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Interventions to integrate care for people with serious mental illness and substance use disorders: A scoping review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-031122
Article Type:	Protocol
Date Submitted by the Author:	17-Apr-2019
Complete List of Authors:	Richardson, Amy; University of Otago, Preventive and Social Medicine Richard, Lauralie; University of Otago, General Practice & Rural Health, Dunedin School of Medicine Gunter, Kathryn Derrett, Sarah; University of Otago
Keywords:	Delivery of Health Care, Integrated, Interventions, Review, Severe Mental Disorders, Substance-Related Disorders

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Interventions to integrate care for people with serious mental illness and substance use disorders: A scoping review protocol

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Abstract

Introduction: People with serious mental illness (SMI) and/or substance use disorders (SUDs) have an elevated risk of premature mortality compared to the general population. This has been attributed to higher rates of chronic illness among these individuals, but also to inequities in healthcare access and treatment. Integrated care has the potential to improve the health of people with SMI/SUDs. The aims of this scoping review are to: 1) identify empirical investigations of interventions designed to integrate care for people with SMI/SUDs, 2) describe the underlying theories, models, and frameworks of integrated care that informed their development, and 3) determine the degree to which interventions address dimensions of a comprehensive and validated framework of integrated care.

Methods and analysis: Guidelines for best practice and reporting of scoping reviews will be followed using the framework of Arksey and O'Malley and the PRISMA-ScR checklist. An iterative and systematic search of peer-reviewed publications reporting empirical research findings will be conducted. This literature will be identified by searching five databases: Medline (Ovid), PsycINFO, CINAHL, Embase (Ovid), and Scopus. Two reviewers will independently screen publications in two successive stages of title and abstract screening, followed by full text screening of eligible publications. A tabular summary and narrative synthesis will be completed using data extracted from each included study. A directed content analysis will also be conducted, with descriptions of interventions mapped against a theoretical framework of integrated care.

Ethics and dissemination: This review will identify the extent and nature of empirical investigations evaluating interventions to integrate care for people with SMI/SUDs. A team of relevant stakeholders, including people with lived experience of mental health conditions, has been established. This team will be engaged throughout the review and will ensure that the findings are widely disseminated.

The review protocol has been registered through Open Science Framework and can be accessed at:

<https://osf.io/njkph/>

Keywords: Delivery of Health Care, Integrated; Interventions; Review; Severe Mental Disorders; Substance-Related Disorders

Article Summary

Strengths and limitations of this study

- This systematic scoping review will identify the extent and nature of empirical investigations evaluating interventions to integrate care for people with serious mental illness (SMI) and/or substance use disorders (SUDs)
- The review will reveal which aspects of integrated care have been targeted in interventions to date and highlight potential opportunities for future research
- A comprehensive team of relevant stakeholders, including people with lived experience of mental health conditions, mental health professionals, other health professionals, and researchers from a range of disciplines, will be involved in all stages of the review process
- The scoping review search strategy has been informed by the stakeholder team as well as an experienced health sciences librarian to ensure the capture of relevant empirical literature

Background

Serious mental illness (SMI; also referred to as severe and enduring mental illness or SEMI) includes a range of conditions, such as major depression, bipolar disorder, and schizophrenia.(1, 2) These conditions are associated with debilitating symptoms that require ongoing treatment or management. People with SMI have a significantly reduced life expectancy and are at risk of poor health outcomes relative to those in the general population.(3) In New Zealand, men and women using mental health services have more than twice the risk of experiencing premature mortality than the general population.(4) This is similar to the United Kingdom (UK), where a recent study of a nationally representative cohort of people with bipolar disorder and schizophrenia found that the rate of all-cause mortality was 1.77 times greater among individuals with bipolar disorder and 2.08 times greater for individuals with schizophrenia.(5) The UK study also found that these disparities in mortality had increased significantly from the year 2000 to 2014.(5)

Evidence suggests that people with substance use disorders (SUDs) are also at increased risk of mortality compared to the general population. These disorders reflect the pattern of symptoms that result from prolonged use of illicit or legal drugs, including alcohol and medicines, despite mental or physical problems associated with their use.(6) The reduced life expectancy associated with SUDs is estimated to be 13.8 years, higher than the 6.3 year reduction associated with depression and the 7.2 year reduction associated with schizophrenia.(7) Of particular concern is the high prevalence of co-occurring SMI and SUDs.(8) A systematic review of studies conducted in the UK found the prevalence of co-occurring SMI and SUDs to be between 0.05-0.16% in the general population.(9) In contrast, current harmful drug use or dependence among people with SMI was 1.9-7.0%, and current harmful alcohol use or dependence was 7.0-15.5%.(9)

The lower average life expectancy evident among people with SMI/SUDs is largely attributable to an increased risk of a number of chronic health conditions.(10) Cardiovascular diseases have been identified as the most common cause of death in the SMI population,(11) far exceeding the number of deaths due to suicide.(12) Metabolic syndrome has been found to affect as many as 1 in 3 people with SMI,(13) and type 2 diabetes occurs at almost twice the rate among people with SMI than the general population.(14) While the incidence of cancer is no greater in people with SMI than in the general population, these individuals are more likely to have metastases at diagnosis, and are less likely to receive specialist cancer treatment resulting in higher cancer mortality rates.(15, 16) Similarly, after adjusting for age and gender, people with SUDs have been identified as at increased risk of diabetes, heart disease, asthma, gastrointestinal disorders, skin infections, malignant neoplasms, and acute respiratory disorders.(17) However, risk of these disorders is substantially

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3 greater for individuals with comorbid SMI and SUDs, particularly individuals with psychosis.(17)

4 There is growing acknowledgement that people with these comorbid conditions experience the
5 worst health, wellbeing, and social outcomes, and are among the most disadvantaged and
6 vulnerable in society.(9)

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10 A number of factors have been found to contribute to the high prevalence of chronic health
11 conditions which, in turn, contribute to reduced life expectancy among people with SMI/SUDs.
12 These include socioeconomic disadvantage,(18) obesity and poor nutrition,(19) reduced physical
13 activity,(20, 21) side-effects of anti-psychotic medication,(10) elevated consumption of alcohol and
14 illicit drugs,(22) and high rates of smoking.(23, 24) However, there is increasing evidence that the
15 poor health outcomes among people with SMI/SUDs are also a result of inequities in the provision of
16 healthcare.(25, 26) In addition, difficulties with access to healthcare or routine screening among
17 people with SMI/SUDs have been identified.(27) Even when healthcare is accessed, these individuals
18 have been found to receive poorer quality care, as well as higher rates of misdiagnosis, and lower
19 rates of specialist interventions that could prevent the progression of a number of diseases,(10, 28)
20 compared to people without SMI/SUDs.

