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A SYSTEMATIC REVIEW OF TELEPHONE DELIVERED PSYCHOSOCIAL INTERVENTIONS ON RELAPSE PREVENTION, ADHERENCE TO PSYCHIATRIC MEDICATION AND HEALTH RISK BEHAVIOURS IN ADULTS WITH A PSYCHOTIC DISORDER (PROTOCOL)

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A SYSTEMATIC REVIEW OF TELEPHONE DELIVERED PSYCHOSOCIAL INTERVENTIONS ON RELAPSE PREVENTION, ADHERENCE TO PSYCHIATRIC MEDICATION AND HEALTH RISK BEHAVIOURS IN ADULTS WITH A PSYCHOTIC DISORDER (PROTOCOL).

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ABSTRACT

Introduction: The mental and physical health of individuals with a psychotic illness are typically poor. When adhered to, medication can reduce relapse. However, despite adherence, relapse remains common and functional outcomes often remain compromised. Compliance is also typically low. Cardiovascular related morbidity and mortality is also elevated, along with several important modifiable health risk behaviours. Access to psychosocial interventions is therefore important, but currently limited. Telephone delivered interventions represent a promising solution, although further clarity is needed. Accordingly, we aim to provide an overview and critical analysis of the current state of evidence for telephone delivered psychosocial interventions targeting key health priorities in adults with a psychotic disorder, including (i)relapse, (ii)adherence to psychiatric medication and/ or (iii)modifiable cardiovascular health risk behaviours.

Methods and Analysis: Our methods are informed by published guidelines. The review is registered and any protocol amendments will be tracked. Ten electronic peer-reviewed and four grey literature databases have been identified. Preliminary searches have been conducted for literature on psychosocial telephone interventions targeting relapse, medication adherence and/ or health risk behaviours in adults with a psychotic disorder. Articles classified as 'evaluation' will be assessed against standardized criteria and checked by an independent assessor. The searches will be re-run just before final analyses and further studies retrieved for inclusion. A narrative synthesis will be reported, structured around intervention type and content, population characteristics, and outcomes. Where possible, 'summary of findings' tables will be generated for each comparison. For the primary outcome of each trial, when data are available, we will calculate a risk ratio and its 95% confidence interval (dichotomous outcomes) and/or effect size according to Cohen's formula (continuous outcomes).

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Ethics and Dissemination: No ethical issues are foreseen. Findings will be disseminated widely to clinicians and researchers via journal publication and conference presentation(s).

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INTRODUCTION

Psychotic illnesses (e.g. schizophrenia spectrum and bipolar disorder) are chronic, relapsing conditions characterised by distortions in thinking, perception and emotional response[1]. These symptoms can have a profound impact on quality of life and functioning[2]. Psychotic illnesses are also associated with a mortality rate double that of the general population[3,4] and a shortening of life expectancy by up to 19 years[5]. Cardiovascular disease (CVD) is the single largest cause of death among this group, accounting for more premature deaths than suicide[6,7,8]. Rates of major health risk behaviours associated with CVD (smoking, physical inactivity, alcohol use and low fruit and vegetable intake) are all higher in people living with psychotic illnesses[9-12]. Furthermore, second generation antipsychotics (SGA), which are commonly used in the treatment of psychotic illnesses, are also associated with a range of serious metabolic side effects, including changes in body weight, glucose utilisation and lipid status[13].

The wellbeing of individuals with psychotic illnesses is further compromised by poor access to treatment. Although SGAs can reduce relapse[14], rates of non-compliance are as high as 50%[15]. A large scale study has also found that almost three quarters of participants diagnosed with schizophrenia chose to discontinue their medication within 18 months[16]. Furthermore, for those individuals who are compliant and do benefit from medication, they often continue to experience difficulties within important psychosocial domains and (e.g. employment, social function) continue to relapse[2,14]. This points to the importance of psychosocial interventions as an adjunct to traditional medication management.

Cognitive Behaviour Therapy (CBT) is one of the most researched psychosocial interventions in psychosis. CBT is associated with small to moderate positive effects for a range of psychotic symptomatology and accompanying difficulties[17,18] and also demonstrates promise as an option for improving adherence to antipsychotic medication[19]. Furthermore, increasing evidence supports the role of CBT alone, or in combination with, other

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psychosocial approaches (e.g. motivational interviewing) for modifying health risk behaviours amongst individuals with psychosis[20-22]. However, despite psychosocial interventions like CBT being recommended by Australian[23], UK[24,25] and other international clinical guidelines[Dixon, Perkins & Calmes, 2009; Hirschfield, 2005] for the treatment of schizophrenia and other psychotic disorders, of those likely to benefit, only 10% or less have access [28-30]. Barriers to access include availability of trained clinicians, accessibility of support services, embarrassment and perceived stigma associated with seeking help[28-30]. Given the limitations of medication management, improving access to psychosocial interventions represents an important priority for enhancing the wellbeing of individuals living with a psychotic illness.

Why it is important to do this review

Technology-based interventions represent a promising avenue for improving access to healthcare. Indeed, a recent systematic reviews points to the acceptability and feasibility of telephone delivered interventions (alone, or in combination with other remote access technology) within schizophrenia[31]. However, this review was restricted to schizophrenia and did not focus on psychosocial interventions or summarising the evidence for key health priorities. Given that the problems seen in schizophrenia surrounding relapse, SGA compliance, cardiovascular disease and treatment access are also shared by other psychotic disorders, in this systematic review we aim to provide an overview and critical analysis of the current state evidence for psychosocial telephone delivered interventions targeting key health priorities in adults with a psychotic disorder, including (i) relapse, (ii) adherence to psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours.

