International Journal of Innovative Technologies in Social Science

e-ISSN: 2544-9435

Operating Publisher
SciFormat Publishing Inc.
ISNI: 0000 0005 1449 8214

2734 17 Avenue SW,
Calgary, Alberta, T3E0A7,
Canada
+15878858911
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ARTICLE TITLE	MOBILE HEALTH APPLICATIONS IN MANAGEMENT OF POLYCYSTIC OVARY SYNDROME (PCOS): A SYSTEMATIC REVIEW OF CLINICAL EFFICACY, QUALITY, AND SOCIO-ECONOMIC IMPLICATIONS
DOI	https://doi.org/10.31435/ijitss.1(49).2026.4653
RECEIVED	30 November 2025
ACCEPTED	13 January 2026
PUBLISHED	28 January 2026
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MOBILE HEALTH APPLICATIONS IN MANAGEMENT OF POLYCYSTIC OVARY SYNDROME (PCOS): A SYSTEMATIC REVIEW OF CLINICAL EFFICACY, QUALITY, AND SOCIO-ECONOMIC IMPLICATIONS

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ABSTRACT

Background: Polycystic Ovary Syndrome (PCOS) constitutes the most prevalent endocrine disorder in reproductive-aged women, affecting approximately 8–13% of this population globally. Although lifestyle modification is the designated first-line therapy, adherence is frequently impeded by economic barriers and the lack of continuous, personalized support. Mobile health (mHealth) technologies propose a scalable solution to this "care gap," yet the digital marketplace remains fragmented, often lacking alignment between commercial usability and clinical evidence.
Objectives: This systematic review evaluates the clinical efficacy, technical quality, and socio-economic implications of mHealth interventions in PCOS management to inform future clinical practice and reimbursement frameworks.
Methods: A systematic search of academic databases covering the period from January 2010 to January 2025 yielded 34 eligible studies. These included Randomized Controlled Trials (RCTs) assessing clinical outcomes and content analyses utilizing the Mobile App Rating Scale (MARS).
Results: Evidence from high-quality RCTs indicates that integrated mHealth interventions can function as effective "digital scaffolds" for behavioral change. Specific digital interventions demonstrated significant weight reduction (mean -3.19 kg) and improved insulin resistance with efficacy comparable to metformin. Furthermore, digital support significantly restored reproductive function, with long-term data showing a substantial increase in the prevalence of regular menstrual cycles, rising from 3.3% at baseline to 43.1% in intervention groups. However, technical analyses reveal a persistent "quality gap," where commercial applications prioritize aesthetics over evidence-based medical content.
Conclusion: Mobile health applications represent a clinically valid and cost-effective adjunct to standard PCOS care. To realize their public health potential, future frameworks must bridge the divide between commercial user experience and academic rigor, ensuring equitable access to validated digital therapeutics.

KEYWORDS

Polycystic Ovary Syndrome (PCOS), mHealth, Digital Therapeutics, Health Economics, Artificial Intelligence

CITATION

Maksymilian Głaz, Łukasz Deska, Szymon Zysiak, Dawid Głaz, Natalia Kamińska, Jędrzej Zaguła, Wojciech Sołtys, Cezary Kosmecki, Mateusz Stronczyński, Kacper Wicha. (2026) Mobile Health Applications in Management of Polycystic Ovary Syndrome (PCOS): A Systematic Review of Clinical Efficacy, Quality, and Socio-Economic Implications. *International Journal of Innovative Technologies in Social Science*. 1(49). doi: 10.31435/ijitss.1(49).2026.4653

1. Introduction

1.1 Background and Rationale: The Biopsychosocial Complexity of PCOS

Polycystic Ovary Syndrome (PCOS) represents the most prevalent endocrine disturbance affecting women of reproductive age, with global prevalence rates estimated between 8% and 13% depending on the diagnostic criteria employed (Bozdag et al., 2016). While the syndrome is clinically heterogeneous—typically diagnosed via the Rotterdam criteria by the presence of oligo-anovulation, hyperandrogenism, and polycystic ovarian morphology—viewing PCOS solely through a reproductive lens constitutes a reductionist approach (Teede et al., 2023). It is intrinsically linked to a metabolic syndrome phenotype that persists across the lifespan, extending well beyond the reproductive years. The metabolic implications are profound; evidence suggests that up to 75% of lean and 95% of obese women with PCOS exhibit intrinsic insulin resistance, predisposing them to type 2 diabetes mellitus and cardiovascular disease (Stepto et al., 2013).

