BMJ Open What is the added value of handsearching Hungarian medical journals and grey literature for identifying controlled clinical trials? Protocol for a metaepidemiological study

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ABSTRACT

Introduction Randomised controlled trials (RCTs) are considered the gold standard for evaluating the efficacy and safety of healthcare interventions. For valid systematic reviews and evidence-based clinical guidelines, it is essential that results of all eligible RCTs are accessible. However, articles about trials published in languages other than English are often not listed in well-known and open trial databases like Medline and therefore scarcely findable. Handsearching national journals is an important approach to identify these articles and enhance their global visibility. Consequently, the results of trials conducted and published in non-English-speaking countries are not lost but rather integrated into the global body of evidence. The present study aims to evaluate the benefits of extensive handsearching in Hungary and to identify key medical fields for future efforts. We will also assess the extent of grey literature in Hungary. We will appraise the risk of bias in the identified RCTs and controlled clinical trials (CCTs; indicating quasi-randomised or possibly randomised controlled trials) and examine the reporting quality of articles in Hungarian medical journals. Additionally, we will explore whether the automation tool Paperfetcher, recommended by Cochrane for handsearching, can effectively support these efforts in a non-English language context.

Methods and analysis We will conduct a cover-to-cover handsearch of all Hungarian medical journals publishing content in the year 2023 to identify all controlled clinical trials, including RCTs, CCTs and non-RCTs, which are trials that use a clearly non-random method for allocating participants to groups. We will also search conference proceedings submitted to the Hungarian National Széchényi Library, abstract supplements from journals available via the Hungarian Medical Bibliography database, preprints available on medRxiv, Hungarian theses and dissertations, as well as Google Scholar to identify grey literature.

Two independent researchers will screen the identified records, assess their eligibility, extract data and evaluate the risk of bias and reporting quality according to the

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Dedicated experts from diverse clinical fields identify all Hungarian medical and health science journals for an entire year, conduct handsearching to ensure comprehensive coverage. The results of handsearching will be published in the Cochrane Library.
- ⇒ Study selection and data extraction will be performed independently by two researchers, which will ensure that all relevant studies are included without personal biases.
- ⇒ Searching for grey literature is a cumbersome task, so despite our best intentions and diligence, we may not find everything we would like to include in our research.

CONSORT statement. To verify the availability of reports and publications derived from the identified trials in electronic databases, we will systematically search MEDLINE, the Cochrane Central Register of Controlled Trials (CENTRAL), Embase and Scopus. All identified RCTs and CCTs not vet included in CENTRAL will be added to the database. Additionally, we will compare handsearching supported by the Paperfetcher tool with unsupported handsearching to evaluate the tool's effectiveness in a Hungarian language context.

Ethics and dissemination Since the publication resulting from the handsearching activity is a retrospective review of publicly available sources of evidence, ethical approval is not required. The study findings will be submitted for publication in a peer-reviewed journal and will be presented at international conferences.

INTRODUCTION Background and rationale

reviews of healthcare Systematic interand evidence-based clinical ventions practice guidelines should include all information from medical research on the clinical



question under consideration. Randomised controlled trials (RCTs) are the most reliable evidence showing whether a cause-effect relation exists between treatment and outcome.¹

The Cochrane Central Register of Controlled Trials (CENTRAL) is a database of the Cochrane Library containing randomised controlled trial (RCT) and controlled clinical trial (CCT) records. RCTs involve the random assignment of participants to intervention groups, whereas CCTs use a quasi-random method of allocation—such as alternation, date of birth, or case record number—or feature unclear reporting of randomisation. CENTRAL is currently the most comprehensive database of information on RCTs and CCTs worldwide. It is maintained by Cochrane's Centralised Search Service (CSS), which routinely identifies RCT/CCT records from MEDLINE, Embase, CINAHL, ClinicalTrials.gov and WHO ICTRP. Besides, records identified through hand-searching are also added.

Handsearching refers to the meticulous, manual review of each page within a journal issue or conference proceeding to identify all eligible trial reports.² Handsearching enables the identification of reports of trials not included in electronic bibliographic databases, for example, because the published articles are not written in English, as well as reports of trials which are available in electronic databases but could not be identified because they are not sufficiently described and indexed.

Additionally, RCTs presented at a conference are often published as short abstracts in a conference abstract book and cannot be found by searching electronic databases. Thus, handsearching is an essential and critical activity to find all relevant trials related to a clinical question.³ As part of the handsearching activity, journals, conference proceedings and other sources serve as valuable resources for identifying trials within articles, conference abstracts, society reports, news, editorials, letters or other types of text.⁴

As part of the CENTRAL-related handsearching activities, some Cochrane Fields search journals relevant to their scope, while certain Cochrane Geographic groups search journals in their respective languages (eg, German, Dutch, Italian and Chinese). About three-quarters of the randomised trials identified by the Cochrane Collaboration through various handsearching projects were published in English and German journals. In Germany, handsearching effort began in 1995. In the first ten years, German-language medical journals were searched, resulting in the recording of approximately 17 000 RCTs and controlled clinical trials (CCTs).