Objectives

The following three questions will be addressed. For adults with a psychotic disorder:

1. Do telephone delivered psychosocial interventions targeting (i) relapse, (ii) adherence to

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psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours result in changes to:

   a. Indicators of relapse, including psychiatric symptomatology (positive and negative symptoms, depression, anxiety), the number and duration of hospitalisations, functioning and quality of life
   b. Medication adherence, including dose count (doses taken); dose days (days where correct number of doses taken); dose time (doses taken on schedule)
   c. Health behaviours (e.g. smoking, substance use, physical activity, fruit and vegetable consumption)
   d. Severity of cardiovascular disease (CVD) risk, including CVD risk index; quantity, severity of CVD risk factors (e.g. weight, BMI, waist circumference, blood pressure, plasma lipids, insulin, glucose)

2. Is the effect of telephone delivered psychosocial interventions targeting (i) relapse, (ii) adherence to psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours on the above listed treatment outcomes influenced by:
   a. other intervention components (e.g. individual and/ or group face-to-face components; supplementary materials; other technology)
   b. implementation factors (staff training; intervention fidelity, treatment engagement/ adherence)
   c. process measures/ mediators/mechanisms [e.g. cognitive (empowerment/ self efficacy/ motivation); behavioral (e.g. active coping, including managing urges); relational (e.g. therapeutic alliance)]
3. What is the evidence for the feasibility of telephone delivered psychosocial interventions for relapse prevention, adherence to psychiatric medication and/ or health risk behaviours, including commentary on economic outcomes and service user and/ or provider satisfaction.

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METHODS AND ANALYSIS

A systematic review will be conducted in accordance with the Preferred Reporting Items for Systematic Review and Meta-analysis Protocols (PRISMA-P)[32].

Eligibility Criteria

Types of Studies

In accordance with the objective of providing an overview of the current evidence for telephone delivered interventions in adults with a psychotic disorder, liberal design criteria will be adopted. The following designs will be included - randomised controlled trials (cluster and parallel design); cross-over trial; case series or case controls; one-arm trial; non-randomised trials; cross-sectional or cohort studies and case reports. As broad inclusion criteria may increase risk of bias, this will be assessed using the Collaboration's Risk of Bias tool, as described in the Cochrane Handbook for Systematic Review of Interventions ([33] detailed under risk of bias assessment below). Qualitative only designs will not be included.

Types of Participants

Adults (≥ 18) with a psychotic disorder, as defined by any criteria. Diagnosis may be self-reported or confirmed via clinical interview. Participants may be residing in the community, rehabilitation, treatment and/or correctional facility. We will include studies with populations involving adults with non-psychotic disorders only if more than 50% had a psychotic disorder, or if data limited to those with psychotic disorders are available.

In order to better inform research and clinical care, we intend to describe the clinical state (acute vs. post-acute vs. partial remission vs. remission), stage (e.g. first episode vs. early illness vs. persistent) and whether the studies target particular clinical presentations (e.g. negative symptoms, positive symptoms, treatment-resistant illnesses).

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Types of Interventions

The intervention of interest is telephone support targeting (i) relapse prevention, (ii) adherence to psychiatric medication and/ or (iii) modifiable health risk behaviours.

'Relapse prevention' will be defined as telephone support designed to recognise and act on early warning signs of episode recurrence and/ or enhance coping strategies (including medication compliance), the number and duration of hospitalisations and/ or the impact of the illness on functioning and/or quality of life.

'Adherence to psychiatric medication' will be defined as telephone support intended to affect adherence with prescribed, self-administered medication for mental disorders. Ethical standards for adherence research dictate that attempts to increase adherence must be judged by their clinical benefits, not simply their effects on adherence rates[34]. Accordingly, adherence studies will only be included if both adherence and treatment effects are measured.

'Modifiable health risk behaviours' will be defined as telephone support that targets health behaviours (nutrition, physical activity, smoking, substance use) associated with modifiable cardiovascular risk factors (weight, cholesterol, blood glucose, blood pressure).

To be included, the telephone support must:

(i) Utilise one or more psychological strategies to modify relapse risk, adherence to psychiatric medication and/ or health risk behaviours. Psychological strategies will be defined as supportive counselling, psychoeducation (including brief advice), cognitive behavioural (including problem solving, dialectical behavioral therapy, acceptance and commitment therapy), mindfulness and/ or motivational interviewing.

(ii) Comprise at least one telephone session, of at least ten minutes, delivered by a healthcare professional and/ or non-professional/ layperson/ peer/ consumer who has been trained in delivering the intervention

The telephone support may be a standalone intervention and/ or delivered in combination with

other treatment components, including pharmacological. However, studies with multiple components will only be included if the telephone is the predominant method of intervention delivery. This is defined as studies in which at least 50% of the total number of participant contacts are conducted by telephone. Interventions delivered in any setting (e.g. community, hospital, rehabilitation or residential treatment centre, etc.) will be included.

Types of Comparison Conditions

The telephone support may be compared to inactive (e.g. standard care, waiting list control) and/ or active controls (e.g. pharmacological and/ or psychological) whereby telephone is not the predominant method of intervention delivery (e.g. individual, group, internet).

Types of Outcome Measures

(1) Indicators of relapse, including psychiatric symptomatology (positive and negative symptoms, depression, anxiety), the number and duration of hospitalisations, functioning and quality of life

(2) Medication adherence, including dose count (doses taken); dose days (days where correct number of doses taken); dose time (doses taken on schedule)

(3) Health behaviours (e.g. smoking, substance use, physical activity, fruit and vegetable consumption)

(4) Severity of cardiovascular risk, including CVD risk index; quantity, severity of CVD risk factors (e.g. weight, BMI, waist circumference, blood pressure, plasma lipids, insulin, glucose)

(5) Treatment engagement (e.g. quantity/ frequency/ duration of telephone support attendance)

(6) Process measures/ mediators/ mechanisms [e.g. cognitive (empowerment/ self efficacy/ motivation); behavioral (e.g. active coping, including managing urges); process (e.g. therapeutic alliance)]

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(7) Feasibility, including economic outcomes (e.g. cost, resource use, cost effectiveness) and/ or satisfaction/ preference. Qualitative outcomes regarding participant and/ or relative satisfaction will be reported as described.