This biological reality intersects with significant psychological challenges. Meta-analytic data indicate that women with PCOS experience anxiety and depression at rates significantly higher than the general population (Brutocao et al., 2018). These comorbidities are driven not only by infertility distress but also by the stigmatizing nature of visible symptoms such as hirsutism and central obesity. Consequently, PCOS acts as a complex biopsychosocial condition requiring holistic management. The economic burden of this multi-faceted disorder is substantial. Recent analyses estimate that the total healthcare-related economic burden of diagnosing and treating PCOS, including its metabolic and psychological sequelae, exceeds $15 billion annually in the United States alone (Yadav et al., 2023). This creates a compelling economic argument for scalable management strategies capable of mitigating these costly long-term complications.

1.2 The Systemic Failure of Traditional Management

The 2023 International Evidence-Based Guideline for the Assessment and Management of PCOS designates lifestyle management—encompassing dietary modification, physical activity, and behavioral strategies—as the first-line therapy (Teede et al., 2023). Clinical data demonstrate that a weight loss of 5% to 10% is often sufficient to restore spontaneous ovulation and improve metabolic profiles (Lim et al., 2019). Theoretically, this offers a cost-effective intervention pathway. However, the translation of these guidelines into clinical practice is often impeded by systemic barriers. Traditional face-to-face counseling is resource-intensive and frequently inaccessible to diverse socio-economic groups. Furthermore, the episodic nature of medical consultations fails to provide the continuous, daily support required for sustained behavioral modification. Patient dissatisfaction with conventional care is high, with many reporting a lack of information and empathy from providers (Hoyos et al., 2020). This "care gap" necessitates a paradigm shift towards models that can deliver continuous, personalized support.

1.3 The Evolution of Mobile Health (mHealth) and Digital Therapeutics

Mobile health (mHealth) technologies have emerged as a transformative solution to these systemic barriers. Evolving from simple Short Message Service (SMS) reminders to sophisticated smartphone applications integrating Artificial Intelligence (AI) and the Internet of Things (IoT), mHealth offers a platform for continuous, "in-pocket" support (Istepanian et al., 2006). In the context of endocrinology, mHealth has shifted from passive information delivery to active "digital therapeutics" (DTx). Modern applications for PCOS not only track menstrual cycles but also employ algorithms to monitor glycemic load, physical activity, and mental well-being. This technological convergence enables "just-in-time" adaptive interventions (JITAI), providing personalized support during critical moments of vulnerability (Hardeman et al., 2019).

1.4 Research Objectives and Socio-Technical Scope

Despite the proliferation of "FemTech" and PCOS-related applications, a significant dichotomy exists between commercial availability and scientific validation. While the market offers numerous applications, few have been rigorously tested in clinical trials, and a "quality gap" persists between user experience and evidence-based content. Moreover, most existing reviews focus narrowly on clinical outcomes, neglecting the broader societal implications of digitizing women's health. This systematic review aims to address these gaps by adopting a multi-dimensional approach:

Clinical Efficacy: Synthesizing evidence from Randomized Controlled Trials (RCTs) regarding the impact of mHealth on metabolic and reproductive outcomes.

App Quality: Evaluating commercial apps using the Mobile App Rating Scale (MARS) to identify disparities between usability and medical accuracy.

Socio-Economic Analysis: Examining cost-effectiveness and the "Digital Divide."

Technological Frontiers: Assessing the role of AI and IoT in future frameworks.

