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Developing a Program Costs Checklist of Digital Health Interventions: A Scoping Review and Empirical Case Study

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Abstract

Introduction The rate of development and complexity of digital health interventions (DHIs) in recent years has to some extent outpaced the methodological development in economic evaluation and costing. Particularly, the choice of cost components included in intervention or *program* costs of DHIs have received scant attention. The aim of this study was to build a literature-informed checklist of program cost components of DHIs. The checklist was next tested by applying it to an empirical case, Mamma Mia, a DHI developed to prevent perinatal depression.

Method A scoping review with a structured literature search identified peer-reviewed literature from 2010 to 2022 that offers guidance on program costs of DHIs. Relevant guidance was summarized and extracted elements were organized into categories of main cost components and their associated activities following the standard three-step approach, that is, activities, resource use and unit costs.

Results Of the 3448 records reviewed, 12 studies met the criteria for data extraction. The main cost categories identified were development, research, maintenance, implementation and health personnel involvement (HPI). Costs are largely considered to be context-specific, may decrease as the DHI matures and vary with number of users.

The five categories and their associated activities constitute the checklist. This was applied to estimate program costs per user for Mamma Mia Self-Guided and Blended, the latter including additional guidance from public health nurses during standard maternal check-ups. Excluding research, the program cost per mother was more than double for Blended compared with Self-Guided (\notin 140.5 versus \notin 56.6, 2022 Euros) due to increased implementation and HPI costs. Including research increased the program costs to \notin 190.8 and \notin 106.9, respectively. One-way sensitivity analyses showed sensitivity to changes in number of users, lifespan of the app, salaries and license fee.

Conclusion The checklist can help increase transparency of cost calculation and improve future comparison across studies.

Plain Language Summary

Estimating program or intervention costs of digital health interventions (DHIs) can be challenging without a checklist. We reviewed scientific literature to identify key cost categories of DHIs: development, research, maintenance, implementation and health personnel involvement. We also summarized relevant information regarding resource use and unit cost for each of the aforementioned categories. Applying this checklist to Mamma Mia, a DHI aimed at preventing perinatal depression, we find that the total cost per user for Mamma Mia Self-Guided is \notin 106.9 and for Mamma Mia Blended is \notin 190.8. Our checklist enhances visibility of DHI cost components and can aid analysts in better estimating costs for economic evaluations.

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Key Points for Decision Makers

Comparing costs in published economic evaluations of digital health interventions is challenging due to limited transparency in the program costs reported.

We have built a literature-informed checklist that categorizes program cost components of digital health interventions in the standard three-step model: activities, resource use and unit costs.

The checklist proved useful in estimating costs of a specific DHI, Mamma Mia, and has the potential to enhance transparency in future economic evaluations.

1 Introduction

Economic evaluations of digital health interventions (DHIs) have increased in recent decades following the widespread development and uptake of DHIs. It is challenging to apply the standard methods of cost and effect estimation on DHIs since these technologies tend to develop both iteratively and quickly, may have multiple intended users and a mixed set of potential control conditions [1, 2]. In the published literature, the choice of cost components included in the DHI intervention or program costs, have received inadequate attention [3]. Whether research and development should be included or not is a matter of debate [4]. Furthermore, what costs should actually be included is often unclear [3, 5]. This makes it difficult to compare the cost effectiveness of DHIs, pool estimates from different sources, or transfer estimates to other contexts [5, 6]. Gomes and colleagues have provided methodological recommendations for economic evaluation of DHIs but comprehensive guidance on the subject of program costs is lacking [7].

DHIs have evolved from simple video or telephone consultations, to programs that can monitor health in real time, motivate behavior change, assist health decision making and manage information sharing between several agents [2]. DHIs can potentially increase access to healthcare at low cost, which is invaluable considering the global challenge of inequities in healthcare [8]. With the advent of artificial intelligence and self-guided technologies, the role of DHIs in assisting health systems is only likely to increase [9, 10]. Before implementation, decision makers need evidencebased assessments that comply with the established principles of economic evaluation in which program costs play a crucial role [11, 12].

The standard practice in health economic evaluations is to quantify all relevant costs and consequences of the choice between options. In this study, we focused specifically on intervention costs or program costs. In line with Drummond and colleagues (2015), we defined program costs similar to the total cost of a program, that is, "cost of producing a particular quantity of output" [13]. The program costs comprise both fixed and variable costs. We distinguished program costs from other economic considerations, such as the cost consequence of a preventive intervention, the societal or productivity gains of an intervention, or the costs accrued due to life-years gained. Program costs are only concerned with the production of a unit of good or service [13].

In many cases, program costs are assumed to be static [13], while in the case of DHIs, program costs may be dynamic. For example, DHIs are often developed iteratively with frequent updates to adapt to user wants and needs. The costs of scaling up to new users may be low, but total costs may increase as more stakeholders are involved [14]. This does not mean that methods for economic evaluation must be altered for DHIs. After all, DHIs compete for the same bulk of resources as other technologies [14]. However, the unique cost structure of DHIs requires further attention and methodological development.

