)	
Studying	11 (16.7)	6 (8.1)	5 (22.7)	2 (8.7)	6 (13.6)	4 (7.8)	
Unable to work due to own illness, injury, or disability	20 (30.3)	24 (32.4)	3 (13.6)	1 (4.3)	17 (38.6)	23 (45.1)	
Caring for an ill or disabled person	5 (7.6)	5 (6.8)	2 (9.1)	2 (8.7)	3 (6.8)	3 (5.9)	
Working in an unpaid voluntary job	4 (6.1)	2 (2.7)	1 (4.5)	1 (4.3)	3 (6.8)	1 (2.0)	

	All part	icipants	Minimal/mild pr	ognostic group	Severe prognostic group	
	Comparison (n=265)	Intervention (n=262)	Comparison (n=128)	Intervention (n=130)	Comparison (n=137)	Intervention (n=132)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Other	1 (1.5)	4 (5.4)	0 (0.0)	2 (8.7)	1 (2.3)	2 (3.9)
Health care card holder	123 (46.4)	116 (44.3)	43 (33.6)	44 (33.8)	80 (58.4)	72 (54.5)
Managing on your available income			CEL C			
Easily	44 (16.6)	33 (12.6)	34 (26.6)	27 (20.8)	10 (7.3)	6 (4.5)
Not too bad	92 (34.7)	94 (35.9)	57 (44.5)	62 (47.7)	35 (25.5)	32 (24.2)
Difficult some of the time	86 (32.5)	85 (32.4)	C33 (25.8)	35 (26.9)	53 (38.7)	50 (37.9)
Difficult all of the time	41 (15.5)	38 (14.5)	7 (5.5) 42 (32.8)	6 (4.6)	37 (27.0)	32 (24.2)
Impossible	2 (0.8)	12 (4.6)	0 (0.0)	0 (0.0)	2 (1.5)	12 (9.1)
Living alone	35 (13.2)	29 (11.1)	MP (7.0)	8 (6.2)	26 (19.0)	21 (15.9)
Self rated health		13 (5.0) 56 (21.4) 100 (38.2)				
Excellent	8 (3.0)	13 (5.0)	7 (5.5)	9 (6.9)	1 (0.7)	4 (3.0)
Very good	54 (20.4)	56 (21.4)	42 (32.8)	51 (39.2)	12 (8.8)	5 (3.8)
Good	105 (39.6)		61 (47.7)	55 (42.3)	44 (32.1)	45 (34.1)
Fair	72 (27.2)	63 (24.0)	16 (12.5)	14 (10.8)	56 (40.9)	49 (37.1)
Poor	26 (9.8)	30 (11.5)	2 (1.6)	1 (0.8)	24 (17.5)	29 (22.0)
Long-term illness which limits daily activities	113 (42.6)	113 (43.1)	25 (19.5)	35 (26.9)	88 (64.2)	78 (59.1)
Reason for visit to GP	7, 7,					
Physical health	143 (54.0)	126 (48.1)	90 (70.3)	82 (63.1)	53 (38.7)	44 (33.3)
Mental health and wellbeing	31 (11.7)	30 (11.5)	6 (4.7)	11 (8.5)	25 (18.2)	19 (14.4)
Both physical and mental health	70 (26.4)	82 (31.3)	21 (16.4)	19 (14.6)	49 (35.8)	63 (47.7)
None of these	21 (7.9)	24 (9.2)	11 (8.6)	18 (13.8)	10 (7.3)	6 (4.5)
History of depression	165 (62.3)	158 (60.3)	38 (29.7)	46 (35.4)	127 (92.7)	112 (84.8)
Currently taking medication for mental health	111 (41.9)	104 (39.7)	29 (22.7)	30 (23.1)	82 (59.9)	74 (56.1)

**Notes**: 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. Discrepancies in totals due to missing responses.

**Table A12-2.** Subgroup analysis of K10 Psychological distress scores according to trial arm, in total sample and stratified by prognostic group at 6, 12 and 18 months (18-month follow-up subsample N = 527)

	All participants		Minimal/mild prognostic group		Severe prognostic group	
Comparison, n	265		128		137	
Intervention, n	262		130		132	
Six-month follow-up			,OEX			
Mean change, mean (SD) [1]			\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\			
Comparison	-0.02 (8.05)		2.77 (7.28)		-2.63 (7.84)	
Intervention	-0.26 (8.87)		3.08 (2:30)		-3.56 (9.03)	
Mean difference, Coef. (95% CI)			0.06 (*2.08 to 2.20) 0.05 (-1.88 to 1.79) -0.05 (-1.85 to 1.76)			
Primary analysis [2]	-0.35 (-1.97 to 1.27)	0.67	0.06 (-2.08 to 2.20)	0.95	-0.76 (-3.09 to 1.57)	0.52
Sensitivity analysis [3]	-0.68 (-2.03 to 0.68)	0.33	<b>1 0</b> .05 (-1.88 to 1.79)	0.96	-1.34 (-3.36 to 0.68)	0.19
Sensitivity analysis [4]	-0.68 (-2.03 to 0.68) -0.68 (-2.02 to 0.67) -0.04 (-0.20 to 0.13)	c0.32(\O)	-0.05 (-1.85 to 1.76)	0.96	-1.34 (-3.33 to 0.65)	0.19
CACE analysis [5]		YK IKW	×		-1.48 (-5.96 to 2.99)	0.51
CACE analysis [6]		O, DS.			-2.02 (-8.15 to 4.11)	0.52
CACE analysis [7]	11/11/20	SEX.			-3.15 (-12.74 to 6.44)	0.52
CACE analysis [8]	COCKY, X	·			-3.60 (-14.63 to 7.43)	0.52
SMD (95% CI) [9]	-0.04 (-0.20 to 0.13)	0.67	0.01 (-0.48 to 0.51)	0.95	-0.10 (-0.41 to 0.21)	0.52
12-month follow-up	THIS HE B					
Mean change, mean (SD) [1]						
Comparison	-1.39 (8.48)		1.43 (6.67)		-4.02 (9.09)	
Intervention	-0.77 (9.43)		2.50 (7.90)		-4.00 (9.65)	
Mean difference, Coef. (95% CI)						
Secondary analysis [2]	0.50 (-1.23 to 2.23)	0.57	0.80 (-1.55 to 3.15)	0.50	0.22 (-2.52 to 2.96)	0.88
Sensitivity analysis [3]	0.47 (-0.95 to 1.89)	0.51	1.07 (-0.69 to 2.84)	0.23	-0.17 (-2.38 to 2.03)	0.88
Sensitivity analysis [4]	0.47 (-0.93 to 1.87)	0.51	1.07 (-0.66 to 2.81)	0.23	-0.17 (-2.35 to 2.00)	0.88
CACE analysis [5]					0.42 (-4.86 to 5.71)	0.87

