Seminars in Oncology Nursing 000 (2024) 151711

Contents lists available at ScienceDirect

Seminars in Oncology Nursing

journal homepage: https://www.journals.elsevier.com/seminars-in-oncology-nursing

Review

Assessment of Nursing Workload and Complexity Associated with Oncology Clinical Trials: A Scoping Review

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ARTICLE INFO

Key Words:
Clinical trials
Cancer
Clinical Research Nurse
Nurse practitioner
Workforce
Workload

ABSTRACT

Objectives: Clinical trials (CTs) play a crucial role in advancing medical knowledge and patient care but are increasingly complex and resource-intensive. This scoping review aims to explore the current approaches for evaluating workload (WL) in oncology CTs and identify tools for measuring clinical research nurses' WL.
Methods: The search was conducted through MEDLINE, Scopus, CINAHL, and COCHRANE databases and carried out through the framework developed by Arksey and O'Malley and revised by the Joanna Briggs Institute. Data extraction and synthesis were performed to analyze instruments used for WL assessment and their dimensions.
Results: Of the 1,005 records identified, 12 meet the inclusion criteria. The complexity and WL associated with CTs can be attributed to five main domains: (1) protocol, (2) single case, (3) data management, (4) regulatory, and (5) worker-related. These instruments varied in their approaches, scoring systems, and domains assessed. Notably, the protocol-related domain was prevalent across most instruments, highlighting its importance in WL evaluation. Furthermore, findings revealed a wide range of WL scores across different studies, emphasizing the complexity and variability in WL management within CTs.
Conclusions: This scoping review underscores the importance of evaluating WL in CTs and provides insights into existing tools and approaches. Nurses, as integral members of clinical research teams, bear significant responsibilities in trial management, necessitating a balanced approach to WL allocation. Future research should focus on validating and standardizing assessment tools to optimize resource allocation and enhance research efficiency in CT centers.
Implications for Nursing Practice: Understanding WL dynamics in CTs is essential for nurses involved in research delivery. By utilizing validated WL assessment tools, nurses can advocate for appropriate staffing levels and promote efficient trial management, ultimately improving patient outcomes and research quality in CT settings.

Introduction

Clinical trials (CTs) serve as pivotal gatekeepers and bottlenecks influencing medical progress.[1] Trials benefit both society and individuals through knowledge generation and improved care, with some considering enrollment in a CT as the best management for a patient with cancer.[2] In recent years, they have displayed a trend toward escalating complexity and costs. Accordingly, billions of dollars are invested annually in CTs, with nearly $10 billion invested each year in oncology trials alone.[3] This is primarily driven by an expanding consortium of stakeholders necessitating more endpoints, a broader spectrum of patient cohorts, and compliance with stringent regulatory frameworks.[1,4] Elements associated with protocol design and execution have seen rapid growth. For instance, the mean number of distinct procedures per protocol has significantly increased across Phases I, II, and III trials.[5] Moreover, cancer Phase I trials have witnessed substantial growth in study-related procedures over the last two decades.[6] Data from the Italian EudraCT public database report that the number of trials submitted in Europe (EU) increased by about 9.3% between 2022 and 2023 (+6.398 trials) and about 16% between 2017 and 2020. European Medicine Agency[7] counts 451 authorized phase I trials, 456 phase II 452 phase III and 143 phase IV studies in 2022. In addition, the emergence of new study designs such as basket trials, umbrella trials, and platform trials increases the complexity in

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https://doi.org/10.1016/j.soncn.2024.151711

Plain English Summary

What we investigated and why

We conducted a literature review to explore tools used for measuring the workload and complexity of clinical studies. The increasing complexity and costs of these studies are major concerns, with billions of dollars invested yearly. Understanding workload and complexity is vital for efficient resource allocation and maintaining high research standards. Our goal was to find existing tools that can measure clinical trial workload, aiming to reduce research waste and improve care quality for those opting for clinical trials as oncologic treatment.

How we did our research

We used a structured plan to conduct our review, searching carefully through various databases to find relevant studies. We looked for studies that used tools to understand how complex and demanding clinical studies are. Once we found these studies, we organized the information using a set format and analyzed the data to give a thorough summary of the tools available.

What we have found

We found 12 tools that measure how busy clinical trials are. Clinical trials are complex and involve a lot of work. This work can be divided into five main areas: the plan for the trial, the specific cases involved, managing the data, following regulations, and the tasks of the workers. Some tools can measure all these areas, helping us understand how the workload is spread out among different tasks.

