

Are diabetes self-management interventions delivered in the psychiatric inpatient setting effective?

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BMJ Open Are diabetes self-management interventions delivered in the psychiatric inpatient setting effective? A protocol for a systematic review

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ABSTRACT

Introduction Diabetes is a major risk factor for cardiovascular disease, which is the most significant contributor to increased mortality due to natural causes in those with severe mental illness (SMI). Self-management interventions for diabetes have been shown to be effective in the general population, however, effects of these interventions in those with SMI is still unclear. Psychiatric admission could be used opportunistically to deliver interventions of this kind and help improve diabetes self-management. This review aims to assess whether interventions of this kind improve diabetes outcomes and have an effect on reducing cardiovascular risk.

Methods and analysis This review will include studies assessing diabetes self-management interventions designed to be delivered to those aged 18 and over with comorbid type 2 diabetes and SMI during admission to psychiatric inpatient settings. Databases including the Cochrane Library, Medline, Psychinfo, CINAHL, Embase, WHO's International Clinical Trials Registry Platform, International Health Technology Assessment Database, UK Clinical Research Network and ClinicalTrials.gov will be searched from inception to September 2022. Where possible, meta-analysis of included studies will be conducted. If heterogeneity is high and meta-analysis is not possible, we will use other means of data synthesis and will include a narrative description of included studies.

Ethics and dissemination Ethical approval is not required as the systematic review will only include data from existing studies. The results will be disseminated via peer-reviewed publication and presentation at relevant national and international conferences.

PROSPERO registration number CRD42022357672

INTRODUCTION

Severe mental illness (SMI) encompasses a range of diagnoses that include psychotic disorders, schizophrenia, schizoaffective disorder, bipolar affective disorder, severe depression and personality disorders. People with SMI have an increased mortality of two to three times the general population,¹ which translates to a shortened life expectancy of 10–20 years. Cardiovascular disease is the most significant contributor to natural

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The review will include studies that are randomised controlled trials (RCTs) and non-RCT in their design, and no publication date restriction has been set, in order to capture as many potential papers for consideration of inclusion as possible.
- ⇒ A wide range of databases will be searched in order to identify papers for potential inclusion.
- ⇒ Each study, including title and abstract screening for inclusion, data extraction and quality assessment, will be reviewed twice independently.
- ⇒ We aim to conduct meta-analysis of included studies, however in the event this is not possible we will look to use other means of data synthesis and will include a narrative description of included studies.
- ⇒ We have restricted to papers published in English language only, which may introduce a potential limitation to the review.

causes of this increased mortality.² Diabetes is a major risk factor for cardiovascular disease,³ and is important to consider in this population as young people with SMI are at nine times the increased risk of developing diabetes, in particular type 2 diabetes, when compared with the general population.⁴ This is due to complex reasons, including medication used to treat SMI and issues relating diet and lifestyle factors.^{5–7}

The effective management of diabetes and tailored interventions should be carefully considered for those with comorbid SMI and diabetes as part of cohesive shared care. Unfortunately, this is often not the case, with disparities in access to healthcare and impaired diabetes outcomes well documented in this population.^{2 8–10}

Behavioural interventions for people with diabetes, such as self-management education programmes, have been shown to be effective in the general population. The effectiveness of these interventions in those with comorbid type 2 diabetes and SMI is largely unknown.

This is important to understand as due to the symptoms associated with SMI, engagement with self-management interventions could differ from the general population leading to worsened outcomes if interventions are not specifically adapted.

A 2016 Cochrane review assessed self-management interventions for adults with comorbid SMI and diabetes. This review identified one small randomised controlled trial (RCT) assessing a 24-week community based programme (Diabetes Awareness and Rehabilitation Training) that did not have a major impact on diabetes outcomes.¹¹ A further 2020 review investigated if diabetes self-management programmes designed for the general population were also effective for those with SMI. This review demonstrated that most trials targeted at the general population exclude people with SMI, with only 2% of reported trials including participants with SMI, therefore it was not possible to assess the effectiveness of these interventions in this population.¹²

One aspect of care that is often forgotten when considering diabetes management in those with SMI is the psychiatric inpatient setting. Psychiatric admission could be used opportunistically to engage people with comorbid diabetes and SMI in behavioural interventions to improve diabetes self-management. By providing these interventions in the inpatient setting, barriers such as needing to attend regular appointments are removed and access to supportive and trained professionals is available.

This review protocol plans to build on the described previous reviews in this area, in particular the 2016 Cochrane review,¹¹ to assess whether there are any available studies that may be able to answer whether diabetes self-management interventions can be effective for people with SMI, specifically in the context of the psychiatric inpatient setting. The proposed review question therefore includes:

‘Do type 2 diabetes self-management interventions designed to be delivered in the psychiatric inpatient setting for people with comorbid diabetes and SMI improve diabetes outcomes and have an effect on reducing cardiovascular risk?’.