	All participants		Minimal/mild prognostic group		Severe prognostic group	
CACE analysis [6]					0.58 (-6.62 to 7.77)	0.88
CACE analysis [7]					0.90 (-10.38 to 12.18)	0.88
CACE analysis [8]					1.03 (-11.87 to 13.92)	0.88
SMD (95% CI) [9]	0.05 (-0.13 to 0.23)	0.57	0.19 (-0.36 to 0.73)	0.50	0.03 (-0.34 to 0.40)	0.88
18-months follow-up			Life .			
Mean change, mean (SD) [1]			12/05			
Comparison	-1.70 (8.51)		0.48 (7.41)		-3.74 (8.92)	
Intervention	-0.68 (9.78)		5 2.64 (8.07)		-3.95 (10.12)	
Mean difference, Coef. (95% CI)			TEN BOY			
Secondary analysis [2]	0.92 (-1.17 to 3.01)	0.39	1.90 (0.81 to 4.61)	0.17	-0.03 (-3.23 to 3.18)	0.99
Sensitivity analysis [3]	0.59 (-0.87 to 2.06)	0.43	2.06 (0.20 to 3.92)	0.030	-0.75 (-2.98 to 1.49)	0.51
Sensitivity analysis [4]	0.59 (-0.86 to 2.05)	0,42	A 100 (0 07 : 0 70)	0.042	-0.75 (-2.95 to 1.46)	0.51
CACE analysis [5]		A WY			-0.05 (-6.23 to 6.12)	0.99
CACE analysis [6]	_11	A FRACTOR			-0.07 (-8.48 to 8.34)	0.99
CACE analysis [7]		V CON			-0.11 (-13.29 to 13.07)	0.99
CACE analysis [8]	CALCO	Or			-0.13 (-15.20 to 14.95)	0.99
SMD (95% CI) [9]	0.10 (-0.12 to 0.31)	0.39	0.44 (-0.19 to 1.07)	0.17	-0.00 (-0.43 to 0.43)	0.99

Notes: SD - Standard Deviation; Coef. - Estimated coefficient; Cl. Confidence Interval; SMD - Standardised mean difference. [1] Estimated using multiple imputation. [2] Mean for intervention arm minus mean for control arm estimated using linear regression adjusted for baseline K10 scores (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [3] Sensitivity analysis using complete cases only with linear regression adjusted for baseline K10 (all models) and prognostic group (model with all participants only). [4] Same as 3 but adjusted for general practice treated as random intercept. [5] CACE analysis. undertaken in the severe prognostic group only. Conducted using two-stage least squares instrumental variable regression where the adherence variable was a binary coded variable representing participation in at least one structed contact with a care navigator and a match between the participant's priorities and the action plan they developed. Estimated using multiple imputation. [6] CACE analysis. As for 5 and the care navigator recommended a specific and new referral or resource to the participant. [7] CACE analysis. As for 6 and the participant was approved for care package funding. [8] CACE analysis. As for 7 and the approved funding was spent. [9] Mean difference in the primary analysis calculated relative to the pooled SD of baseline scores.

**Table A12-3.** Subgroup analysis of secondary outcomes in all participants and stratified by prognostic group at 6, 12 and 18 months (18-month follow-up subsample N = 527)

			Adiational facility and an extension			
	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Depressive symptom severity (PHQ 9)						
Six-month follow-up			0			
Comparison, mean (SD)	-1.88 (6.20)		0.00 (5.70)		-3.64 (6.11)	
Intervention, mean (SD)	-1.48 (6.98)		0.40 (6.14)		-3.33 (7.23)	
Mean difference, Coef. (95% CI) [1]	0.35 (-1.05 to 1.76)	0.62	0.34 (-1.52 to 2.20)	0.72	0.35 (-1.63 to 2.32)	0.73
Mean difference, Coef. (95% CI) [2]	0.49 (-0.66 to 1.64)	0.40	0.19 (-1.84 to 1.72)	0.80	0.76 (-0.93 to 2.46)	0.38
Mean difference, Coef. (95% CI) [3]	0.51 (-0.63 to 1.64)	0.38	0.19 (-1.31 to 1.69)	0.80	0.87 (-0.78 to 2.51)	0.30
SMD (95% CI) [4]	0.05 (-0.16 to 0.26)	0.62	0.14 (0.61 to 0.89)	0.72	0.08 (-0.37 to 0.53)	0.73
12-month follow-up			CANA OF			
Comparison, mean (SD)	-2.54 (6.78)	8,0	-0.61 (5.33)		-4.33 (7.43)	
Intervention, mean (SD)	-1.99 (7.47)	JAS IN	-0.61 (5.33) -0.26 (6.47) 0.33 (-1.74 to 2.39) 0.24 (-1.28 to 1.76)		-3.70 (7.90)	
Mean difference, Coef. (95% CI) [1]	0.50 (-1.09 to 2.10)	0.532	0.33 (-1.74 to 2.39)	0.75	0.67 (-1.80 to 3.14)	0.59
Mean difference, Coef. (95% CI) [2]	0.44 (-0.78 to 1.67)	0.48	0.24 (-1.28 to 1.76)	0.76	0.63 (-1.29 to 2.54)	0.52
Mean difference, Coef. (95% CI) [3]	0.38 (-0.82 to 1.58)	0.53	0.24 (-1.25 to 1.73)	0.75	0.66 (-1.20 to 2.52)	0.49
SMD (95% CI) [4]	0.07 (-0.16 to 0.31)	0.53	0.13 (-0.70 to 0.96)	0.75	0.15 (-0.41 to 0.71)	0.59
18-months follow-up	15,4,2					
Comparison, mean (SD)	-2.92 (7.10)		-1.20 (6.53)		-4.54 (7.16)	
Intervention, mean (SD)	-1.79 (8.92)		0.18 (7.33)		-3.73 (9.75)	
Mean difference, Coef. (95% CI) [1]	1.09 (-0.93 to 3.11)	0.29	1.33 (-1.04 to 3.70)	0.27	0.84 (-2.17 to 3.86)	0.58
Mean difference, Coef. (95% CI) [2]	0.82 (-0.53 to 2.16)	0.23	0.86 (-0.80 to 2.52)	0.31	0.77 (-1.32 to 2.87)	0.47
Mean difference, Coef. (95% CI) [3]	0.81 (-0.52 to 2.14)	0.23	0.86 (-0.76 to 2.48)	0.30	0.81 (-1.24 to 2.85)	0.44
SMD (95% CI) [4]	0.16 (-0.14 to 0.46)	0.29	0.54 (-0.42 to 1.49)	0.27	0.19 (-0.49 to 0.87)	0.58
Anxiety symptom severity (GAD 7)						
Six-month follow-up						
Comparison, mean (SD)	-1.61 (5.42)		-0.59 (4.54)		-2.56 (5.96)	