What it means

Our research underscores the significance of measuring workload in clinical trials to effectively allocate resources and uphold high-quality research standards. By comprehending the intricacies of clinical trials and the workload linked to various tasks, research teams can streamline staffing, cut down on delays, and diminish the squandering of research resources. Future investigations in this area could prioritize the use of validated tools and standardized methods to strike a better balance between clinical protocols and nurse workload, ultimately resulting in substantial cost savings and enhanced research outcomes.

the field of clinical investigations.[8] Consequently, in the last decade, the workload (WL) of each individual trial site has also increased.[5,4] The WL of a CT refers to the measurement of the length of time and resources necessary to complete the various tasks associated with a CT. Despite some inherent complexity in evaluating interventions, investigators often have the opportunity to streamline complexity without compromising the trial's efficacy, understanding staffing variables and time requirements.[9] Conducting cancer studies in CT centers (CTCs) requires a large time commitment, that includes both clinical and nonclinical tasks. It requires specialized knowledge and diverse abilities in scientific, ethical, and regulatory domains, which may be difficult for professionals whose primary focus is on their daily clinical duties.[10] The CT multidisciplinary team supports the principal investigator in fulfilling its responsibilities as sponsor for the trial. The team will usually include clinical research coordinators (CRCs), clinical research nurses (CRNs), and clinical research associates. CRNs play a critical role in the trial process.[11,12] The nursing workforce, specializing in clinical nursing research, bears the complex responsibility of ensuring participants' clinical safety and maintaining research quality.[13] The evolution of CTs nursing into a specialized practice recognized by the American Nurses Association[14] signifies the increased impact of oncology CRNs in multicenter international trials.[15] Despite nurses' increasing involvement in trial management, clinical research programs lack tools and resources to quantify nursing WL associated with trials, crucial for staffing and budgetary planning.[9] Quantifying WL activity remains challenging for CRCs and regulatory staff, impacting research organization efficiency and success.[5,12,16] In CTCs should be best practice to incorporate WL measurement per trial into routine procedures.[17] In fact, management has become increasingly aware of an imbalanced WL distribution and lack of accountability among research nurses.[12] Despite this increasing responsibility and WL, the role of the research nurse remains ambiguous, fragmented, and nebulous.[18-20] This scoping review aims to clarify the gaps in WL assessment for nurses in CTs. This scoping review aimed to clarify the gap in current approaches, for evaluating WL in CTs. In order to achieve this, the review examined the following questions:

1. What tools exist for measuring complexity and/or WL in CTs?
2. How has CTs complexity been assessed?
3. How can the complexity of CTs be assessed using validated tools?

This study will serve as the initial phase of a broader research endeavor aimed at investigating all facets related to the development of a staffing model for the CRN. This model will be recognized and integrated into both clinical practice and the research team.

Methods

Search Strategy

A scoping review was conducted following the framework proposed by the Joanna Briggs Institute.[21] Findings are following the Preferred Reporting Items for Systematic reviews and Meta-analysis extension-Scoping Reviews (PRISMA-ScR) statement.[22] A priori protocol was established and published (available at https://osf.io/x67nm/).

Identifying Relevant Studies

Inclusion criteria: Studies were included if they met the following eligibility criteria (Table 1): (1) employed tools to evaluate the intricacy and burden of clinical studies; (2) being published in English, French, or Italian (the languages spoken by the researchers); (3) used quantitative and qualitative (eg, Delphi studies) methods, theses, dissertations, and review articles; (4) published with no time limits. Exclusion criteria: Studies were excluded if they (1) were unrelated to review's main aim; (2) pertaining to different fields (eg, pharmacy systems, regulatory world) due to their lack of direct relevance to the patient enrolled in clinical studies.

Information Sources and Search Strategies

Following a facet analysis,[23] consistent with the methodology recommended by Joanna Briggs Institute for scoping reviews, an initial search was conducted in September 2023 using the PubMed and SCOPUS databases. The search terms included "Clinical Trials," "Workload," "Complexity," and "Difficulties." This initial research facilitated the identification of new synonyms and terms to be considered for refining the primary bibliographic search. Collaborating with a medical librarian, literature search strategies were developed using keywords restricted to article titles to mitigate confusion, given the vastness of the CTs topic. The search was conducted on September 30, 2023, utilizing the following databases: MEDLINE

TABLE 1
Eligibility Criteria

Eligibility
Articles that include a tool to evaluate protocols' workload or complexity
Articles in English, French, or Italian
Quantitative and qualitative methods, theses, dissertations, and review articles
No time limits

(via PubMed), CINAHL (via EBSCO), SCOPUS (via ELSEVIER), and COCHRANE Central. Additionally, grey literature sources such as Google Scholar were manually searched, and the references of included articles were reviewed to identify any further relevant papers. We have scoured the first 100 pages and identified the significant articles. Contact with authors was also made to identify additional sources. A final review was conducted on April 1 to identify any published literature. An updated final review was conducted on April 1 to identify any potential studies that were published after the main search. The search strings outlined in Table 2 were employed.