Recent literature reviews have shed light on the heterogeneity in program costs of DHIs reported in published economic evaluations. Jacobs and Barnett highlighted the inconsistencies in cost reporting and underscored how estimating these costs are a particular challenge for telemedicine and new technologies [15]. Mitchell and colleagues reported difficulty in comparing the cost effectiveness of various interventions, particularly owing to how program costs were reported [3]. Kidholm and Kristensen made a similar observation and summarized the program costs variability in a tabular form [5]. It is noteworthy, that while these studies also offered some solutions, for example, Mitchell and colleagues (2021) proposed an overall cost components checklist, the question of program costs of DHIs has not been systematically explored in scientific literature thus far [3].

Existing methodological guidance on costing does not adequately capture the complexity of program cost estimation of DHIs. For example, ISPOR best practices guideline for estimating drug costs in economic evaluations recommends estimating marginal costs based on the drug's negotiated price [16]. In the case of DHIs, there is often no negotiated price, and the price, or license fee, may not capture all aspects of the program costs. Similarly, frameworks developed for complex interventions have also not sufficiently addressed program cost estimation [17–20]. Methodological guidance is emerging for specific cost components, such as implementation costs of public health programs [21, 22], but this cannot account for the full breadth of program costs of DHIs. Therefore, the existing scientific literature is insufficient to help standardize the estimation and reporting of program costs of DHIs.

The specific challenges of DHIs are only to a small extent addressed by the regulatory bodies [23]. Leading guidelines for DHIs, such as those developed by the National Institute of Healthcare and Excellence (NICE), UK [11, 24], Food and Drug Administration, USA [25] and the Medical Device Coordination Group of the European Commission [26], focus on classifying DHIs by risk categories and offer methodological recommendations for measuring clinical outcomes and effectiveness. The question of cost structure, criteria for cost inclusion or methods for program cost estimation have not been specifically addressed [27].

The aim of this study is to build a checklist of program cost components of DHIs that is specific for health economic evaluations. The foundation of this checklist lies in the standard three-step approach in costing: list and identify activities, measure resource use and evaluate using appropriate unit costs. A challenge is what activities to include. The basis for the development of the checklist is a scoping review. The data extracted from the review informs the checklist's main cost components and their associated activities and resource use. Methodological challenges pertinent to program cost estimation were charted and analyzed. The scoping review also shed light on factors and assumptions that must be considered as part of the cost estimation. To test the application of the checklist, we used Mamma Mia as an example case. Mamma Mia is a DHI developed to prevent perinatal depression and increase subjective well-being. The paper is organized in two sections: the scoping review and the resulting checklist, followed by the empirical case study.

2 Method

2.1 Scoping Review

Box 1 Scoping review criteria

	Inclusion	Exclusion
Context	Digital Health Inter- ventions (DHIs)	Any intervention other than DHI
Concept	Program costs	
Study type	Reviews: systematic, scoping, rapid, umbrella (quantita- tive and qualita- tive) Guidance or method- ology literature	Primary studies (e.g., cost analyses, cost-effectiveness analyses, health technology assess- ments)

We performed a scoping review to identify and analyze the literature on the costing of DHIs. The detailed protocol for our scoping review is available elsewhere [28]. The review was performed in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) [29].

The primary inclusion criteria were reviews (systematic, scoping or other) and studies that examined and offered guidance on program costs of DHIs. We defined DHIs similar to the NICE criteria for technologies suitable for the Evidence Standards Framework, that is, smartphone applications, standalone software, digital diagnostic tools and analytical programs for medical devices [24]. Telemedicine, telehealth, mHealth and eHealth were also included. Studies that focused on the effectiveness or cost effectiveness of DHIs, and did not discuss program costs of DHIs, were excluded. The review included qualitative as well as quantitative studies.

To identify relevant studies, a structured literature search was conducted in MEDLINE, Embase, Web of Science and Google Scholar in January 2023. The two main concepts 'digital health interventions' and 'cost estimation', were searched as thesaurus or free-text terms in the title, abstracts and keywords fields. We included records from January 2010 and onwards. This was a pragmatic consideration given that the term e-Health first appeared in 2000 [30] and mHealth first appeared in 2002 [31]. Research in mHealth technologies experienced an upsurge between 2007 and 2008 [31].

The resulting list of titles and abstracts were compiled in an EndNote library, and after duplicate removal, uploaded to PICO Portal [32]—an artificial intelligence (AI)-based software for systematic reviews. The first author screened all abstracts whereas the last author screened articles identified as relevant by the first author. Articles identified as relevant by both authors were retrieved for full-text review for data extraction. We used the 'charting approach' to summarize each study's findings [33]. The fields of data extracted from the selected papers were:

- 1. Study title
- 2. Author(s)
- 3. Year
- 4. Study type: review or guidance
- 5. Did the study describe or use a guideline or framework?
- 6. What are the program cost categories of DHIs considered?
- 7. Which resources and activities are associated with program cost categories?
- 8. Are methodological approaches to estimate program costs described?

- 9. In order to report costs, which specific challenges are described?
- 10. Which specific factors influence program costs?
- 11. What are the study's overall methodological recommendations?
- 12. Are there any specific recommendations regarding which cost categories to include (or exclude) in an economic evaluation?