Outcomes may be clinician and/or patient rated; assessed by objective and/ or subjective indices (e.g. blood, urine, actigraph, questionnaire, monitoring form/ diary) with or without collateral information (e.g. using a family member to validate use) and of any time frame (e.g. baseline, short and/ or medium and/ or long term follow-up).

Information Sources

Search strategy

Consistent with methods detailed in Cochrane Guidelines for systematic reviews[33], the search strategy will be conducted as follows. First, in May 2015 we identified ten relevant scientific electronic databases (Medline, PubMed, Embase, CINAHL, Science Direct, Wiley, PsychInfo, Central, Amed, Scopus) and four electronic non-scientific databases (Translating Research into Practice; Virginia Commonwealth University; Project Cork; Prevention, Information and Evidence Library) to search. Search terms related to telephone will be combined with psychosis related search terms and then outcome related search terms (see appendix 1 for the full MEDLINE search strategy).

Abstract, title, key words and subject headings specific to each of the identified database will be searched. All subject headings will be exploded so that narrower terms are included. No limits will be placed on publication year. Publications must be available in English. Reference lists of identified publications will be hand searched to identify any additional publications. All publications will be organised in reference manager Endnote. The searches will be re-run just before final analyses and further studies retrieved for inclusion.

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Classification of studies

The titles and abstracts of identified references will be classified in a three step process.

Step 1: Identification of studies for exclusion

AKB will review the titles and/or abstracts and exclude articles if they: a) are duplicates, b) do not focus on adults with a psychotic disorder, c) do not focus on telephone delivered support, or d) if the outcomes, process and/ or predictor variables do not include or specifically relate to relapse, medication adherence and/ or health behaviours, e) are not journal articles, reports, book chapters or newsletter articles. If eligibility is unclear from the title and/ or abstract, the full text article will be accessed and assessed.

Step 2: Classification of studies

The abstracts and/ or full text of the remaining studies will be examined by AKB to identify studies that are: (i) *Evaluation*, defined as an evaluation of a telephone delivered intervention as per the PICO criteria outlined above; (ii) *Reviews*, including summaries, descriptive, critical and/ or systematic reviews; *Discussion*, defined as general discussion of telephone delivered interventions, including development, principles, methods and implementation. References that are not evaluation, review or discussion papers (e.g. treatment manuals) will classified as 'Other'.

Step 3: Cross Checking

Publications from step two will re-classified by the primary author (AB), for cross-checking. In case of disagreement, the final classification will be made by consensus, with the involvement of GH, PK, KB and/or SB. The articles excluded in step one will not be cross-checked because they will not be relevant to the review. The evaluation studies identified in step two will retained for further examination.

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Data Extraction from Evaluation Studies

Data extraction will be performed by AB and checked by AT. Extraction forms will be piloted on several papers and modified as needed before use. When multiple reports of the same study are identified (e.g. related journal articles, conference proceedings which are then published), data from each report will be extracted separately and then combined across multiple data collection forms. Methodological critique and assessment of risk of bias will be performed independently by AB and AT. In the event of disagreement, final ratings will be made via consensus, following discussion with GH, PK, KB and/or SB. In the event that inadequate trial details are reported, study authors will be contacted no more than twice to obtain further information.

To enable methodological critique of both observational research and RCTs, criteria for data extraction will be adapted from the Downs and Black Scale[35] and the Cochrane Handbook for Systematic Reviews[33] and include

(1) Participant information, including n-values at each stage of the study (and reasons for non-participation), treatment setting, eligibility criteria, descriptive data including age, gender, ethnicity, socio-economic status, diagnostic criteria, treatment history

(2) Methods, including study design, country, setting(s), methodological limitations reported, methodological limitations observed (e.g. recruitment allocation and data collection methods; blinding; comparability of groups at baseline; appropriateness of analysis methods)

(3) Interventions, including number of groups, duration of treatment (number, frequency and duration of phone and non-phone components), delivery method(s), description of control intervention(s)

(4) Primary and secondary outcomes, including data collection sources/ methods, percentage of treatment sessions attended, other process measures/ mediators/

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mechanisms, economic outcomes, satisfaction related qualitative outcomes, follow-up period

(5) Results, including indicators of relapse, medication adherence, health behaviours, severity of cardiovascular risk, treatment engagement, process measures/ mediators/ mechanisms, economic outcomes and patient satisfaction collected at all available follow-up time points.

Methodological Critique of Evaluation Research

To provide a thorough overview of the literature we will implement procedures to evaluate the quality of both observational studies and RCTs. A narrative synthesis of the findings from the included studies will be reported, structured around intervention type and content, population characteristics, and outcomes. This qualitative review will be supplemented with the following quantitative measures.

For observational studies, methodological quality will be assessed against the Downs and Black Scale[35]. Criteria will be assigned a yes (1 point); no (0 points); or unclear (0 points) rating. All criteria will have the same weight, and a quality score ranging from 0 to 27 points will be calculated for each study.

For RCTs, methodological quality will be assessed against the eleven item Physiotherapy Evidence Database (PEDro) scale[36]. Consistent with published reviews of psychological interventions (e.g.[21,37]) two items regarding blinding of subjects and therapists will not be scored in the present review, as these criteria are not appropriate for the studies under review. The remaining nine criteria will be assigned a assigned a yes (1 point) or no (0 points) rating, and a quality score ranging from 0 to 8 points will be calculated for each study (as item one is not included in the quality score;[36]).

