
Article:
Carswell, C. orcid.org/0000-0003-3781-3286, Taylor, J. orcid.org/0000-0001-5898-0900, Holt, R.I.G. orcid.org/0000-0001-8911-6744 et al. (8 more authors) (2024) A core outcome set for trials evaluating self-management interventions in people with severe mental illness and coexisting type 2 diabetes. Diabetic Medicine, 41 (4). e15288. ISSN 0742-3071

https://doi.org/10.1111/dme.15288

Received: 11 August 2023 | Accepted: 9 January 2024

DOI: 10.1111/dme.15288

DIABETIC Medicine

RESEARCH ARTICLE

A core outcome set for trials evaluating self-management interventions in people with severe mental illness and coexisting type 2 diabetes

Claire Carswell[1] | **Jo Taylor**[1] | **Richard I. G. Holt**[2,3] | **Jennifer V. E. Brown**[1] | **Ramzi Ajjan**[4] | **Jan R. Böhnke**[5] | **Tim Doran**[1] | **Ian Kellar**[6] | **David Shiers**[7,8,9] | **Judy Wright**[4] | **Najma Siddiqi**[1,10,11]

[1]Department of Health Sciences, University of York, York, UK

[2]Human Development and Health, Faculty of Medicine, University of Southampton, Southampton, UK

[3]National Institute for Health Research Biomedical Research Centre, University Hospital Southampton NHS Foundation Trust, Southampton, UK

[4]Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds, UK

[5]School of Health Sciences, University of Dundee, Dundee, UK

[6]Department of Psychology, University of Sheffield, Sheffield, UK

[7]Psychosis Research Unit, Greater Manchester Mental Health NHS Trust, Manchester, UK

[8]Division of Psychology and Mental Health, University of Manchester, Manchester, UK

[9]School of Medicine, Keele University, Keele, UK

[10]Bradford District Care NHS Foundation Trust, Bradford, UK

[11]Centre for Health and Population Sciences, Hull York Medical School, York, UK

Correspondence
Claire Carswell, Department of Health Sciences, University of York, York YO10 5DD, UK.
Email: claire.carswell@york.ac.uk

Funding information
National Institute for Health and Care Research

Abstract

Background: People with severe mental illness (SMI), such as schizophrenia, have higher rates of type 2 diabetes and worse outcomes, compared to those without SMI and it is not known whether diabetes self-management interventions are effective for people who have both conditions. Research in this area has been impeded by a lack of consensus on which outcomes to prioritise in people with co-existing SMI and diabetes.

Aims: To develop a core outcome set (COS) for use in effectiveness trials of diabetes self-management interventions in adults with both type 2 diabetes and SMI.

Methods: The COS was developed in three stages: (i) identification of outcomes from systematic literature review of intervention studies, followed by multi-stakeholder and service user workshops; (ii) rating of outcomes in a two-round online Delphi survey; (iii) agreement of final 'core' outcomes through a stakeholder consensus workshop.

Results: Seven outcomes were selected: glucose control, blood pressure, body composition (body weight, BMI, body fat), health-related quality of life, diabetes self-management, diabetes-related distress and medication adherence.

Conclusions: This COS is recommended for future trials of effectiveness of diabetes self-management interventions for people with SMI and type 2 diabetes. Its use will ensure trials capture important outcomes and reduce heterogeneity so findings can be readily synthesised to inform practice and policy.

KEYWORDS

core outcome set, self-management, severe mental illness, type 2 diabetes

1 | BACKGROUND

Severe mental illness (SMI; i.e. conditions such as schizophrenia and bipolar disorder)[1] is associated with a higher risk of developing physical long-term conditions, such as type 2 diabetes.[2] People with SMI are 2–3 times more likely to develop type 2 diabetes and experience poorer physical health outcomes compared with the general population.[2] For example, people with SMI die on average 15–20 years earlier than those without SMI, mainly because of co-existing physical long-term conditions.[3]

Good outcomes for type 2 diabetes depend on effective self-management.[4] The National Institute for Health and Care Excellence (NICE) recommends structured self-management education to support diabetes self-management,[5] as they are effective at improving diabetes outcomes in the general population.[6] However, the effectiveness of these programmes for people with SMI remains largely unknown.[7]