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Intervention, mean (SD)	-2.00 (5.89)		-0.14 (4.67)		-3.84 (6.34)	
Mean difference, Coef. (95% CI) [1]	-0.29 (-1.48 to 0.90)	0.63	0.50 (-0.92 to 1.91)	0.49	-1.04 (-2.87 to 0.79)	0.26
Mean difference, Coef. (95% CI) [2]	-0.02 (-0.96 to 0.93)	0.97	0.46 (-0.74 to 1.66)	0.45	-0.44 (-1.89 to 1.02)	0.55
Mean difference, Coef. (95% CI) [3]	-0.02 (-0.95 to 0.92)	0.97	0.46 (-0.72 to 1.64)	0.44	-0.44 (-1.87 to 0.99)	0.55
SMD (95% CI) [4]	-0.05 (-0.26 to 0.16)	0.63	0.17 (-0.32 to 0.66)	0.49	-0.21 (-0.58 to 0.16)	0.26
12-months follow-up			$\omega^{0}$			
Comparison, mean (SD)	-2.18 (6.24)		-0.82 (4.37)		-3.45 (7.10)	
Intervention, mean (SD)	-1.98 (6.92)		·0.54 (5.45)		-3.39 (7.80)	
Mean difference, Coef. (95% CI) [1]	0.37 (-1.11 to 1.86)	0.62	( 0.34 (-1.45 to 2.13)	0.71	0.41 (-1.89 to 2.72)	0.72
Mean difference, Coef. (95% CI) [2]	0.39 (-0.67 to 1.44)	0.47	0.58 (-0.72 to 1.87)	0.38	0.20 (-1.47 to 1.88)	0.81
Mean difference, Coef. (95% CI) [3]	0.37 (-0.68 to 1.41)	0.49	0.58 (-0.69 to 1.84)	0.37	0.20 (-1.44 to 1.84)	0.81
SMD (95% CI) [4]	0.07 (-0.19 to 0.32)	0.62	9.12 (-0.50 to 0.74)	0.71	0.08 (-0.38 to 0.55)	0.72
18-month follow-up		SIF	0.34 (-1.45 to 2.13) 0.58 (-0.72 to 1.87) 0.58 (-0.69 to 1.84) 9.12 (-0.50 to 0.74) -1.33 (4.98) -0.76 (4.95) 0.64 (-1.28 to 2.55) 1.10 (-0.14 to 2.35)			
Comparison, mean (SD)	-2.69 (6.44)	41/2/11/4/	-1.33 (4.98)		-3.95 (7.28)	
Intervention, mean (SD)	-1.82 (6.22)	NO. PK	-0.76 (4.95)		-2.87 (7.06)	
Mean difference, Coef. (95% CI) [1]	1.04 (-0.53 to 2.60)	0.19	0.64 (-1.28 to 2.55)	0.51	1.43 (-0.97 to 3.83)	0.24
Mean difference, Coef. (95% CI) [2]	0.99 (-0.09 to 2.07)	0.072	1.10 (-0.14 to 2.35)	0.083	0.89 (-0.84 to 2.63)	0.31
Mean difference, Coef. (95% CI) [3]	0.94 (-0.13 to 2.02)	0.086	0.99 (-0.21 to 2.20)	0.11	0.89 (-0.81 to 2.59)	0.30
SMD (95% CI) [4]	0,18 (-0.09 to 0.45)	0.19	0.22 (-0.44 to 0.88)	0.51	0.29 (-0.20 to 0.77)	0.24
Quality of life VAS (EQ-5D-5L)						
Six-month follow-up						
Comparison, mean (SD)	4.12 (26.77)		0.22 (25.03)		7.77 (27.71)	
Intervention, mean (SD)	1.21 (26.63)		1.52 (24.91)		0.92 (28.09)	
Mean difference, Coef. (95% CI) [1]	-1.95 (-7.25 to 3.35)	0.47	1.90 (-5.21 to 9.02)	0.60	-5.65 (-13.02 to 1.72)	0.13
Mean difference, Coef. (95% CI) [2]	-2.05 (-6.08 to 1.97)	0.32	1.37 (-4.12 to 6.85)	0.62	-5.15 (-11.01 to 0.71)	0.084
Mean difference, Coef. (95% CI) [3]	-2.05 (-6.04 to 1.93)	0.31	1.37 (-4.03 to 6.76)	0.62	-5.80 (-11.48 to -0.11)	0.046