Risk of bias will also be assessed using the Collaboration's Risk of Bias tool, as described in the *Cochrane Handbook for Systematic Review of Interventions*[33]. We will judge each item

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as being high, low or unclear risk, as per the criteria provided by Higgins and Green[33] and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table. Given that growing empirical evidence suggests that sequence generation and allocation concealment are particularly important potential sources of bias, studies will be deemed to be at the highest risk of bias if either item is scored as 'high' or 'unclear'.

Measures of Treatment Effect

Where possible, 'summary of findings' (SOF) tables will be generated for each comparison (phone vs multi-component phone; phone vs other active control; phone vs other inactive control). SOF tables will provide key information regarding evidence quality, the magnitude of effect of the interventions examined, and a summary of available data on the outcome variables defined under 'Outcome Measures' above.

Scale Derived Data

We intend to include continuous data from rating scales only if:

a) The psychometric properties of the instrument have been described in a peer review journal
b) The instrument was not written or modified by one of the authors for that particular trial
c) The instrument was self-report or completed by an independent assessor (in the event that this is not clearly reported, a note will be made in 'Description of Studies')

Data presented in Graphs and Figures

Where possible, we intend to extract data that is only represented in graphs and figures, but only if the same result(s) are independently derived by AB and AT.

Dichotomous Outcome Measures

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When data are available, a risk ratio (RR) and its 95% confidence interval will be provided for the primary outcome of each trial. RR has been selected in preference to odds ratios as evidence suggests that RR is more intuitive[38] and clinicians tend to misinterpret odds ratios as RR[39].

Continuous Outcome Measures

When data are available, effect sizes will be calculated according to Cohen's formula, to allow for comparison across studies. Effect sizes will be interpreted according to published guidelines, where 0.2-0.49 is defined as a small effect size, 0.5-0.79 is moderate and greater than 0.8 is large.

A study will be considered to have a positive outcome if at least 50% of reported outcomes demonstrate a between group difference in favour of the telephone support group at the end of the intervention. Positive maintenance outcome(s) will be evidenced when this effect is also evident at short and/ or medium and/ or long-term follow-up (defined as 1-6; 7-12 and >12 months after intervention completion, respectively). We anticipate there will be limited scope for meta-analysis due to the range of different outcome measures.

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ETHICS AND DISSEMINATION

As no primary data collection will be undertaken, no formal ethical assessment is required. We plan to present the findings of this systematic review for peer-review in an appropriate journal. We also intend to present to clinicians and researchers at appropriate conferences.

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ABOUT THE ARTICLE

Authors' contributions

Dr Beck is the guarantor of the review protocol, wrote the protocol for the systematic review, performed the preliminary searches and cross-checked article inclusion. Prof Baker will perform data extraction, conduct quality assessments and draft the systematic review paper. Dr Turner will cross-check data extraction and perform independent quality ratings. All other authors made substantial contributions to conception, design and writing of the systematic review and will assist Prof Baker and Dr Turner to resolve any discrepancies regarding study inclusion, data extraction and quality ratings. All authors offered critical revisions to the protocol manuscript and will offer critical revisions for the systematic review manuscript.

Funding Statement

Funding support for the conduct of this review has been provided by the NHMRC Centre of Research Excellence for Mental Health and Substance Use. The funder has no involvement in developing this protocol.

Competing Interests

Dr Beck, Dr Baker, Dr Turner and Dr Kelly have no competing interests to declare. Dr Bucci, Dr Berry and Prof Haddock are current grant holders for a mobile application delivered CBT intervention for early psychosis (Medical Research Council: R116690).

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Appendix One:

Date	Database	Search Strategy	Notes
14.05.15 (preliminary search)	Medline	Telephone [MH] OR ("telephone intervention"[Title] OR "phone intervention"[Title] OR "telephone program"[Title] OR "phone program"[Title] OR "telephone trial"[Title] OR "phone trial"[Title]) OR ("telephone intervention"[Abstract] OR "phone intervention"[Abstract] OR "telephone program"[Abstract] OR "phone program"[Abstract] OR "telephone trial"[Abstract] OR "phone trial"[Abstract]) AND Psychosis[MH] OR schizophrenia [MH] OR psychosis [Title] OR schizo*[Title] OR bipolar [Title]OR psychosis [Abstract] OR schizo*[Abstract] OR bipolar [Abstract] AND Cardiovascular[MH] OR diet [MH] OR nutrition [MH] OR physical activity [MH] OR exercise [MH] OR smoking[MH] OR medication compliance [MH] OR alcoholism[MH] OR alcohol-related disorders[MH] OR substance-related disorder[MH] OR relapse prevention [MH] OR Cardiovascular [Title] OR dietary intake [Title] OR diet [Title] OR nutrition [Title] OR fruit [Title] OR physical activity [Title] OR exercise [Title] OR smoking [Title] OR medication compliance [Title] OR alcoholism [Title] OR alcohol abuse [Title] OR alcohol dependence [Title] OR substance abuse [Title] OR substance dependence [Title] OR addiction [Title] OR smok* [Title] OR Cardiovascular [Abstract] OR dietary intake [Abstract] OR diet [Abstract] OR nutrition [Abstract] OR fruit [Abstract] OR physical activity [Abstract] OR exercise [Abstract] OR smoking [Abstract] OR medication compliance [Abstract] OR alcoholism [Abstract] OR alcohol abuse [Abstract] OR alcohol dependence [Abstract] OR substance abuse [Abstract] OR substance dependence [Abstract] OR addiction [Abstract] OR smok* [Abstract]	Limited to articles available in English

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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	YES
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	YES
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	YES
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	YES
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	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	YES
Sponsor	5b	Provide name for the review funder and/or sponsor	YES
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	YES
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	YES
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	YES
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	YES
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	YES

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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	YES
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	YES
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)	YES
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	YES
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	YES
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	YES
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	YES
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	YES
	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)	YES
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	YES
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	YES
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	YES
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	YES

