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A protocol for establishing a core outcome set for studies examining treatments for Problematic Internet use

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Abstract

Background

Randomised controlled trials (RCTs) evaluating Problematic internet use (PIU) have reported many different outcomes, which are themselves often defined and measured in distinct ways. Numerous clinical trials have been conducted on the efficacy and safety of different interventions in the treatment of PIU, resulting in many different outcome measures and different ways of measuring them. In order to facilitate the future research of PIU, it is necessary to produce the core Outcome Set (COS), which can help to translate the results into high-quality evidence.

Methods and analysis:

This mixed-method project has a three-phase tool: Phase 1, a scoping review of the literature to identify outcomes that have been reported in clinical trials and systematic reviews of interventions for PIU. Phase 2, a systematic review of PIU literature was conducted to identify potential outcome indicators. Phase 3, final outcome indicators were determined through Modified Delphi Method, Consensus Meetings, Stakeholder Perspectives and Stakeholder Consultations.

Conclusions

We will develop a COS that should be reported in future clinical trials of PIU.

Trial registration:

Core Outcome Measures in Effectiveness Trials (COMET) Initiative database registration: www.comet-initiative.org/Studies/Details/2109. Registered in August 2022.

Introduction

Since the 1990's, the Internet has gained importance in lives of youth and its intensive use adds to the list of classic risky behaviors such as alcohol and cannabis use [1]. People have acknowledged the fact that the Internet has been present in all aspects of our lives, as it has reached the role of informing, educating and entertaining all ages, especially teenagers [2]. The time spent on the Internet is increasing and it impacts health in various ways: sleep disorders, obesity, academic difficulties and vision problems [3, 4]. Data show that Internet use has a very important impact on society, individuals, society and health [5]. Over the past decade, studies have shown that the prevalence of Internet use among teenagers has been surprisingly high; In the United States and Japan, more than 90% of teenagers and 72% of Chinese teenagers use the Internet every day, while among high school students, the rate of Internet overuse has surpassed 20% in India and Iran [6–8]. Problematic internet use (PIU) is defined as "(a) Maladaptive preoccupation with the Internet experienced an irresistible use longer than expected, (b) remarkable distress resulting from behavior and (c) absence of other axis pathology that might explain the behavior, i.e., mania or hypomania" [9]. Compulsive or problematic Internet users will spend too much time on the

Internet for fun and not for work, which may cause them to neglect other important areas of daily life or important work, such as work tasks or schoolwork, social relationships, food or rest [10–13]. There is no standardized name for PIU, so many synonyms are used in the literature, such as Internet addiction, compulsive use, pathological Internet use, and heavy Internet use. PIU can be defined as excessive and impulsive Internet use, inability to control one's Internet use time, affecting one's health or impairing daily life [14]. In recent years, PIU has become more and more obvious and common in young people [15, 16].

At present, there is no complete set of outcome indicators to evaluate PIU in clinical practice. The lack of consensus and the degree of difference lead to the inability to compare the results of individual RCTS, resulting in the diversification of outcome indicators and the lack of a complete evaluation system, which directly affects the effectiveness of research in informing patients and clinicians in clinical practice. The development of a core outcome set allows for standardization of outcome reporting and ultimately enables healthcare consumers to collaborate with healthcare professionals to make more informed healthcare decisions.

Core outcome sets (COSs) refer to the minimum results that should be measured and reported in clinical trials in a specific area of healthcare [17]. To facilitate future PIU studies, COS are required. Through standardization will report the results of specific areas, in addition to being able to form a set of standardized system, help clinical decision makers, can also reduce the waste and improve the effectiveness of randomized controlled trials, promote treatment comparison between different sources of evidence, and accelerate to generate systematic review and meta-analysis and evidence-based clinical guidelines [18, 19]. These core outcomes will standardize PIU outcome measures through a variety of means, including measurement and reporting, enabling key stakeholders-including individuals with life experience, healthcare professionals, research clinicians, and patient to compare, combine, and contrast trial results [17]. Our study will develop a COS for PIU clinical trials.