Outside Western Europe, extensive handsearching was conducted, for example in Turkey with the aim to compensate for the lack of a database of national medical journals, ¹⁰ or in Russia, where handsearching has proven essential for identifying additional relevant RCTs and quasi-RCTs due to challenges in character recognition. ¹¹ In other regions, handsearching was limited to a few relevant journals. This way, for example, 21 RCTs/q-RCTs not

included in the main databases were identified across fourteen volumes of the Annals of Saudi Medicine, ¹² while 50 trials in twelve volumes of twelve medical journals in Cuba, ¹³ and 15 RCTs and 24 non-randomised CCTs in nineteen volumes of five medical journals in Sri Lanka. ¹⁴

Language-specific handsearching is important as it aims to identify RCTs and q-RCTs published in local journals that are not included in large electronic databases. Without the targeted efforts of handsearching, this trial information would remain unrecognised, rendering it unavailable for informing systematic reviews of interventions and evidence-based clinical practice guidelines. Failure to consider study results published in non-English languages might lead to incomplete and biased systematic reviews.

In Hungary, handsearching has not been conducted yet, although two decades ago a pilot study showed that in the field of neuroscience, a considerable number of RCTs and q-RCTs were published exclusively in Hungarian language. ¹⁵ Therefore, till now, the Cochrane CENTRAL database does not contain study results published in the Hungarian language.

Recently we performed a national survey among researchers who published medical or health-related research as first or last author in 2020 with a Hungarian affiliation in a PubMed-indexed journal. As part of this survey, we tried to assess in advance the extent of research results published in Hungarian journals. Out of 469 Hungarian first and last authors participating in our survey, 150 researchers (32%) answered the question, 'Have you ever made a decision to publish your research results exclusively in a Hungarian journal?' with a 'Yes'. When we asked for further explanation, 105 researchers answered that they 'feel this will make it easier for my research to reach the right target audience' (detailed survey results are under publication). Our research results confirm that there may be specific fields or research areas in Hungary where the number of research results published in domestic journals is significant.

In addition to the clinical trial results published in Hungarian language journals, we currently do not have accurate information on the extent of the Hungarian grey literature. Grey literature is usually defined as literature not formally published in sources such as books or journal articles 16 and not controlled by commercial publishers.² 17 It can exist in many formats: reports including preprints; preliminary progress and advanced reports; institutional, internal; research memoranda; reports of commissions and study groups; as well as conference proceedings, even translations, or diverse official documents. 18 19 Access to grey literature remains difficult.²⁰ Although a Cochrane Methodology Review indicated that studies published in journal articles showed a greater treatment effect than studies published in the grey literature, there is still a possibility that the failure to identify studies published in conference proceedings and other grey literature may affect the results



of a systematic review. 16 21 The aim of the present meta-epidemiological study is to answer the question whether there are relevant medical studies in Hungary that may not be captured in traditional databases, to specify medical fields where handsearching would be valuable and worthwhile and to compare the effectiveness of automated and traditional handsearching within the Hungarian language context.

OBJECTIVE

The primary objectives of the present metaepidemiological study are as follows:

- ▶ Identify those healthcare-related intervention studies which have at least two groups and can be classified as RCTs, CCTs or non-randomised controlled studies.
- ▶ To determine the extent of grey literature in Hungary by assessing all 133 Hungarian medical journals publishing content in the year 2023.

Our secondary aims are as follows:

- ► Evaluate the reporting quality by measuring adherence to the CONSORT guideline.
- ► Assess the risk of bias in RCTs/q-RCTs published in Hungarian medical journals by using Cochrane risk-of-bias and ROBINS-I tools.
- ► Compare the effectiveness of handsearching supported by the automation tool Paperfetcher²² with unsupported handsearching by measuring the number of unique trial records identified and accuracy in the Hungarian language environment.

METHODS AND ANALYSIS

Our project will be realised with the support of the Pekár Mihály Medical and Life Sciences Library, Medical School, University of Pécs, Hungary. This collaboration will grant our research team the necessary access to journals and other grey literature, such as conference proceedings. In addition, the library's well-established networks and comprehensive cataloguing systems will facilitate the identification and retrieval of a wide range of medical publications, including those not included in the main databases.