To establish the effectiveness of diabetes self-management programmes for people with SMI randomised controlled trials (RCTs) and systematic reviews of RCTs are needed.[8] While there is limited research evaluating self-management interventions specifically for people with SMI and co-existing type 2 diabetes,[7] previous research on generic self-management interventions has included those with both conditions.[9] Systematic reviews have found variation in outcome selection, and incomplete reporting of outcomes, due in part to the lack of consensus about what outcomes are most important to those with type 2 diabetes and SMI, making it difficult to synthesise the results.[10]

Core outcome sets (COS) are an agreed standardised set of outcomes that should be used in all trials addressing a specific question.[11] They provide a method of reducing outcome reporting bias in trials and ensure the clinical outcomes being reported are ones that are of greatest importance to all involved parties.[12] They also reduce the heterogeneity of outcomes in trials, so findings can be more readily synthesised to inform policy and practice. Several COSs have already been developed for specific conditions and interventions, including for people with SMI.[13] However, there is no COS for diabetes self-management interventions targeting people who have co-existing SMI and type 2 diabetes. People with SMI and co-existing physical long-term conditions experience unique issues and barriers to accessing healthcare services, and also have different priorities to those without SMI, due to the difficulties of managing co-existing symptoms and treatment burdens, therefore it is important to develop a specific COS for people who have co-existing SMI and type 2 diabetes, that accounts for these unique experiences and priorities.[14,15]

What's new?

What is already known

- People with severe mental illness are more likely to have type 2 diabetes. We need high-quality trials of self-management interventions in this population and a consensus on what outcomes should be prioritised.

What has this study found

- This study developed a core outcome set for self-management interventions for people with co-existing type 2 diabetes and severe mental illness.

What are the implications of the study

- This core outcome set will enable consistent reporting in future trials and help develop a robust evidence base for self-management interventions for those with co-existing type 2 diabetes and severe mental illness.

The 'Diabetes and Mental Illness—Improving Outcomes and Services (DIAMONDS)' programme is a research programme that aims to develop and evaluate a tailored self-management intervention for people who have type 2 diabetes and SMI.[16,17] A necessary first step in this programme is to develop a COS for diabetes self-management interventions that are tailored specifically to people who have co-existing SMI. This will ensure the outcomes included in evaluation trials are of importance to those most affected, and the evidence can be synthesised to inform future policy.

2 | AIMS AND OBJECTIVES

This study aimed to develop a COS for trials evaluating the effectiveness of diabetes self-management interventions for adults (over 18 years) who have SMI and co-existing type 2 diabetes. To achieve this, we followed three steps:

1. Identify a list of potential outcomes from a systematic review of the literature (to identify those used in previous studies) and a multi-stakeholder workshop and service user panel meeting.[10]
2. Rate identified outcomes for priority to include in the COS through a two-round Delphi survey with interested parties.
3. Agree on which outcomes are included in the COS through a consensus workshop.

3 | METHODS

We followed best practice methods as described in the COMET Initiative.[18,19] We reviewed methods employed in studies identifying health outcomes,[20] to select appropriate consensus methods and ensure meaningful input from service users, carers and healthcare professionals.

We have published the study protocol[21] and the study was registered on the COMET initiative website on 1 July 2016.[22] Ethical approval was obtained from the Research Ethics Committee East Midlands—Leicester Central (reference: 16/EM/0149). Informed consent was obtained from all participants in the study.

Developing the COS included three steps:

3.1 | Step 1—identifying outcomes

3.1.1 | Review of existing evidence

We identified systematic reviews of trials and experimental studies involving people with SMI and physical long-term conditions. We used these to identify relevant studies with sample sizes over 20 participants,[10] to ensure outcomes were practicable to measure in large trials.[21] We extracted information about the outcomes used in these studies. We also incorporated outcomes from the AADE DSME Outcomes Continuum[23] and from a systematic review of self-management outcomes which identified outcomes that are important to affected groups.[24]

3.1.2 | Multi-stakeholder workshop and service user panel

We held a workshop attended by 19 stakeholders, including research team members and healthcare professionals who were identified through the research team's networks. Table 1 provides an overview of the attendee's professional background. Some participants had multiple professional roles.

Attendees worked in three groups to identify relevant outcomes. Following this discussion, findings from the review were presented and the groups were asked to create a list of potential outcomes and remove any outcomes identified by the review that overlapped with each other.

This list was then presented to DIAMONDS Voice, our service user and carer panel consisting of between 6 and 8 members during the period of the study. The panel was invited to review the list and add relevant outcomes that had not already been identified, which was followed by telephone discussions with members who

TABLE 1 Professional backgrounds of workshop attendees.