Primary outcome

To develop a core outcome set in PIU.

Materials And Methods

The methods have been informed by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative Handbook and other core outcome set development studies relevant to human’s mental health. This study protocol is reported in accordance with established methodology in development of core outcome sets.

Prospective registration

This study has been prospectively registered with the Core Outcome Measures in Effectiveness Trials (COMET) initiative; the registration number is 2109 and is available online (www.comet-initiative.org/Studies/Details/2109)

Steering group

The study included patients aged 18 to 40 years with a diagnosis of PIU and healthy subjects. This COS will cover all interventions. The COS is designed for use in both research and routine clinical care, in any health care system. We plan to involve patients, caregivers, healthcare professionals, and researchers in developing the COS in order to identify the outcomes of most importance to all stakeholders.

Patient and public involvement

We will recruit patients and the public (caregivers and journal editors) to participate in semi-structured interviews or a questionnaire-based survey.

Study design

A multistage study is necessary to achieve this goal. The design of this study is outlined in Fig. 1 and is divided into four stages: a scoping review, stakeholder key informant interviews, an online international Delphi survey, and a consensus meeting.

Phase 1: A scoping review of the literature to identify outcomes that have been reported in clinical trials and systematic reviews of interventions for PIU.

Phase 2: A systematic review of PIU literature was conducted to identify potential outcome indicators.

Phase 3: Final outcome indicators were determined through Modified Delphi Method, Consensus Meetings, Stakeholder Perspectives and Stakeholder Consultations.

The steering group consists of public and patient involvement representatives, journal editors, methodologists, statisticians, senior nurses, clinicians, experts in COS development, and researchers with expertise in PIU. The collective knowledge of this group will inform the development of this COS.

Phase 1: scoping review

Research question: what outcomes should PIU studies report?

We will conduct scoping reviews of clinical trials and a systematic review of clinical trials evaluating PIU interventions to determine and collate reported results and determine PICOS principles for PIU based on the collated systematic reviews.

Study eligibility criteria defined by PICOS are shown in Table 1.

Literature search

A study showed that literature searches could be improved by searching more sources [20]. Hence, we searched through four English and three Chinese databases: PubMed, Embase, Cochrane Library, Web of

Science, China Online Journals, China Academic Journals Full-text Database, and China Biomedical Literature Database. In addition, we will search the China Clinical Trial Registration Center. The retrieval time range is from inception until the date that the searches were conducted.

Relevant key search terms will include “pathological internet use”, “PIU”, “network addiction” “Internet Addiction”, “Internet Usage”, “Internet Overuse”, “Problematic Internet”,“Online Addiction”, “Computer Game Addiction” and “Internet Gaming Disorder”. Randomized or non-randomized studies, prospective or retrospective studies, will be included. We will exclude cohort studies, case–control studies, case series, case reports, qualitative research, economic evaluation studies, letters to the editor, commentaries, editorials, conference abstracts that do not describe clinical outcomes, and reviews that do not report on outcomes or contain original research.

Table 1
Study eligibility criteria defined by PICOS

PICOS component	Description
Population	Patients diagnosed with PIU between 18 and 40 years of age
Interventions/exposures	No restrictions on interventions
Comparators	No restrictions on comparators
Outcomes	No restrictions on outcomes
Study design	Non-animal intervention studies of PIU

Study selection and data extraction

Two reviewers independently screened the literature, extracted data, and cross-checked against inclusion and exclusion criteria. Any objections will be resolved through discussion after a thorough reading of the paper, or in consultation with a third researcher. All literatures meeting the inclusion criteria were imported into endnote X8 software for management. We will design an Excel sheet to collect relevant basic information, such as information about the author, journal, type of intervention, and outcome [21]. Reporting results the extracted data will include the name, definition, measurement time point, and measurement instrument or method. The extracted results are reported verbatim to ensure the authenticity and traceability of the original data. Any changes to the data extracted during this process are recorded.