We commenced this study in 2024 by inviting experts from various medical fields to contribute to our project. We identified non-indexed Hungarian journals relevant to their areas of expertise and began conducting handsearching in 2025 on a selected number of these journals. This work is currently ongoing.

Journals selected for handsearching

We identified 133 eligible Hungarian journals (see online supplemental material) that published articles in the field of medical sciences in 2023. While a limited number of these journals are included in indexed databases, their contents are only partially displayed, so handsearching of these journals might be relevant as well.

Criteria for inclusion

All 133 Hungarian medical journals publishing content in the year 2023 will be included. We will handsearch these journals cover to cover for controlled clinical trials.

The decision algorithm for determining whether a trial report qualifies as a controlled clinical trial will closely resemble the eligibility criteria used to decide if a record should be added to the CENTRAL database.²³ However, it will also include the identification of controlled clinical trials that employ a clearly non-random method for allocating participants to groups:

- ▶ Participants in reports must be living human beings.
- ► All trial reports must involve an intervention related to healthcare.
- ► Experimental studies, but not observational studies.
- ► The study has to include at least two groups (both an intervention and a comparator group).
- ▶ Must have definitely or possibly used some form of randomisation (RCT) or quasi-randomisation or possibly randomisation (CCT) to form the different intervention groups, as well as trials defined as non-randomised (non-RCTs).

The following report types will be considered as eligible sources for a controlled clinical trial:

- ► Report with the primary results of the trial.
- ► Report with secondary or subgroup analysis.
- ► Report that presents details regarding the study design or protocol of a trial, without presenting results.
- ► Report that describes a pilot for a trial that is being planned.
- ▶ Report that describes the development or implementation of an intervention for a trial that is planned, underway, or completed.
- ► Report of a retrospective analysis of the randomised data of a trial.
- ▶ Report providing patient-level data for a trial.
- Report describing baseline characteristics of an RCT/q-RCT.
- ▶ Report on a trial-based economic evaluation.
- Erratum to a RCT/q-RCT.
- ▶ Reply/comment/letter that presents new information about the conduct, methods, or results of a trial.

We will exclude reports of observational studies using participants or materials from a trial if these reports no longer relate to the randomised comparison. We will also exclude a report of an open-label extension study where all participants receive the intervention in a single-arm way.

Data collection and management

Print journals will be searched page by page for controlled clinical trials, from the most recent, backward in time.²⁴

Electronic journals (ie, journals that are available in electronic format) will be searched in a similar way as print journals. We will screen the journal content webpage by webpage or pdf by pdf for controlled clinical trials. Two researchers will independently screen the articles in the journals and decide on their eligibility.² In case of

disagreement, they will discuss their decision with a third researcher with a strong methodological background, to make an appropriate final decision.

We will document the following information in an Excel sheet for each reviewed journal:

- Name of handsearched journal.
- ▶ Print or electronic journal.
- ▶ Year
- ▶ Volume.
- ► Issue.
- Screeners' name.
- ▶ Whether a controlled clinical trial was found in the given issue of the journal, and if so, the number of controlled clinical trials identified in the journal.

Identified controlled clinical trials will be categorised as RCT, CCT or non-RCT. Trials in which participants are definitely assigned to intervention groups using randomisation will be classified as RCTs. Trials in which participants are assigned to intervention groups using quasi-randomisation will be classified as quasi-RCTs. Within the quasi-RCT category, there are two subcategories: (1) trial reports in which the method of allocation is known but is considered quasi-random (eg, alternating assignment) rather than strictly random and (2) trial reports where the method of allocation is not clearly reported but may be either random or quasi-random. We will also identify studies that can be classified as nonrandomised controlled clinical trials (non-RCTs), which involve participants being allocated to two or more groups without the use of randomisation.²³ These studies do not meet the criteria for RCTs or q-RCTs.

From the identified clinical trials, we will record the bibliographical reference (authors, authors' affiliation, journal and title) and extract information on participants, intervention, comparator, outcomes and study design. We will develop our data extraction tool according to the CONSORT 2024 checklist. ²⁵

Identification of grey literature

In order to get a comprehensive picture of Hungarian grey literature, we are planning to review not only Hungarian health journals but also other sources, including society reports and conference abstracts.

In Hungary, there are no grey literature databases, such as the European multidisciplinary OpenGrey²⁶ or the UK English-language resource collection website at Newcastle University.²⁷ Conference proceedings are covered by the Legal Deposit Act,²⁸ so a copy must be sent to the Hungarian National Széchényi Library and made available in the library. We will use the Hungarian National Széchényi Library's search interface (https://nektar2.oszk.hu/librivision_hun.html). This search interface also provides access to the National Bibliography, which will also be searched.