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30 One strategy to address inequities in healthcare access and treatment for people with SMI/SUDs is
31 the integration of healthcare and social services. Integration of care is increasingly recognised as the
32 most appropriate method for delivering care to people with multiple, complex chronic conditions,
33 and has been found to be associated with significant improvements in condition-specific quality of
34 life.(29) However, a consensus on the concept of integrated care is yet to be reached, presenting
35 difficulties for meaningful evaluation of integrated care approaches.(30, 31) Some definitions are
36 process oriented, some (albeit few) are person-centred, and others are health service oriented.(32)
37 In an effort to provide a comprehensive concept of integrated care, Singer et al. developed an
38 integrated care framework that emphasises the importance of both care-coordination and person-
39 centred care, acknowledging the central role of service users/patients and their families in the
40 management of their own health.(33) They describe integrated care as: “patient care that is
41 coordinated across professionals, facilities, and support systems; continuous over time and between
42 visits; tailored to the patients’ needs and preferences; and based on shared responsibility between
43 patient and caregivers for optimising health” (p. 113).(33) Because of the varied definitions of
44 integrated care, it is important to understand the underlying theories, models, or frameworks of
45 integrated care that are being used to inform empirical research in this area.

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57 In the mental health context, a number of strategies to integrate care have been investigated.(34,
58 35) Examples of intervention strategies include the co-location of mental and physical health
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3 services within a single setting,(36-38) collaborative care meetings between general practitioners
4 and mental health professionals,(39) and the appointment of case managers to liaise between
5 services and coordinate the overall care of individuals with SMI.(40, 41) Interventions for people
6 with co-occurring mental and addictive disorders have also been explored, such as on-site medical
7 consultations, team-based approaches, and facilitated referrals to primary care.(26) Despite
8 substantial research in this area, the number and types of integrated care interventions that have
9 been investigated empirically among each population is unknown. It is also unclear which outcomes
10 have been examined in evaluations of interventions aiming to integrate care (for example, whether
11 the goal has been to increase contact with healthcare professionals or to improve the physical
12 health of mental health/addiction service users). Most importantly, the types of integrated care
13 interventions that have produced positive changes in outcomes for people with SMI/SUDs are yet to
14 be identified, in addition to the underlying theoretical models on which these interventions have
15 been based.

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17 These gaps in evidence suggest that a scoping of the literature could help to identify the
18 characteristics of interventions that have successfully integrated care for people with SMI/SUDs to
19 date. While these individuals represent groups with distinct diagnoses, the symptom burden
20 associated with the diagnoses is highly similar,(42) and they frequently co-occur.(43) Both groups
21 also face barriers to receiving integrated care that could lead to more timely and effective treatment
22 of physical health conditions.(44)

23
24 Scoping reviews are recommended to examine the extent, range, and nature of the evidence
25 relating to a topic, providing an opportunity to clarify concepts, identify knowledge gaps, and inform
26 future research, practice, and policymaking.(45, 46) We anticipate that interventions and strategies
27 addressing key components of a widely-recognised framework for the delivery of integrated care(33)
28 will be associated with positive outcomes for people with SMI/SUDs, and for the providers delivering
29 the interventions. Given the significance of the inequities in the health and mortality for people with
30 SMI/SUDs, the wide-scale implementation of approaches that effectively integrate care is urgently
31 needed.

32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 **Objectives**

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53 The aims of the proposed scoping review are to: 1) systematically identify and describe empirical
54 investigations of interventions to integrate care for people with SMI/SUDs, 2) describe the
55 theories/models/frameworks of integrated care informing the empirical research, and 3) determine
56 the degree to which identified interventions address components of a comprehensive and validated
57 framework of integrated care.
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Methods

This scoping review will be conducted according to the methods developed by Arksey and O'Malley,(47) and the subsequent refinements to these methods.(48, 49) There are six steps including: 1) defining the research question/s, 2) identifying relevant studies, 3) study selection, 4) charting the data, 5) collating, summarising, and reporting the results, and 6) consultation. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines will be followed using the PRISMA extension for scoping reviews (PRISMA-ScR) checklist.(45) An iterative approach will be taken toward searching the literature, refining the search strategy, reviewing articles for inclusion, and extracting relevant data. The review protocol has been registered through Open Science Framework and can be accessed at: <https://osf.io/njkph/>.

Defining the Research Question

Research questions were formulated by considering the concept (integrated care), target population (people with SMI/SUDs), context (healthcare settings), and outcomes (empirically investigated outcomes) of interest in order to clarify the focus of the review and establish an effective search strategy. This scoping review intends to answer the following research questions:

- 1) What types of interventions have been designed to integrate care for people with SMI/SUDs across a broad range of healthcare settings?
- 2) What outcomes have studies examining interventions to integrate care for people with SMI/SUDs sought to modify?
- 3) Which intervention types have been associated with positive outcomes?
- 4) Which theories, models or frameworks of integrated care have been used to inform intervention development?
- 5) Which components of an existing comprehensive and validated framework of integrated care have been addressed by interventions to integrate care for people with SMI/SUDs?