Data analysis and presentation

The proportion of studies that reported each primary and secondary outcome, the proportion that did not report the primary outcome at all or reported the primary outcome in a non-reproducible manner, and the components and definitions of each primary, secondary, and composite outcome were recorded. The extracted data will be imported into an Excel spreadsheet. Similar to systematic reviews, we will

determine the number of trials to report on each outcome domain. For each outcome domain, we will evaluate the number of different outcomes (including measures) and the number of trials evaluating each particular outcome.

Phase 2: To identify potential outcome indicators

Scope of this core outcome set

The steering group recommends that the core outcome set should apply to RCTs, systematic reviews and clinical practice guidelines evaluating interventions for PIU.

Identifying potential core outcomes

According to a pre-developed literature search strategy, a comprehensive search was conducted to extract the results of published PIU management trials and identify potential core outcomes.

Phase 3

To identify final outcome indicators

Delphi study pilot

A Delphi survey pilot will be developed using the Delphi Manager software to ensure feasibility and ease of completion for stakeholders using the appropriate and patient-friendly terminology. This Delphi study will be piloted by the study committee and a sample of stakeholders prior to being accessible to all stakeholders. This initial steering group was formed via email invitation through existing research networks.

Round 1

In the first round of the Delphi survey, all participants will be invited to provide their demographic information, such as name, age, gender and other basic information, and will be provided with a unique identifier to facilitate anonymous answers in future polls. Results will be listed in individual areas and key stakeholders will be asked to rate individual results using a 9-point Likert scale created by the Recommendation, Evaluation, Development, and Evaluation Grading (GRADE) Working group and frequently used by developers of core outcome sets [22]. In addition, participants will be invited to submit additional results before completing the first round of the survey, which will have a 4-week completion window. All results were summarized as a whole and used with Delphi Manager for individual stakeholder groups. Any additional results will be considered by the steering group and may be reviewed in a second round.

Round 2

All results from the first round will be carried over to the second round, where key stakeholders will receive individual and group responses. Participants will be asked to reflect on the similarities or differences between groups before they rate each outcome, as well as any other outcomes presented in the first

round using a Likert scale. After the second round, each outcome will be summarized by the responses of the whole and individual stakeholders. Standardized definitions are applied to outcomes to identify core outcomes, as defined by the 70/15% consensus definition advocated by the COMET initiative [23]. A consensus outcome was determined when more than 70% of participants considered the potential outcome to be "critical to the decision" (score 7–9) and less than 15% considered the outcome to be "of limited importance to the decision" (score 1–3).

Stakeholder consultation

A final consensus meeting with the core steering group will review the results with the aim of developing the final core outcome set for the PIU. The conference will ensure the participation and fair representation of all stakeholder groups to promote an impartial consensus. If necessary, the steering group may recommend the need for a further Delphi study round.

Standardising core outcome measure

After the above steps, the final core results set is formed, and the steering group will decide how to measure these results. High quality outcome measures will be sought for each core outcome. Potential definitions of each core outcome will be assessed in consultation with national and international guidelines, then entered into a consensus development workshop involving key stakeholders. The objective of the consensus workshop will be to identify and standardise definitions for individual core outcomes. Potential measurement instruments will be inventoried across systematic reviews, RCTs, and national and international guidelines.

Dissemination

Finalising a core outcome set in PIU could help guide and advance future clinical guidelines, RCTs and systematic reviews. Its implementation could ensure that outcomes important to individuals with lived experience, researchers and healthcare professionals are collected in a standardised fashion, to guide and inform clinical practice in the future.

The Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement recommends the use of core outcome sets where they exist [24].

Discussion

This study took PIU clinical trial core index set as practice to explore the development method of PIU core index set. The study identified participants from methodologists, clinicians, patients, researchers, and health policy makers. For the rational use of COS-PIU, there are three points to be explained: 1.COS is the minimum total of indicators that should be reported in every clinical study, but the specific study can add necessary evaluation indicators according to the purpose of the study; 2. COS is not equal to the main curative effect index, and different studies can choose one or more COS indexes as the main curative effect index according to their research purposes; 3.COS does not restrict intervention measures and

measurement nodes, but different studies need to clarify their intervention courses in terms of science and feasibility. At present, the COS efficacy evaluation index of PIU is not clear, so our study is very necessary.