Professional role
• Health services researcher
• Clinical psychiatrist
• Applied health researcher
• Trialist
• Specialist diabetes nurse
• Diabetes Care Lecturer
• Mental Health Nursing Lecturer
• Diabetologist
• Carer
• General practitioner
• Clinical academic
• Health technologist
• Commissioner
• Statistician
• Health economist
• Social epidemiologist
• Primary care epidemiologist
• Dietitian
• Mental health nurse

TABLE 2 Overview of the respondents to round one of the Delphi survey.

Stakeholder group	Number of respondents round 1 (*n*)	Number of respondents round 2
Service user	23	10
Carer	4	3
Health and social care staff		
Mental healthcare staff	24	13
Physical healthcare staff	17	11
Health service managers and commissioners	7	2
Academic experts	9	9
Total	84	48

were not in attendance at the meeting. In total 4 service users and two carers reviewed the initial list through DIAMONDS Voice.

3.2 | Step 2—rating outcomes

The aim of step 2 was to rate outcomes according to percentage agreement on the importance of each outcome, for inclusion in the COS through a two-round Delphi survey with all relevant stakeholders. Participants completed a survey which included the outcomes identified in step 1. The purpose of this survey was to reduce the list based on collated responses, considering different views between groups and allowing changes in opinion to enable the development of a group consensus.

3.2.1 | Participants

Stakeholders were purposively sampled to ensure representation across multiple groups. We aimed to recruit between 50 and 75 participants into the first round of the Delphi survey from the following groups:

- Adults with SMI and co-existing type 2 diabetes living in the community. We defined SMI as conditions which can present with psychosis, for example., schizophrenia and bipolar disorder.
- Carers of people who have SMI and co-existing type 2 diabetes. Carers were defined as anyone who provides unpaid support to the person, including family or friends.
- Health and social care staff from a range of professional backgrounds who provide care to people with coexisting SMI and type 2 diabetes.
- Health service managers and commissioners with responsibility for SM and/or type 2 diabetes
- Academic experts in relevant areas, such as diabetes, SMI, primary care and methodologists.

The DIAMONDS Voice Panel was also invited to take part in the Delphi survey.

3.2.2 | Recruitment

Service users and carers were recruited through NHS community mental health teams using care coordinators. Other participants were recruited through NHS Trusts and third-sector organisations. Table 2 provides an overview of respondents.

3.2.3 | Data collection: Delphi survey round 1

The survey was administered online using Qualtrics, on paper or by telephone with a researcher. There was a four-week period for participants to complete the survey. While most healthcare staff and academics completed the survey online, most service users and carers used postal questionnaires and several service users accessed face-to-face or telephone support. The survey presentation was informed by DIAMONDS Voice, who piloted the survey prior to data collection.

During the first round, all potential outcomes that were agreed in step 1 were presented, and respondents were asked to rate the importance of each outcome on a scale from 1 to 9, independent of other outcomes, ranging from 1 being not important, to 9 being of critical importance. The survey also included free text boxes where participants could provide comments about their responses and suggest additional outcomes that were not included in the original survey. To reduce the risk of attrition we informed all participants that there would be two rounds of the survey before data collection.

3.2.4 | Data analysis: Delphi survey round 1

Data were analysed by group (participants were grouped into academic experts, health services managers, mental health staff, physical health staff and service users and carers) and for all participants together. The number of respondents and distribution of scores were summarised and analysed. The proportion of participants scoring 1–3, 4–6 and 7–9 for each outcome was calculated.

Written responses by participants were analysed to assess how the survey should be modified for round 2. The main feedback was that the list was too long, and outcomes were often similar, making it difficult to differentiate their importance. Therefore, the research team merged certain outcomes which were able to be grouped into a single larger outcome.

3.2.5 | Data collection: Delphi survey round 2

Respondents who completed the round one survey were invited to participate in round two. Participants were presented with the following results from round one:

- Rating of outcomes across all participants.
- Rating of outcomes for their own group.
- Their individual scores from round one.

Participants were asked again to rate these outcomes, using the same 1–9 scale. This allowed participants to adjust their scores and enabled comparison between the rounds.