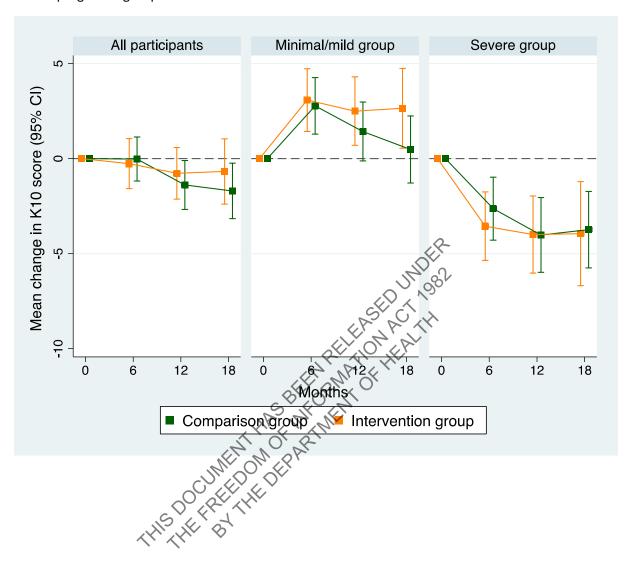
	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Comparison, mean (SD)	6.41 (30.76)		1.89 (29.64)		10.63 (30.97)	
Intervention, mean (SD)	4.64 (33.53)		3.67 (27.69)		5.58 (38.12)	
Mean difference, Coef. (95% CI) [1]	-0.67 (-7.76 to 6.43)	0.85	2.45 (-7.10 to 11.99)	0.61	-3.64 (-14.80 to 7.52)	0.52
Mean difference, Coef. (95% CI) [2]	-0.90 (-5.60 to 3.79)	0.71	1.99 (-3.95 to 7.93)	0.51	-3.66 (-10.95 to 3.64)	0.32
Mean difference, Coef. (95% CI) [3]	-0.90 (-5.54 to 3.74)	0.70	1.99 (-3.83 to 7.82)	0.50	-3.63 (-10.59 to 3.34)	0.31
18-month follow-up			$\omega^{0}$			
Comparison, mean (SD)	9.13 (31.20)		8.53 (25.38)		9.69 (35.59)	
Intervention, mean (SD)	2.08 (41.58)		0.92 (33.11)		3.23 (47.97)	
Mean difference, Coef. (95% CI) [1]	-5.87 (-14.97 to 3.23)	0.20	(-6.88 (-17.55 to 3.80)	0.20	-4.88 (-19.79 to 10.04)	0.52
Mean difference, Coef. (95% CI) [2]	-5.34 (-10.35 to -0.34)	0.036	-6.61 (-13.02 to -0.20)	0.043	-4.23 (-11.85 to 3.40)	0.27
Mean difference, Coef. (95% CI) [3]	-5.25 (-10.18 to -0.33)	0.037	-6.10 (-12.24 to 0.04)	0.052	-4.23 (-11.69 to 3.24)	0.27
Quality of life Utility (EQ-5D-5L)		0.84 0.76	-6.88 (+17.55 to 3.80) -6.61 (+13.02 to -0.20) -6.40 (-12.24 to 0.04) -0.02 (0.25) -0.02 (0.23)			
Six-month follow-up		SIF				
Comparison, mean (SD)	0.03 (0.28)	YI E II VI	-0.02 (0.25)		0.09 (0.29)	
Intervention, mean (SD)	0.02 (0.30)	NO PK	-0.02 (0.23)		0.06 (0.34)	
Mean difference, Coef. (95% CI) [1]	0.02 (0.30) -0.01 (-0.07 to 0.05)	0.84	0.01 (-0.06 to 0.08)	0.74	-0.02 (-0.11 to 0.07)	0.62
Mean difference, Coef. (95% CI) [2]		0.76	0.02 (-0.04 to 0.07)	0.57	-0.03 (-0.10 to 0.04)	0.35
Mean difference, Coef. (95% CI) [3]	-0.01 (-0.05 to 0.04)	0.76	0.02 (-0.04 to 0.07)	0.56	-0.03 (-0.10 to 0.04)	0.35
12-month follow-up	THIS HE BY					
Comparison, mean (SD)	0.06 (0.31)		0.03 (0.26)		0.09 (0.34)	
Intervention, mean (SD)	0.03 (0.34)		-0.01 (0.24)		0.07 (0.41)	
Mean difference, Coef. (95% CI) [1]	-0.03 (-0.10 to 0.04)	0.44	-0.04 (-0.12 to 0.05)	0.37	-0.02 (-0.14 to 0.11)	0.78
Mean difference, Coef. (95% CI) [2]	-0.02 (-0.07 to 0.03)	0.36	-0.03 (-0.08 to 0.02)	0.28	-0.02 (-0.10 to 0.06)	0.64
Mean difference, Coef. (95% CI) [3]	-0.02 (-0.07 to 0.03)	0.45	-0.03 (-0.08 to 0.02)	0.27	-0.01 (-0.09 to 0.06)	0.73
18-month follow-up						
Comparison, mean (SD)	0.04 (0.31)		0.02 (0.23)		0.07 (0.36)	
Intervention, mean (SD)	-0.01 (0.36)		-0.04 (0.25)		0.03 (0.43)	

	All participants	P-value	Minimal/mild prognostic group	P-value	Severe prognostic group	P-value
Mean difference, Coef. (95% CI) [1]	-0.05 (-0.14 to 0.04)	0.29	-0.06 (-0.15 to 0.03)	0.19	-0.04 (-0.18 to 0.11)	0.64
Mean difference, Coef. (95% CI) [2]	-0.05 (-0.11 to -0.00)	0.047	-0.04 (-0.09 to 0.02)	0.19	-0.07 (-0.16 to 0.02)	0.11
Mean difference, Coef. (95% CI) [3]	-0.05 (-0.11 to -0.00)	0.049	-0.04 (-0.09 to 0.02)	0.19	-0.07 (-0.16 to 0.01)	0.10
Days out of role (K10+)						
Six-month follow-up			LR.			
Comparison, mean (SD)	9.92 (10.56)		6.13 (9.34)		13.46 (10.38)	
Intervention, mean (SD)	9.91 (10.52)		5.67 (8:29)		14.08 (10.79)	
Relative risk, RR (95% CI) [5]	1.01 (0.77 to 1.33)	0.94	0.99 (0.60 to 1.63)	0.96	1.05 (0.78 to 1.39)	0.76
Relative risk, RR (95% CI) [6]	0.99 (0.74 to 1.33)	0.95	0.94 (0.53 to 1.67)	0.84	1.05 (0.77 to 1.42)	0.76
Relative risk, RR (95% CI) [7]	1.02 (0.96 to 1.09)	0.55	0.88 (0.77 to 1.01)	0.062	1.07 (0.99 to 1.16)	0.082
12-month follow-up		H 0.93	NA CHI			
Comparison, mean (SD)	9.88 (10.70)		5.71 (8.62)		13.78 (10.94)	
Intervention, mean (SD)	9.32 (10.06)	SIF	5.56 (8.20)		13.03 (10.33)	
Relative risk, RR (95% CI) [5]	0.99 (0.73 to 1.34) 🔏	0.93 0.78	1.07 (0.59 to 1.94)	0.83	0.94 (0.71 to 1.26)	0.69
Relative risk, RR (95% CI) [6]	1.05 (0.76 to 1.43)	0.78	1.30 (0.68 to 2.51)	0.43	0.92 (0.67 to 1.27)	0.63
Relative risk, RR (95% CI) [7]	0.99 (0.92 to 1.06)	0.78	1.02 (0.87 to 1.18)	0.85	0.94 (0.87 to 1.03)	0.17
18-month follow-up		<b>(</b> , \				
Comparison, mean (SD)	9.16 (10.30)	•	5.12 (8.49)		12.94 (10.36)	
Intervention, mean (SD)	9.32 (10.67)		5.27 (8.46)		13.31 (11.07)	
Relative risk, RR (95% CI) [5]	1.06 (0.76 to 1.49)	0.72	1.11 (0.56 to 2.20)	0.77	1.04 (0.74 to 1.45)	0.84
Relative risk, RR (95% CI) [6]	1.15 (0.81 to 1.62)	0.44	1.35 (0.66 to 2.77)	0.41	1.04 (0.73 to 1.47)	0.83
Relative risk, RR (95% CI) [7]	1.07 (0.99 to 1.16)	0.074	1.07 (0.91 to 1.27)	0.42	1.03 (0.94 to 1.12)	0.54