Aims and objectives

Aim

To assess the effects of diabetes self-management interventions for people with comorbid type 2 diabetes and SMI, designed for delivery in the psychiatric inpatient setting.

Objectives

- ▶ To review whether diabetes self-management interventions designed for delivery in the psychiatric inpatient setting are effective in improving diabetes control, reducing cardiovascular risk factors and promoting positive self-care behaviours.
- ▶ To assess the described interventions ability to improve related aspects of care, including metabolic factors, all-cause mortality and quality of life.

Search methods

The review has been registered with PROSPERO prior to initiation of the search.¹³ The review will be conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance and will include a PRISMA flow diagram to demonstrate both included and excluded studies.¹⁴

Sources

Databases will be systematically searched for appropriate trials, from the date of inception to September 2022. This will include both published trials and unpublished trials identified via registration in trial databases. Databases searched will include the Cochrane Library, Medline, Psycinfo, CINAHL, Embase, WHO’s International Clinical Trials Registry Platform, International Health Technology Assessment Database, UK Clinical Research Network and ClinicalTrials.gov. Medline alerts will also be created to ensure any newly published trails from this database can be reviewed while the systematic search is ongoing. Reference lists of included studies will also be reviewed, as well as any relevant systematic reviews identified via the search, in order to obtain as much evidence as possible and reduce the risk of publication bias affecting the results.

No restrictions on publication date will be set. Trials not available in English will be excluded due to limited translation resources. If unpublished trials are identified via search of the trial databases listed above, then the authors will be contacted to obtain a copy of the trial methods and results for review.

Search strategy

McBain *et al*’s Cochrane Review Medline search strategy¹¹ has been used and added to, to include a search relevant to the context of the psychiatric inpatient setting and exclude RCT only filters. This strategy was chosen over the 2020 systematic review,¹² as the Cochrane Review focused on interventions tailored specifically to those with SMI, rather than general diabetes self-management interventions that included people with SMI. The search strategy for Ovid MEDLINE is included in online supplemental file 1.

Study selection for inclusion

Studies identified via systematic review will be imported into EndNote 20 Reference Management Software for review. Duplicates will be assessed and removed via review of title, authors, DOI and abstracts of the imported articles.

Three authors (ZG, CP, AB) will independently review two-thirds of the titles and abstract of each included article to assess whether the article meets the inclusion criteria, ensuring that each article is assessed two times. If inclusion or rejection cannot be determined via the title and abstract, then the full text will be obtained for more in-depth review. Any differences in decision relating to inclusion of trials will be resolved via discussion with

Table 1 PICO question

Population	People aged 18 or over with comorbid type 2 diabetes and severe mental illness admitted to a psychiatric inpatient unit. Type 2 diabetes will be defined via National Institute for Health and Care Excellence (NICE) criteria for haemoglobin A1c (HbA1c), fasting blood glucose and oral glucose tolerance tests ^{16 17}
Intervention	Diabetes self-management interventions delivered during an acute psychiatric admission
Comparator	Community-based self-management interventions, standard care or waitlist control
Outcome	<p>Primary outcomes</p> <ul style="list-style-type: none"> ▶ Self-care behaviours, including medication adherence, capillary blood glucose monitoring, diet, level of physical activity ▶ Clinical indicators of diabetic control, including HbA1c, fasting blood glucose, oral glucose tolerance tests and diabetes-related complications ▶ Adverse effects caused by the intervention, including any negative effects on self-care behaviours, clinical issues such as hypoglycaemia or harmful effects on quality of life <p>Secondary outcomes:</p> <ul style="list-style-type: none"> ▶ Clinical, including medication changes, all-cause mortality and cardiovascular risk factors such as body mass index, weight, blood pressure, blood lipids, Q-Risk ▶ Psychosocial, including health-related quality of life, diabetes knowledge

the wider review team. The third author not involved in review of the article in question will arbitrate any discrepancies. When necessary, trial authors will be contacted for further information and clarification. Authors will be contacted via email. If there is no response from initial contact, a further email will be sent.

Patient and public involvement

There was no patient or public involvement in the development of this protocol.

PICO

Please see [table 1](#) for the PICO question.

Criteria for inclusion

Study type

RCTs and non-RCT studies in which participants are allocated to interventions using non-random methods will be included.

Participants

Adults, defined as those ≥ 18 years of age, with comorbid type 2 diabetes and SMI. SMI is defined as diagnoses that include psychotic disorders, schizophrenia, schizoaffective disorder, bipolar affective disorder, severe depression and personality disorders. Where studies have been conducted in an inpatient psychiatric setting comprising of those with SMI and other mental disorders, we will include these in our analysis.