3.2.6 | Data analysis: Delphi survey round 2

We based our approach to analysis on consensus methods used in similar studies. Data from each group and the whole group were analysed to determine the percentage of respondents who scored each outcome 1–3, 4–6 and 7–9. The following thresholds were applied to categorise the outcomes across all groups during round 2 of the Delphi survey:

a. Consensus 'IN', outcomes that should be included in the COS: >70% of respondents score the outcome as 7–9 (highest importance), and <25% score the outcome as 1–3 (least importance).
b. Consensus 'out', outcomes that should not be included in the COS: >70% of respondents score the outcome as 1–3 (least importance) and <15% score the outcome as 7–9 (highest importance)
c. No consensus, outcomes for which there is no consensus on their importance: Any other distribution of the scores.

We descriptively analysed the consistency of these categorisations within and across groups to explore the relevance of outcomes across all respondents, and to ensure the voices of minority parties were not overruled by the majority. However, no weighting was applied to the different stakeholder groups during the analysis.

3.3 | Step 3—consensus workshop

We organised a Delphi consensus workshop that was attended by 10 participants. The purpose of the consensus workshop was to agree on a final set of outcomes. The attendees included a social epidemiologist, a clinical psychiatrist, two health services researchers, an academic diabetologist, a GP, a carer, a service user, a mental health professional and a lecturer in health psychology. Four additional clinical experts (1 diabetologist, 1 GP, 2 psychiatrists) provided virtual input in advance.

A summary of the results from rounds one and two of the survey was provided to participants in advance of the workshop. The results were also presented at the workshop, with an emphasis on the top 15 rated outcomes as there were no outcomes that met consensus for exclusion. Participants were guided by informing them of the following considerations: the purpose of the COS, the burden associated with the measurement of outcomes, the number of outcomes included in published COSs and whether the outcomes were measurable and feasible. The workshop participants were then asked to select two outcomes they considered the most important. This, along with the Delphi results, informed decisions within the group.

4 | RESULTS

4.1 | Step 1—identifying outcomes

We extracted 48 outcomes from relevant trials and key studies, and a further 28 outcomes were identified in a multi-stakeholder workshop and a service user panel (DIAMONDS Voice) meeting. The DIAMONDS Voice members added two outcomes to the list, specifically sleep problems and being listened to by healthcare professionals. This resulted in 76 outcomes which were included in round 1 of the survey in step 2. The final list of 76 outcomes is available in Data S1, these fell into the outcome domains outlined in Table 3.

TABLE 3 Outcome domains identified during Step 1.

Domain
SMI symptoms and complications
Glucose control
Diabetes complications
Quality of life
Health state
Functioning (how well you can do things)
Self-management
Diabetes monitoring and treatment
Service utilisation
Patient experience

4.2 | Step 2—rating outcomes

4.2.1 | Delphi survey round 1 results

In total, 84 people participated in round one of the surveys. The top-rated outcomes for round one (for which >90% of participants scored the outcome 7–9) were medication adherence, self-management of diabetes, glucose control, mental health-related quality of life (HRQoL), prescribed medications, attendance at annual diabetes check-ups, self-management of SMI and physical HRQoL. A summary of the proportion of respondents scoring 7–9 for these top-rated outcomes can be seen below in Table 4, and an overview of the full results can be found in the Data S1.

4.2.2 | Delphi round two survey results

The list of outcomes was reduced to 42 for round two of the survey, to minimise participant burden and ensure each outcome measured a distinct concept to better enable participants to assess each outcome.

A total of 48 participants from round one provided data for round two, giving a response rate of 57%. No formal analysis of attrition bias was conducted. Fifty-nine outcomes reached consensus to be considered for the COS and 17 outcomes did not reach consensus. Differences between scores on outcomes across different groups were marginal, with participant groups agreeing on what outcomes were important. No outcomes reached a consensus for exclusion; therefore, all outcomes were carried forward to the next step.

The top-rated outcomes in round two were self-management of diabetes, glucose control, blood pressure, diabetes complications, annual diabetes care review, depression, SMI symptoms, episodes of high and low blood glucose, diabetes distress, cholesterol levels, self-efficacy, health literacy, anxiety and satisfaction with care.

TABLE 4 Proportion of respondents in round one scoring top-rated outcomes as a high priority.

Outcome	Percentage of all participants scoring 7–9
Medication adherence	99%
Self-management of diabetes	96%
Glucose control (HbA_{1c})	95%
Mental health-related quality of life	94%
Prescribed medications	93%
Annual diabetes care review	92%
Self-management of SMI	91%
Physical health-related quality of life	90%

TABLE 5 Proportion of respondents in round two scoring top-rated outcomes as a high priority.