Notes: SD - Standard Deviation; Coef. - Estimated coefficient; RR. - Rate ratio; CI - Confidence Interval. [1] Mean for intervention arm minus mean for control arm estimated using linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [2] Sensitivity analysis using complete cases only with linear regression adjusted for baseline outcome measure (all models) and prognostic group (model with all participants only). [3] Same as 2 but adjusted for general practice treated as random intercept. [4] Mean difference from 1 calculated relative to the pooled SD of baseline scores.[5] Rate ratio estimated using negative binomial regression adjusted for baseline days out of role (all models) and prognostic group (model with all participants only). Estimated using multiple imputation. [6] Sensitivity analysis using complete cases only with negative binomial regression adjusted for baseline days out of role (all models) and prognostic group (model with all participants only). [7] Same as 6 but adjusted for general practice treated as random intercept.

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**Figure A12-2.** 6-, 12- and 18-month psychological distress outcomes for the sub-sample of 527 participants recruited before 30 April 2018, for all eligible participants and eligible minimal/mild and severe prognostic groups



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# Appendix 13. Implementation case study

As part of the process evaluation, we conducted whole of practice meetings with GPs and/or staff in one PHN region. These meetings formed a case study of implementation which is presented in Box A13-1.

Box A13-1. Implementation case study

### An implementation case study of Link-Me

General practice staff were positive about the Link-me model despite some early teething issues around streamlining the recruitment of patients in the waiting room. GPs reported that the Decision Support Tool could be an important practice resource in the longer term. However, they noted that not all of the practice population were comfortable with the use of technology. They also noted the need to attend to privacy concerns and to provide adequate time for patients to complete the DST before an appointment.

There was overall support for the role of the care navigator within the practice. Practice staff and GPs reported that care navigators added value to usual care. GPs reinforced the importance of the 'clinical companion' concept of the care navigation model and the value of care navigator checking in with the GP about patient care and appropriate referrals. Some GPs commented that whilst the care navigation process did not necessarily identify issues that the GP was unaware of, the care navigator often found new services in the local community which were beneficial for the patient. Some patients expressed confusion as to whether the care navigator was a counsellor or psychologist.

GPs welcomed the idea of the structured action plan and detailed notes provided by care navigator following patient appointments. GPs found these action plans helpful and said that they used them to ensure continuity of care once the appointments with the care navigator ended. GPs considered that the time-limited nature of the model and the limits to available care package funding helped the care navigators to set achievable goals. The GPs also noted that the care navigator often played an important role supporting patients who were waiting for specialist mental health care, which was a common problem for the practice in this region. Overall GPs reported positive benefits of the support package funding.

There was agreement that the skill set, training and personality of care navigators were all equally important for fitting into practice culture and for engaging with patients. GPs agreed that care navigators must be 'mental health sympathetic' but they did not necessarily need to have a mental health qualification (e.g., psychologist or counsellor). They reinforced the idea that a care navigator was not there to provide therapy or treatment. From a practice perspective, the main skill of the care navigator was around 'tapping into' local support services, providing tailored web or app information, and identifying activities to meet physical or social needs. Navigating the health and social systems where GPs may not have the time is what was particularly valued.

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# Appendix 14. Process evaluation – characteristics of participants interviewed

To inform the process evaluation, interviews were conducted with a subset of participants in the minimal/mild and severe prognostic groups randomised to the intervention arms. Approximately equal numbers of participants were interviewed across all three PHNs in the minimal/mild and severe prognostic groups within the intervention arm. Interviews with participants in the minimal/mild prognostic group ranged from four minutes to 35 minutes and for the severe prognostic group the range was between 20 and 40 minutes. Table A14-1 provides an overview of the characteristics of the participants interviewed by prognostic group.

**Table A14-1.** Characteristics of interviewees for the process evaluation by intervention arm and by prognostic group

Interview length (minutes)  Days since randomisation  Age (years)  Importance of making a change in priority areas  Confidence in making a change in priority areas  # care navigation appointments attended	Minimal/mild prognostic group (N = 32)	Severe prognostic group (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	7.4 (2.3)	5.5 (2.8)
# care navigation appointments attended	n/a	6.5 (2.2)
THISTIE BY	n (%)	n (%)
PHN		
A	10 (32)	10 (31)
В	11 (36)	12 (38)
С	10 (32)	10 (31)
Approved for care package funding	n/a	25 (78)
Gender (female)	23 (74)	24 (75)
	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)