*** 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.**

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A PROTOCOL FOR A SYSTEMATIC REVIEW OF TELEPHONE DELIVERED PSYCHOSOCIAL INTERVENTIONS ON RELAPSE PREVENTION, ADHERENCE TO PSYCHIATRIC MEDICATION AND HEALTH RISK BEHAVIOURS IN ADULTS WITH A PSYCHOTIC DISORDER

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Keywords:	psychotic disorder, psychosocial telephone intervention, relapse, medication compliance, cardiovascular risk

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ABSTRACT

Introduction: The mental and physical health of individuals with a psychotic illness are typically poor. When adhered to, medication can reduce relapse. However, despite adherence, relapse remains common and functional outcomes often remain compromised. Compliance is also typically low. Cardiovascular related morbidity and mortality is also elevated, along with several important modifiable health risk behaviours. Access to psychosocial interventions is therefore important, but currently limited. Telephone delivered interventions represent a promising solution, although further clarity is needed. Accordingly, we aim to provide an overview and critical analysis of the current state of evidence for telephone delivered psychosocial interventions targeting key health priorities in adults with a psychotic disorder, including (i)relapse, (ii)adherence to psychiatric medication and/ or (iii)modifiable cardiovascular health risk behaviours.

Methods and Analysis: Our methods are informed by published guidelines. The review is registered and any protocol amendments will be tracked. Ten electronic peer-reviewed and four grey literature databases have been identified. Preliminary searches have been conducted for literature on psychosocial telephone interventions targeting relapse, medication adherence and/ or health risk behaviours in adults with a psychotic disorder. Articles classified as 'evaluation' will be assessed against standardized criteria and checked by an independent assessor. The searches will be re-run just before final analyses and further studies retrieved for inclusion. A narrative synthesis will be reported, structured around intervention type and content, population characteristics, and outcomes. Where possible, 'summary of findings' tables will be generated for each comparison. For the primary outcome of each trial, when data are available, we will calculate a risk ratio and its 95% confidence interval (dichotomous outcomes) and/or effect size according to Cohen's formula (continuous outcomes).

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Ethics and Dissemination: No ethical issues are foreseen. Findings will be disseminated widely to clinicians and researchers via journal publication and conference presentation(s).

Registration Details: PROSPERO CRD42015025402

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INTRODUCTION

Psychotic illnesses (e.g. schizophrenia spectrum and bipolar disorder) are chronic, relapsing conditions characterised by distortions in thinking, perception and emotional response[1]. These symptoms can have a profound impact on quality of life and functioning[2]. Psychotic illnesses are also associated with a mortality rate double that of the general population[3,4] and a shortening of life expectancy by up to 19 years[5]. Cardiovascular disease (CVD) is the single largest cause of death among this group, accounting for more premature deaths than suicide[6,7,8]. Rates of major health risk behaviours associated with CVD (smoking, physical inactivity, alcohol use and low fruit and vegetable intake) are all higher in people living with psychotic illnesses[9-12]. Furthermore, second generation antipsychotics (SGA), which are commonly used in the treatment of psychotic illnesses, are also associated with a range of serious metabolic side effects, including changes in body weight, glucose utilisation and lipid status[13].

The wellbeing of individuals with psychotic illnesses is further compromised by poor access to treatment. Although SGAs can reduce relapse[14], rates of non-compliance are as high as 50%[15]. A large scale study has also found that almost three quarters of participants diagnosed with schizophrenia chose to discontinue their medication within 18 months[16]. Furthermore, for those individuals who are compliant and do benefit from medication, they often continue to experience difficulties within important psychosocial domains and (e.g. employment, social function) continue to relapse[2,14]. This points to the importance of psychosocial interventions as an adjunct to traditional medication management.

Cognitive Behaviour Therapy (CBT) is one of the most researched psychosocial interventions in psychosis. CBT is associated with small to moderate positive effects for a range of psychotic symptomatology and accompanying difficulties[17,18] and also demonstrates promise as an option for improving adherence to antipsychotic medication[19]. Furthermore, increasing evidence supports the role of CBT alone, or in combination with, other

psychosocial approaches (e.g. motivational interviewing) for modifying health risk behaviours amongst individuals with psychosis[20-22]. However, despite psychosocial interventions like CBT being recommended by Australian[23], UK[24,25] and other international clinical guidelines[26,27] for the treatment of schizophrenia and other psychotic disorders, of those likely to benefit, only 10% or less have access [28-30]. Barriers to access include availability of trained clinicians, accessibility of support services, embarrassment and perceived stigma associated with seeking help[28-30]. Given the limitations of medication management, improving access to psychosocial interventions represents an important priority for enhancing the wellbeing of individuals living with a psychotic illness.

Why it is important to do this review

Technology-based interventions represent a promising avenue for improving access to healthcare. Indeed, a recent systematic reviews points to the acceptability and feasibility of telephone delivered interventions (alone, or in combination with other remote access technology) within schizophrenia[31]. However, this review was restricted to schizophrenia and did not focus on psychosocial interventions or summarising the evidence for key health priorities. Given that the problems seen in schizophrenia surrounding relapse, SGA compliance, cardiovascular disease and treatment access are also shared by other psychotic disorders, in this systematic review we aim to provide an overview and critical analysis of the current state evidence for psychosocial telephone delivered interventions targeting key health priorities in adults with a psychotic disorder, including (i) relapse, (ii) adherence to psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours.