Identifying Relevant Studies

Our search strategy was developed with the goal of undertaking a comprehensive review of the existing evidence base. An experienced subject librarian at the University of Otago has been consulted to assist with the identification of relevant search terms and databases. Search terms have also been reviewed by a team of relevant stakeholders, including people with lived experience of

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3 mental health conditions, mental health professionals, other health professionals, and researchers
4 from a range of disciplines.
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7 In order to identify empirical literature, an initial limited search of a selection of relevant databases
8 has been performed followed by a review of text words contained in the titles and abstracts, and of
9 index terms used to describe the articles. A second search will be conducted using all identified
10 keywords and index terms and will be undertaken across five databases: Medline (Ovid), PsycINFO,
11 CINAHL, Embase (Ovid), and Scopus. The reference lists of all included articles will be searched for
12 additional studies. The search will be restricted to articles and reports published in English. The
13 search strategy has been developed in Medline (Ovid) and will be adapted to other databases (see
14 Table 1). All searches will include a combination of subject headings, related terms, and key words.
15 Boolean logic and operators (i.e., 'and', 'or') will be used to combine and refine search terms and
16 concepts.
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19 *Study Selection*

20 All records retrieved from the searches will be exported to Endnote referencing database. Following
21 this, duplicate records will be removed, and the number of unique records identified.
22

23 A two-stage collaborative review process will select studies for inclusion. Screening of studies will be
24 piloted on the first 20 citations of the initial Medline (Ovid) search to test eligibility criteria and
25 reviewer agreement. Two reviewers (authors AR and LR) will independently apply eligibility criteria
26 during the initial title/abstract review. Titles and abstracts will be retained for full text review if they:
27 1) refer to an intervention to integrate care; 2) the intervention is for people with mental health
28 conditions, people with substance use problems, or health professionals responsible for their care;
29 and 3) the intervention is set in a health-oriented context. The full text of relevant studies will then
30 be obtained and independently assessed for eligibility by two reviewers (AR and LR). After each
31 review stage, the reviewer's agreement will be assessed and a third reviewer (SD) will be consulted
32 in cases of disagreement, until consensus is achieved.
33

34 Eligibility criteria for a full text academic article to be included have been developed a priori with the
35 assistance of the stakeholder team. This criteria is identified below in relation to participants,
36 interventions, outcomes, context, and study design.
37

38 i. Participants

39 Populations of interest will include: 1) adults with SMI/SUDs who have received an intervention
40 designed to integrate care or 2) health care professionals or associated staff (including unregistered
41 health workers, managers, and administrators; hereafter referred to collectively as 'health
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3 providers') who were involved in the delivery of an intervention to integrate care for people with
4 SMI/SUDs. In the present investigation, SMI is defined as mental illnesses (schizophrenia,
5 schizoaffective disorder, bipolar disorder, major depression, and other psychoses) that produce
6 severe and debilitating symptoms for 12 months or more.(2, 50) Following feedback from our
7 stakeholder group, and the widely recognised challenges associated with integrating care for people
8 with SUDs, the decision was made to also review interventions for this population. SUDs is defined
9 problems resulting from alcohol or other drug use for 12 months or more.(6) Despite facing many of
10 the same health and mortality burdens as people with SMI, as well as inequities in access to
11 appropriate care, this population is frequently overlooked in the development and evaluation of
12 clinically integrated service delivery approaches.(44)

20 ii. Interventions

21
22 Studies and reports describing interventions i.e. activities, programmes or strategies with the explicit
23 goal of integrating care for people with SMI/SUDs will be eligible for inclusion. This includes studies
24 endeavouring to integrate care both within and between organisations and services. Eligible
25 integrated care interventions can be very specific or can be implemented across a broad range of
26 domains i.e. funding, administrative, organisational, service delivery, and clinical domains.(51)

31 iii. Outcomes

32
33 No restrictions on the types of outcomes under investigation will be applied. Examples of potential
34 outcomes of interest are: patterns of healthcare utilisation, health behaviours, health outcomes, and
35 perceived satisfaction with an intervention (from service user and/or provider perspectives).

39 iv. Context

40
41 Studies and reports published between January 2000 and May 2019 will be eligible for inclusion. This
42 time period was selected to ensure identification of interventions likely to be relevant and applicable
43 to contemporary healthcare contexts. Interventions delivered in any healthcare settings will be
44 eligible, including primary care and community care settings, forensic settings, outpatient clinics,
45 acute care hospitals, and long-term care facilities.

51 v. Study Design

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53 Interventions that have been empirically evaluated using quantitative, qualitative, or mixed methods
54 designs will be eligible for inclusion. Quantitative studies will include randomised and non-
55 randomised controlled trials, as well as studies implementing before-after designs (with or without a
56 control group), and cross-sectional studies. Qualitative investigations of participants' perceptions or
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3 experiences of an intervention will also be considered, including (but not limited to) designs such as
4 qualitative description, phenomenology, grounded theory, ethnography, and action research.

6 7 *Data Extraction*

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9 Data will be extracted according to the recommendations of Arksey and O'Malley.⁽⁴⁷⁾ A
10 standardised extraction excel spreadsheet will be used to record: author(s), year of publication,
11 study location, intervention type (and any comparator), underlying theory of integrated care,
12 duration of the intervention, study population, aims of the study, methods, outcomes, and key
13 findings. Data extraction will be performed independently by two researchers (AR and KG), and
14 compared by a third researcher (SD). The third researcher will be consulted to resolve any
15 discrepancies in data extraction relating to each study. Possible additions/modifications to the data
16 extraction form may be made after review of the first five references in order to ensure that all
17 relevant information will be captured.

24 25 *Collating, Summarising and Reporting*

26
27 A two-step approach will be used to summarise the findings of included studies. Step one will
28 involve a narrative synthesis of the characteristics and findings of the studies (including tabular
29 and/or graphical summaries). Studies will be organised according to intervention type in order to
30 highlight the range of integrated care approaches for people with SMI/SUDs that have been
31 empirically evaluated. The underlying theory of integrated care associated with each included
32 intervention will also be described (where this information is available).

33
34 Step two will identify the degree to which interventions for people with SMI/SUDs have addressed
35 dimensions of integrated care as conceptualised by Singer et al.⁽³³⁾ A directed content analysis will
36 be conducted to review the included interventions, with coding and analysis directed by the
37 integrated care framework. Specifically, we are interested in qualitatively analysing the extent to
38 which each intervention description addresses the seven elements of integrated care: 1)
39 coordination within a care team; 2) coordination across care teams; 3) coordination between care
40 teams and community resources; 4) continuous familiarity with patients over time; 5) continuous
41 proactive and responsive action between visits; 6) service user-centred care; and 7) shared
42 responsibility.⁽³³⁾ To do so, descriptions of the interventions will be imported to an excel
43 spreadsheet and analysed by two authors (AR and LR); both researchers have previous experience
44 coding qualitative data. An a priori coding framework based on the seven elements of the integrated
45 care framework will be applied independently by the researchers. Results from these analyses will
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3 be summarised in order to highlight dimensions of integrated care that require further investigation
4 and implementation among people with SMI/SUDs.
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6 7 *Consultation Process*