Outcome	Percentage of all participants scoring 7–9
Self-management of diabetes	100%
Glucose control (HbA_{1c})	98%
Blood pressure	98%
Diabetes complications	98%
Annual diabetes care review	98%
Hypers (high blood glucose)	96%
Depression	94%
SMI symptoms	94%
Hypos (low blood glucose)	94%
Diabetes distress	91%
Cholesterol levels	91%
Self-efficacy	90%
Health literacy	90%
Anxiety	90%
Satisfaction with care	90%

A summary of the proportion of respondents scoring 7–9 for these top-rated outcomes can be seen below in Table 5. A summary of the full results can be found in Data S2.

4.3 | Step 3—agree outcomes

The final consensus workshop was facilitated by JT. A short report of the results from step 2 was provided to all workshop participants in advance of the meeting so they could see how different outcomes were rated across stakeholder groups. Service users/carer invitees were also offered a telephone call with a researcher to talk through the report in advance of the workshop.

The introduction to the workshop included reminding participants about the purpose of the core outcome set and how it would be used and summarised what would happen in the workshop and the overall aim. The workshop began with small group informal discussions about the results from step 2 with an emphasis on top-rated outcomes from both rounds of the Delphi survey. Groups were also provided with copies of the report they received in advance of the workshop. All outcomes from stage 2 of the Delphi survey were discussed, as no outcomes met the consensus for exclusion. The top 15 rated outcomes from the survey were identified.

In the whole group discussion that followed, the top 15 outcomes were discussed in turn. Specific discussions were also held about outcomes that were rated higher by service users than other stakeholder groups but did not make the top 15, round 1 outcomes that were rated highly but had been merged together to ensure these were not missed and other outcomes participants wanted to discuss.

A visual display of all the outcomes that were discussed was placed at the front of the room and updated as the workshop progressed. To ensure all outcomes could be covered in the time available, an informal voting technique was used, with the first question asked of the whole group being 'should this outcome be included?', with participants asked to raise their hands. All participants were offered an opportunity to express their views, starting with service user/carer participants to ensure discussions were led from this position. Participants were also reminded of any differences in the overall rating of these outcomes between stakeholder groups.

For outcomes that lacked consensus through discussion and informal voting, participants were asked to consider these outcomes in relation to the purpose of the COS and whether they were aligned with this. This helped participants consider factors other than importance, including the aim of diabetes self-management interventions and the feasibility of measurement. As these were more technical discussions, the facilitator ensured that any terminology used was explained so service user/carer participants could continue to contribute. As the focus of self-management interventions is to improve diabetes outcomes, a decision was made during these discussions to remove outcomes focused exclusively on mental health. Diabetes distress and HRQoL were selected to represent the emotional burden of managing diabetes alongside SMI.

Through a process of deliberation and discussion, we formed a consensus on seven outcomes to include in the COS:

- Blood pressure
- Body composition (body weight, body mass index (BMI) and body fat)
- Diabetes distress
- Diabetes self-management
- Glucose control (HbA_{1c})
- HRQoL
- Medication adherence

5 | DISCUSSION

We have established for the first time a COS for diabetes self-management interventions for people who have type 2 diabetes and co-existing SMI. The seven outcomes included in the COS were selected through best practice methods described in the COMET Initiative.[18] The outcomes relate to important clinical measures for type 2 diabetes, such as blood pressure, body composition and glucose control; measures of self-management itself, including diabetes self-management and medication taking; as well as subjective experiences associated with living with diabetes, including diabetes distress and HRQoL. While mental health outcomes were consistently prioritised, the focus of this COS is to evaluate self-management interventions for type 2 diabetes. Therefore, in Step 3 we decided to exclude measures related to symptoms of mental illness, but to include distress related to diabetes and overall HRQoL to ensure that mental health was retained in the COS. The need to focus on a narrow range of outcomes highlights the potential shortcomings of disease-specific interventions being too narrowly focused to address the broad range of issues experienced by people living with co-existing SMI.