Objectives

The following three questions will be addressed. For adults with a psychotic disorder:

1. Do telephone delivered psychosocial interventions targeting (i) relapse, (ii) adherence to psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours result in

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changes to:

a. Indicators of relapse, including psychiatric symptomatology (positive and negative symptoms, depression, anxiety), the number and duration of hospitalisations, functioning and quality of life
b. Medication adherence, including dose count (doses taken); dose days (days where correct number of doses taken); dose time (doses taken on schedule)
c. Health behaviours (e.g. smoking, substance use, physical activity, fruit and vegetable consumption)
d. Severity of cardiovascular disease (CVD) risk, including CVD risk index; quantity, severity of CVD risk factors (e.g. weight, BMI, waist circumference, blood pressure, plasma lipids, insulin, glucose)

2. Is the effect of telephone delivered psychosocial interventions targeting (i) relapse, (ii) adherence to psychiatric medication and/ or (iii) modifiable cardiovascular health risk behaviours on the above listed treatment outcomes influenced by:
   a. other intervention components (e.g. individual and/ or group face-to-face components; supplementary materials; other technology)
   b. implementation factors (staff training; intervention fidelity, treatment engagement/ adherence)
   c. process measures/ mediators/mechanisms [e.g. cognitive (empowerment/ self efficacy/ motivation); behavioural (e.g. active coping, including managing urges); relational (e.g. therapeutic alliance)]
3. What is the evidence for the feasibility of telephone delivered psychosocial interventions for relapse prevention, adherence to psychiatric medication and/ or health risk behaviours, including commentary on economic outcomes and service user and/ or provider satisfaction.

METHODS AND ANALYSIS

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This systematic review will be informed by published guidelines[32] and reported according to the Preferred Reporting Items for Systematic Review and Meta-analysis (PRISMA)[33].

Eligibility Criteria

Eligibility of papers for inclusion in the review will be informed by inclusion and exclusion criteria applied to each of the following domains: types of studies, types of participants, types of interventions and comparison conditions, and the outcome measures assessed. Inclusion and any exclusion criteria within each of these domains is described in turn below:

Types of Studies

In accordance with the objective of providing an overview of the current evidence for telephone delivered interventions in adults with a psychotic disorder, liberal design criteria will be adopted. The following designs will be included - randomised controlled trials (cluster and parallel design); cross-over trial; case series or case controls; one-arm trial; non-randomised trials; cross-sectional or cohort studies and case reports. As broad inclusion criteria may increase risk of bias, this will be assessed using the Collaboration's Risk of Bias tool, as described in the Cochrane Handbook for Systematic Review of Interventions ([32] detailed under risk of bias assessment below). Qualitative only designs will not be included.

Types of Participants

Studies that include adults (≥ 18) with a psychotic disorder, as defined by any criteria will be included. Diagnosis of study participants may be self-reported or confirmed via clinical interview. Study participants may be residing in the community, rehabilitation, treatment and/or correctional facility. We will include studies with populations involving adults with non-psychotic disorders only if more than 50% had a psychotic disorder, or if data limited to those with psychotic disorders are available.

In order to better inform research and clinical care, we intend to describe the clinical state (acute

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vs. post-acute vs. partial remission vs. remission), stage (e.g. first episode vs. early illness vs. persistent) and whether the studies target particular clinical presentations (e.g. negative symptoms, positive symptoms, treatment-resistant illnesses).

Types of Interventions

The intervention of interest is telephone support targeting (i) relapse prevention, (ii) adherence to psychiatric medication and/ or (iii) modifiable health risk behaviours.

'Relapse prevention' will be defined as telephone support designed to recognise and act on early warning signs of episode recurrence and/ or enhance coping strategies (including medication compliance), the number and duration of hospitalisations and/ or the impact of the illness on functioning and/or quality of life.

'Adherence to psychiatric medication' will be defined as telephone support intended to affect adherence with prescribed, self-administered medication for mental disorders. Ethical standards for adherence research dictate that attempts to increase adherence must be judged by their clinical benefits, not simply their effects on adherence rates[34]. Accordingly, adherence studies will only be included if both adherence and treatment effects are measured.

'Modifiable health risk behaviours' will be defined as telephone support that targets health behaviours (nutrition, physical activity, smoking, substance use) associated with modifiable cardiovascular risk factors (weight, cholesterol, blood glucose, blood pressure).

To be included, the telephone support must:

(i) Be administered over the telephone using person delivered (professional or layperson) spoken word (i.e. text, web-based and/ or automated systems collecting or transmitting data will not be included)

(ii) Utilise one or more psychological strategies to modify relapse risk, adherence to psychiatric medication and/ or health risk behaviours. Psychological strategies will be defined as supportive counselling, psychoeducation (including brief advice), cognitive behavioural

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(including problem solving, dialectical behavioral therapy, acceptance and commitment therapy), mindfulness and/ or motivational interviewing.

(iii) Comprise at least one telephone session, of at least ten minutes, delivered by a healthcare professional and/ or non-professional/ layperson/ peer/ consumer who has been trained in delivering the intervention

The telephone support may be a standalone intervention and/ or delivered in combination with other treatment components, including pharmacological. However, studies with multiple components will only be included if the telephone is the predominant method of intervention delivery. This is defined as studies in which at least 50% of the total number of participant contacts are conducted by telephone. Interventions delivered in any setting (e.g. community, hospital, rehabilitation or residential treatment centre, etc.) will be included.

Types of Comparison Conditions

The telephone support may be compared to inactive (e.g. standard care, waiting list control) and/ or active controls (e.g. pharmacological and/ or psychological) whereby telephone is not the predominant method of intervention delivery (e.g. individual, group, internet).

Types of Outcome Measures

(1) Indicators of relapse, including psychiatric symptomatology (positive and negative symptoms, depression, anxiety), the number and duration of hospitalisations, functioning and quality of life

(2) Medication adherence, including dose count (doses taken); dose days (days where correct number of doses taken); dose time (doses taken on schedule)

(3) Health behaviours (e.g. smoking, substance use, physical activity, fruit and vegetable consumption)

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(4) Severity of cardiovascular risk, including CVD risk index; quantity, severity of CVD risk factors (e.g. weight, BMI, waist circumference, blood pressure, plasma lipids, insulin, glucose)

(5) Treatment engagement (e.g. quantity/ frequency/ duration of telephone support attendance)

(6) Process measures/ mediators/ mechanisms [e.g. cognitive (empowerment/ self efficacy/ motivation); behavioral (e.g. active coping, including managing urges); process (e.g. therapeutic alliance)]

(7) Feasibility, including economic outcomes (e.g. cost, resource use, cost effectiveness) and/ or satisfaction/ preference. Qualitative outcomes regarding participant and/ or relative satisfaction will be reported as described.