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9 The aim of this review is to identify and describe empirical investigations of interventions to
10 integrate care for people with SMI/SUDs in order to highlight which interventions have been
11 associated with positive outcomes and which dimensions of integrated care have been targeted. This
12 information will have potential to inform both future research activity and clinical practice. In order
13 to ensure that findings of the review are of relevance to mental health and addiction service users,
14 and those who provide care to these individuals, we have engaged a stakeholder team as mentioned
15 above. Stakeholders have been involved in developing the research questions guiding this review
16 and have reviewed the search strategy to identify key terms that are relevant to the population,
17 concept, and contexts of interest presented in this protocol. Stakeholders will also be involved in
18 interpreting the review findings and will advise on dissemination.
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26 27 *Patient and Public Involvement*

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29 This scoping review protocol has engaged the expertise of individuals with lived experience of SMI.
30 These individuals have contributed to the development of the research questions, reviewed and
31 made suggestions to the proposed search terms, and will be extensively involved during the
32 interpretation and dissemination phases of this project.
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36 37 **Ethics and Dissemination**

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39 Although integrated care is increasingly recommended for people with SMI/SUDs, it is unclear what
40 elements of integrated care have been investigated in empirical evaluations of interventions
41 designed to improve outcomes for these populations. To our knowledge, our scoping review will be
42 the first to systematically describe the extent and nature of interventions to integrate care for
43 people with SMI and people with SUDs, including which outcomes these interventions have
44 endeavoured to modify and which have been successful in doing so. Therefore, the scoping review
45 findings are expected to be of interest to service users, researchers, clinicians, and policy makers.
46 Our dissemination strategy will include publication of the review in an open-access peer-reviewed
47 journal (i.e. available to service users, their families and the general public), and scientific
48 presentations of the findings at conferences and to staff working within a range of mental health
49 and addiction settings. All stakeholders will be involved in interpreting the review findings and
50 ensuring that these are widely disseminated through their respective networks – including to service
51 users. This will be facilitated by a half-day round-table meeting with our stakeholder group. During
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3 this meeting, findings of the review will be discussed and opportunities for future areas of research
4 and clinical practice work will be brainstormed. It is hoped that stakeholders' knowledge and
5 interpretations of the review findings will identify clear priorities for changes in the development
6 and delivery of integrated care.
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3 **Word count:** 3238
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5 **Acknowledgements:** We would like to acknowledge Christy Ballard, the subject librarian for the
6 Department of Preventive and Social Medicine at the University of Otago for her assistance with
7 developing a preliminary search strategy. We would also like to acknowledge the members of our
8 stakeholder group who helped to develop the research questions guiding the proposed review and
9 who also provided suggestions regarding additional relevant search terms. Stakeholder group
10 members include: Dr Emma Wyeth, Professor Tim Stokes, Ms Mel Green, Ms Adell Cox, Mr Martin
11 Burke, Mr Shaun McNeil, Dr Ruth Cunningham, Mrs Helen Lockett, and Dr Helen Hamer.
12
13

14 **Author Statement:** AR completed an initial draft of the review protocol. LR assisted with
15 development of the research questions and eligibility criteria. KG helped to develop the methods for
16 article screening and data extraction. SD led the conceptualisation of the review. All authors have
17 provided feedback on multiple iterations of the manuscript.
18
19

20 **Funding:** This research is funded by a University of Otago Research Grant (NZD \$34743).
21
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23 **Conflicts of Interests:** None declared.
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26 **Patient consent:** Not required.
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29 **Data Statement:** All relevant data is provided in the appendix of this manuscript.
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Appendix

Table 1. Medline (Ovid) Search Strategy

Line number	Search term entered into Ovid (Medline)	Results
1	intervention.mp.	464809
2	Program Evaluation/ or Evaluation Studies/ or evaluation.mp.	1404582
3	program.mp. or Programs/	411198
4	programme.mp	79501
5	<i>1 or 2 or 3 or 4</i>	2132570
6	Primary Health Care/ or "Delivery of Health Care, Integrated"/ or integrated care.mp.	83223
7	integrated services.mp.	516
8	integrated health.mp.	2604
9	integration of care.mp.	280
10	integration of services.mp.	294
11	integrating care.mp.	119
12	care integration.mp.	320
13	collaborative care.mp.	1681
14	Patient Care Team/ or coordinated care.mp.	63179
15	<i>6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14</i>	145318
16	(severe and enduring mental illness).mp.	48
17	serious mental illness.mp	2474
18	Mental Disorders/ or serious mental disorder.mp.	155387
19	serious psychiatric illness	53
20	serious psychiatric disorder	83
21	severe mental illness	3208
22	severe mental disorder	282
23	severe psychiatric illness	106
24	severe psychiatric disorder	159
25	Schizophrenia, Catatonic/ or Schizophrenia, Disorganized/ or Schizophrenia, Paranoid/ or schizophrenia.mp.	123422
26	Psychosis.mp. or Psychotic Disorders/	58808
27	bipolar disorder.mp. or Bipolar Disorder/	42908

28	Depressive Disorder, Major/ or major depression.mp.	39682
29	Substance-Related Disorders/	91316
30	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	434086
31	5 and 15 and 30	2979

Note: Run date = 17/04/2019

For peer review only

BMJ Open

Interventions to integrate care for people with serious mental illness and substance use disorders: A systematic scoping review protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-031122.R1
Article Type:	Protocol
Date Submitted by the Author:	26-Sep-2019
Complete List of Authors:	Richardson, Amy; University of Otago, Preventive and Social Medicine Richard, Lauralie; University of Otago, General Practice & Rural Health, Dunedin School of Medicine Gunter, Kathryn Derrett, Sarah; University of Otago
Primary Subject Heading:	Public health
Secondary Subject Heading:	Mental health, Addiction
Keywords:	Delivery of Health Care, Integrated, Interventions, Review, Severe Mental Disorders, Substance-Related Disorders

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Interventions to integrate care for people with serious mental illness and substance use disorders: A systematic scoping review protocol

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Abstract

Introduction: People with serious mental illness (SMI) and/or substance use disorders (SUDs) have an elevated risk of premature mortality compared to the general population. This has been attributed to higher rates of chronic illness among these individuals, but also to inequities in healthcare access and treatment. Integrated care has the potential to improve the health of people with SMI/SUDs. The aims of this scoping review are to: 1) identify empirical investigations of interventions designed to integrate care for people with SMI/SUDs, 2) describe the underlying theories, models, and frameworks of integrated care that informed their development, and 3) determine the degree to which interventions address dimensions of a comprehensive and validated framework of integrated care.

