inclusion of under-served groups in recent acne trials: protocol for a scoping review.

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Abstract

Acne vulgaris, being one of the most common dermatological conditions, possesses a spectrum of potential presentations across individuals. Considering the broad range of patients, responses to new or current treatment for acne also varies substantially. Individuals within ‘under-served ’categories defined by NIHR INCLUDE framework are frequently underrepresented within clinical trials. Therefore, it is paramount that research on acne remains inclusive of all groups, under-served or not, in order to produce generalisable results. The aim of this scoping review is to establish the extent and type of evidence in relation to inclusion of under-served groups in clinical research on acne. The review will also highlight gaps in evidence to inform future research and policy efforts on managing acne trials inclusively. This review will look at participants involved in studies regarding acne. The focus will be on randomised controlled trials conducted in any country or health-care setting. Both trials that include participants from under-served categories or report their efforts on maintaining inclusivity, as well as those that do not, will be considered. This approach enables an analysis of the extent to which inclusion is achieved or participant characteristics are reported. Sources from MEDLINE and Embase via Ovid will be extracted using a three-step strategy with language being one of the limits. Collation of data will be done by independently reviewing through Rayyan AI. Key data from articles will be charted in a standardised extraction tool developed on Microsoft Excel and will be used to map under representation of under-served groups within acne trials. Qualitative and Quantitative data will be presented accordingly, including tables depicting characteristics of participants in comparison to NIHR INCLUDE groups.

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Introduction

Acne Vulgaris, hereafter referred to as acne throughout this protocol, is an inflammatory skin condition that frequents a display of pimples, whiteheads and blackheads. Around 9% of the world population is affected by this condition at some point in their lives. Acne itself is an umbrella term with numerous sub-categories such as acne congloblata, comedonal acne or acne fulminans. It predominantly affects individuals in the pubescent stages of life.[1] Current evidence highlights the potential emotional, physical, social as well as psychological consequences that acne poses. The condition can manifest differently across specific populations due to factors such as age, sex or complexion ultimately leading to stark contrasts in prognosis. For example, the population who have acne and also possess that of a deeper complexion may experience increased risk of post-inflammatory hyperpigmentation (PIH).

Randomised clinical trials form the foundation of evidence based management for acne through new data on pharmacological and non-pharmacological interventions. It is therefore paramount that clinical trials regarding acne and its treatments mirror the entire population that could be affected. Results that are applicable to a broad range of demographics allow for a more generalisable approach towards the treatment of acne. Maintaining inclusivity in randomised trials is essential to address knowledge gaps regarding variations in acne presentation and treatment response. Principles from WHO,FDA and NIHR outline the need for diversity in participants across trials in order to benefit the broadest range of individuals. Without testing in underrepresented cohorts there remains the risk of these populations being under-served in research.[2]

The NIHR INCLUDE project established framework with the goal of providing a map which shows key points across the life course of a study that inclusivity should be considered.[3] After completion in 2021, a list was developed outlining categories of people who could fall under the term of an ‘under-served ’group such as those with protected characteristics or socioeconomically disadvantaged populations. Recognition of these groups and application of the framework in acne trials offers an opportunity to systematically assess how inclusive acne trials have been to date.

A preliminary search of MEDLINE, Embase via Ovid and PROSPERO was conducted and no current or underway scoping reviews addressing the inclusion of under-served groups in acne clinical trials were identified.Several systematic reviews and narrative analyses were found that examined participant diversity in dermatology or acne trials more broadly. However, none of the identified reviews specifically mapped inclusivity within acne trials using the NIHR INCLUDE framework nor did they consider the full range of under-served populations that are pertinent to acne.

Hence, this identifies a gap in literature and warrants the need for a scoping review to map the breadth of evidence on representation of under-served groups in acne trials in alignment with the NIHR INCLUDE framework.