2.2 Analytical Approach

After charting the studies, the authors critically appraised the extracted data to identify relevant program cost categories. Subsequently, the information recorded in the review chart was reorganized to complete the checklist of program cost components, that is, a tabular delineation of DHI program costs with corresponding comments on activities, resource use and unit costs. The checklist is primarily derived from the literature review, but relevant additional items were suggested by authors and finalized via discussion.

The checklist was then applied to Mamma Mia to estimate the DHI's program costs per user. We performed several one-way deterministic sensitivity analyses to explore how varying selected cost inputs influenced the program cost components of the checklist. Figure 1 summarizes our analytical approach.

3 Results

3.1 Scoping Review

The structured search yielded 6614 records, which were reduced to 3448 after duplicate removal from EndNote v20.4.1 [34]. The PICO Portal [32] removed an additional 53 duplicate records. The first author screened 3395 records and shortlisted 176 abstracts that were reviewed by the last

author. After excluding a further 135 abstracts, both authors concurrently reviewed the full text of 41 studies. Of these, 12 were identified as relevant and were included in the data extraction. The Preferred Reporting Items for Systematic Reviews and Meta Analyses (PRISMA) diagram (Fig. 2) details the screening process for the scoping review [35]. The data extraction results from the charting process are summarized in Table 1. The full data extraction chart is provided in the electronic supplemental material (ESM).

Among the 12 studies included in the data extraction, there were three systematic reviews [36-38], two scoping reviews [39, 40], one review [41] and six guidance or methodology style studies [7, 15, 42-45]. While these studies discussed program costs of DHIs from different angles, they did not exclusively focus on program costs. Five studies referred to some guidelines, but none of these were specific to program costs [15, 36-38, 44].

The studies examined program costs from various perspectives. Some mentioned development costs exclusively [7, 44, 45], whereas others used synonymous concepts such as capital [37, 43], technology [38], equipment [15, 39, 41, 42] or production-related expenses [36]. Certain studies touched upon costs of implementation [15, 45], user engagement [7, 36, 40] and dissemination [37]. Furthermore, costs of maintenance [7, 37–39, 44], hosting [37] and updates [45] were also taken into account. The exploration of costs of health personnel training and support was a recurring theme in literature [15, 37, 41–43]. While the included studies did not specifically mention research costs, they underscored the importance of evidence generation for measuring effectiveness.

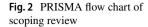
The studies highlighted that DHIs evolve quickly [[7, 15, 41, 44, 45] and their program costs are often context specific [36, 39]. This makes it difficult to pool estimates from different sources [37]. Two systematic reviews reported a lack of methodological guidance on program cost estimation and heterogeneity in cost components included in the published estimates [36, 37].

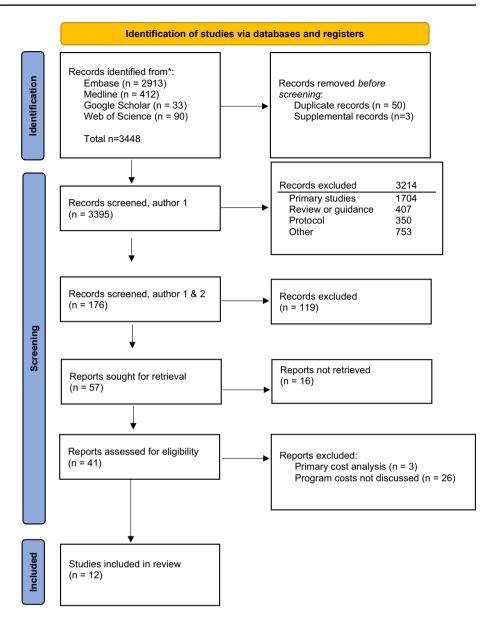
Fig. 1 Analytical approach. *DHIs* digital health interventions

Scoping Review Identify reviews and guidance style peer-reviewed literature on program costs of DHIs Data Extraction Chart data on program cost components, resource use, methodological challenges and recommendations from the selected literature Informed Checklist of Program Costs Categorize the charted data into the standard three-step costing model. Summarize findings on costing challenges and methodogical recommendations

Empirical Case Study

Test the checklist by applying it to estimate program costs of Mamma Mia - a DHI that prevents perinatal depression





3.2 Literature-Informed Checklist of Program Cost Components

Following the scoping review, we developed a checklist that categorizes the program costs of DHIs and lists common activities associated with each cost category (see Table 2). The checklist also details resource use and types of unit costs that can inform the cost estimation. We have commented on the methodological considerations and relevant cost analyses for each cost category.