Methods and analysis: Guidelines for best practice and reporting of scoping reviews will be followed using the framework of Arksey and O'Malley and the PRISMA-ScR checklist. An iterative and systematic search of peer-reviewed publications reporting empirical research findings will be conducted. This literature will be identified by searching five databases: Medline (Ovid), PsycINFO, CINAHL, Embase (Ovid), and Scopus. The search will be restricted to articles published between January 2000 and April 2019. Two reviewers will independently screen publications in two successive stages of title and abstract screening, followed by full text screening of eligible publications. A tabular summary and narrative synthesis will be completed using data extracted from each included study. A framework synthesis will also be conducted, with descriptions of interventions mapped against a theoretical framework of integrated care.

Ethics and dissemination: This review will identify the extent and nature of empirical investigations evaluating interventions to integrate care for people with SMI/SUDs. Ethical approval was not required. A team of relevant stakeholders, including people with lived experience of mental health conditions, has been established. This team will be engaged throughout the review and will ensure that the findings are widely disseminated. Dissemination will include publication of the review in a peer-reviewed journal.

The review protocol has been registered through Open Science Framework and can be accessed at: <https://osf.io/njkph/>

Keywords: Delivery of Health Care, Integrated; Interventions; Review; Severe Mental Disorders; Substance-Related Disorders

Article Summary

Strengths and limitations of this study

- This systematic scoping review will identify the extent and nature of empirical investigations evaluating interventions to integrate care for people with serious mental illness (SMI) and/or substance use disorders (SUDs)
- The review will reveal which aspects of integrated care have been targeted in interventions to date and highlight potential opportunities for future research
- A comprehensive team of relevant stakeholders, including people with lived experience of mental health conditions, mental health professionals, other health professionals, and researchers from a range of disciplines, will be involved in all stages of the review process
- The review will be restricted to articles published in English and this may prevent a number of integrated care interventions from being detected
- No quality appraisal of included studies will be completed, precluding conclusions about the effectiveness of different integrated care approaches at improving outcomes

Background

Serious mental illness (SMI; also referred to as severe and enduring mental illness or SEMI) includes a range of conditions, such as major depression, bipolar disorder, and schizophrenia.(1, 2) These conditions are associated with debilitating symptoms that require ongoing treatment or management. People with SMI have a significantly reduced life expectancy and are at risk of poor health outcomes relative to those in the general population.(3) In New Zealand, men and women using mental health services have more than twice the risk of experiencing premature mortality than the general population.(4) This is similar to the United Kingdom (UK), where a recent study of a nationally representative cohort of people with bipolar disorder and schizophrenia found that the rate of all-cause mortality was 1.77 times greater among individuals with bipolar disorder and 2.08 times greater for individuals with schizophrenia.(5) The UK study also found that these disparities in mortality had increased significantly from the year 2000 to 2014.(5)

Evidence suggests that people with substance use disorders (SUDs) are also at increased risk of mortality compared to the general population. These disorders reflect the pattern of symptoms that result from prolonged use of illicit or legal drugs, including alcohol and medicines, despite mental or physical problems associated with their use.(6) The reduced life expectancy associated with SUDs is estimated to be 13.8 years, higher than the 6.3 year reduction associated with depression and the 7.2 year reduction associated with schizophrenia.(7) Of particular concern is the high prevalence of co-occurring SMI and SUDs.(8) A systematic review of studies conducted in the UK found the prevalence of co-occurring SMI and SUDs to be between 0.05-0.16% in the general population.(9) In contrast, current harmful drug use or dependence among people with SMI was 1.9-7.0%, and current harmful alcohol use or dependence was 7.0-15.5%.(9)

The lower average life expectancy evident among people with SMI/SUDs is largely attributable to an increased risk of a number of chronic health conditions.(10) Cardiovascular diseases have been identified as the most common cause of death in the SMI population,(11, 12) contributing to more than 30% of all deaths among public mental health clients across eight US states between 1997 and 2000.(12) This contrasts to the percentage of deaths due to suicide over the same time period, which did not exceed 15% in any state, during any year examined.(12) Metabolic syndrome has been found to affect as many as 1 in 3 people with SMI,(13) and type 2 diabetes occurs at almost twice the rate among people with SMI than the general population.(14) While the incidence of cancer is no greater in people with SMI than in the general population, these individuals are more likely to have metastases at diagnosis, and are less likely to receive specialist cancer treatment resulting in higher cancer mortality rates.(15, 16) Similarly, after adjusting for age and gender, people with SUDs have

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3 been identified as at increased risk of diabetes, heart disease, asthma, gastrointestinal disorders,
4 skin infections, malignant neoplasms, and acute respiratory disorders.(17) However, risk of these
5 disorders is substantially greater for individuals with comorbid SMI and SUDs, particularly individuals
6 with psychosis.(17) There is growing acknowledgement that people with these comorbid conditions
7 experience the worst health, wellbeing, and social outcomes, and are among the most
8 disadvantaged and vulnerable in society.(9)

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14 A number of factors have been found to contribute to the high prevalence of chronic health
15 conditions which, in turn, contribute to reduced life expectancy among people with SMI/SUDs.
16 These include socioeconomic disadvantage,(18) obesity and poor nutrition,(19) reduced physical
17 activity,(20, 21) side-effects of anti-psychotic medication,(10) elevated consumption of alcohol and
18 illicit drugs,(22) and high rates of smoking.(23, 24) However, there is increasing evidence that the
19 poor health outcomes among people with SMI/SUDs are also a result of inequities in the provision of
20 healthcare.(25, 26) In addition, difficulties with access to healthcare or routine screening among
21 people with SMI/SUDs have been identified.(27) Even when healthcare is accessed, these individuals
22 have been found to receive poorer quality care, as well as higher rates of misdiagnosis, and lower
23 rates of specialist interventions that could prevent the progression of a number of diseases,(10, 28)
24 compared to people without SMI/SUDs. Stigma has a pervasive influence on the quality of care that
25 is provided to people with SMI/SUDs,(25) with medical professionals frequently disregarding the
26 physical health concerns of this population and misinterpreting physical symptoms as mental
27 illness.(29) One strategy to address inequities in healthcare access and treatment for people with
28 SMI/SUDs is the integration of healthcare and social services. Integration of care is increasingly
29 recognised as the most appropriate method for delivering care to people with multiple, complex
30 chronic conditions, and has been found to be associated with significant improvements in condition-
31 specific quality of life.(30) However, a consensus on the concept of integrated care is yet to be
32 reached, presenting difficulties for meaningful evaluation of integrated care approaches.(31, 32)
33 Some definitions are process oriented, some (albeit few) are person-centred, and others are health
34 service oriented.(33) In an effort to provide a comprehensive concept of integrated care, Singer et
35 al. developed an integrated care framework that emphasises the importance of both care-
36 coordination and person-centred care, acknowledging the central role of service users/patients and
37 their families in the management of their own health.(34) They describe integrated care as: "patient
38 care that is coordinated across professionals, facilities, and support systems; continuous over time
39 and between visits; tailored to the patients' needs and preferences; and based on shared
40 responsibility between patient and caregivers for optimising health" (p. 113).(34) Because of the
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3 varied definitions of integrated care, it is important to understand the underlying theories, models,
4 or frameworks of integrated care that are being used to inform empirical research in this area.

