**Project Title:** A review of core outcome sets for mental health conditions

**Lead applicant:** Paula Williamson

**Co-applicants:** Sarah Gorst, Susie Dodd

**Introduction**

When designing clinical trials, it is important to measure appropriate outcomes, so that the results can be compared with other trials and be as useful as possible to decision makers. However, many studies which explore the effects of the same intervention on a specific health condition measure and report different outcomes, making it difficult to compare, contrast or combine their findings. This inadequate attention to the choice of outcomes has led to avoidable waste in the production and reporting of research, and the outcomes included in research have not always been those patients regard as most important or relevant.

These problems are prevalent in mental health clinical trials, with many trials reporting only generic, non-specific scales, resulting in important outcomes being overlooked.(1) Such problems have also been highlighted in routine care.(2) This has led to calls for standardisation in the outcomes being measured and the prioritisation of outcomes that are most relevant to patients.(2,3)

Core outcome sets (COS) are one solution to these problems. These are agreed standardised sets of outcomes that should be measured and reported, as a minimum, in all clinical trials in specific areas of healthcare.(4) COS allow pooling and comparison of data from different studies, ensuring efficient use of valuable research resources. The use of COS is actively endorsed by trialists, funders, regulatory authorities, guideline developers, and others.(5) The international Core Outcome Measures in Effectiveness Trials (COMET) Initiativeprovides an online searchable repository of published and ongoing studies relating to the development of COS.(6) Additionally, COMET has developed international consensus standards to guide the rigorous development of high-quality COS.

The use of COS can enhance consistency and comparability across mental health trials, facilitating improved data synthesis and contributing a stronger evidence base to inform clinical decision making. Three stakeholder groups are considered essential in the development of COS: healthcare professionals, researchers and patients or their representatives.(7) Thus, the development and implementation of COS in mental health trials will help ensure that the outcomes measured are relevant to the experiences and needs of those most affected by mental health conditions.

**Objectives**

The objectives of this review are to:

1. identify all published COS studies relating to mental health, and assess the methodological quality of such studies;
2. classify the outcomes included in the COS according to an outcome taxonomy and explore how the recommended outcomes compare to those included in non-mental health COS.

**Progress**

We searched the COMET database to identify all mental health COS published up to the end of 2024. We identified 20 studies, reporting the development of 22 COS across a range of diseases within the broader mental health and addiction disease categories. The first mental health COS was published in 1999 and since then there has been a steady increase in the number of studies addressing mental health conditions, with a notable acceleration post-2020.

We extracted data on study scope, COS development methods, participating stakeholder groups and locations; and assessed the COS against the Core Outcome Set-STAndards for Development (COS-STAD).(8)

We extracted the core outcomes from each COS and classified them according to the outcome taxonomy developed by Dodd et al.(9) We compared the outcome profiles (summarised using frequency and percentages) in mental health COS against those in the total cohort of COS for research as reported in the latest COMET systematic review update.(10) We also compared the outcome profiles of addiction vs non-addiction mental health COS.

Additionally, we explored the distribution of ‘mental health outcomes’, defined as those categorised within the Life Impact ‘Emotional functioning/wellbeing’ or Physiological ‘Psychiatric’ domains of the outcome taxonomy.(9) We compared the distribution of such outcomes between mental health and non-mental health COS, and between addiction and non-addiction mental health COS.

This review provides a complete assessment of COS that have been developed to standardise the outcomes being measured and reported in mental health research. Key findings include:

* Patients/public representatives less likely to be included in the addiction-related mental health COS studies.
* Many mental health COS studies include participants from a single country, which may limit the generalisability of some COS.
* COS relating to addiction prioritise the immediate behavioural aspects of addiction, but they may benefit from incorporating broader emotional and social functioning outcomes to fully capture the impact of addiction on individuals' day-to-day lives.
* Lack of data on ‘how to measure’ the outcomes included in mental health COS

**Outputs**

Sarah Gorst presented the project at the Mental Health Trials Methodology Showcase Event, which was held at King’s College London on 25th April 2025.

**Future plans**

The findings from this project will be written up and submitted for publication in a peer-reviewed journal.

We are providing consultation to a team at [Orygen](https://www.orygen.org.au/) on a project commissioned by the Wellcome Trust. The project aims to support the online sharing and organisation of open-access, common mental health measures.

**References**

1. <https://doi.org/10.1002/14651858.CD012956.pub2>

2. <https://www.kingsfund.org.uk/insight-and-analysis/long-reads/mental-health-360>

3. <https://doi.org/10.1016/j.lanepe.2024.100993>

4. <https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-1978-4#Abs1>

5. <https://www.comet-initiative.org/COSEndorsement>

6. <https://www.comet-initiative.org/Studies>

7. <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002447>

8. <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002447>

9. [https://linkinghub.elsevier.com/retrieve/pii/S0895-4356(23)00073-2](https://linkinghub.elsevier.com/retrieve/pii/S0895-4356%2823%2900073-2)

10. Gorst SL, Lucas JP, Dodd S, Lucas SW, Baldwin FD, Williamson PR. Adverse events are considered but not always explicitly selected as core outcomes in research: an updated systematic review. *Under review.*