Data Management

The management of articles was conducted using the Zotero[24] program. Removal of duplicates was accomplished through a manual inspection of the records entered into the software.

Selection Process

Two researchers independently assessed the titles and abstracts of the articles according to the predetermined inclusion and exclusion criteria using Microsoft Excel®. Any discrepancies were resolved through consensus, with input sought from a third researcher, if needed. Subsequently, two researchers independently conducted a thorough evaluation of the full text to select papers for review. Any discrepancies were resolved by consulting with the last author. Due to the inherent nature of the study, methodological quality was not analyzed.

Data Extraction and Synthesis

A predetermined grid was generated using Microsoft Excel. 30% of the papers included in the analysis were used to test this grid. The initial two authors, under the guidance of the final author, autonomously initiated and conducted the process of extracting data. The results section extracted and presented data on general information, including the title, authors, country, major purpose, year, language, and setting. It also included information on the assessment, such as the scoring system, domains tested, sample, and research team perspective.

TABLE 2
Summary of Search Strategies

Databases	Search strategy
PubMed	(complexit*[Title] OR workload*[Title] OR difficult*[Title]) AND (clinical stud*[Title] OR clinical trial*[Title] OR clinical research*[Title])
CINAHL	(TI clinical trial* OR TI clinical research* OR TI clinical stud*) AND (TI workload OR TI complexit* OR TI difficult*)
SCOPUS	((TITLE (complexit*) OR TITLE (workload*) OR TITLE (difficult*))) AND ((TITLE (clinical AND trial*) OR TITLE (clinical AND research*) OR TITLE (clinical AND stud*)))
COCHRANE Central	#1 (*complexit*):ti OR (workload*):ti OR (difficult*):ti (Word variations have been searched) #2 (clinical stud*):ti OR (clinical trial*):ti OR (Clinical research*):ti (Word variations have been searched) #3 #1 AND #2

Results

The selection process is depicted in Fig. (PRISMA Flow Diagram).[22] Initially, a total of 1,005 titles were identified through searches across databases. After screening the titles and abstracts, 25 studies remained for full-text review, ultimately resulting in 9 studies being included in this scoping review (from databases). An additional 3 studies were included by analyzing the grey literature (Google Scholar, ...), for a total of 12 included studies. The results ranged from 2002 to 2020.

Instruments Used to Evaluate WL

Literature search yielded 12 instruments:

- IRST Workload Assessment Tool (IWAT),[25]
- ASCO Clinical Trial Assessment Tool,[16]
- Research Effort Tracking Application (RETA),[17]
- Relative Value of Work (RVW),[26]
- Workload Measurement Index (WMI),[27]
- Nursing Time Required by Clinical Trial-Assessment Tool (NTRCT-AT),[9]
- Ontario Protocol Assessment Level (OPAL),[28]
- Trial Rating and Complexity Assessment Tool (TRACAT),[29]
- Wichita Community Clinical Oncologic Program (WCCOP),[12]
- NCI Trial Complexity Elements & Scoring Model,[30]
- a nonspecified tool by the National Cancer Institute of Canada[31] and
- a complexity tool by Malikova.[32]

While most ($n = 5$) of the instruments originated in the United States of America (WWCOP, ASCO, RETA, NCI Scoring Model, Complexity tool),[12,16,17,30,32] the research samples were drawn from various nations. Among these, four studies were conducted in EU, two in the United Kingdom (TRACAT, WMI),[27,29] and two in Italy (IWAT, NTRCT-AT).[9,25] Additionally, two studies emerged from Canada (OPAL and unspecified tool),[28,31] and one from South Korea (RVW).[26] Notably, the majority of the instruments ($n = 11$) were originated from an oncologic setting, with only one exploring other settings such as cardiology and endocrinology in addition to oncology.[26] All the instruments mentioned in the articles were identified as summarized in Table 3. Of the 12 instruments retrieved 7 were from observational studies,[9,16,17,25,27,31] one from a pilot observational study,[28] one from a Delphi study,[29] and three were brief descriptions of the instruments.[12,30,32]