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7 In the mental health context, a number of strategies to integrate care have been investigated.(35,
8 36) Examples of intervention strategies include the co-location of mental and physical health
9 services within a single setting,(37-39) collaborative care meetings between general practitioners
10 and mental health professionals,(40) and the appointment of case managers to liaise between
11 services and coordinate the overall care of individuals with SMI.(41, 42) Interventions for people
12 with co-occurring mental and addictive disorders have also been explored, such as on-site medical
13 consultations, team-based approaches, and facilitated referrals to primary care.(26) Despite
14 substantial research in this area, the number and types of integrated care interventions that have
15 been investigated empirically among each population is unknown. It is also unclear which outcomes
16 have been examined in evaluations of interventions aiming to integrate care (for example, whether
17 the goal has been to increase contact with healthcare professionals or to improve the physical
18 health of mental health/addiction service users). Most importantly, the underlying theoretical
19 models on which these interventions have been based are yet to be identified.

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22 These gaps in evidence suggest that a scoping of the literature could help to identify the
23 characteristics of interventions that have integrated care for people with SMI/SUDs to date. While
24 these individuals represent groups with distinct diagnoses, the symptom burden associated with the
25 diagnoses is highly similar,(43) and they frequently co-occur.(44) Both groups also face barriers to
26 receiving integrated care that could lead to more timely and effective treatment of physical health
27 conditions.(45)

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30 Scoping reviews are recommended to examine the extent, range, and nature of the evidence
31 relating to a topic, providing an opportunity to clarify concepts, identify knowledge gaps, and inform
32 future research, practice, and policymaking.(46, 47) We intend to identify the types of empirically
33 tested interventions aiming to integrated care for people with SMI/SUDs that have been
34 investigated; the range of outcomes these investigations have endeavoured to modify; the theories,
35 models, and frameworks of integrated care that have informed intervention development; and the
36 extent to which interventions have addressed key components of a widely-recognised framework for
37 the delivery of integrated care(34). Given the significance of the inequities in health and mortality
38 for people with SMI/SUDs, an understanding of the degree to which interventions to integrate care
39 for this population are meeting key components of successful integrated care delivery, is extremely
40 important.

41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 **Objectives**

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3 The aims of the proposed scoping review are to: 1) systematically identify and describe empirical
4 investigations of interventions to integrate care for people with SMI/SUDs, 2) describe the
5 theories/models/frameworks of integrated care informing the empirical research, and 3) determine
6 the degree to which identified interventions address components of a comprehensive and validated
7 framework of integrated care.
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11 **Methods**

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14 This scoping review will be conducted according to the methods developed by Arksey and
15 O'Malley,(48) and the subsequent refinements to these methods.(49, 50) There are six steps
16 including: 1) defining the research question/s, 2) identifying relevant studies, 3) study selection, 4)
17 charting the data, 5) collating, summarising, and reporting the results, and 6) consultation. Preferred
18 Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines will be followed
19 using the PRISMA extension for scoping reviews (PRISMA-ScR) checklist.(46) An iterative approach
20 will be taken toward searching the literature, refining the search strategy, reviewing articles for
21 inclusion, and extracting relevant data. The review protocol has been registered through Open
22 Science Framework and can be accessed at: <https://osf.io/njkph/>. Any amendments or deviations
23 from the protocol will be reported in the methods section of the final published review.
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31 *Defining the Research Question*

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33 Research questions were formulated by considering the concept (integrated care), target population
34 (people with SMI/SUDs), context (healthcare settings), and outcomes (empirically investigated
35 outcomes) of interest in order to clarify the focus of the review and establish an effective search
36 strategy. This scoping review intends to answer the following research questions:
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- 41 1) What types of interventions have been designed to integrate care for people with SMI/SUDs
42 across a broad range of healthcare settings, and which have been associated with improvements in
43 outcomes?
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- 45 2) What outcomes have studies examining interventions to integrate care for people with SMI/SUDs
46 sought to modify?
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- 48 3) Which theories, models or frameworks of integrated care have been used to inform intervention
49 development?
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- 51 4) Which components of an existing comprehensive and validated framework (Framework for
52 Measuring Integrated Patient Care)(34) have been addressed by interventions to integrate care for
53 people with SMI/SUDs?
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Identifying Relevant Studies

Our search strategy was developed with the goal of undertaking a comprehensive review of the existing evidence base. An experienced subject librarian at the University of Otago has been consulted to assist with the identification of relevant search terms and databases. Search terms have also been reviewed by a team of relevant stakeholders, including people with lived experience of mental health conditions, mental health professionals, other health professionals, and researchers from a range of disciplines.

In order to identify empirical literature, an initial limited search of a selection of relevant databases has been performed followed by a review of text words contained in the titles and abstracts, and of index terms used to describe the articles. A second search will be conducted using all identified keywords and index terms and will be undertaken across five databases: Medline (Ovid), PsycINFO, CINAHL, Embase (Ovid), and Scopus. The reference lists of all included articles will be searched for additional studies. The search will be restricted to articles and reports published in English and to articles published between January 2000 and April 2019. The search strategy has been developed in Medline (Ovid) and will be adapted to other databases (see Table 1). All searches will include a combination of subject headings, related terms, and key words. Boolean logic and operators (i.e., 'and', 'or') will be used to combine and refine search terms and concepts.