Declarations

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None.

Authors' contributions

All listed authors formed a steering group to the outline formation of the project including the study design, critical analysis, and discussion, as well as the final approval of the manuscript. LW and TMZ drafted the manuscript. TMZ, XYZ, and YW was the supervising chief investigator and conceived the study and led protocol development. MZZ, TY, PG, and JRC led patient and public involvement in the study design and delivery. All authors have read and approved the manuscript.

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analyzed during the current study.

Competing interests

The authors declare no competing interests.

Ethics approval and consent to participate

This study has been approved by the Ethics Approval Committee of Chengdu Sport University. All participants involved will be asked for consent prior to registration and participation in the Delphi study.

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Figures

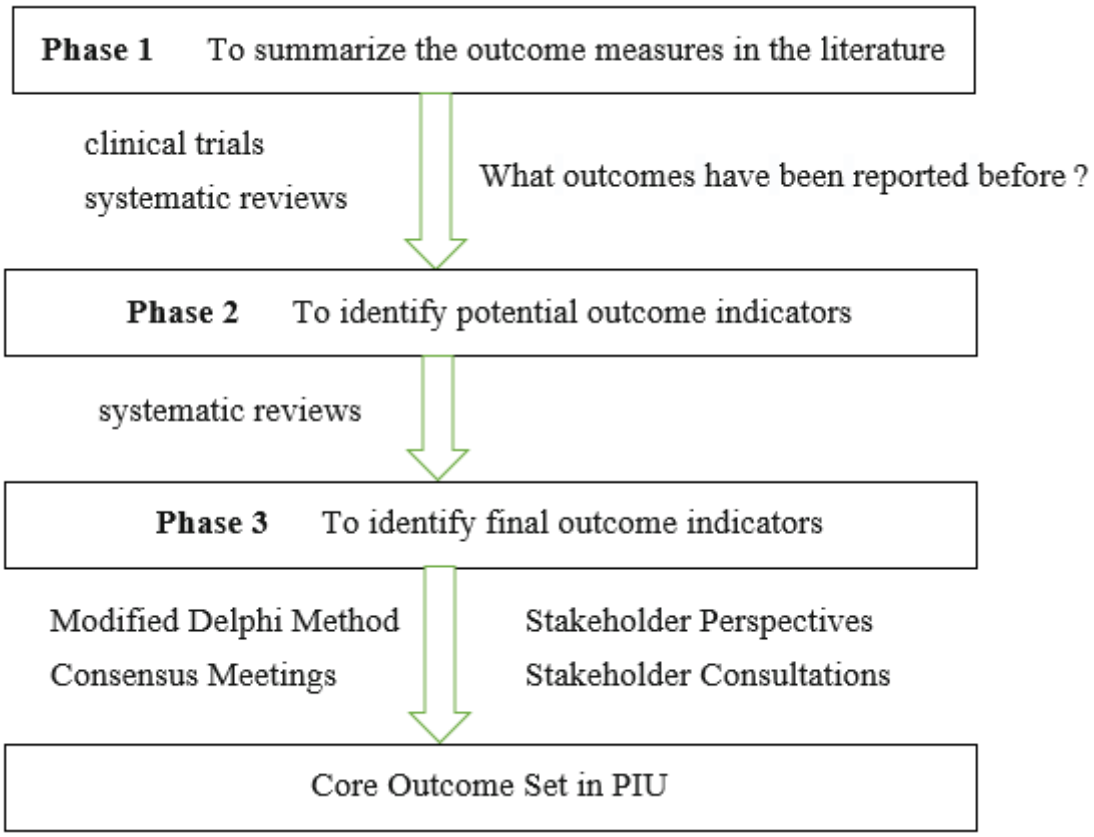


Figure 1

Flow chart of the study design for COS on PIU