WL as Evaluated from Various Role Perspectives

These various tools were developed from the diverse perspectives of research team participants: CRCs,[25] CRN/CTN,[10,13,17,29] CRC and regulatory coordinators,[17] clinical research associates,[31] three from the perspective of a multidisciplinary team.[27,29,30,32]

Dimensions of Complexity and WL

The complexity of a CT and the effort it entails can be ascribed to five primary domains: protocol-related, case-related, data management related factors/tasks, regulatory-related, and worker-related. Out of all the instruments discovered in literature, five instruments were identified as being able to measure all domains. These instruments include: NCI, NTRCT-AT, RVW, TRACAT, WMI.[9,26,27,29,30] Table 4 contains information regarding the domains covered by the instruments. Upon thorough examination of all instruments listed in the

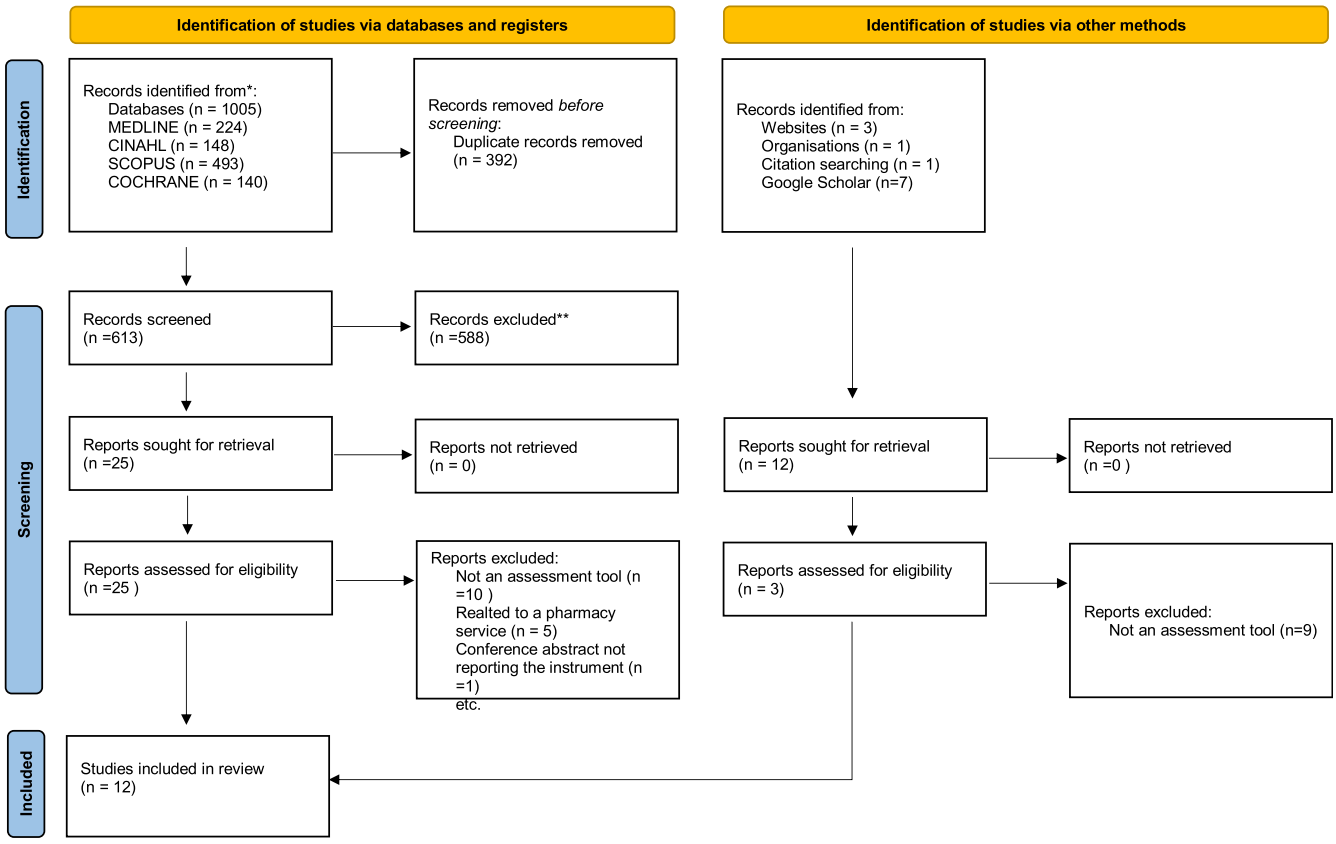

FIG 1. PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers, and other sources.

literature, a grand total of 127 unique items were initially detected. After removing any duplicate entries, the final count was reduced to 97. Among the entire set of items, 77.3% ($n = 75$) were specifically related to tasks, 18.5% ($n = 18$) were associated with factors related to CTs, and the remaining 4% ($n = 4$) were connected to mixed items. A total of 12 items were categorized under the protocol-related domain, 31 under the case-related domain, 16 under the data management domain, 28 under the regulatory-related domain, and 10 under the worker-related domain.