Inclusion criteria

POPULATION

This review will look at studies involving participants enrolled in randomised clinical trials on acne vulgaris. Descriptive sub-types such as nodular cystic, comedonal, acne conglobata and acne fulminans will be considered. All severities will also be addressed.Data that focuses on acne scarring, post-inflammatory hyperpigmentation or post-inflammatory erythema will be included. There will be no restrictions placed on characteristics of participants such as age, sex or ethnicity.

CONCEPT

The core concept of this review will be the representation of NIHR INCLUDE defined under-served categories within acne trials. This includes but is not limited to: ethnic minorities, age extremes, women of childbearing age and women who are lactating. Trials that report participant demographics, their inclusion and exclusion criteria and anything related to maintaining inclusivity across their study will be eligible.

CONTEXT.

Randomised controlled trials on acne, regardless of country or the healthcare setting where it was conducted, will be included. Studies published in the English language or for which a translation is available will be considered for the review. In addition, clinical trial registries such as clinical trials.gov, will be searched looking at unpublished and ongoing trials.[4] Trials within or having just completed the recruiting stage will be assessed against remaining eligibility criteria before being integrated into the review.

Exclusion criteria

Types of acne that do not fit the description of acne vulgaris will be excluded, those being: infantile acne, acne inversa, neonatal acne or any non-inflammatory acne.Trials that have not been published within the last 5 years will be disregarded. Trials that are not solely conducted on humans will be excluded as well as trials that do not concern both acne and randomised controlled trials.

Method

the proposed scoping review will be conducted in line with the JBI methodology for scoping reviews.[5]

Search strategy

The search strategy will aim to focus on studies that have been published. A three step approach will be applied in this review as follows.

First, an initial limited search for randomised controlled trials on acne in the last 5 years on data bases MEDLINE and Embase via Ovid. Synonyms of keywords derived from the search question will be utilised in this initial search. The key terms being 'acne vulgaris 'and 'randomised controlled trials'.

Secondly, keywords within abstracts and titles of potential articles as well as their index will be used to further develop the search string with the intention of building a full search strategy that is sensitive yet specific.

Lastly, the search strategy will be adapted for each data base to better suit them. full texts of any citations that meet the eligibility criteria, and for citations where it was not possible to screen, will be obtained manually.

Clinical research evolves and so by keeping the scope as recent as possible makes it more relevant towards how acne is managed and researched today. The scope itself can produce a broad spectrum of trials so by limiting the time frame it helps maintain sensitivity. Studies published within the last 5 years will be included but the search date will be changed if limited articles appear. Honing in on specific treatments is not necessary for the search strategy. Sources of grey literature to be searched include the centre of evidence based dermatology and clinicaltrials.gov.[4,6] Appendix A and B list the search strings used for each database.

Evidence selection

Titles and abstracts obtained will be screened using Rayyan AI for assessment against the inclusion criteria for the scoping review and to prevent deduplication. An independent secondary reviewer will also be screening the titles and abstracts.

After screening for eligibility, all identified citations will be collated and transferred to EndNote 25 to manage references. Once relevant articles have been sourced, full-text papers will then be considered independently. Any discrepancies that arise when reviewing will be discussed with an additional third reviewer. Results of the selection process will be displayed in a PRISMA-ScR flow diagram.

Data extraction

Data will be extracted from suitable sources by a single extractor with 25% of the information being checked independently. This will then be charted using a standardised data extraction form developed on Microsoft Excel. The form will include general characteristics of the study itself and additionally capture detailed information regarding representation and inclusion of participants.

The following information will be extracted from each article:

- Year of publication
- Author
- Objective of trial
- Number of participants
- Context of trial such as geographical location or location of care

Characteristics of participants in these trials will also be extracted with reference to the underserved population groups, these being:

- Age extremes, ethnic minorities,
- Gender
- Comorbidities
- Geographical location
- Language and literacy barriers
- Fitzpatrick skin type or skin tone
- Reproductive status
- Mental health conditions
- Care setting
- Full time employment
- Digital exclusion
- Disease challenge/severity
- Physical disabilities
- Economic status/education

The form will be pilot tested on a sample of included studies and refined as necessary. Any key findings that relate back to the aim of the scoping review will be included. Approaches reported by the trial team to increase inclusivity will be noted. If appropriate, authors of included papers will be contacted to request missing or additional data, where required.