Another source of conference abstracts is the abstract supplements of different journals. We will search for these abstract supplements by performing systematic searches

in the Hungarian Medical Bibliography (MOB) database (https://mob.aeek.hu/search.jsp).

We will search preprints through medRxiv (which is an online preprint disciplinary repository of health sciences). Our preliminary search identified nearly 800 Hungarian manuscripts available as preprints via medRxiv.

To search for Hungarian theses/dissertations (either completed or available as a preprint), we will use the database of the Scientific Document Common Search Service. ³⁰ We will also search the multidisciplinary Hungarian database called Hungarian Electronic Library (MEK), ³¹ which is a well-known repository for publications and manuscripts that are not published, have low circulation or are not available in book circulation. Additionally, we will explore Google Scholar.

For each search interface, we develop an appropriate search strategy to achieve the most relevant results, using the Hungarian equivalent of search terms like 'medic*', 'conference*', 'proceed*', 'trial*', 'clinical*', 'RCT*', 'randomi?ed*' and combine them with Boolean operators. ³²

Identified records will be classified into the following format categories: articles, letters, conference abstracts/proceedings, reports, dissertations and preprints. We then independently assess the topic of the reports and the relevance of the reports to the Cochrane Collaboration.³³

Examining the originality of research published in Hungarianlanguage journals

To check whether the identified RCTs, q-RCTs and CCTs were also reported in scientific publications available in indexed databases, we will conduct systematic searches in the databases MEDLINE (via Ovid), Cochrane CENTRAL, Embase (via embase.com) and Scopus. As search terms, we will combine various study information such as the registry identification number (if available), study title, acronym, information on the content of the study (participants, intervention, comparator and outcomes) and/or name of the applicant or principal investigator.

The identified English language publications will be categorised into one of the following four categories: (1) a study independent of the study described in the Hungarian publication, (2) a study identical to the study described in the Hungarian publication but reporting completely different results, (3) a study identical to the study described in the Hungarian publication but reporting partially different results and (4) a study identical to the study described in the Hungarian publication reporting completely identical results.

Inclusion of Hungarian RCTs and q-RCTs in the CENTRAL database

RCTs and q-RCTs identified within this project will be added via the Cochrane CRS (Cochrane Register of Studies) interface to CENTRAL, taking into account the HarmoniSR guidance.³⁴



Comparison of unsupported handsearching and automated handsearching

In the case of manual handsearching, the first step is visiting each journal's website or hard copies and browsing through the tables of contents of different issues. In contrast, when Paperfetcher is used, 22 first the list of journals or conference proceedings has to be entered. Paperfetcher—the algorithm which queries the database of academic content registered with Crossref—returns bibliographic metadata, which can be imported first into a citation management tool (eg, EndNote), and in a subsequent step into a systematic review screening tool (eg, Covidence) for screening based on inclusion or exclusion criteria. The step of screening is the same for both methods.

In our research, we will be investigating whether Paperfetcher is suitable for supporting handsearching in a Hungarian language environment. According to the article on Paperfetcher, the programme can be used to look up journals that use a DOI number based on CrossRef (Digital Object Identifier Registration Agency). According to data from the Hungarian Medical Bibliography, about one-third of Hungarian journals have a DOI. We will process a few years of data with both methods (ie, supported and unsupported with Paperfetcher).

Reporting quality and risk of bias assessment in RCTs/q-RCTs published in Hungarian medical journals

Adherence to the CONSORT guideline²⁵ will be evaluated by two independent researchers. We will use a 19-item checklist described by Elagami et al, 35 each scored from 0 to 2 (maximum of 38 points). To evaluate the risk of bias, we will use the Cochrane risk-of-bias (RoB 2) tool for RCTs and the ROBINS-I tool for q-RCTs. The RoB 2 tool comprises five specific domains: bias arising from the randomisation process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of the outcome and bias in the selection of the reported results. The ROBINS-I tool has seven domains, including confounding, selection bias, bias in measurement classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes and bias in selection of the reported result. Any discrepancies in evaluation will be resolved through consultation with a third expert reviewer.

We will conduct a descriptive analysis of the characteristics of the included studies. Qualitative variables will be summarised using frequency distributions, while quantitative variables will be described by means and SD. Analyses will be performed with R Statistical Software (V. 4.4.3; R Core Team 2024). ³⁶ We will conduct regression analyses to investigate the association between exploratory variables and CONSORT adherence/RoB overall assessment (outcome variable).

Patient and public involvement

None.

ETHICS AND DISSEMINATION

Since the publication resulting from the handsearching activity is a retrospective review of publicly available sources of evidence, ethical approval is not required. The results of the Hungarian handsearching study will be disseminated through peer-reviewed publications, workshops and academic conferences.

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