2. Methodology

2.1 Study Design and Protocol Adherence

This study was designed as a comprehensive systematic review bridging clinical data and technical assessments of mobile health tools. The review protocol was developed and executed in strict adherence to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement to ensure methodological transparency, reproducibility, and the minimization of selection bias (Page et al., 2021). Given the interdisciplinary nature of the research objectives—which encompass clinical endocrinology, digital technology, and socio-economic analysis—a mixed-methods synthesis approach was adopted. This framework facilitated the integration of quantitative efficacy data from Randomized Controlled Trials (RCTs) with qualitative and quantitative evaluations of mobile application quality.

2.2 Data Sources and Search Strategy

To capture the full spectrum of the "cyber-physical" landscape of PCOS management, a multi-database search strategy was employed. The search period was defined from January 1, 2010, to January 20, 2025. This inception date was selected to coincide with the proliferation of modern smartphone ecosystems (iOS and Android) and the subsequent emergence of the app-based economy, which marked a definitive shift in the capabilities of mHealth interventions (Silva et al., 2015).

The following electronic bibliographic databases were queried:

- PubMed/MEDLINE and Scopus: To identify high-quality clinical trials and biomedical reviews.
- Web of Science: To broaden the search to interdisciplinary citations.
- CINAHL (Cumulative Index to Nursing and Allied Health Literature): To capture studies focusing on patient education, self-management, and nursing interventions.
- IEEE Xplore: Included specifically to identify technical papers focusing on the architecture of mHealth systems, Artificial Intelligence (AI) algorithms, and Internet of Things (IoT) sensors, which are frequently omitted in purely clinical reviews.

The search strategy utilized a Boolean logic framework combining Medical Subject Headings (MeSH) and free-text keywords across three conceptual blocks:

1. Condition: "Polycystic Ovary Syndrome", "PCOS", "Stein-Leventhal Syndrome", "Hyperandrogenism".
2. Intervention (Technology): "mHealth", "Mobile Applications", "Telemedicine", "Smartphone", "Wearable Device", "Internet of Things", "IoT", "Digital Therapeutics".
3. Outcomes (Clinical & Social): "Self-management", "Weight loss", "Insulin Resistance", "Menstrual Regularity", "Fertility", "Cost-effectiveness", "Quality of Life".

2.3 Eligibility Criteria

To ensure the review remained focused yet inclusive of socio-technical dimensions, strict inclusion and exclusion criteria were applied.

Inclusion Criteria:

- Population: Women aged 18 years and older with a confirmed diagnosis of PCOS according to recognized international standards (Rotterdam ESHRE/ASRM-Sponsored PCOS Consensus Workshop Group, 2004).
- Intervention: Studies evaluating the use of mobile health technologies, including standalone smartphone applications, SMS-based interventions, wearable tracking devices, and social-media-based interventions (e.g., WeChat, WhatsApp) structured specifically for disease management.
- Outcomes: The review targeted three distinct categories:
  - Clinical: Anthropometric (weight, BMI, waist circumference), metabolic (insulin resistance, lipid profiles), and reproductive (menstrual cyclicity, ovulation, pregnancy rates).
  - Technical/Quality: Assessment of app usability, engagement, and information accuracy (utilizing scales such as MARS).
  - Socio-Economic: Cost-effectiveness, accessibility, impact on rural vs. urban disparities, and psychological well-being.
- Study Design: Randomized Controlled Trials (RCTs), quasi-experimental studies, observational cohort studies, and cross-sectional content analyses.
- Language: Full-text articles published in English.

Exclusion Criteria:

Studies were excluded if they focused solely on pediatric/adolescent populations, utilized general telemedicine (video consultations) without a continuous monitoring app component, were animal studies, or were conference abstracts lacking full datasets.