Outcomes may be clinician and/or patient rated; assessed by objective and/ or subjective indices (e.g. blood, urine, actigraph, questionnaire, monitoring form/ diary) with or without collateral information (e.g. using a family member to validate use) and of any time frame (e.g. baseline, short and/ or medium and/ or long term follow-up).

Information Sources

Search strategy

Consistent with methods detailed in Cochrane Guidelines for systematic reviews[32], the search strategy will be conducted as follows. First, in May 2015 we identified ten relevant scientific electronic databases (Medline, PubMed, Embase, CINAHL, Science Direct, Wiley, PsychInfo, Central, Amed, Scopus) and four electronic non-scientific databases (Translating Research into Practice; Virginia Commonwealth University; Project Cork; Prevention, Information and Evidence Library) to search. Search terms related to telephone will be combined with psychosis related search terms and then outcome related search terms (see appendix 1 for the full MEDLINE search strategy).

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Abstract, title, key words and subject headings specific to each of the identified database will be searched. All subject headings will be exploded so that narrower terms are included. No limits will be placed on publication year. Publications must be available in English. Reference lists of identified publications will be hand searched to identify any additional publications. All publications will be organised in reference manager Endnote. The searches will be re-run just before final analyses and further studies retrieved for inclusion.

Classification of studies

The titles and abstracts of identified references will be classified in a three step process.

Step 1: Identification of studies for exclusion

AKB will review the titles and/or abstracts and exclude articles if they: a) are duplicates, b) do not focus on adults with a psychotic disorder, c) do not focus on telephone delivered support, or d) if the outcomes, process and/ or predictor variables do not include or specifically relate to relapse, medication adherence and/ or health behaviours, e) are not journal articles, reports, book chapters or newsletter articles. If eligibility is unclear from the title and/ or abstract, the full text article will be accessed and assessed.

Step 2: Classification of studies

The abstracts and/ or full text of the remaining studies will be examined by AKB to identify studies that are: (i) *Evaluation*, defined as an evaluation of a telephone delivered intervention as per the PICO criteria outlined above; (ii) *Reviews*, including summaries, descriptive, critical and/ or systematic reviews; *Discussion*, defined as general discussion of telephone delivered interventions, including development, principles, methods and implementation. References that are not evaluation, review or discussion papers (e.g. treatment manuals) will classified as 'Other'.

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Step 3: Cross Checking

Publications from step two will re-classified by the primary author (AB), for cross-checking. In case of disagreement, the final classification will be made by consensus, with the involvement of GH, PK, KB and/or SB. The articles excluded in step one will not be cross-checked because they will not be relevant to the review. The evaluation studies identified in step two will retained for further examination.

Data Extraction from Evaluation Studies

Data extraction will be performed by AB and checked by AT. Extraction forms will be piloted on several papers and modified as needed before use. When multiple reports of the same study are identified (e.g. related journal articles, conference proceedings which are then published), data from each report will be extracted separately and then combined across multiple data collection forms. Methodological critique and assessment of risk of bias will be performed independently by AB and AT. In the event of disagreement, final ratings will be made via consensus, following discussion with GH, PK, KB and/or SB. In the event that inadequate trial details are reported, study authors will be contacted no more than twice to obtain further information.

To enable methodological critique of both observational research and RCTs, criteria for data extraction will be adapted from the Downs and Black Scale[35] and the Cochrane Handbook for Systematic Reviews[32] and include

(1) Participant information, including n-values at each stage of the study (and reasons for non-participation), treatment setting, eligibility criteria, descriptive data including age, gender, ethnicity, socio-economic status, diagnostic criteria, treatment history

(2) Methods, including study design, country, setting(s), methodological limitations reported, methodological limitations observed (e.g. recruitment allocation and data collection

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methods; blinding; comparability of groups at baseline; appropriateness of analysis methods)

(3) Interventions, including number of groups, duration of treatment (number, frequency and duration of phone and non-phone components), delivery method(s), description of control intervention(s)

(4) Primary and secondary outcomes, including data collection sources/ methods, percentage of treatment sessions attended, other process measures/ mediators/ mechanisms, economic outcomes, satisfaction related qualitative outcomes, follow-up period

(5) Results, including indicators of relapse, medication adherence, health behaviours, severity of cardiovascular risk, treatment engagement, process measures/ mediators/ mechanisms, economic outcomes and patient satisfaction collected at all available follow-up time points.

Methodological Critique of Evaluation Research

To provide a thorough overview of the literature we will implement procedures to evaluate the quality of both observational studies and RCTs. A narrative synthesis of the findings from the included studies will be reported, structured around intervention type and content, population characteristics, and outcomes. This qualitative review will be supplemented with the following quantitative measures.

For observational studies, methodological quality will be assessed against the Downs and Black Scale[35]. Criteria will be assigned a yes (1 point); no (0 points); or unclear (0 points) rating. All criteria will have the same weight, and a quality score ranging from 0 to 27 points will be calculated for each study.

For RCTs, methodological quality will be assessed against the eleven item Physiotherapy Evidence Database (PEDro) scale[36]. Consistent with published reviews of psychological

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interventions (e.g.[21,37]) two items regarding blinding of subjects and therapists will not be scored in the present review, as these criteria are not appropriate for the studies under review. The remaining nine criteria will be assigned a assigned a yes (1 point) or no (0 points) rating, and a quality score ranging from 0 to 8 points will be calculated for each study (as item one is not included in the quality score;[36]).