Similar to other COS studies,[13,25] none of the originally identified outcomes reached consensus for exclusion, therefore we refined our list based on outcomes with the highest consensus for inclusion using a modified Delphi process with expert stakeholders involved in the final workshop. The outcomes included in our COS overlap with those identified in other COSs for effectiveness trials in diabetes, for example, blood glucose and body composition.[25] Our set also features outcomes included in COSs for SMI-focused interventions, such as medication adherence and quality of life.[13] While the outcomes included in other COSs for diabetes, including the COS developed for use in practice with people with type 1 and type 2 diabetes (ICHOM Diabetes),[26] and the COS developed for trials evaluating interventions for type 2 diabetes (SCORE-IT),[25] are relevant to the people who have co-existing SMI, they do not completely overlap. For example, we did not include outcomes related to complications of diabetes.[25] While complications of diabetes were highly rated in the Delphi survey, these were excluded during discussions in the consensus workshop as we considered the implementation of the COS within

a trial context. We needed to ensure that the number of outcomes was manageable and would not be burdensome to measure and that they would be relevant across all trials evaluating self-management of people with type 2 diabetes and co-existing SMI, including trials focused on people who are newly diagnosed with type 2 diabetes. However, glucose control, blood pressure and body composition represent key clinical indicators of future diabetes complications.[27] In contrast to SCORE-IT,[25] we also included diabetes distress. This reflects the need to account for the relationship between mental and physical health in interventions for type 2 diabetes in people who have co-existing SMI.

The next step is to identify measures that can be administered consistently across trials. Some outcomes have standardised clinical measures that are already in widespread use, such as HbA_{1c} for measuring blood glucose control, or standardised blood pressure measures. Other clinical measures, such as body composition, are associated with more controversy in relation to their measurement. Body Mass Index (BMI) and body weight are not direct measures of body composition,[28] while waist circumference is a particularly important measure in type 2 diabetes.[29] Clinical guidelines, therefore, recommend that BMI and waist circumference are used together.[5]

Other outcomes included in our COS do not have the same widely recognised standardised clinical measures. There are many measures of HRQoL, some are generic while others are disease-specific.[30] A recent narrative review has recommended the use of a combination of disease-specific and generic measures to capture an overall picture of HRQoL. However, it is key that the measures capture physical- as well as mental-HRQoL, to represent what is important to service users. Diabetes self-management measures can capture different self-care activities and other aspects of adherence to self-management regimen.[31] Measures for medication taking are plentiful,[32] and any measure would need to account for the medication regimens of both type 2 diabetes and SMI. Additionally, diabetes distress can be captured using several different instruments.[33] Future research is needed to identify specific measures that can adequately capture the experiences of people living with co-existing SMI and diabetes.

The strengths of this study include the involvement of service users consistently throughout the consensus exercises, including during the final decisions about which outcomes to include. This was facilitated through strong networks in the research team and a flexible approach to collecting data, including providing support to complete surveys face-to-face and over the phone. The high level of consensus and prioritisation of outcomes reflect the relevance of items identified during the first stage. While we aimed to recruit a diverse range of participants, they may not be representative of all interested parties and our findings may not be transferable outside the UK. The provision of diabetes care for people with SMI varies across countries, and we were only able to include people from the UK who spoke English and had the capacity to engage in the process. The Delphi process was not effective in highlighting the most important outcomes for inclusion in the COS, and future studies may need to consider other methods to use that allow for this, as other COS studies have experienced similar problems.

6 | CONCLUSION

This study is the first to develop a COS for evaluations of type 2 diabetes self-management interventions for people with co-existing SMI. This COS can be used in future trials to ensure a coordinated approach that will enable the synthesis of results, as well as ensure the outcomes being captured are those prioritised by service users, healthcare professionals and policymakers.

ACKNOWLEDGEMENTS

This paper reports work undertaken as part of a National Institute for Health and Care Research Programme development grant (Award ID: RP-DG-1214-10002).

CONFLICT OF INTEREST STATEMENT

DS is an expert adviser to the National Institute for Health and Care Excellence Centre for Guidelines; the views expressed are those of the authors and not those of National Institute for Health and Care Excellence. RIGH has received honoraria for speaker engagement, conference attendance and advisory boards from Abbott, AstraZeneca, Boehringer Ingelheim, European Association for the Study of Diabetes, Eli Lilly, Encore, Janssen, Menarini, Napp Pharmaceuticals Limited, Novo Nordisk, Omniamed, Roche and Sanofi.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Claire Carswell https://orcid.org/0000-0003-3781-3286
Jo Taylor https://orcid.org/0000-0001-5898-0900
Richard I. G. Holt https://orcid.org/0000-0001-8911-6744
Jennifer V. E. Brown https://orcid.org/0000-0003-0943-5177