Scoring System

The number of items measured ranged 2 to 66. The scoring system of the tools differed: four instruments utilized time-based scales: RETA, RVW, NTRCT-AT, and National Cancer Institute of Canada,[9,17,26,31] which were combined to generate a composite score representing an individual's WL related with cognitive tasks. Five instruments employed numerical integer rating scales: ASCO, WCCOP, OPAL, NCI[12,16,28,30] and Complexity tool developed by Malikova.[32] The IWAT[25] relied on the multiplication of the number of tasks completed by the number of patients enrolled and the number of sections. Details on the scoring systems are provided in Table 3. Out of all the tools, only one provided information about the duration required for data collection.[25] The IWAT score for each research was assessed using a chronometer, and it ranged from 3 to 6 minutes.

Validity and Reliability

Among the 12 studies analyzed, only IWAT[25] showed reliability analysis. It exhibited interobserver reproducibility ranging from 82% to 100% for each item. The OPAL instrument is the sole instrument that has undergone cross-cultural adaptation and validation beyond its original context.[33]

WL Scores

The analysis of multiple studies (involved 1,678 protocols and 952 staff members) reveals a complex scenario regarding WL and complexity within CT management, shedding light on various factors influencing operational efficiency and resource allocation. Investigation into WL scores unveils a wide range of scores. Median IWAT[25] scores exhibit significant variability across studies, ranging from 2 to 188. Similarly, monthly WL scores for CRCs vary widely, spanning from 150 to 930. Notably, an optimal monthly WL score of 500 to 600 for full-time CRCs is identified, highlighting the importance of establishing benchmarks for WL management. Additionally, RVW[26] illuminates varying task importance across specialties, with tasks such as preparing auditing and monitoring visits assigned higher values of work.

A longitudinal analysis[12] spanning 11 years reveals a substantial increase in acuity scores, indicating heightened WL intensity in CT management. This trend emphasizes the need for adaptive strategies to accommodate evolving WL patterns. Furthermore, the utilization of WL measurement tools over a 4-year period[17] not only aids in WL management but also informs budget development and fosters critical reflection on management practices, showcasing the significance of data-driven insights in optimizing operational performance. Examination of trial acuity scores uncovers discernible patterns,[16,31] with treatment trials consistently displaying higher acuity scores compared to cancer control trials. Additionally, trials sponsored by industry demonstrate elevated acuity scores relative to those funded by NIH/NCI,[13] suggesting a link between trial sponsorship and WL intensity. Phase I studies and industry-sponsored trials require significantly more time across various stages, highlighting the nuanced relationship between trial complexity and WL allocation.[28,31] Main findings are reported in Table 5.