Data analysis and presentation

Extracted data will be collated and analysed with the goal of mapping under representation of under-served groups within acne trials. It is important to note that the aim of this scoping review is to outline the breadth of evidence on under-served groups in acne trials and not to synthesise results on individual included studies. Quantitative data will be presented descriptively in a tabular form. Qualitative data describing the strategies or approaches trials have employed improve inclusivity will be presented thematically in order to group common concepts and highlight any patterns that arise. Simple frequency counts will be used to present information regarding the study characteristics, population data and the proportion of studies that mention the demographics of their participants. Findings regarding what under-served groups were included will also be displayed in tabular form and will be mapped to the NIHR INCLUDE ‘under-served’ categories. A narrative summary will accompany these results including how they relate back to inclusivity within randomised controlled acne trials.

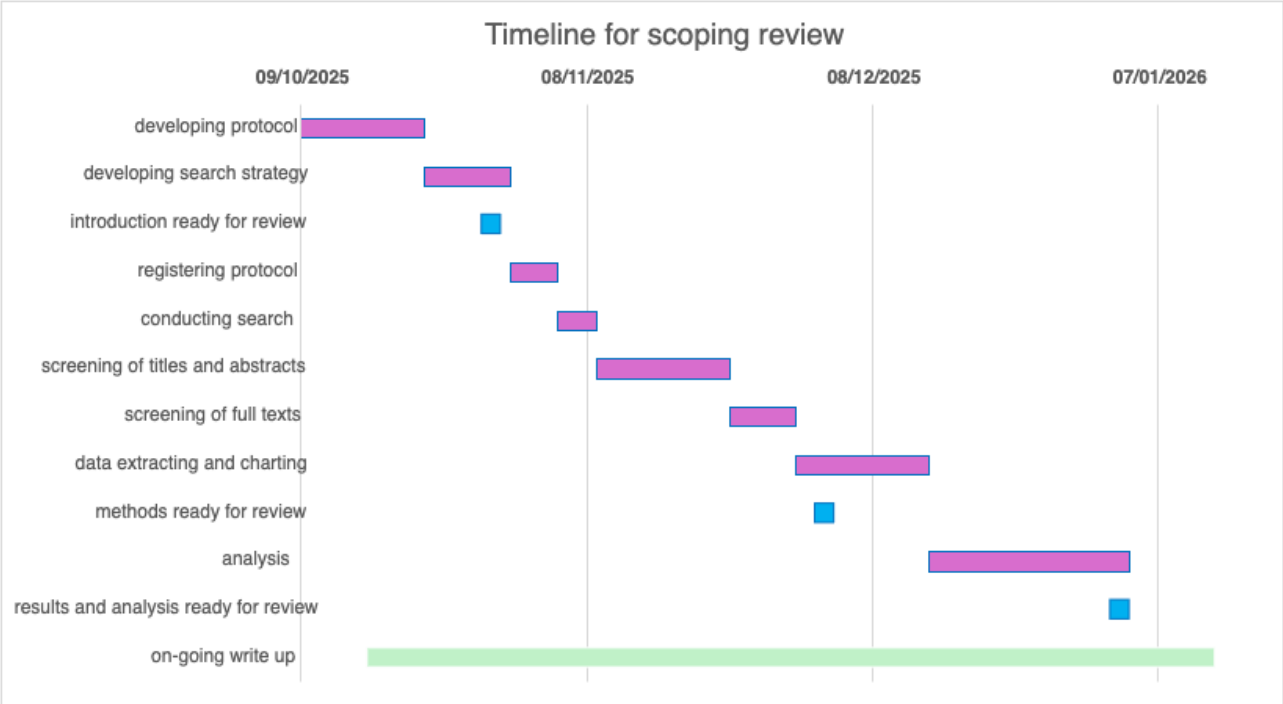

Figure 1. Gantt chart showing the planned timeline for the scoping review, including overlapping analysis

Reference list

1- NICE. (23AD). *CKS is only available in the UK*. [online] Available at: https://cks.nice.org.uk/topics/acne-vulgaris/background-information/definition/.