2.4 Data Extraction and Quality Assessment

Data extraction was performed using a standardized piloting form capturing: Author, Year, Country, Study Design, Sample Size, Intervention Details, Main Outcomes, and Key Findings. To address the "Quality Gap" hypothesis, the quality assessment was bifurcated based on the study type:

1. Assessment of Clinical Trials (Internal Validity): The methodological quality of included RCTs was evaluated using the Cochrane Risk of Bias tool 2 (RoB 2) (Sterne et al., 2019). This tool assesses bias across five distinct domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. This rigorous assessment was critical to differentiate whether reported clinical benefits were attributable to the digital intervention itself or to study design limitations.
2. Assessment of Mobile Applications (Technical & User Quality): For studies evaluating the applications themselves, the Mobile App Rating Scale (MARS) was utilized (Stoyanov et al., 2015). MARS is a validated, multidimensional tool that evaluates apps on a 5-point scale across four objective subscales:

- Engagement: Fun, interest, customization, and interactivity.
- Functionality: Performance, ease of use, and navigation.
- Aesthetics: Graphic design, visual appeal, and layout.
- Information Quality: Accuracy, evidence base, and credibility of the content.

2.5 Data Synthesis and Analysis

Due to the significant heterogeneity in study designs (ranging from clinical RCTs to technical app reviews) and the diversity of reported outcomes, a statistical meta-analysis was not feasible for all parameters. Consequently, a narrative synthesis approach was adopted (Popay et al., 2006). Clinical data were tabulated to compare effect sizes, while app quality data were synthesized to identify patterns in the commercial landscape, allowing for a holistic interpretation of how technical features influence clinical and social outcomes.

3. Results

3.1 Search Results and Study Selection

The initial systematic search across the designated electronic databases yielded a total of 543 records. Following the removal of duplicate entries (n=112), 431 titles and abstracts were screened for relevance against the pre-defined inclusion criteria. A significant portion of these records (n=353) were excluded at the preliminary screening stage; these largely consisted of pharmacological drug trials lacking a digital component or studies focusing on general obesity without a specific PCOS diagnosis.

Subsequently, 78 full-text articles were assessed for eligibility. This rigorous full-text review resulted in the exclusion of a further 44 studies due to reasons such as lack of specific PCOS diagnostic criteria, interventions being solely web-based without mobile optimization, or insufficient quantitative outcome data.

Ultimately, 34 studies met the stringent inclusion criteria for this review. The final pool comprised 8 Randomized Controlled Trials (RCTs), 12 observational/cohort studies, and 14 technical content analyses utilizing frameworks such as the Mobile App Rating Scale (MARS). (Table 1)

Table 1. PRISMA Flow Description and Study Selection Stages

Stage	Action	Count (n)	Notes
Identification	Records identified from databases	543	Databases queried: PubMed, Scopus, Web of Science, CINAHL, IEEE Xplore.
Screening	Records screened after duplicate removal	431	Duplicates removed: n=112.
	Records excluded (Title/Abstract)	353	Excluded due to irrelevance (e.g., animal studies, non-PCOS, drug-only trials).
Eligibility	Full-text articles assessed	78	Detailed review against inclusion criteria.
	Full-text excluded	*44*	Reasons: Wrong population (n=15), Web-based only/No app (n=12), Insufficient outcome data (n=17).
Included	Studies included in synthesis	34	RCTs (n=8), Observational (n=12), Technical/MARS Analysis (n=14).

3.2 Clinical Efficacy: Anthropometric and Metabolic Outcomes

The review identified robust evidence suggesting that mHealth interventions can drive clinically significant weight loss and metabolic improvements, acting as a "digital scaffold" for behavioral change.

Weight Loss and Body Composition

Weight management is the cornerstone of PCOS therapy, yet sustained adherence remains a challenge. Evidence from the included RCTs indicates that mobile applications provide the necessary frequency of interaction to sustain motivation. Choi et al. (2023) demonstrated that a 12-week integrated app-based intervention resulted in a mean weight loss of 3.19 kg in the intervention group, compared to a mere 0.79 kg reduction in the control group receiving standard care ($p < 0.05$). This differential is clinically pivotal, as current international guidelines establish that a weight loss of 5% to 10% is the threshold required to restore spontaneous ovulation and improve metabolic features (Teede et al., 2023). The app utilized in the Choi et al. study functioned as a "digital health coach," offering features for logging meals and tracking exercise, suggesting that the continuous behavioral feedback loop drives efficacy.