Risk of bias will also be assessed using the Collaboration's Risk of Bias tool, as described in the *Cochrane Handbook for Systematic Review of Interventions*[32]. We will judge each item as being high, low or unclear risk, as per the criteria provided by Higgins and Green[32] and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table. Given that growing empirical evidence suggests that sequence generation and allocation concealment are particularly important potential sources of bias, studies will be deemed to be at the highest risk of bias if either item is scored as 'high' or 'unclear'.

Measures of Treatment Effect

Where possible, 'summary of findings' (SOF) tables will be generated for each comparison (phone vs multi-component phone; phone vs other active control; phone vs other inactive control). SOF tables will provide key information regarding evidence quality, the magnitude of effect of the interventions examined, and a summary of available data on the outcome variables defined under 'Outcome Measures' above.

Scale Derived Data

We intend to include continuous data from rating scales only if:

a) The psychometric properties of the instrument have been described in a peer review journal

b) The instrument was not written or modified by one of the authors for that particular trial

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c) The instrument was self-report or completed by an independent assessor (in the event that this is not clearly reported, a note will be made in 'Description of Studies')

Data presented in Graphs and Figures

Where possible, we intend to extract data that is only represented in graphs and figures, but only if the same result(s) are independently derived by AB and AT.

Dichotomous Outcome Measures

When data are available, a risk ratio (RR) and its 95% confidence interval will be provided for the primary outcome of each trial. RR has been selected in preference to odds ratios as evidence suggests that RR is more intuitive[38] and clinicians tend to misinterpret odds ratios as RR[39].

Continuous Outcome Measures

When data are available, effect sizes will be calculated according to Cohen's formula, to allow for comparison across studies. Effect sizes will be interpreted according to published guidelines, where 0.2-0.49 is defined as a small effect size, 0.5-0.79 is moderate and greater than 0.8 is large.

A study will be considered to have a positive outcome if at least 50% of reported outcomes demonstrate a between group difference in favour of the telephone support group at the end of the intervention. Positive maintenance outcome(s) will be evidenced when this effect is also evident at short and/ or medium and/ or long-term follow-up (defined as 1-6; 7-12 and >12 months after intervention completion, respectively). We anticipate there will be limited scope for meta-analysis due to the range of different outcome measures.

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ETHICS AND DISSEMINATION

As no primary data collection will be undertaken, no formal ethical assessment is required. We plan to present the findings of this systematic review for peer-review in an appropriate journal. We also intend to present to clinicians and researchers at appropriate conferences.

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ABOUT THE ARTICLE

Authors' Contributions

Dr Beck is the guarantor of the review protocol and wrote the draft protocol for the systematic review. All authors made substantial contributions to the conception and design of this protocol, revising it critically for important intellectual content and gave final approval of the version to be published. All authors agree to be accountable for all aspects of the work to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding Statement

Funding support for the conduct of this review has been provided by the NHMRC Centre of Research Excellence for Mental Health and Substance Use. The funder has no involvement in developing this protocol.

Competing Interests

Dr Beck, Dr Baker, Dr Turner and Dr Kelly have no competing interests to declare. Dr Bucci, Dr Berry and Prof Haddock are current grant holders for a mobile application delivered CBT intervention for early psychosis (Medical Research Council: R116690).

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Appendix One:

Date	Database	Search Strategy	Notes
14.05.15 (preliminary search)	Medline	Telephone [MH] OR ("telephone intervention"[Title] OR "phone intervention"[Title] OR "telephone program"[Title] OR "phone program"[Title] OR "telephone trial"[Title] OR "phone trial"[Title]) OR ("telephone intervention"[Abstract] OR "phone intervention"[Abstract] OR "telephone program"[Abstract] OR "phone program"[Abstract] OR "telephone trial"[Abstract] OR "phone trial"[Abstract]) AND Psychosis[MH] OR schizophrenia [MH] OR psychosis [Title] OR schizo*[Title] OR bipolar [Title]OR psychosis [Abstract] OR schizo*[Abstract] OR bipolar [Abstract] AND Cardiovascular[MH] OR diet [MH] OR nutrition [MH] OR physical activity [MH] OR exercise [MH] OR smoking[MH] OR medication compliance [MH] OR alcoholism[MH] OR alcohol-related disorders[MH] OR substance-related disorder[MH] OR relapse prevention [MH] OR Cardiovascular [Title] OR dietary intake [Title] OR diet [Title] OR nutrition [Title] OR fruit [Title] OR physical activity [Title] OR exercise [Title] OR smoking [Title] OR medication compliance [Title] OR alcoholism [Title] OR alcohol abuse [Title] OR alcohol dependence [Title] OR substance abuse [Title] OR substance dependence [Title] OR addiction [Title] OR smok* [Title] OR Cardiovascular [Abstract] OR dietary intake [Abstract] OR diet [Abstract] OR nutrition [Abstract] OR fruit [Abstract] OR physical activity [Abstract] OR exercise [Abstract] OR smoking [Abstract] OR medication compliance [Abstract] OR alcoholism [Abstract] OR alcohol abuse [Abstract] OR alcohol dependence [Abstract] OR substance abuse [Abstract] OR substance dependence [Abstract] OR addiction [Abstract] OR smok* [Abstract]	Limited to articles available in English

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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	YES
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	NA
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	YES
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	YES
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	YES
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	NA
Support:			
Sources	5a	Indicate sources of financial or other support for the review	YES
Sponsor	5b	Provide name for the review funder and/or sponsor	YES
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	YES
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	YES
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	YES
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	YES
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	YES

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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	YES
Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	YES
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)	YES
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	YES
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	YES
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	YES
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	YES
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	YES
	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)	YES
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	YES
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	YES
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	YES
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	YES

*** 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.**

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