TABLE 3
Details of Assessment Instruments

Tool	Author	Y	Country	Aim	Items	Scoring system	Total score	Validity	Perspective	Setting
IRST Workload Assessment Tool IWAT	Fabbri et al.[25]	2020	Italy (IT)	Determines the appropriate WL of a CRC and how can a cancer institute estimate personnel requirements within a CTC	6	Protocol (1-3-5), on treatment (range 2-10), follow-up (range 0.2-1)	Sum of patients * Sum of section scores	Interobserver ranged 82-100	CRC	Oncology
Wichita Community Clinical Oncology Program WCCOP	Good et al.[12]	2013	United States of America (USA)	Estimate the number of research staff needed for clinical trial recruitment, maintenance, compliance, and follow-up	2	Type of study and patient classification a 4-point scale (1-4)	Range 1-4	NS	CRN	Oncology
Clinical Trial Workload Assessment Tool ASCO	Good et al.[16]	2016	USA	Measurement of protocol-specific complexity and workload effort for clinical trials	2	Protocol acuity scores and individual staff acuity scores on a 4-point scale (1-4)	Range 1-5	NS	CRN	Oncology
Research Effort Tracking Application RETA	James et al.[17]	2011	USA	Quantifying data management and regulatory workload for clinical research, assess and allocate effort	8	Data management, regulatory and nontrial logs	Sum of logged tasks (h)	NS	CRC, RT	Oncology
Trial Rating and Complexity Assessment Tool TRACAT	Jones et al.[29]	2020	United Kingdom (UK)	Evaluating patient follow-up and complexity in cancer clinical trial delivery	14	Trial Rating Indicators (eg, Protocol procedures, resource demands feasibility and personnel impact, Investigational treatment complexity, follow-up)	NS	NS	RT	Oncology
Relative value of Work RVW	Lee and Jeong[26]	2018	South Korea (SK)	Measurement of relative value of CRN workload based on the resource-based relative value scale	66	Time spent and intensity (66 services across 10 domains)	Time (min) spent from preparation to completion of each service	NS	CRN	Oncology, Cardiology, Endocrinology
Workload Measurement Index WMI	Lyddiardc and Briggs[27]	2011	United Kingdom (UK)	Measurement of CT workload associated	5	Consists in planning stage, implementation stage, trial data management, closure/final stage	Sum of tasks completed	NS	RT	Oncology
NA	Malikova[32]	2016	USA	Criteria for a trial complexity assessment	10	Study arms, informed consent, enrollment feasibility, registration, administration, length of investigation, study team, data collection, follow-up, ancillary studies (+ modifiers); Scoring (0-1-2)	NS	NS	RT	Oncology
Nursing Time Required by Clinical Trial-Assessment Tool NTRCT-AT	Milani et al.[9]	2016	Italy (IT)	Measurement of CRN workload	30	Comprised of 30 core activities, 11 related to the trial activation phase and the remainder to trial conduct	Mean time per specified activities and mathematic functions to return the total estimated time	NS	CRN	Oncology
NCI Trial Complexity Elements & Scoring Model NCI	National Cancer Institute[30]	2009	USA	Address the trial complexity	10	Complexity model (0-9)	NS	NS	RT	Oncology
National Cancer Institute of Canada NA	Roche et al.[31]	2002	Canada (CA)	Measure personeel task times	14	Includes protocol management, eligibility and entry, treatment, follow-up, and final stage. Total score is time measured in minutes for every task	Time measured for every task	NS	CRA	Oncology
Ontario Protocol Assessment Level OPAL	Smuck et al.[31]	2011	Canada (CA)	Evaluate clinical trial complexity to facilitate WL measurement for cancer research sites	8	Visual model based on a pyramid diagram	Range 1-10 (optional elements +0.5)	NS	CRN	Oncology

CRA, clinical research associate; CRC, clinical research coordinator; CRN, clinical research nurse; NS, not specified; RT, research team.

TABLE 4
Domains Covered by Included Assessment Tools

Workload domains	Tools											
	ASCO[16]	IWAT[25]	OPAL[28]	NCI[30]	NS[32]	NTRCT-AT[9]	RETA[17]	RVW[26]	TRACAT[29]	WCCOP[12]	WMI[27]	NS[31]
Protocol-related factors	X	X	X	X	X	X	.	X	X	X	X	X
Case-related factors	.	.	X	X	X	X	X	X	X	.	X	X
Data management factors	.	.	.	X	X	X	X	X	X	.	X	X
Regulatory factors	.	.	X	X	X	X	X	X	X	.	X	X
Worker workload factors	X	.	.	X	.	X	.	X	X	.	X	.

NS, not stated.

Discussion

CRNs play a crucial role in CTs.[20,34] They are accountable for the majority of the actions that comprise a clinical investigation. It is crucial to evaluate the appropriate equilibrium between workforce size and trial quantity in order to guarantee patient safety, adherence to protocols, and data integrity.[5] This scoping review offers objective instruments that can quantify the WL related with CTs from the viewpoint of those working in clinical research teams. The evaluation of WL is increasingly becoming a standard daily procedure in the management of CTs, therefore emphasizing the crucial need of a guide containing the necessary instruments to track such screening. To the best of the authors' knowledge, this is the sole scoping review conducted on assessment instruments utilized for measuring CTs WL.