Metabolic Health vs. Pharmacotherapy

Perhaps the most striking finding is the comparative efficacy of digital interventions against standard pharmacological treatments. Dilimulati et al. (2024) conducted a landmark RCT comparing a WeChat-based digital lifestyle intervention directly against Metformin (1000 mg/day). The study found no statistically significant difference in the reduction of HOMA-IR between the digital intervention group and the Metformin group (change of -0.93 vs. -0.73, p = 0.62), implying non-inferiority for improving insulin sensitivity.

Furthermore, the digital group achieved a significantly greater reduction in waist circumference (-4.52 cm) compared to the Metformin group (-2.66 cm) (Dilimulati et al., 2024). Given that central adiposity is a key driver of metabolic inflammation, the ability of mHealth tools to target visceral fat represents a superior outcome profile to medication alone in this domain.

Table 2. Summary of Key Characteristics and Findings of Included Interventional Studies

Author (Year)	Design & Sample (N)	Intervention Details	Key Clinical & Technical Findings	Quality Assessment
Choi et al. (2023)	RCT (N=72)	**Integrated App:** Diet logging, exercise tracking, CBT modules vs. General advice.	**Weight:** Sig. loss in App group (-3.19 kg) vs. Control (-0.79 kg) ($p < 0.05$). **Insulin:** Improved postprandial levels. **Psych:** Sig. reduction in depression scores.	Low Risk (RoB 2)
Dilimulati et al. (2024)	RCT (N=160)	**WeChat Intervention** vs. **Metformin** (1000mg/day).	**Non-Inferiority:** Digital intervention showed comparable HOMA-IR reduction to Metformin (-0.93 vs -0.73, p=.62). **Waist:** Greater reduction in digital group (-4.52 cm vs -2.66 cm).	Some Concerns (RoB 2)
Jiskoot et al. (2020)	RCT (N=183)	**Lifestyle Program + SMS Support** vs. Care as Usual.	**Menstruation:** Regular cycles increased from 3.3% at baseline to 43.1% ($p = 0.001$). **Psych:** Higher self-esteem reported in SMS group.	Low Risk (RoB 2)
Dietz de Loos et al. (2023)	RCT Follow-up (N=574)	Long-term follow-up of Lifestyle + SMS intervention.	**Fertility:** 58.3% spontaneous conception rate in lifestyle groups. **Safety:** Lower incidence of pregnancy complications (GDM, hypertension) vs. control.	Low Risk (RoB 2)
Arabkermani et al. (2025)	Content Analysis (15 apps)	**MARS Evaluation** of commercial PCOS apps.	**Quality Gap:** High scores for Functionality/Aesthetics (~4.5/5) but low for Information Quality (~2.8/5). Only 12% cited medical guidelines.	Avg MARS Score: 3.6/5
Boyle et al. (2019)	Mixed Methods (N=238)	Development of **"AskPCOS"** app based on user needs.	**User Needs:** Identified critical gap for evidence-based information. Validated "AskPCOS" as a high-quality educational tool vs. commercial alternatives.	N/A (Survey/Dev)

3.3 Reproductive Outcomes: The Cyber-Biological Link

Restoring reproductive function is often the primary motivation for women with PCOS to engage with healthcare services. The reviewed studies confirm that digital interventions can successfully bridge the gap between behavioral input and reproductive output.

Menstrual Regularity and Fertility

Digital interventions demonstrated a potent capacity to restore menstrual cyclicity. In the Dilimulati et al. (2024) study, both the digital intervention and Metformin groups saw significant improvements in menstrual frequency ($p < 0.001$). This finding was corroborated by a secondary analysis of a large-scale RCT by Jiskoot et al. (2020), which found that supplementing a lifestyle intervention with SMS support significantly increased the prevalence of regular menstrual cycles. At baseline, only 3.3% of participants reported regular cycles; after 12 months of digitally supported intervention, this figure rose to 43.1% ($p = 0.001$). regarding fertility, Dietz de Loos et al. (2023) reported that 58.3% of participants across lifestyle groups conceived spontaneously within 24 months. Crucially, the intervention group experienced fewer pregnancy complications, such as gestational diabetes, indicating that mHealth prepares the metabolic environment for safer pregnancies (Dietz de Loos et al., 2023).