Interventions

The intervention must be targeted for use in the psychiatric inpatient setting and can be of any duration. Behavioural interventions may target a range of different factors relating to diabetes self-management and associated behaviours, including medication adherence, self-monitoring of capillary blood glucose, engagement in diabetes monitoring programmes (eg, eye screening, foot care) and other life-style factors including diet and

exercise. Where there are several self-management interventions implemented, we will assess the data separately.

Geographical

Studies conducted in any geographical location will be included.

Outcome measures

Outcome measures of the intervention include:

- ▶ Self-care behaviours including medication adherence, monitoring of blood-glucose, diet and exercise.
- ▶ Clinical outcomes, including HbA1c, diabetes-related complications, body mass index (BMI), weight, blood pressure, blood lipids, medication changes, all-cause mortality.
- ▶ Adverse effects caused by the intervention.
- ▶ Psychosocial outcomes, including health-related quality of life and diabetes knowledge.

Exclusions

Interventions that target:

- ▶ Outpatient settings.
- ▶ Exclusively patients with type 1 diabetes—studies where a combination of patients with type 1 and type 2 diabetes are targeted will be included.
- ▶ Participants under the age of 18.
- ▶ Interventions directed at mental health professionals only, rather than patients.

Data collection

The following primary and secondary outcomes for trial interventions will be assessed.

Primary outcomes

Self-care behaviour outcomes

- ▶ Medication adherence, for example, as yes/no.
- ▶ Self-monitoring of capillary blood glucose monitoring, for example, as yes/no.

- ▶ Diet, as self-reported measure, for example, changes in self-reported dietary records.
- ▶ Level of physical activity, as self-reported measure, for example, International Physical Activity Questionnaire.¹⁵

Clinical indicators of diabetic control

- ▶ Glycosylated haemoglobin A1c (HbA1c), with cut-off for type 2 diabetes defined as ≥ 48 mmol/L.¹⁶
- ▶ Fasting blood glucose, with cut-off defined for type 2 diabetes as ≥ 7.0 mmol/L.¹⁶
- ▶ Oral glucose tolerance test, with cut-off for type 2 diabetes defined as ≥ 11.1 mmol/L.¹⁷
- ▶ Diabetes-related complications, including cardiovascular disease, neuropathy, nephropathy and diabetic foot disease.

Adverse effects caused by the intervention

- ▶ Any harm caused by the intervention, including negative effects on self-care behaviours, clinical issues such as hypoglycaemia or harmful effects on quality of life.

Secondary outcomes

Clinical outcomes

- ▶ BMI (kg/m^2).
- ▶ Weight (kg or pounds).
- ▶ Blood pressure (mm Hg).
- ▶ Blood lipids (cholesterol and/or triglycerides).
- ▶ Medication changes for diabetes management.
- ▶ All-cause mortality.

Psychosocial outcomes

- ▶ Health-related quality of life, including validated measurements tools such as the EQ-5D.¹⁸
- ▶ Diabetes knowledge, including validated measurement tools such as the Brief Diabetes Knowledge Test.¹⁹

Data extraction

Data will be extracted independently by three authors (ZG, CP, AB). Each author will extract data from two-thirds of the included articles, to ensure that data is extracted from each article twice by two authors. The modified version of the Cochrane Standard Data Extraction Form for RCTs and non-RCTs will be used to extract data, including information pertaining to the study methods, participants, intervention group and outcomes.²⁰ This form provides a transparent structure for data extraction, including clear structure, use of closed or non-ambiguous questions, opportunity to record raw data where applicable and recording of location in text, which will be of use in aiding resolution of any discrepancies. The form will be pilot tested on existing studies. Disagreements between the two authors when data is extracted will be resolved by discussion with the review team.

Google Forms will be used to electronically record onto the data extraction tool, as an alternative to specific software that may require licensing and specialist training. Use of electronic form was deemed appropriate, as previous systematic reviews of similar topics^{11 12} indicate that the

described review is likely to be of small to medium scale. Use of electronic forms will be beneficial to the review team as this method allows for electronic storage, sharing and integration of data, as well as electronic editing and analysis and also eliminates the need for manual data entering that may introduce errors.²¹ When only figures are presented within the article, Web Plot Digitizer will be used.

Assessing risk of bias

The Revised Cochrane risk-of-bias tool for randomised trials (RoB 2) Cribsheet form will be used to assess the risk of bias for each included study, including assessment of individual domains of risk-of-bias and provide and overall estimate. This tool has been selected as this is Cochrane's recommended risk assessment tool.²¹ RoB 2 includes information relating to risk of bias due to: the randomisation process; deviations from the intended interventions; missing outcome data; measurement of the outcome; selection of the reported result; overall risk of bias. Overall risk of bias will be presented as low, high or some concerns.²² Three authors (ZG, CP, AB) will work independently to assess and document the risk of bias for each included study, with each study assessed two times for risk of bias.