The presence of quantifiable measures is beneficial for maintaining a balance in the WL of staff in CTCs. In light of the recent application of European regulation n. 536/2014, it has become increasingly crucial to adopt this method, since it now mandates that centers involved in CTs must do a feasibility analysis to assess the suitability of their facilities, equipment, human resources, and expertise. Establishing a CTC with a proficient workforce, which includes qualified nurses, is essential for guaranteeing the delivery of superior clinical

TABLE 5
Workload Scores in Included Studies

Tool	Author	Sample	Main Findings
IRST Workload Assessment Tool IWAT	Fabbri et al.[25]	448 protocols	Median IWAT WL score for each study was 20.98 ± 22.90 (range; 2-188) and 475 ± 229 (range, 150 [junior staff]—930 [extreme heavy WL]) for each CRC. A monthly workload score of 500-600 was considered an appropriate value for a full-time CRC.
Wichita Community Clinical Oncology Program WCCOP	Good et al.[12]	2,529 patients	Acuity scores increased from 65% to 181% during the 11 y period. WCCOP was able to decrease individual research nurse staff full-time equivalent (FTE) acuity scores and number of patients per FTE.
Clinical Trial Workload Assessment Tool ASCO	Good et al.[16]	323 staff members 963 protocols	Treatment trial acuity scores were consistently higher compared with cancer control trials (22.8-37.6), and industry trials had higher acuity scores than NIH/NCI-funded trials. Evidence of trial acuity (complexity) being a better measure of workload was also evident when comparing groups.
Research Effort Tracking Application RETA	James et al.[17]	NS	Over a 4-y period, the data obtained from use of this tool have not only assisted with workload management, trial budget development, and cost recovery but have also compelled the group to think critically about clinical trials management and enabled them to identify the most complex and time-consuming tasks that affect the bottom line.
Trial Rating and Complexity Assessment Tool TRACAT	Jones et al.[29]	NS	Expert panel developed 75 consensus statements illustrating factors contributing to complexity, follow-up intensity, and operational performance in trial delivery, and specified 14 ranked trial rating indicators.
Relative value of Work RVW	Lee and Jeong[26]	70 staff members	RVW of the services ranged from 5.0 of paying compensation to 360.0 of preparing auditing. The top 5 RVW overall were preparing auditing, preparing monitoring visits, reviewing the protocol, completing study-related training, and reporting AEs. The range of RVW differed by specialty: from 3.67 to 279.0 in oncology, from 5.0 to 390.0 in cardiology, and from 5.0 to 480.0 in endocrinology.
Workload Measurement Index WMI	Lyddiardc and Briggs[27]	NS	WMI was developed to be a generic tool and can be used locally, nationally, or internationally to review the trial workload of an individual researcher, team, hospital, or network of centers.
NS_a	Malikova[32]	NS	NS
Nursing Time Required by Clinical Trial-Assessment Tool NTRCT-AT	Milani et al.[9]	141 protocols 7 CTNs	A total of 141 clinical trials were analyzed. The nursing time required by these trials was 1.254.578 min/y. Comparing the total number of working days required in theory (excluding holidays, sick leave, and permits) and the actual worked days showed a greater theoretical workload in hours per year, with the theoretical daily commitment in the year for each research nurse on average 11.13 h.
NCI Trial Complexity Elements & Scoring Model NCI	National Cancer Institute[30]	NS	Measurement of CTN workload expressed in time spent to complete core activities.
National Cancer Institute of Canada NS*	Roche et al.[31]	83 staff members	Each staff member was responsible for, on average, an overall number of 28 clinical trials. Local, industry-sponsored, and other cooperative group studies all took significantly more CRA time in the protocol management stage than did other studies ($P = .006$). Trials sponsored by industry took more time at the treatment stage than did trials with other sponsors ($P = .0002$) with local studies requiring significantly less time ($P = .0001$). Phase I studies in the follow-up and final stages were more time-consuming than phase I/II, II, and III trials ($P = .0001$). Industry studies took significantly more time than trials coordinated locally or by cooperative groups ($P = .0001$).
Ontario Protocol Assessment Level OPAL	Smuck et al.[28]	126 protocols	27 protocols were reviewed by multiple sites, and the majority of the sites reported OPAL score differences between 0 and 1.5.

AEs, adverse events; CRA, clinical research associate; CRC, clinical research coordinator; CTN, clinical trial nurse; NS, not specified.

research. A streamlined data-gathering system is crucial for accurately evaluating and allocating job assignments. Research investigations have shown that more complex study protocols are associated with increased costs, both in terms of financial resources and personnel WL. Studies have found that more complex protocols are associated with poorer study outcomes, especially in terms of recruiting and retaining subjects, as well as the quality of the collected data.[35,36]

Within the instruments examined, there existed a varied and complex structure, resulting in differences in the selection of instruments and the weighting of the WL, which hindered the comparison of research. Currently, there is no universally accepted and definitive tool for evaluating WL. The tools mentioned in research publications typically involve the use of various activities or criteria. However, it is important to note that every instrument has its own set of pros and cons. Therefore, it is emphasized that the perfect effort-tracking tool should possess certain qualities such as objectivity, wide applicability, high functionality, minimal maintenance, and user-friendliness in order to make the best selection.[17]