3.4 Psychological Outcomes: Virtual Companionship and Risks

The psychological burden of PCOS is a primary driver of patient dissatisfaction, with women reporting high rates of depression and anxiety.

Depression and Self-Esteem

The review found that mHealth tools can mitigate psychological distress. Jiskoot et al. (2020) reported that lifestyle interventions supplemented by SMS significantly improved self-esteem compared to usual care. Similarly, Choi et al. (2023) observed a significant reduction in depression scores in the app-based group ($p < 0.05$). The mechanism appears to be the reduction of isolation through "virtual companionship."

The Risk of Disordered Eating

However, a nuanced finding emerges regarding body image. Women with PCOS are already at an elevated risk for disordered eating behaviors compared to the general population (Lee et al., 2017). Qualitative analyses highlight that apps focusing heavily on caloric restriction or utilizing "green/red" food categorization can exacerbate these tendencies (Earle et al., 2021). While users appreciate tracking features, rigid algorithmic enforcement can trigger feelings of shame and failure when daily targets are missed, underscoring the need for psychologically safe interface design.

3.5 App Quality and Technical Analysis (MARS)

While academic interventions show promise, the commercial landscape presents a significant "Quality Gap." Studies utilizing the Mobile App Rating Scale (MARS) reveal a disconnect between usability and clinical accuracy.

Functionality vs. Information Quality

Commercial apps consistently score high on MARS subscales for "Functionality" and "Aesthetics" but poorly on "Information Quality." Arabkermani et al. (2025) analyzed apps designed for PCOS and found that while technical performance was sufficient (mean MARS score 3.6), critical limitations persisted regarding the credibility of information. Many apps provided generic weight-loss advice not tailored to the insulin-resistant phenotype of PCOS, with a minority citing medical guidelines to substantiate their recommendations.

The "Fertility Trap" in Design

A content analysis of menstrual tracking apps revealed a phenomenon often termed the "Fertility Trap." The majority of commercial apps default to the assumption that the user is trying to conceive (Epstein et al., 2017). For a woman with PCOS utilizing an app to manage symptoms without pregnancy intent, the interface's constant focus on "fertile windows" and ovulation prediction can be alienating. Furthermore, standard algorithms often fail to account for the irregular cycle lengths typical of PCOS, rendering prediction features inaccurate (Epstein et al., 2017; Symul et al., 2019).

4. Discussion

4.1 Interpretation of Principal Findings: The "Digital Scaffold"

This systematic review reinforces the emerging consensus that mobile health technologies are no longer merely optional adjuncts but essential components of modern PCOS management. The clinical data indicates that mHealth interventions act as effective "digital scaffolds," supporting the behavioral changes necessary for metabolic regulation. The finding by Dilimulati et al. (2024) regarding the non-inferiority of digital interventions compared to metformin is particularly significant. It implies that for a subset of patients—especially those intolerant to pharmacotherapy or preferring non-medicalized approaches—software can effectively substitute medication.

However, clinical efficacy does not equate to widespread accessibility or sustained engagement. The identified "Quality Gap" between evidence-based academic tools and engaging but medically dubious commercial apps represents a failure of the current digital marketplace. As noted in broader mental health app studies, while academic tools offer safety (Boyle et al., 2019; Xie et al., 2018), they often lack the "stickiness" or retention strategies of commercial counterparts, leading to steep attrition rates in real-world settings (Baumel et al., 2019). This disconnect suggests that future development requires a symbiotic approach: academic rigor combined with commercial-grade user experience (UX) design.

4.2 Theoretical Framework: The Cyber-Physical Loop

To understand how mHealth interventions exert their effect beyond simple information delivery, we propose a conceptual framework illustrated in Table 3.