Ramzi Ajjan https://orcid.org/0000-0002-1636-3725
Jan R. Böhnke https://orcid.org/0000-0003-0249-1870
Tim Doran https://orcid.org/0000-0001-7857-3704
Ian Kellar https://orcid.org/0000-0003-1608-5216
David Shiers https://orcid.org/0000-0003-2531-5837
Judy Wright https://orcid.org/0000-0002-5239-0173
Najma Siddiqi https://orcid.org/0000-0003-1794-2152

REFERENCES

1. Ruggeri M, Leese M, Thornicroft G, Bisoffi G, Tansella M. Definition and prevalence of severe and persistent mental illness. *Br J Psychiatry*. 2000;177:149-155. doi:10.1192/bjp.177.2.149
2. Reilly S, Olier I, Planner C, Doran T, Reeves D, Ashcroft DM. Inequalities in physical comorbidity: a longitudinal comparative cohort study of people with severe mental illness in the UK. *BMJ Open*. 2015;5:e009010.
3. Fiorillo A, Sartorius N. Mortality gap and physical comorbidity of people with severe mental disorders: the public health scandal. *Ann General Psychiatry*. 2021;20(1):52. doi:10.1186/s12991-021-00374-y
4. American Association of Diabetes Educators. An effective model of diabetes care and education: revising the AADE7 self-care behaviors®. *Diabetes Educ*. 2020;46(2):139-160. doi:10.1177/0145721719894903
5. National Institute for health and care excellence. Type 2 diabetes in adults: management. NICE Guideline [NG28]. 2019.
6. Vas A, Devi ES, Vidyasagar S, et al. Effectiveness of self-management programmes in diabetes management: a systematic review. *Int J Nurs Pract*. 2017;23(5):e12571. doi:10.1111/ijn.12571
7. McBain H, Mulligan K, Haddad M, Flood C, Jones J, Simpson A. Self management interventions for type 2 diabetes in adult people with severe mental illness. *Cochrane Database Syst Rev*. 2016;4(4):CD011361. doi:10.1002/14651858.CD011361.pub2
8. Hariton E, Locascio JJ. Randomised controlled trials–the gold standard for effectiveness research: study design: randomised controlled trials. *BJOG*. 2018;125(13):1716. doi:10.1111/1471-0528.15199
9. Chwastiak LA, Freudenreich O, Tek C, et al. Clinical management of comorbid diabetes and psychotic disorders. *Lancet Psychiatry*. 2015;2(5):465-476. doi:10.1016/S2215-0366(15)00105-4
10. Taylor J, Stubbs B, Hewitt C, et al. The effectiveness of pharmacological and non-pharmacological interventions for improving Glycaemic control in adults with severe mental illness: a systematic review and meta-analysis. *PLoS One*. 2017;12(1):e0168549. doi:10.1371/journal.pone.0168549
11. Williamson PR, Altman DG, Blazeby JM, et al. Developing core outcome sets for clinical trials: issues to consider. *Trials*. 2012;13:132. doi:10.1186/1745-6215-13-132
12. Tunis SR, Clarke M, Gorst SL, et al. Improving the relevance and consistency of outcomes in comparative effectiveness research. *J Comp Eff Res*. 2016;5(2):193-205. doi:10.2217/cer-2015-0007
13. Retzer A, Sayers R, Pinfold V, et al. Development of a core outcome set for use in community-based bipolar trials—a qualitative study and modified Delphi. *PLoS One*. 2020;15(10):e0240518. doi:10.1371/journal.pone.0240518
14. Balogun-Katung A, Carswell C, Brown JVE, et al. Exploring the facilitators, barriers, and strategies for self-management in adults living with severe mental illness, with and without long-term conditions: a qualitative evidence synthesis. *PLoS One*. 2021;16(10):e0258937. doi:10.1371/journal.pone.0258937
15. Carswell C, Brown JVE, Lister J, et al. The lived experience of severe mental illness and long-term conditions: a qualitative exploration of service user, carer, and healthcare professional perspectives on self-managing co-existing mental and physical conditions. *BMC Psychiatry*. 2022;22(1):479. doi:10.1186/s12888-022-04117-5
16. Brown JVE, Ajjan R, Alderson S, et al. The DIAMONDS intervention to support self-management of type 2 diabetes in people with severe mental illness: study protocol for a single-group feasibility study. *SSM–Mental Health*. 2022;2:100086. doi:10.1016/j.ssmmh.2022.100086
17. Carswell C, Coventry PA, Brown JVE, et al. Development of a supported self-management intervention for people with severe mental illness and type 2 diabetes: theory and evidence-based Co-design approach. *J Med Internet Res*. 2023;25:e43597. doi:10.2196/43597
18. The COMET Initiative. The COMET (Core outcome measures in effectiveness trials) initiative. 2016 http://www.comet-initiative.org/
19. Kirkham JJ, Davis K, Altman DG, et al. (2017) Core outcome set-STAndards for development: the COS-STAD recommendations. *PLoS Med*. 2017;14(11):e1002447. doi:10.1371/journal.pmed.1002447
20. Gargon E, Gurung B, Medley N, et al. Choosing important health outcomes for comparative effectiveness research: a systematic review. *PLoS One*. 2014;9(6):e99111. doi:10.1371/journal.pone.0099111
21. Taylor J, Böhnke JR, Wright J, et al. A core outcome set for evaluating self-management interventions in people with comorbid diabetes and severe mental illness: study protocol for a modified Delphi study and systematic review. *Trials*. 2017;18:70.
22. COMET Initiative. Developing a Core Outcome Set for evaluating self-management interventions in people with comorbid diabetes and severe mental illness. 2016 http://www.comet-initiative.org/studies/details/911
23. Peeples M, Tomky D, Mulcahy K, Peyrot M, Siminerio L. Evolution of the American Association of Diabetes Educators' diabetes education outcomes project. *Diabetes Educ*. 2007;33(5):794-817. doi:10.1177/0145721707307615
24. Boger E, Ellis J, Latter S, et al. Self-management and self-management support outcomes: a systematic review and mixed research synthesis of stakeholder views. *PLoS One*. 2015;10(7):e0130990. doi:10.1371/journal.pone.0130990
25. Harman NL, Wilding JPH, Curry D, et al. Selecting Core outcomes for randomised effectiveness trials in type 2 diabetes (SCORE-IT): a patient and healthcare professional consensus on a core outcome set for type 2 diabetes. *BMJ Open Diabetes Res Care*. 2019;7(1):e000700. doi:10.1136/bmjdrc-2019-000700
26. Nano J, Carinci F, Okunade O, et al. A standard set of person-centred outcomes for diabetes mellitus: results of an international and unified approach. *Diabet Med*. 2020;37(12):2009-2018. doi:10.1111/dme.14286
27. Essafi MA, Bouabdellaoui L, Aynaou H, Salhi H, El Ouahabi H. Metabolic syndrome in patients with diabetes mellitus. *Cureus*. 2022;14(4):e24469. doi:10.7759/cureus.24469