The main cost categories identified through the full-text review were development, research, maintenance, implementation and health personnel involvement. *Development* comprises the conception, planning, content and service design, software development and testing of the intervention [7, 15, 37, 38, 40, 41, 43–45]. *Research* entails evidence generation for usability, patient satisfaction, clinical efficacy and cost effectiveness including feasibility studies and pilot testing, based on trial design like randomized controlled trials (RCTs) or natural experiments [15, 40, 41, 44]. The technical *maintenance* of a DHI involves data management, privacy protection, hosting, updating, troubleshooting and help desks [7, 15, 37, 39, 40, 44]. *Implementation* encompasses a large set of activities to promote the DHI and align it with an organization's workflow, patient pathway, legal requirements and the technical system [7, 36–42, 44, 45], for both the healthcare provider and the user. Some DHIs also require *health personnel involvement* as part of service delivery [7, 15, 38, 41–44] in the form of guidance, consultation, examination, diagnosis or screening performed through or alongside the DHI.

Author(s), year and study type	Program cost categories and associated activities	Challenges in reporting costs	Factors that influence costs	Recommendations on program cost estimation
Hazel et al. (2021) Systematic review [36]	Production Delivery Consumption of intervention	Future costs of apps are not assessed Cost categories are excluded without justification Limited availability of data for cost estimation	Economies of scale: cost per user may decrease as number of users increase Time spent by user may be impor- tant for DHIs requiring high user engagement	Early assessments of costs may not hold true for later stages of the intervention
Jankovic et al. (2021) Systematic review [37]	Development Website maintenance and hosting Dissemination Patient recruitment Capital costs: computers, staff train- ing and software purchase	DHIs are complex and subject to heterogeneous populations and delivery settings Pooling estimates from various data sources can be a challenge		Increase transparency in costs reported
Kumar et al. (2013) Systematic review [38]	Technology: hardware, software, licenses, communication, staff training, real estate and infrastruc- ture Hospital variable: resources that fluctuate based on usage e.g. nurs- ing supplies	Studies do not consider depreciation and report overall costs, as opposed to cost per user	Depreciation period and choice of method for depreciation Case volume or patient throughput, i.e. efficiency Number of patients or users, i.e. economies of scale	Report cost per user so that results are comparable across studies Standardize the resources included in program cost estimation Account for depreciation
Hilty et al. [2022] Scoping review [39]	Fixed: equipment, technology, depre- ciation and office expenses Variable: maintenance, telecom and overheads Other: travel, stipends, training and promotion	Costs are rarely measured systemati- cally and are context specific		Adjust estimates to differential timing (discounting and future costs) Use a toolkit or guideline Consider cost as part of broader imple- mentation outcomes Perform sensitivity analyses
Sülz et al. (2021) Scoping review [40]	Implementation: Device purchase, license/software fee, equipment installation, staff training, equipment installation Operating: Maintenance, fees, medical and non- medical staffing, technical travel time Direct and indirect costs borne by the patient	Research and development costs are often excluded implying that these costs are sunk		
Huter et al. (2022) Review [41]	Research and development Equipment Health personnel support Indirect costs Support costs: training, helpdesks and change management	DHIs evolve rapidly Limited generalizability of costs Strong context dependency Heterogeneity of interventions	Assumptions regarding depreciation periods influences costs Unit costs decline as caseload increases	Consider DHI's lifecycle and apply appropriate depreciation periods Report costs transparently to allow for transferability Micro costing when no price informa- tion is available Perform sensitivity analyses and itera-

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#	Author(s), year and study type	Program cost categories and associated activities	Challenges in reporting costs	Factors that influence costs	Recommendations on program cost estimation
7	Bergmo (2015) Guidance [42]			The expected lifetime of the equip- ment and the assumed discount rate influence costs	Use an annuitization method that incorporates both the depreciation period and opportunity cost of capi- tal, i.e. discount factor
∞	Gomes et al. (2022) Guidance [7]	Development User engagement Human support Maintenance: hosting, updating and security	DHIs evolve rapidly High proportion of fixed costs imply a potential overestimation of mean cost per user if the number of users is low	Unit price declines as scale increases DHI's place in the technology life cycle affects cost estimate Evaluating number of users based on RCT participants will bias results DHIs have high proportion of fixed costs, and low marginal costs	Identify a priori different development stages of the DHI and use a flexible data collection plan Collect user engagement time through the app and evaluate costs using minimal wages Assess staff training costs using clini- cal records Perform iterative costing
0	Jacobs and Barnett (2017) Guidance [15]	Equipment Implementation Health personnel support: training, help desks, transition costs, start-up and troubleshooting costs	DHIs evolve rapidly Equipment costs are upfront and usually high Report amortized costs	Technology price declines over time Ignoring the life cycle of the DHI will bias cost estimates	Bottom-up costing for components with high variability or impact on total costs Micro costing for early phase tech- nologies but activity-based costing for mature DHIs Amortize equipment costs Perform sensitivity analyses and itera- tive costing
10	10 Luxton (2013) Guidance [43]	Health personnel support: staff, consumables, equipment, installa- tion etc. Capital and technology: equipment and buildings		Changes in technology prices influ- ence costs of DHIs	Amortize capital costs Multiply an asset's undepreciated (gross) value by interest rate to esti- mate opportunity cost of investing elsewhere Perform sensitivity analysis based on future predictions of costs
Ξ	McNamee et al. (2016) Guidance [44]	Development: literature reviews, research identifying user wants and needs, content development, design features, software features and user experience testing Maintenance: hosting and security Operating: health personnel training	DHIs evolve as they are implemented Product reach and future costs of updating technology are highly unpredictable Marginal costs tend to zero as the number of users increases	DHIs with personnel support are more effective than standalone DHIs Adding personnel support increases costs and variability of costs Majority of program costs of DHIs are fixed	Determine if the DHI is simple or complex For simple DHIs, current methods, e.g. three-step approach, may be sufficient