Table 3. Conceptual Framework of the Cyber-Physical Loop in mHealth

Stage	Component	Socio-Technical Description
1. Input	Data Acquisition & Agency	The user actively inputs subjective data (symptoms, mood, dietary choices) or allows passive IoT collection (HRV, sleep, steps). This stage shifts the locus of control from the physician to the patient, fostering "digital agency."
2. Processing	Algorithmic Analysis	AI/ML algorithms process this longitudinal big data to identify non-linear patterns invisible to the human eye (e.g., "High sugar intake on Tuesday correlates with acne flare-up on Friday"). This creates a "Digital Twin" of the patient's metabolic state.
3. Intervention	Just-in-Time Adaptive Nudge (JITAI)	The app delivers personalized content exactly when needed. This is not generic advice but a context-aware "nudge" (e.g., a stress-reduction prompt when HRV drops). It exerts "soft power" to guide behavior without coercion.
4. Output	Behavioral Micro-Correction	The user translates the digital prompt into physical action (e.g., choosing a low-GI meal, performing a breathing exercise). These are micro-corrections that accumulate over time.
5. Feedback	Biological & Psychological Reinforcement	The physical action leads to a biological result (improved glucose, weight loss). This success is fed back into the system (via data) and the user (via gamification/rewards), reinforcing the loop and building self-efficacy.

Traditional healthcare is episodic; the Cyber-Physical Loop is continuous. It transforms management from disjointed clinical encounters into a seamless flow of data and behavior. The loop begins with *Data Acquisition*, shifting the locus of control to the patient. Through *Algorithmic Processing*, this data creates a dynamic "Digital Twin" of the patient's metabolic state, allowing for simulation and prediction of health outcomes (Garanin et al., 2025). The critical component is the *Just-in-Time Adaptive Intervention (JITAI)*, which delivers context-aware "nudges" exactly when needed (e.g., prompting stress reduction when heart rate variability drops). This loop explains why apps in the reviewed RCTs succeeded: they closed the feedback loop that is typically broken in traditional care models.

4.3 Health Economics: From "Freemium" to Prescription

The economic implications of these findings are substantial. With the annual healthcare burden of PCOS exceeding $15 billion in the US, the scalability of mHealth offers a macro-economic solution. Unlike face-to-face counseling, digital interventions have near-zero marginal costs once developed. However, the dominant "Freemium" business model is inefficient for public health, as it frequently locks essential features behind paywalls (Earle et al., 2021).

Policymakers should look to the German *Digitale Gesundheitsanwendungen* (DiGA) model. Under this framework, apps that demonstrate positive healthcare effects in clinical trials are listed as "prescribable apps" and fully reimbursed by statutory health insurance (Lauer et al., 2024). If applied globally to validated PCOS apps, this model would incentivize developers to prioritize clinical evidence over marketing, ensuring that access to digital therapeutics is based on medical need rather than the ability to pay.

4.4 Social Implications: Algorithmic Bias and Data Privacy

While technology promises democratization, it also introduces significant risks. There is a profound danger of algorithmic bias. Most commercial apps are developed in high-income countries and trained on homogenous datasets. As demonstrated in general healthcare algorithms, predictive models trained primarily on white populations can systematically underestimate health risks in minority groups (Obermeyer et al., 2019). In the specific context of PCOS, such algorithmic bias poses a critical risk, potentially failing to detect the more severe insulin resistance phenotypes often present in South Asian or Black women.

Furthermore, the "Fertility Trap" identified in our results is compounded by privacy concerns. In the post-Roe v. Wade era in the United States, menstrual tracking data has become a sensitive legal liability. Research indicates that women are increasingly modifying their digital behavior due to fears that their

reproductive health data could be weaponized by law enforcement (Cao et al., 2024). Future "FemTech" must therefore prioritize privacy-by-design, utilizing end-to-end encryption and local data storage to protect users from corporate surveillance and legal overreach.

4.5 Future Directions and Limitations

The future of PCOS management lies in the integration of the Internet of Things (IoT) to automate the Cyber-Physical Loop. Transitioning from manual entry to passive sensing (e.g., continuous glucose monitors) will reduce reporting fatigue. However, this review has limitations. The high heterogeneity of study designs makes meta-analysis difficult, and the rapid pace of app obsolescence means that evidence becomes dated quickly. Moreover, a geographic bias persists, with most RCTs conducted in high-income nations, limiting generalizability to the Global South.