	Minimal/mild prognostic group (N = 32)	Severe prognostic group (N = 31)
Bachelor degree	10 (32)	4 (13)
Graduate diploma / certificate	2 (7)	0 (0)
Postgraduate degree	5 (16)	1 (3)
Current employment	3 (10)	1 (5)
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	15 (42)	14 (44)
Caring for ill or disabled person	0 (0)	1 (3)
Caring for children	2 (7)	0 (0)
Home duties	1 (3)	3 (9)
	2	
Studying Unable to work due to own illness, injury, or disability Lives alone Managing on available income Easily / not too bad / difficult some of the time Difficult all of the time / impossible Holds a health care card Takes medication for mental health Reason for GP visit Mental health and wellbeing Physical health Both physical and mental health None of these Chronic illness	7 (23)	1 (3)
	7 10x861	- (o/)
Charling	n (%)	n (%)
Studying	EPS POLICE	3 (9)
Unable to work due to own lilness, injury, or disability	4(8)	6 (19)
Lives alone	(26)	6 (19)
Wanaging on available income	24 (400)	25 (04)
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 nealth		
Excellent / very good / good	26 (84)	11 (34)
Fair / poor	5 (16)	21 (66)
Priority areas		
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	1 (3)	3 (10)
Concentration	1 (3)	2 (6)

	Minimal/mild prognostic group (N = 32)	Severe prognostic group (N = 31)
Interest or pleasure in doing things	6 (19)	2 (6)
Thoughts of self-harm or death	0 (0)	1 (3)

**Notes**: n = count; PHN, Primary Health Network; SD = Standard deviation. Priority areas are not mutually exclusive as participants were assigned or able to select up to two priorities each.



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### Appendix 15. Participant journeys

In Figure A15-1 through Figure A15-3, three typical participant journeys are illustrated to provide a detailed overview of the care navigation model as implemented for participants in the severe prognostic group. These three participant journeys were compiled from reviewing interview data (where available), care navigator notes, scores from the structured assessment that care navigators conducted using the K10 and documented handover summaries provided to GPs at the conclusion of care navigation. These journeys show the typical supports offered by care navigators to support participants to set and achieve their goals, the referrals and service linkages that were made, information provided by care navigators to mental health support programs online and via apps, local community groups for exercise and well-being, and they highlight how participants experienced the model of care.

The participants and their journeys are presented, followed by a discussion of the key elements of care navigation and a summary of the implementation lessons that can be observed from these three journeys. Our three anonymised participants for these journeys are Sally who was 20 years old at the time of the trial, Glenda 31 years old and Peter 36 years old.

### Sally:

Sally identified energy and anxiety as her priority areas. Sally participated in five care navigation contacts during which her care navigator provided information about online programs (e.g. e-couch) and arranged referral to a bulk billing psychologist. Sally's care navigation experience was negatively impacted by the resignation of her care navigator which caused a three-month lag between the first and second structured contact. The second care navigator found it difficult to engage with Sally initially, but this improved over time and Sally's K10 score went from 28 (likely to have a moderate mental disorder) at the start of Link-me to 15 (likely to be well) at her fifth final structured contact, a reduction of 13 points over the 8-9 month timeframe from the completion of the DST in the waiting room to the care navigator handover back to the GP.

#### Glenda:

Glenda also received five care navigation contacts. At the start of care navigation, Glenda was seeking an assessment from a specialist personality disorder service. Her care navigator supported Glenda to attend appointments with this service and attended joint meeting with her GP to discuss the report they ultimately provided. The care navigator researched separate web information and supports for Glenda and secured care package funding for a psychologist specialising in dialectical behaviour therapy (DBT) including getting Glenda to use the diary function on her phone to manage appointments. Glenda commented that she would not have gotten her diagnosis and be receiving therapy without the assistance of her care navigator. Glenda's K10 score was 40 (likely to have a severe mental disorder) when she completed the DST and 33 at her last appointment with the care navigator (still likely to have a severe mental disorder). This was a 7-point reduction in Glenda's symptoms over a 5-6 month engagement period and while Glenda's symptoms indicated that she was still likely to be experiencing severity of symptoms, she experienced a decrease that is important for her self-management and sense of self.

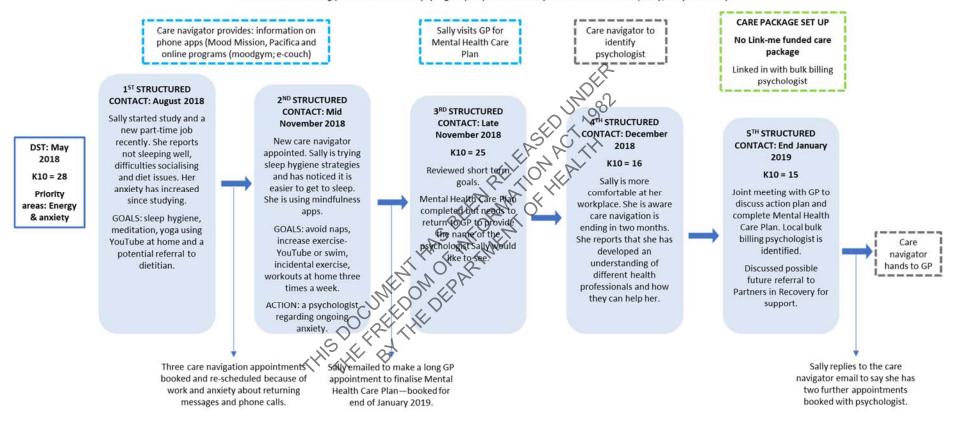
#### Peter:

In contrast to Sally and Glenda, Peter had physical pain that impacted on his ability to work. His journey of care navigation involved nine 9 structured contacts. Peter was unable to work after a motor vehicle accident and was estranged from his family. His initial goals were to work with a psychologist, pain specialist, and have a sleep assessment. His care navigator organised care package funding to support psychologist visits and helped Peter identify activities to improve his pain and sleep. This included Qigong (for which care package funding was arranged) and, using mindfulness techniques with a mobile phone app to support this, and playing guitar for relaxation. Peter experienced a relationship breakdown during his time in care navigation and his usual GP went on leave causing him disruption. His care navigator supported him to bring psychologist appointments forward and identify an alternative GP to ensure so that he was well supported during this difficult time. Peter's K10 score was 43 at commencement of the trial and 45 on completion indicating the likelihood of having a severe mental disorder.