Data synthesis and analysis

In the event that included trials are deemed homogeneous enough in terms of clinical and methodological parameters to be pooled, then a meta-analysis of the pooled results will be presented. Due to the nature of the review questions, it is likely that there will be a degree of heterogeneity between trials. This is because of the potential for high variation in reported methods and results, such as type of SMI diagnosis, diabetes treatment plans, behavioural intervention designs and outcomes measured. Review Manager (RevMan Web) Cochrane software will be used to compare study data and complete meta-analysis where applicable.

For continuous outcomes, for example, HbA1c or self-reported questionnaires, when possible the standard mean difference and 95% CIs will be extracted and reported as an estimate of effect. Cohen's d will be used to measure the effect size, with a small effect defined as 0.0–0.2, medium as 0.3–0.7 and large ≥ 0.8 . Binary outcomes for example, medication adherence, presence of diabetes-related complications, will be assessed via risk ratios with 95% CIs.

Heterogeneity

Heterogeneity will be assessed and reported via the χ^2 test (significance level of $\alpha=0.1$) and the I^2 statistic. Forest plots will also be visually assessed to look for evidence of heterogeneity between included trials. An I^2 of $>50\%$ will be used to indicate a high degree of heterogeneity.

Reporting bias

Reporting bias and small sample bias will be assessed via use of funnel plots and Debray *et al*'s D-FIV for detecting

funnel plot asymmetry, due to improved type-1 error rates compared with other well-known tests for funnel plot asymmetry.²³ Asymmetry of the Funnel plot may be due to a variety of reasons, including time lag bias, language bias, citation bias, selective outcome reporting or selective analysis reporting.²⁴

Data synthesis and analysis

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach will be used to assess quality of evidence and will be presented as a 'Summary of Findings' table, produced using GRADEpro GDT software. GRADE assessments include consideration of risk of bias, inconsistency, indirectness, imprecision and publication bias.²¹ The risk of bias will be addressed within the data synthesis by restricting studies to include only those at low risk of bias.

Where meta-analysis is deemed possible, for example when outcomes between trials are comparable, heterogeneity will be assessed, and appropriate meta-analysis used to analyse and present the results. It is likely a random effects model will be used to as the statistical method to analyse the results, in order to account for levels of variation between studies secondary to the reasons described above. If results are deemed to be homogenous, then a fixed effect model could be used. The results will be presented as a Forest plot.

When meta-analysis is not possible due to issues such as limited evidence for comparison, incomplete reported outcomes, different effect measures, high risk of bias in the available evidence, clinical or methodological diversity or statistical heterogeneity, then alternative synthesis methods should be considered. Depending on minimum available data, alternative acceptable synthesis methods may include summarising effect estimates, combining p values or vote counting based on the direction of effect.²¹ A narrative description of studies will also be included.

Sensitivity analysis will also be conducted to assess the effect of including previously excluded studies on the review results. Alternative sensitivity analysis may also be identified during the review process. The results of the sensitivity analysis will be presented as a summary table.²¹

Subgroup analysis

Where possible, subgroup analysis will be considered for the following issues, which may introduce heterogeneity and have an impact on the behavioural intervention outcomes:

- ▶ Demographic issues, such as age and gender.
- ▶ SMI related factors, including diagnosis, duration of SMI and SMI treatment (eg, psychotropic medication which may impact diabetes control and management).
- ▶ Diabetes related factors, including baseline HbA1c, duration of diabetes and diabetes treatment (eg, insulin use).
- ▶ Intervention factors, including targeted behaviours, duration, intensity and underlying behaviour change theory applied.

Implication of results

This systematic review will look to demonstrate whether behavioural interventions for comorbid type 2 diabetes and SMI, designed specifically for delivery in the psychiatric inpatient setting, are effective at improving clinical, behavioural and psychosocial outcomes. It will primarily assess whether this type of intervention is beneficial to reducing cardiovascular risk, which is a major contributor to increased mortality in those with SMI.

Ethics and dissemination

Ethical approval is not required as the systematic review will only include data from existing studies. The results will be disseminated via peer-reviewed publication and presentation at relevant national and international conferences.

Contributors ZG, CP and AB developed the search strategy. ZG drafted the protocol manuscript and registered the review with PROSPERO. ZG, CP, AB and FJ were involved in the design of the review, provided feedback on protocol manuscript drafts and approval of the final protocol. ZG, CP and AB will be involved in abstract review and data extraction from included papers. ZG will act as guarantor of the review.

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Disclaimer This protocol has not previously been completed or published. Any important amendments will be acknowledged during dissemination of the review results.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

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