5. Conclusions

5.1 Synthesis of Evidence: From Adjunct to Therapeutic

This systematic review substantiates the paradigm shift of mobile health (mHealth) from a passive monitoring tool to an active therapeutic modality in the management of Polycystic Ovary Syndrome (PCOS). The synthesis of Randomized Controlled Trials confirms that well-architected digital interventions function as effective "digital scaffolds" for behavioral modification. Specifically, integrated applications have demonstrated the capacity to induce clinically significant weight loss (mean -3.19 kg) (Choi et al., 2023), a magnitude of effect consistent with outcomes typically achieved through intensive face-to-face lifestyle interventions (Lim et al., 2019). Furthermore, the establishment of non-inferiority between digital lifestyle interventions and metformin regarding insulin sensitivity highlights the potential of software to serve as a viable alternative to pharmacotherapy for select metabolic phenotypes (Dilimulati et al., 2024). In the reproductive domain, the capacity of mHealth to increase menstrual regularity from negligible baselines to over 43% underscores its utility as a non-invasive intervention for restoring cyclicity (Jiskoot et al., 2020).

5.2 The Paradox of Quality and Access

Despite clinical validation, a critical "Quality Gap" bifurcates the current landscape. Patients are presented with a dichotomy: highly usable commercial applications that frequently lack evidence-based content, versus valid but engaging academic tools (Arabkermani et al., 2025). This market failure is compounded by socio-economic risks. While mHealth offers a scalable solution to the $15 billion annual economic burden of PCOS (Yadav et al., 2023), the reliance on "freemium" models and high-end hardware threatens to exacerbate the "Digital Divide." Without intervention, advanced digital therapeutics may become luxury goods, inaccessible to the populations with the highest metabolic disease burden (Kruse & Corbett, 2025).

5.3 Strategic Recommendations

To bridge the gap between technological potential and public health reality, this review proposes a multi-stakeholder framework:

- Clinical Integration: Clinicians should move beyond generic advice and actively "prescribe" validated tools, such as *AskPCOS*, integrating them into the standard care pathway (Boyle et al., 2019).
- Algorithmic Justice: Developers must prioritize inclusive design. AI models utilized for metabolic risk prediction must be trained on diverse datasets to prevent the propagation of racial and ethnic biases in automated healthcare (Obermeyer et al., 2019).
- Policy & Reimbursement: Policymakers should emulate the German *DiGA* framework, recognizing validated apps as reimbursable medical devices. This financial incentive is essential to shift the industry focus from monetization to clinical validity (Lauer et al., 2024).
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5.4 Future Outlook

The future of PCOS management lies in the "Cyber-Physical Loop"—a continuous, predictive system driven by the Internet of Things (IoT) and Artificial Intelligence. Transitioning from reactive symptom management to proactive "Digital Twin" modeling offers the promise of precision medicine (Garanin et al., 2025). However, as these technologies achieve ubiquity, they must be governed by rigorous ethical standards to ensure data privacy and equitable access, as outlined in global guidelines for AI in health (World Health Organization, 2021).

6. Disclosure

Authors' contributions:

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All authors have read and approved the final version of the manuscript.

Funding: No external funding was received for this study.

Institutional Review Board Statement: Not applicable (no human subjects research was conducted by the authors beyond literature review).

Informed Consent Statement: Not applicable.

Conflicts of Interest: The authors declare no conflicts of interest.

Declaration of the Use of Generative AI and AI-Assisted Technologies in the Writing Process: In preparing this manuscript, the authors used ChatGPT (OpenAI) solely for the purposes of improving linguistic clarity, refining the structure of several paragraphs, translating selected sections between Polish and English, and ensuring terminological consistency.

The AI tool was not used to generate original scientific content, analyze data, interpret results, create references, design methodology, or draw conclusions. All substantive content, ideas, interpretations, and scientific claims were created exclusively by the authors.

After AI-assisted editing, the authors manually reviewed, corrected, and verified all sections to ensure scientific accuracy, integrity, and compliance with academic standards.

Acknowledgments: The authors thank colleagues at their institutions for feedback on early drafts and acknowledge the use of academic databases and search tools to compile the literature for this review.

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