Figure A15-1. Sally's journey through care navigation

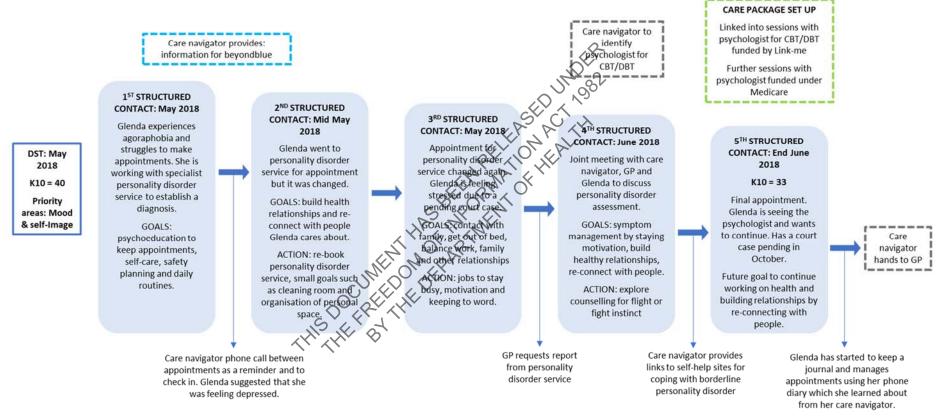
"I get very anxious with phone calls and calling people myself, so it was a bit of a struggle for me to ring the care navigator back to get the ball rolling. I did not realise the issues that I have with answering phone calls and replying to people...that they were not normal" (Sally, 20 years old)



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Figure A15-2. Glenda's journey through care navigation

"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)

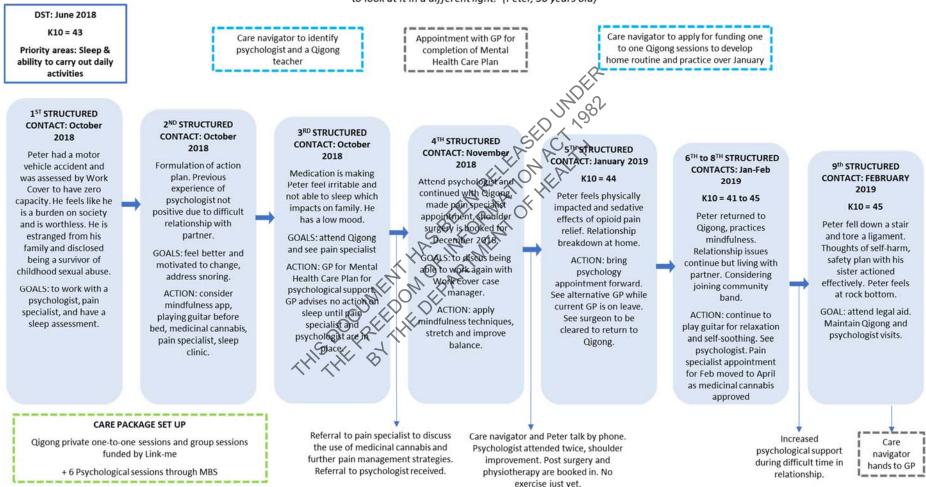


Notes: CBT = Cognitive behavioural therapy; DBT = Dialectical behaviour therapy

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Figure A15-3. Peter's journey through care navigation

"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)



These three participant journeys illustrate how care navigation provided people with care pathways and management options that led to symptom reduction in some people's K10 scores, but not for others. Overall, the participant journeys help to highlight the different components of care navigation that are essential to the delivery and implementation of the model, these are shown in the following three implementation lessons drawn from the participant journeys.

Implementation lesson #1: Sally's case shows the importance of continuity of the care navigator and how this is critical for participant experiences. A lack of continuity can impact on people engaging in clinical care particularly in the early stages, this makes it important to consider early engagement strategies for successful implementation. From an individual case study perspective, Sally experienced a substantive shift from being moderate in her symptoms to likely to be well in five appointments. She was provided with strategies for self-management at home such as increasing her exercise and at the time of care navigation finishing, was connected with the psychologist, and her GP had all of her information from Link-me. Here, it is possible to note that dialogue and affirmation are essential components of successful care navigation experiences.

Implementation lesson #2: from Glenda's journey it is possible to see that care navigators provided information to participants about self-help services, by either looking up websites or relevant apps and other self-management support tools readily available for the person to access from home. In Glenda's example, care navigation taught her the skills to use a diary for self-management of appointments which was initially causing her stress, it gave her the plan of action which provided opportunities for insight and reflection. This illustrates that small changes can sometimes make a big difference in the ability of individuals to self-manage their symptoms even for when they are likely to be severe. Having a central and focused plan of action is essential in the implementation of care navigation.

Implementation lesson #3: Peter's journey highlights a bridging role that care navigators can play in participant's lives. In a time of disruption and uncertainty, the care navigator was able to provide support to Peter to ensure that he accessed psychological services earlier when he was starting to experience symptom exacerbation. Peter's story also shows that care navigators need to have a broad skill-set that can meet the bio-psycho-social needs of individuals. In this instance Peter required support for surgery, for intense pain, and he needed to be referred to mindfulness and Qigong from which he benefitted. Peter's journey really shows the importance of the action plan outlining self-management strategies as he expresses, similar to Glenda and Sally, more self-responsibility and self-confidence as a result.

### **Appendix 16. Costing methods**

### **Costing other resource use**

The resource use questionnaire completed as part of the six-month and 12-month follow-up surveys 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 A16-1. 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 [89]. 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 participant out of pocket costs for covered medications [96]. Online Australian retail pharmacy sites were accessed to determine participant 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. The cost of an ambulance call was based on a national average cost [91]. 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 Australian Institute of Health and Welfare 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 Australian Institute of Health and Welfare's total health price index.

Table A16-1. Unit cost sources

Resource	Source of unit costs
GP, practice nurse, mental health nurse, psychiatrist and psychologist	
Consulting rooms or private practice	MBS item reports
Other locations	National Hospital Cost Data Collection
Allied and other health professionals	
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
Palliative care and Drug and Alcohol workers Disability support officer Kinesiology, Counselling Massage, Personal trainer, and Yoga Helpline, Hypnotherapist, Naturopath Dentists Other healthcare resources Ambulance  Emergency department Hospital and residential care unit admission Specialist/community based units  Medications PBS listed drugs	National Mental Health Report (Department of Health)
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
Notes: MDC - Medicare Denefits Cabadula, DDC - Dearmacout	

**Notes**: 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 [92]. 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 [93].

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 lost 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.