Study Selection

All records retrieved from the searches will be exported to Endnote referencing database. Following this, duplicate records will be removed (using both the Endnote 'de-duping' function and a manual scan of records), and the number of unique records will be identified.

A two-stage collaborative review process will select studies for inclusion. Screening of studies will be piloted by two reviewers (AR and LR) on the first 5% of citations retrieved from the database search to test eligibility criteria and reviewer agreement. After consensus on each of these citations is reached, the reviewers will independently apply eligibility criteria during the initial title/abstract review. Titles and abstracts will be retained for full text review if they: 1) refer to an intervention to integrate care; 2) the intervention is for people with mental health conditions, people with substance use problems, or health professionals responsible for their care; and 3) the intervention is set in a health-oriented context. The full text of relevant studies will then be obtained and independently assessed for eligibility by two reviewers (AR and LR). After each review stage, the reviewer's agreement will be assessed and a third reviewer (SD) will be consulted in cases of disagreement, until consensus is achieved.

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3 Eligibility criteria for a full text article to be included have been developed a priori with the
4 assistance of the stakeholder team. This criteria is identified below in relation to participants,
5 interventions, outcomes, context, and study design.
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8 9 i. Participants

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11 Populations of interest will include: 1) adults with SMI/SUDs who have received an intervention
12 designed to integrate care or 2) health care professionals or associated staff (including unregistered
13 health workers, managers, and administrators; hereafter referred to collectively as 'health
14 providers') who were involved in the delivery of an intervention to integrate care for people with
15 SMI/SUDs. In the present investigation, SMI is defined as mental illnesses (schizophrenia,
16 schizoaffective disorder, bipolar disorder, major depression, and other psychoses) that produce
17 severe and debilitating symptoms for 12 months or more.(2, 51) Following feedback from our
18 stakeholder group, and the widely recognised challenges associated with integrating care for people
19 with SUDs, the decision was made to also review interventions for this population. SUDs is defined
20 problems resulting from alcohol or other drug use for 12 months or more.(6) Despite facing many of
21 the same health and mortality burdens as people with SMI, as well as inequities in access to
22 appropriate care, this population is frequently overlooked in the development and evaluation of
23 clinically integrated service delivery approaches.(45)
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34 ii. Interventions

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36 Studies and reports describing interventions (i.e. activities, programmes or strategies) with the
37 explicit goal of integrating care for people with SMI/SUDs, addressing any of the key components of
38 integrated care defined by Singer et al.,(34) will be eligible for inclusion. This includes studies
39 endeavouring to integrate care both within and between organisations and services. Eligible
40 integrated care interventions can be very specific or can be implemented across a broad range of
41 domains i.e. funding, administrative, organisational, service delivery, and clinical domains.(52)
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47 iii. Outcomes

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49 A broad range of service user and provider outcomes will be included in order to identify which
50 outcomes have been most frequently examined. However, primary outcomes of interest will be
51 service user health behaviours and physical health outcomes, given the potential of integrated care
52 to increase access to treatments designed to improve physical health. Examples of secondary
53 outcomes for consideration include: cost-effectiveness, patterns of healthcare utilisation, and
54 perceived satisfaction with an intervention (from service user and/or provider perspectives). Studies
55 investigating process-oriented indicators and evaluation outcomes will be excluded, as the focus of
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3 this scoping review is on identifying the specific outcomes integrated care approaches are
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5 endeavouring to improve.

6 7 iv. Context

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9 Studies and reports published between January 2000 and May 2019 will be eligible for inclusion. This
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11 time period was selected to ensure identification of interventions likely to be relevant and applicable
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13 to contemporary healthcare contexts. Interventions delivered in any healthcare settings will be
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15 eligible, including primary care and community care settings, forensic settings, outpatient clinics,
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17 acute care hospitals, and long-term care facilities.

18 19 v. Study Design

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21 All empirical investigations examining outcomes following the implementation of an integrated care
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23 intervention using quantitative, qualitative, or mixed methods designs will be eligible for inclusion.
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25 Quantitative studies will include randomised and non-randomised controlled trials, as well as studies
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27 implementing before-after designs (with or without a control group), and cross-sectional studies.
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29 Qualitative investigations of participants' perceptions or experiences of an intervention will also be
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31 considered, including (but not limited to) designs such as qualitative description, phenomenology,
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33 grounded theory, ethnography, and action research. Pilot studies will be included, whereas
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35 conceptual articles will be excluded, in addition to those reporting case study and quality
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37 improvement designs.

38 39 *Data Extraction*

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41 Data will be extracted according to the recommendations of Arksey and O'Malley.⁽⁴⁸⁾ A
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43 standardised extraction excel spreadsheet will be used to record: author(s), year of publication,
44
45 study location, intervention type (and any comparator), underlying theory of integrated care,
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47 duration of the intervention, study population, aims of the study, methods, outcomes, and key
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49 findings. Data extraction will be performed independently by two researchers (AR and KG), and
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51 compared by a third researcher (SD). The third researcher will be consulted to resolve any
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53 discrepancies in data extraction relating to each study. Possible additions/modifications to the data
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55 extraction form may be made after review of the first five references in order to ensure that all
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57 relevant information will be captured.

58 59 *Collating, Summarising and Reporting*

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A two-step approach will be used to summarise the findings of included studies. Step one will
involve a narrative synthesis of the characteristics and findings of the studies (including tabular

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3 and/or graphical summaries). Studies will be organised according to intervention type in order to
4 highlight the range of integrated care approaches for people with SMI/SUDs that have been
5 empirically evaluated. The underlying theory of integrated care associated with each included
6 intervention will also be described (where this information is available).
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10 Step two will identify the degree to which interventions for people with SMI/SUDs have addressed
11 dimensions of integrated care as conceptualised by Singer et al.(34) A framework synthesis will be
12 conducted to review the included interventions, with coding and analysis directed by the integrated
13 care framework. Specifically, we are interested in qualitatively analysing the extent to which each
14 intervention description addresses the seven elements of integrated care: 1) coordination within a
15 care team; 2) coordination across care teams; 3) coordination between care teams and community
16 resources; 4) continuous familiarity with patients over time; 5) continuous proactive and responsive
17 action between visits; 6) service user-centred care; and 7) shared responsibility.(34) To do so,
18 descriptions of the interventions will be imported to an excel spreadsheet and analysed by two
19 authors (AR and LR); both researchers have previous experience coding qualitative data. The a priori
20 coding framework will be applied to each intervention description independently by the researchers.
21 Results from these analyses will be summarised in order to highlight dimensions of integrated care
22 that require further investigation and implementation among people with SMI/SUDs.
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33 *Consultation Process*