Table 1 (continued)

study type Program cost categories and ated activities			
	associ- Challenges in reporting costs	Factors that influence costs	Recommendations on program cost estimation
12 Michie et al. (2017) Development Guidance Implementation [45] Update	DHIs evolve rapidly Lack of techniques to measure cost effectiveness across digital lifecycle	There is a trade-off between develop- At every stage, including concept ment and personnel involvement development, identify all releva costs future costs future costs Number of users significantly affects Take account of projected uptake cost effectiveness of DHIs well as reach Select a modelling framework appriate for the complexity of the Perform iterative costing	There is a trade-off between develop- At every stage, including concept ment and personnel involvement development, identify all relevant costs future costs future costs Number of users significantly affects Take account of projected uptake as cost effectiveness of DHIs Select a modelling framework appro- priate for the complexity of the DHI Perform iterative costing

DHI digital health intervention, RCT randomized controlled trial

3.3 Empirical Case Study—Mamma Mia

The Mamma Mia app is a smartphone/tablet-based program for the prevention of perinatal depression. The program comprises 44 interactive weekly sessions, which start mid-pregnancy and last 6 months postpartum [51]. The app was originally designed as an internet-based program and underwent a feasibility study, which helped tailor the program's content and presentation [52]. The intervention was then evaluated in an RCT where it was found to be effective in preventing perinatal depression as an add-on treatment compared with standard treatment alone [51].

Mamma Mia is currently undergoing a second RCT (ISRCTN11387924) where the effectiveness and cost effectiveness of added guidance from health personnel is evaluated ('Mamma Mia Blended') against the standalone app ('Mamma Mia Self-Guided'). The mothers in the blended group follow the same program as the self-guided group, except that they receive additional guidance from midwives and public health nurses during standard maternal checkups. The health personnel do not have access to the mothers' responses in the app. Mothers that indicate a moderate or high risk of depression in the app's built-in depression screening are recommended to seek social support (e.g., partner, friends or relatives), consult their general practitioner, or call a mental health helpline. The symptom scores on the depression screening are not communicated to health personnel, however, health personnel are trained in the program contents and to provide supportive counselling related to perinatal depression.

We applied the checklist from the scoping review to estimate the program costs per user of Mamma Mia Self-Guided and Blended. Mamma Mia Self-Guided is available to all women in Norway, whereas Blended is only available as part of the ongoing RCT. Costs for Self-Guided represent the resource use of the standalone app, whereas Blended adds the cost of health personnel involvement. Costs were annuitized using straight-line depreciation, assuming a lifespan of 5 years and no salvage value. The estimates were made in Norwegian kroner and converted to 2022 Euros (1 Euro = 10.10 NOK) [53]. Resource use and unit costs for each cost category of Mamma Mia are summarized in the ESM (ESM Table 3).

We made top-down estimates of costs of development, research and maintenance. The 1-year license fee paid by the Norwegian Directorate of Health of \notin 474,920, covers the costs of both development and maintenance. Total research costs from national projects are estimated at \notin 2177,657 for the app's lifetime.

Implementation costs are threefold: overall implementation costs (Self-Guided and Blended), program administration (Blended) and training of health personnel (Blended). For the overall implementation costs, two

	Activities	Resource use	Unit costs	Comments
Development	Product design conception and planning Service design conception and planning Financial planning Tender applications Hardware and equipment Development of content: videos, text, images, narratives. May be new or sourced Database specification Software development Graphic and interaction design User experience testing: Create prototype for testing Test intervention using dummy accounts Third party software costs/licenses	Physical infrastructure Technical infrastructure Staff time for content creation, software development, prototype creation and testing the prototype version Travel and venue for stakeholder engage- ment meetings Compensation to patients, advisory board members or other stakeholders	Office rent, supplies and overhead Technology costs: computers, equipment, software and tools Salaries of: Content curators Software developers and designers Intervention testers and quality control staff Managers Administrative support staff Hourly reimbursement to stakeholders or equivalent estimation of opportunity costs Venue and travel costs Invoices to third party vendors, if any	Development costs vary according to the complexity of the intervention. AI-based interventions or DHIs requiring interac- tive design will be more costly than simple text-based DHIs Development costs also vary depending on whether the DHI is a new product or modification of an existing product Examples: Joshi et al. 2022 [46] and Pater- son et al. 2022 [47]
Research	Literature review Identifying user wants and needs through focus groups, qualitative studies or surveys Feasibility studies and pilot testing RCTs, natural experiments or other study designs to evaluate effectiveness Health technology assessments, including economic evaluations	Researchers Study participants Equipment and tools Communication and dissemination Travel	Salaries of researchers and administrative support Costs of equipment, tools and technical infrastructure Costs of travel Compensation for study participants	Research in this context concerns scientific activity contributing to the production of solutions and knowledge needed for implementation purposes (effectiveness, cost effectiveness, user satisfaction etc.) Example: Monashefsky et al. 2023 [48]
Maintenance	Safeguarding/security/data protection Web hosting Equipment installation Periodically updating content Web application maintenance Intervention engagement (through prompts and reminders) Reporting of usage to clients	Technicians Administrative support staff Equipment and technological services	Salaries of relevant staff Equipment and technology costs Invoices to third party vendors, if any	A company which has developed several DHIs may simultaneously maintain these DHIs with shared human and technologi- cal resources Appropriation of resource use for each DHI would require expert estimation