28. O'Neill D. Measuring obesity in the absence of a gold standard. *Econ Hum Biol*. 2015;17:116-128. doi:10.1016/j.ehb.2015.02.002
29. Després JP, Lemieux I, Prud'homme D. Treatment of obesity: need to focus on high risk abdominally obese patients. *BMJ*. 2001;322(7288):716-720. doi:10.1136/bmj.322.7288.716
30. Speight J, Reaney MD, Barnard KD. Not all roads lead to Rome-a review of quality of life measurement in adults with diabetes. *Diabet Med*. 2009;26(4):315-327. doi:10.1111/j.1464-5491.2009.02682.x
31. Toobert DJ, Hampson SE, Glasgow RE. The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care*. 2000;23(7):943-950.
32. Forbes CA, Deshpande S, Sorio-Vilela F, et al. A systematic literature review comparing methods for the measurement of patient persistence and adherence. *Curr Med Res Opin*. 2018;34(9):1613-1625. doi:10.1080/03007995.2018.1477747
33. Lee EH, Lee YW, Lee KW, Kim YS, Nam MS. Measurement of diabetes-related emotional distress using the problem areas in diabetes scale: psychometric evaluations show that the short form is better than the full form. *Health Qual Life Outcomes*. 2014;12(1):142. doi:10.1186/s12955-014-0142-z

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Carswell C, Taylor J, Holt RIG, et al. A core outcome set for trials evaluating self-management interventions in people with severe mental illness and coexisting type 2 diabetes. *Diabet Med*. 2024;00:e15288. doi:10.1111/dme.15288