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35 The aim of this review is to identify and describe empirical investigations of interventions to
36 integrate care for people with SMI/SUDs in order to highlight which interventions have been
37 associated with positive outcomes and which dimensions of integrated care have been targeted. This
38 information will have potential to inform both future research activity and clinical practice. In order
39 to ensure that findings of the review are of relevance to mental health and addiction service users,
40 and those who provide care to these individuals, we have engaged a stakeholder team as mentioned
41 above. Stakeholders have been involved in developing the research questions guiding this review
42 and have reviewed the search strategy to identify key terms that are relevant to the population,
43 concept, and contexts of interest presented in this protocol. Stakeholders will also be involved in
44 interpreting the review findings and will advise on dissemination.
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53 *Patient and Public Involvement*

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55 This scoping review protocol has engaged the expertise of individuals with lived experience of SMI.
56 These individuals have contributed to the development of the research questions, reviewed and
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3 made suggestions to the proposed search terms, and will be extensively involved during the
4 interpretation and dissemination phases of this project.
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7 **Ethics and Dissemination**

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10 Although integrated care is increasingly recommended for people with SMI/SUDs, it is unclear what
11 elements of integrated care have been investigated in empirical evaluations of interventions
12 designed to improve outcomes for these populations. To our knowledge, our scoping review will be
13 the first to systematically describe the extent and nature of interventions to integrate care for
14 people with SMI and people with SUDs, including which outcomes these interventions have
15 endeavoured to modify. Therefore, the scoping review findings are expected to be of interest to
16 service users, researchers, clinicians, and policy makers. Our dissemination strategy will include
17 publication of the review in an open-access peer-reviewed journal (i.e. available to service users,
18 their families and the general public), and scientific presentations of the findings at conferences and
19 to staff working within a range of mental health and addiction settings. All stakeholders will be
20 involved in interpreting the review findings and ensuring that these are widely disseminated through
21 their respective networks – including to service users. This will be facilitated by a half-day round-
22 table meeting with our stakeholder group. During this meeting, findings of the review will be
23 discussed and opportunities for future areas of research and clinical practice work will be
24 brainstormed. It is hoped that stakeholders' knowledge and interpretations of the review findings
25 will identify clear priorities for changes in the development and delivery of integrated care.
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3 **Word count:** 3488
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5 **Acknowledgements:** We would like to acknowledge Christy Ballard, the subject librarian for the
6 Department of Preventive and Social Medicine at the University of Otago for her assistance with
7 developing a preliminary search strategy. We would also like to acknowledge the members of our
8 stakeholder group who helped to develop the research questions guiding the proposed review and
9 who also provided suggestions regarding additional relevant search terms. Stakeholder group
10 members include: Dr Emma Wyeth, Professor Tim Stokes, Ms Mel Green, Ms Adell Cox, Mr Martin
11 Burke, Mr Shaun McNeil, Dr Ruth Cunningham, Mrs Helen Lockett, and Dr Helen Hamer.
12
13

14 **Author Contributions:** AR completed an initial draft of the review protocol. LR assisted with
15 development of the research questions and eligibility criteria. KG helped to develop the methods for
16 article screening and data extraction. SD led the conceptualisation of the review. All authors have
17 provided feedback on multiple iterations of the manuscript.
18
19

20 **Funding:** This research is funded by a University of Otago Research Grant (NZD \$34743). The funder
21 had no role in the development of this protocol.
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24 **Conflicts of Interests:** None declared.
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27 **Patient consent:** Not required.
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30 **Data Statement:** All relevant data is provided in this manuscript.
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Table 1. Medline (Ovid) Search Strategy

Line number	Search term entered into Ovid (Medline)	Results
1	intervention.mp.	464809
2	Program Evaluation/ or Evaluation Studies/ or evaluation.mp.	1404582
3	program.mp. or Programs/	411198
4	programme.mp	79501
5	<i>1 or 2 or 3 or 4</i>	2132570
6	Primary Health Care/ or "Delivery of Health Care, Integrated"/ or integrated care.mp.	83223
7	integrated services.mp.	516
8	integrated health.mp.	2604
9	integration of care.mp.	280
10	integration of services.mp.	294
11	integrating care.mp.	119
12	care integration.mp.	320
13	collaborative care.mp.	1681
14	Patient Care Team/ or coordinated care.mp.	63179
15	<i>6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14</i>	145318
16	(severe and enduring mental illness).mp.	48
17	serious mental illness.mp	2474
18	Mental Disorders/ or serious mental disorder.mp.	155387
19	serious psychiatric illness	53
20	serious psychiatric disorder	83
21	severe mental illness	3208
22	severe mental disorder	282
23	severe psychiatric illness	106
24	severe psychiatric disorder	159
25	Schizophrenia, Catatonic/ or Schizophrenia, Disorganized/ or Schizophrenia, Paranoid/ or schizophrenia.mp.	123422
26	psychosis.mp. or Psychotic Disorders/	58808
27	bipolar disorder.mp. or Bipolar Disorder/	42908
28	Depressive Disorder, Major/ or major depression.mp.	39682

29	Substance-Related Disorders/	91316
30	16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29	434086
31	5 and 15 and 30	2979

Note: Run date = 17/04/2019

For peer review only

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PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	P1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	P2
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	P1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	P13
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	P7
Support:			
Sources	5a	Indicate sources of financial or other support for the review	P13
Sponsor	5b	Provide name for the review funder and/or sponsor	P13
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	P13
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	P4-P7
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	P7-P8
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	P7-P10
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	P8
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	P18-P19
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	P10-P11

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3	Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	P8-P9
4				
5	Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	P10-P11
6				
7	Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	P10
8				
9	Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	P10
10				
11	Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	N/A
12				
13	Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	
14		15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2 , Kendall's τ)	N/A
15		15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	
16		15d	If quantitative synthesis is not appropriate, describe the type of summary planned	P11
17				
18	Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	N/A
19				
20	Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A
21				

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.