 Table 2
 Checklist of program cost components of digital health interventions

	Activities	Resource use	Unit costs	Comments
Implementation	Implementation Alignment with technical specifica- tions. Hardware or software needed to facilitate the DHI, such as smartphones, computers or a new patient management system. This includes any necessary equipment provided by the user Alignment with regulatory framework Physical infrastructure for service provi- sion Consumables and supplies Marketing, advertisement, promotion and dissemination Helpdesks, support and troubleshooting Change management: Transition costs Organizational readiness for DHIs Recruitment, training and supervision of health personnel Creation or revision of policies and manuals	Implementation team for patient recruit- ment, provider recruitment, stakeholder engagement or general communication and dissemination Health personnel training: Health personnel and trainers' time Other resources, e.g. venue, communica- tion materials or equipment Organizational management and adminis- trative support Legal and technical staff	Costs of relevant physical and technical infrastructure Costs of communication materials, venue, travel etc. Salaries of Administrative support Communication staff Helpdesk/support staff Technical and legal staff Health personnel Trainers Invoices to third party vendors, if any	Implementation costs can be difficult to evaluate since implementation often involves reorganization of existing resources Examples: Cidav et al. 2020 [49] for time-driven activity-based costing of implementation strategies Powell et al. (2015) for taxonomy of imple- mentation strategies [50]
Health person- nel involve- ment	Examination of patient Diagnostic decision making based on patients' symptoms Guidance to patients Logging and reporting in patient journal or electronic health records Supervision and compliance	Time for guidance, examination or assess- ment Time for entering information in health records Physical and technical infrastructure, e.g. examination room and equipment	Salaries of health personnel Costs of health infrastructure, e.g. clinics and equipment	Personnel support costs increase with each additional user, but the relationship might be stepwise rather than linear

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Table 3Mamma Mia base-casecost per user (CPU) in Euros(2022)

		Self-Gui	ded	Blended		Blended - Research	F
		CPU	%	CPU	%	CPU	%
I	Development	54.9	97	54.9	39	54.9	29
Π	Maintenance						
III	Research					50.3	26
IV	Implementation*	1.7	3	47.6	34	47.6	25
V	Health personnel involvement*			38.0	27	38.0	20
	Total cost	56.6	100	140.5	100	190.8	100

*Only staff-related costs

authors concurrently reviewed the Expert Recommendations for Implementing Change (ERIC) taxonomy [50], marked activities that were performed for Mamma Mia and estimated annual hours spent based on a pre-defined gradient of intensity (see ESM). Implementation costs related to program administration in well baby clinics and health personnel training are based on the ongoing RCT's implementation guidelines [54], supplemented with expert opinion.

As for the cost of health personnel involvement (Blended only), the RCT guidelines indicate that each mother receives four guidance sessions in total. We assume that 30% of the national average consultation time for a routine maternal checkup [55] would be spent on Mamma Mia-related guidance.

In order to evaluate the cost per user, we used information from Mamma Mia's developer, ChangeTech. A total of 8656 women, or roughly 16% of pregnant mothers in Norway, used the Mamma Mia app on a self-guided basis in 2022 [56]. Applying the percentage to the average number of women per midwife in municipal health services in Norway [57], we assume that 15 mothers per health personnel use the app in the Blended group.

Based on the aforementioned estimates of resource use, unit costs and number of users, we find that if research is not included, the total cost per mother is \notin 56.6 for Mamma Mia Self-Guided and \notin 140.5 for Mamma Mia Blended. If research is included, the total costs are \notin 106.9 and \notin 190.8, respectively (see Table 3).

3.3.1 Sensitivity Analyses

We performed one-way sensitivity analyses on the 'Blended + Research' costs (Table 3) to examine the effect of varying the following items on the total cost per mother: salary of health personnel, guidance time per mother, license fee (annualized), implementation time, lifespan of the app, number of users and women per health personnel. We found that our cost per mother estimates are especially sensitive to changes in the number of users, lifespan of the app, personnel salary, women per health personnel and the license fee (see Table 4).

4 Discussion

This study illustrates the challenges and complexity of estimating the program costs of DHIs. To our knowledge, it is the first study that examines the existing literature on program costs of DHIs, builds a simplified checklist for understanding common cost components and then applies the cost checklist to a case. In the process, we have identified the main cost categories, factors that influence the costs of DHIs, such as the number of users and the assumed lifespan of the technology, and explored how uncertainty surrounding these estimates affected the calculated cost. The program cost checklist is intended for economic evaluations but may also be a useful tool for planning the development, implementation and maintenance of DHIs, and for efficiency measurement.