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### Appendix 17. Link-me dissemination

Throughout the duration of the Link-me trial, presentations and brief updates were delivered to key stakeholders, trial sites, participants and at national and international forums. A brief overview is given below:

April 2017 - Mar 2019	Link-me e-newsletter for PHNs and participating GP practices [via email]
- <u>-</u>	First Wednesday of every month – newsletters sent to lead site PHNs via CEO,
	Regional Trial Coordinators, Care Navigators, who were asked to forward to
	participating GP practices across their PHN.
Aug 2018	Conference Presentation [Oral]
	Fletcher S, Pirkis J, Chondros C, Wood A, Palmer V, Mihalopoulos C, Harris M,
	Burgess P, Spittal M, Bassilios B & Gunn J. 2018. Link-me: Testing a systematic
	approach to stepped care in PHN Lead Sites, PHCRIS, Primary Health Care
	Research Conference. Melbourne Australia; 1-3 Aug 2018.
N 2010	Conference Decembering [Decta 6]
Nov 2018	Conference Presentation [Poster
	Fletcher S, Chondros C, Wood A, Palmer V, Mihalopoulos C, Harris M, Burgess P,
	Spittal M, Bassilios B, Pirks J, & Gunn J. 2018. Link-me: Protocol for a randomised controlled trial of a systematic approach to stepped mental health
	care in Primary Health Network Lead Sites. North American Primary Care
	Research Group (NAPCRG) Annual Meeting. Chicago USA; 9-13 Nov 2018.
	HILL III TANK
Dec 2018	Individual general practice site recruitment progress updates [Flyer]
	A 1-page flyer provided to all participating general practices as part of ongoing
	engagement. Flyer provided a summary table of the number of general practice
.5	attendees screened in their waiting room and the number of participants
ZHIZY	recruited from their practice, as well as a brief summary of next steps in the
	trial.
Mar 2019	Workshop Presentation [Oral]
	Pirkis J, Gunn J. 2019. Evaluation of the PHN Lead Site Project: a focus on
	consumers. National PHN Mental Health Stepped Care Workshop, Melbourne
	Australia; 6-7 March 2019.
Mar 2019	Trial site brief report [Flyer]
	Preliminary Trial Update sent to all 23 participating practices as part of ongoing
	engagement with the trial. 15 March 2019
Aug 2019	Site reports [brief reports]
	Individual site reports sent to all 23 practices presenting the 'A screening report
	from the 2017-2018 Link-me GP waiting room screening survey'. 3 August 2019.
	This presented the overall screening processes within respective practices and
	incorporated a RACGP QI&CPD General Practice Activity for GPs to complete for
	L.I. 2017 2010 I

the 2017-2019 triennium.

#### Aug 2019

Link-me e-newsletter for participants [via email]

Participants received a newsletter as part of ongoing engagement with the study.

#### Nov 2019

Presentation [Oral]

Gunn J. 2019. Link-me: A systematic approach to stepped mental health care in primary care. Million Minds Forum. Nov 2019.

#### July 2020

Conference Presentation [Abstracts for oral presentations submitted] – Cancelled due to COVID-19 pandemic

(Submitted abstract title) Fletcher S, Spittal M, Chondros P, Palmer V, Chatterton ML, Bassilios B, Harris M, Burgess P, Mihalopoulos C, Pirkis J, Gunn J. 2020. The Link-me pragmatic randomised controlled trial: Can a patient-completed decision support tool improve mental health outcomes in primary care? Society for Academic Primary Care Annual Scientific Meeting. Leeds UK. 15-17 July 2020.

(Submitted abstract title) Chatterton ML, Mihalopoulos C, Faller J, Fletcher S, Spittal M, Harris M, Burgess P, Chondros P, Palmer V, Bassilios B, Pirkis J, Gunn J. 2020. Trial based cost-effectiveness evaluation of Link-me: A systematic approach to stepped mental health care in primary care. Society for Academic Primary Care Annual Scientific Meeting. Leeds UK. 15-17 July 2020.

(Submitted abstract title) Paimer V, Fletcher S, Spittal M, Chondros P, Chatterton ML, Bassilios B, Harris M, Burgess P, Mihalopoulos C, Pirkis J, Gunn J. 2020. The development of a patient-reported experiential model of care navigation for complex mental health needs in primary care: Process evaluation findings from Link-me. Society for Academic Primary Care Annual Scientific Meeting, Leeds UK. 15-17 July 2020.

### **Appendix 18. 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 inform	ation Start date	End date
Engaged general practices		ER ROLL		
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	AT HAS INTERNET	A OF HEAD		
Promote the role of care navigators as a conduit between the practice as an incentive to practice engagement	OCHNELOW PEDE			
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 general practice attendees	THIS HE BY			
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				

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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		Q-		
Skilled care navigator workforce		JDE.		
Recruit health professionals with a skill set aligned to the position description		FD 7 981		
Ensure all care navigators receive training in the Link-me motivational interviewing-inspired approach from accredited trainers, and access to up-to-date resources and support	THIS DOCUMENT HAS INTERNATIONAL BY THE BYTHE BY THE	SACTIVE SERVICE SERVIC		
Foster a sense of professional belonging amongst care navigators	IT HAS INTENTED			
Secure web platform	IET MI PA			
Ensure platform updates are communicated to users in a timely manner, and that users receive additional training as required	SO FRETHER			
Ensure all users are operating correct version of platform and related materials	THILTHE A.			
Ensure interoperability with existing IT infrastructure, and advise of any incompatibilities				
Monitor participant, care navigator, and site numbers to enable sufficient hosting and user support				

Roles / responsibilities	Additional information	Start date	End date
	IDER .		
	ED JAOSE		
BEENRING	KHE		
THASINITATE			
OCHNETON DEPA			
	J. RELEA	Roles / responsibilities Additional information  Additional information  Additional information	ARELIA OF HEALTH

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# Appendix 19. 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 participants 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 general practice attendees and develop a structured management plan in collaboration with participants and their GP. Your role is to help participants 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 participants. In addition, you will maintain close links with the RHN 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, participants 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 general practice attendees in waiting rooms to take part and assist with responding to enquiries about Link-me;
- Contact participants allocated to receive care navigation, introduce the approach and schedule an appointment to meet the participant in the general practice;
- Conduct up to eight structured contacts with participants, adhering to protocol, to develop and implement a structured care plan;
- Navigate available services, link participants 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 participants' 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.