2-World (2024). *New global guidance puts forward recommendations for more effective and equitable clinical trials*. [online] Who.int. Available at: https://www.who.int/news/item/25-09-2024-new-global-guidance-puts-forward-recommendations-for-more-effective-and-equitable-clinical-trials.

3-National Institute for Health and Care Research (2020). *Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project*. [online] Nihr.ac.uk. Available at: https://www.nihr.ac.uk/improving-inclusion-under-served-groups-clinical-research-guidance-include-project.

4-U.S. National Library of Medicine. Clinicaltrials.gov [Internet]. Clinicaltrials.gov. 2025. Available from: https://clinicaltrials.gov/

5-JBI (2021). *JBI Manual for Evidence Synthesis*. [online] Refined.site. Available at: https://jbi-global-wiki.refined.site/space/MANUAL.

6-Nottingham.ac.uk. (2025). *Our research - The University of Nottingham*. [online] Available at: https://www.nottingham.ac.uk/research/groups/cebd/projects/index.aspx [Accessed 22 Oct. 2025].

Appendix A - EMBASE via Ovid search strategy

The search was conducted on 24/10/25 with limits of : human and english language and "remove clinical trial (clinicaltrials.gov) records" and "remove preprint records" and randomized controlled trial and english and yr="2020 - 2025" and last 5 years)

	Search	Results
1	(acne or "acne vulgaris").mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word]	52356
2	pimples.mp.	319
3	Pustules.mp.	5674
4	blackheads.mp. or open comedones/de	109
5	whiteheads.mp. or closed comedones/de	187
6	"nodular cystic acne".mp.	24
7	papules.mp.	19779
8	"cystic acne".mp.	361
9	"acne fulminans".mp.	448
10	"comedonal acne".mp.	134
11	"inflammatory acne".mp.	1128
12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	74647
13	RCT.mp.	81656
14	"randomi?ed controlled trial".mp.	1440583
15	"randomi?ed clinical trial".mp.	86922
16	"randomi?ed study".mp.	65368
17	"randomi?ed trial".mp.	117879
18	13 or 14 or 15 or 16 or 17	1533487
19	12 and 18	5589

	Search	Results
20	limit 19 to (human and english language and "remove clinical trial (clinicaltrials.gov) records" and "remove preprint records" and randomized controlled trial and english and yr="2020 - 2025" and last 5 years)	1141

Appendix B - MEDLINE via Ovid search strategy

The search was conducted on the 24/10/25 with limits of: english language and humans and yr="2020 - 2025" and english and randomized controlled trial and last 5 years.

	Search	Results
1	acne vulgaris/ or acne conglobata/ or acne.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word]	24891
2	Pimples.mp.	166
3	pustules.mp.	3381
4	Blackheads.mp.	60
5	Whiteheads.mp.	174
6	“Nodular cystic acne”.mp.	12
7	papules.mp.	11425
8	“Cystic acne”.mp.	257
9	"acne fulminans".mp.	225
10	"comedonal acne".mp.	71
11	"inflammatory acne".mp.	691
12	1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11	38220

	Search	Results
13	RCTS.mp.	70501
14	"randomi?ed controlled trials".mp.	281999
15	"randomi?ed clinical trial ".mp.	54572
16	"randomi?ed study ".mp.	36325
17	"randomi?ed trial ".mp.	73496
18	13 or 14 or 15 or 16 or 17	428433
19	12 and 18	732
20	limit 19 to (english language and humans and yr="2020 - 2025" and english and randomized controlled trial and last 5 years)	48