The challenge of heterogeneous costing in economic evaluations has been recognized. The comprehensive PECUNIA Project represents a network of partners that aim to establish standardized costing and outcome assessment measures with a multi-sectorial and multi-national approach [58]. In the digital health arena, there are efforts underway to define DHIs [59], classify them according to risks [60], or build frameworks to assess their value [61]. As indicated by our scoping review, the question of DHI program costs has been raised from various perspectives but comprehensive guidance is lacking [62]. Our proposed program cost checklist bridges this gap and we have illustrated the application of the checklist through a case study.

Our case example, Mamma Mia, may be considered a Tier B intervention in the NICE Evidence Standards Framework (i.e. informs the patients about a condition, collects

 Table 4
 Effect of selected cost inputs on change in cost per user in each program cost category

Input varied	Change from baseline	Change in cost per user € (% change from baseline)					
		Development and mainte- nance	Research	Implementation	HPI	Total	
Number of users	+ 20%	- 9.1 (- 17%)	- 8.4 (- 17%)	- 7.9 (- 17%)	No change	- 25.5 (- 13%)	
	- 20%	13.7 (25%)	12.6 (25%)	11.9 (25%)	No change	33.4 (20%)	
Lifespan of the app	+ 2 years	No change	- 14.4 (- 29%)	0.2 (0.3%)	No change	- 14.2 (- 7%)	
	- 2 years	No change	33.5 (67%)	- 0.2 (- 0.3%)	No change	33.4 (18%)	
Health personnel salary	+ 20%	No change	No change	9.5 (20%)	7.6 (20%)	17.1 (9%)	
	- 20%	No change	No change	- 9.5 (- 20%)	- 7.6 (- 20%)	- 17.1 (- 9%)	
Women per health personnel	+ 20%	No change	No change	- 7.6 (- 16%)	No change	- 7.6 (- 4%)	
	- 20%	No change	No change	11.5 (24%)	No change	11.5 (6%)	
Implementation time	+ 20%	No change	No change	9.5 (20%)	No change	9.5 (5%)	
	- 20%	No change	No change	- 9.5 (- 20%)	No change	- 9.5 (- 5%)	
Guidance time per mother	+ 20%	No change	No change	No change	7.6 (20%)	7.6 (4%)	
	- 20%	No change	No change	No change	- 7.6 (- 20%)	- 7.6 (- 4%)	

HPI health personnel involvement

information on patients' subjective wellbeing and records measurable patient outcomes) [24]. However, our cost checklist is adaptable to a wide range of technologies. For instance, DHIs involving artificial intelligence may completely replace the need for health personnel involvement but are also costly to develop and maintain. This cost trade-off between development and health personnel guidance, which has been emphasized by Michie and colleagues [45], can be accommodated within our checklist.

A rapid digital transformation is underway, aiming to empower patients and enhance health personnel efficiency [63]. The level of health personnel involvement varies between DHIs and the attribution of their resource use is a topic of inquiry in economic evaluations [3]. Mamma Mia Blended has relatively low health personnel involvement but we find that program cost per user more than doubles when health personnel are involved (€140.5 vs €56.6, 2022 Euros), taking into account both personnel involvement and implementation. For guided DHIs led entirely by clinicians or therapists, the program costs will be higher.

There is currently a debate on whether DHIs should be subjected to the same standards for evidence generation for cost effectiveness as pharmaceuticals, medical devices, or non-digital health interventions [1]. The debate arises due to the relatively short lifespans of DHIs, paired with their quick evolution. Methods for health technology assessment analyses of early effectiveness are being developed to accommodate the rapid growth of DHIs [64]. Referring to the NICE Evidence Standards Framework, Greaves and colleagues argued that evidence standards for DHIs should not be compromised for expediency [12]. Likewise, we emphasize that while the cost estimation of DHIs may be an iterative process, the justification of costs must comply with the established standards of health economic evaluations.

Program costs of DHIs are dynamic. For instance, development costs may decrease with each iteration due to enhanced efficiency [65]. Maintenance costs may also decline as the price performance ratio of equipment increases (Moore's Law) [47]. Likewise, implementation expenses may reduce as the DHI matures. Considering the iterative development and implementation of DHIs, economic evaluations performed in the early phases of the DHI lifecycle become less relevant in the later stages [40, 44, 45]. Therefore, a clear recommendation is to perform iterative cost analysis, that is, use flexible data collection methods to make rapid and frequent cost estimation throughout the DHI's lifecycle [7, 15, 41, 44, 45]. Our checklist can be used as a tool for iterative costing since it allows for sequentially estimating and updating individual cost components as the DHI matures. Specific methods for iterative costing are discussed elsewhere [66, 67].

Several studies in our scoping review underscored the relationship between economies of scale and cost effectiveness of DHIs [36, 38, 41]. Since most DHIs have large upfront costs—development and research—unsurprisingly, the cost per user decreases as the number of users increases. However, for cost components that are partially variable, such as maintenance or implementation, the changes in cost per user may be stepwise rather than linear. For example, costs per user initially decrease as demand increases owing to increased efficiency of existing servers or health personnel. Eventually these costs increase as server capacity is upgraded or new health personnel are trained [47].