The protocol-related domain was found in the majority of instruments ($n = 11$) in the analyzed articles. The other domains (case, data management, and regulatory) were present in most of the instruments ($n = 9$). The worker-associated domain was less represented ($n = 6$) in the following instruments. This could be attributed to the evolving concept of CTs, which does not exclusively focus on experimentation but also encompasses interpersonal relationships and individual factors such as barriers, facilitators, stress, and job satisfaction, which are emerging as significant themes within trials. This concept encompasses multifactorial and personal aspects. Elevated WL can lead to inadequate time for nurses and other personnel to engage in research endeavors,[37] research teams should aim to minimize the WL for nurses involved in research delivery.[38] The burnout levels of researchers can be influenced by a high WL volume,[39] which is occurring at a period of very high numbers of CT commencements in recent times. The involvement of research staff in enhanced safety monitoring and multidisciplinary communication between clinical providers and research collaborators is necessary due to the intricate nature of experimental drugs, their shifting safety profiles, and the emphasis on enrolling individuals in the community.[34,40,41] Several time-based instruments, including RETA, RVW, NTRCT-AT, and the instrument developed by the National Cancer Institute of Canada for assessing WL, necessitate the use of specialized tools such as a chronometer. On the other hand, instruments (eg, IWAT, OPAL), which solely rely on subjective evaluation through rating scales, dichotomous measures, or visual scales, do not require any additional specific equipment. This distinction in equipment requirements can also impact the selection of the assessment instrument. Out all the instruments examined in this study, only IWAT has reliability measurements. Additionally, to our knowledge, OPAL is the only instrument that has been validated outside of its original setting. Future study should prioritize the psychometric assessment of dependability and content validity in various circumstances. The assessment instruments used in CTCs must be appropriate for the specific context in which they are implemented. The wide range of parameters pertaining to roles, duties, and legislation complicates the selection of an instrument, the comparison of outcomes, and the establishment of a suitable work-life balance. Thus, this review serves as a comprehensive reference by identifying the assessment tools for measuring WL in CTs that have been validated and/or cross-culturally adapted in the existing literature.

Strengths and Limitations

This scoping review is subject to limits and constraints. The absence of a globally recognized professional profile for research professionals, such as CRCs and CRNs along with the wide range of tasks they perform and the various roles they assume within the research team, can pose challenges in predicting the effectiveness of tools in a different setting. It is worth mentioning that these professional figures are not officially recognized in Italy, resulting in variations in their responsibilities across different centers.[18,42] Furthermore, not all instruments take into account all domains. An additional significant concern pertains to the substantial variation in the intricacy of phase I trials, particularly in relation to emerging study designs such as basket trials, umbrella trials, and platform trials. This variability is further influenced by the recent enactment of Italian legislation that imposes specific criteria for clinical centers involved in high-risk studies versus nonhigh-risk studies. The primary advantage of the scoping review is its thorough and extensive search, as well as its meticulous extraction of data from each activity considered by the instruments. The review moreover incorporated an extensive consultation approach to guarantee that no pertinent studies were disregarded.

Conclusions

This scoping review offers a comprehensive summary of the measurement of WL in CTs. Research nurses offer support in the domains of CT recruitment, upkeep, adherence, and subsequent monitoring. These responsibilities are increasingly challenging, particularly for businesses that may not be equipped to recruit additional personnel. In the midst of this increasing inequality, nurses make great efforts to maintain high-quality standards, often feeling dissatisfied and powerless, mainly because they are unable to objectively demonstrate their burden. Future research on the evaluation of CTs could be improved by using validated tools and standardized approaches to address the need for balancing clinical protocols and nurse WL. This could result in significant cost savings for CTCs by optimizing staffing, reducing delays, and minimizing wastage of research resources.

Patient Consent for Publication

Not applicable.

Declaration of competing interest

The authors declare that they do not possess any identifiable conflicting financial interests or personal ties that could have potentially influenced the findings presented in this article.

CRediT authorship contribution statement

Mattia Bozzetti: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Silvia Soncini:** Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Conceptualization. **Maria Chiara Bassi:** Methodology, Investigation, Formal analysis, Conceptualization. **Monica Guberti:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Conceptualization.

Funding

This study was partially supported by the Italian Ministry of Health Ricerca Corrente Annual Program 2025.

Acknowledgments

None.

Data Availability

All data relevant to the study are included in the article or uploaded as Supplementary Information.

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