There are several challenges with determining the number of users for the cost per user estimate. Firstly, it may be difficult to retrieve or project this information. Secondly, the definition of a user is elusive. Many DHIs require active and sustained engagement by the user. Level of engagement or program compliance may also need to be considered in addition to the absolute number of users [36]. While many studies estimate number of users based on RCT participants, this can overestimate the costs per user [7]. One solution is to update the number of users as the app matures, that is, iterative costing. In our empirical analysis, we received the number of registered users by Mamma Mia's developer and used a mixed approach to predict the number of users in the blended group in a Norwegian setting. Our sensitivity analysis underscored the importance of our assumptions. Therefore, estimating the number of users requires further development of methodological guidance.

The choice of method of annuitization of costs influences the program cost estimate [38]. Bergmo recommends annuitizing costs using discount factors in order to account for both the depreciation period and the opportunity cost of capital [42]. Luxton similarly stresses incorporating opportunity costs in the annuity estimation by multiplying the asset's undepreciated value with the interest rate [43]. Connected to the question of annuitization of costs is the expected lifetime of the app and its associated capital resources. One study in our scoping review assumed the expected life of their case DHI as 5 years, which is in line with the 3-5 years assumption reported in another scoping review [5]. So far, these lifespan estimates are based on assumptions whereas the program cost estimate would be strengthened with a more scientific approach to estimating the expected life of the DHI.

Reviews of economic evaluations of DHIs reveal that there is lack of transparency in costs that are included [65, 68]. Many economic evaluations disregard development costs [3], but Sülz and colleagues warn that exclusion of research and development costs assumes that these costs are sunk, whereas in reality these costs may be recurring [40]. Jacobs and Barnett recommend including research and development costs in the societal perspective [15]. A broader approach is to include development costs if the decision involves creation of a new DHI [7, 44]. In our empirical case study, we found that development, research and maintenance account for roughly 55% of the app's program costs per user. Disregarding them without justification can potentially bias the results of an economic evaluation. Similarly, implementation costs are often ignored in economic evaluations but can represent a substantial burden for the health system [69]. In the case of Mamma Mia, implementation costs represent a significant proportion of the overall costs (25%).

The Second Panel on Cost-Effectiveness in Health and Medicine recommends that health economic evaluations report reference cases from both the health care sector perspective and the societal perspective [70]. Naturally, all program costs are relevant in the societal perspective. In the health care sector perspective, the choice of program cost categories can be complex as these costs may be distributed across various budgets [41]. For example, in the case of Mamma Mia, research was performed outside the scope of the health care sector, and as such these costs were not included in the license fee. Similarly, when comparing privately versus publicly funded health systems, the program costs may be experienced by different groups. Mamma Mia was provided at no cost to the user since the license was purchased by a national payer. In a privately funded health system, the user may be expected to pay for the DHI either directly, or indirectly via an insurer or health plan manager.

4.1 Limitations

Our scoping review and the resulting checklist is a first step in developing guidelines for cost estimation of DHIs. We underscore that methodological guidance on economic evaluations of DHIs is emerging and our resulting checklist reflects weaknesses found in the nascent literature. While our wide search yielded several relevant studies, our scoping review is not exhaustive and our proposed checklist can be refined with guidance from experts and practitioners in the field.

In our empirical estimation, we could not separate maintenance costs from the license fee. A pragmatic solution to understand the fixed versus variable costs in terms of the license fee is to examine the changes in license fee per annum. For example, if the license is renewed for subsequent years and the license fee is reduced, this could indicate that the original license primarily accounted for development costs, whereas the subsequent licenses account for maintenance costs. Scientific literature on estimation of maintenance costs is lacking [71], but an industry rule of thumb is to expect maintenance to account for 15–25% of the development costs in the long term [72].

5 Conclusion

The program cost checklist and our pragmatic case study illuminate the cost components that should be considered and identified when estimating program costs within economic evaluations of DHIs. Certainly, the perspective, time horizon and the comparator of the economic evaluation will in general influence which costs are included, but applying the checklist will increase transparency and facilitate comparison across studies. Reporting according to the checklist may help future analysts improve their justification of costs in economic evaluations. Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40273-024-01366-y.

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Declarations

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Conflicts of interest The authors declare no conflicts of interest.

Availability of data and material All data used in this study are presented in the text of the paper or the supplemental materials.

Ethics approval No specific ethics approval was sought because this study does not collect or report data from human subjects or biological material.

Author contributions VH, ZK and KK conceptualized the study and defined the methodology. SP performed the structured search for the scoping review, whereas ZK and VH performed the formal analysis of retrieved records (i.e. screening records, data extraction and categorization for the cost checklist). ZK, VH, FD, SH, EO and TS investigated data for the empirical cost analysis and ZK performed the analysis. VH organized resources for the project, in addition to project administration and supervision. The first draft of the manuscript was written by ZK, which was reviewed and edited by all authors. All authors approved the final manuscript.

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