Supplementary Figure 1: Preferred reporting items for systematic reviews and meta-analysis (PRISMA 2020) flow diagram for framework study selection

**Identification of studies via databases and registers**

Reports not retrieved

*(n=0)*

Records removed before screening *(n=5,148)*:

*Duplicates 2,666*

*Reference types that are not published papers 1,533*

*Protocols 949*

Reports sought for retreival

*(n=222)*

New studies included in review *(n=178)* Reports of new included studies

*(n=201)*

Records identified through databases:

MEDLINE, Embase, Econolit,

CINAHL, Cochrane searches over period 1 January 2015 to 20 March 2020

*(n=11,824)*

Records screened for eligibility

*(n=6,676)*

Records excluded *(n=6,454):*

*Excluded study type 1,874*

*Not digital technology 1,511*

*Not for patient use 1,417*

*Not chronic disease 1,131*

*Prevention/wellness 255*

*Not an intervention 118*

*Not health related 80*

*Mental/behavioural 64*

*Abstract not in english 4*

Reports excluded (*n=29):*

*Not digital 12*

*Not comparative study 6*

*Not chronic 5*

*Excluded study type 3*

*Prevention/wellness 2*

*Not in english 1*

Reports assessed for eligibility

*(n=222)*

Included

Screening

Identification

Reports from included study reference lists

*(n=8)*

*Supplementary Table 1: Peer-reviewed literature search strategy*

| **Database**[[1]](#footnote-1)**(Ovid)** | **Search terms**[[2]](#footnote-2) |
| --- | --- |
| MEDLINE, Embase, CINAHL, Econolit, Cochrane | (1)[[3]](#footnote-3) exp Telemedicine/ or (telehealth or telemedicine) or exp Medical Records Systems, Computerized/ or (ehealth or (electronic adj2 health)) or (digital adj2 health) or (digital adj1 health adj1 intervention) or exp Mobile Applications/ or ((mobile adj1 health) or mhealth) or ((mobile adj1 health adj1 app) or (mobile adj1 health adj1 application)) or (((mobile adj1 medical adj1 app) or (mobile adj1 medical adj1 application))) or exp Text Messaging/ or (sms or text messag$) or (chat room$ or chatroom$ or chatbot$ or avatar) or (wearable$) or ((artificial adj1 intelligence) or (machine adj1 learning)) |
| (2)[[4]](#footnote-4) (health adj evaluation\*) or (project adj evaluation\*) or (program\* adj evaluation) or (evidence adj1 standards) or (health adj service adj evaluation) or (health adj promotion adj evaluation\*) or (systematic adj1 review) or (technology adj2 evaluation) or (implementation adj evaluation\*) or (impact adj evaluation\*) or (outcome\* adj evaluation\*) or (decision adj2 making adj2 framework) or (decision adj2 making adj2 standard\*) or (decision adj2 making adj2 guideline\*) or (technology adj2 appraisal\*) or (technology adj validation) or (evaluation adj1 framework\*) or ((implementation or translation\*) adj2 (study or research)) or (subsid\* or rebat\* or reimburs\*) or Comparative Effectiveness Research/ or exp patient harm/ or exp patient safety/or exp Insurance, Health, Reimbursement/ or exp Legislation, Medical/ or exp Financing, Government/ |
| (3)4 Economics/ or exp "Costs and Cost Analysis"/ or (cost benefit analysis) or (economic\* adj evaluation\*) or (cost adj effect\*) or (cost adj benefit) or (cost adj utility) or (cost adj effic\*) or (economic\* adj analysis) or quality-adjusted life years/ or (quality adjusted life years) or (QALY\*)  |
| (4) randomized controlled trial.pt. or controlled clinical trial.pt. or randomized.ab. or placebo.ab. or Clinical Trials as Topic/ or randomly.ab. or (crossover or cross-over).tw or trial.ti. |
| (5) 4 exp epidemiologic studies/ or (Case control) or (cohort adj (study or studies)) or (Cohort analy$) or (Follow up adj (study or studies)) or (observational adj (study or studies)) or (Longitudinal) or (Retrospective) or (Cross sectional) |
| (6) ((Health adj2 technology adj2 assessment) or HTA or (technology adj2 assessment)).tw. |
|  | (7) Animals/ not (animals/ and Humans/) |

*Supplementary Table 2: Content items for use in primary studies and criteria for "fair" and "good" coverage*

| **Checklist 1: Digital-specific content to be considered when undertaking a Health Technology Assessment (HTA) of Digital Health Technology (DHT)** |
| --- |
| **HTA****Domaina** | **Topic *(EUN)*a/(*NEW)*b** | **Issue content (***Modifications***)** | **“Fair” coverage**  | **“Good” coverage**  | **Issue IDa c (Item No.)** |
| CUR | Utilization *(EUN)* | Do/will health workers/patients invest in the personal digital technologies required to use the DHT? Costly/difficult to support?*Provide evidence of whether health workers/patients do or will invest in the personal digital technologies required to use the DHT? Estimate current investment by workers/patients, detail direct and add-on costs, and user willingness to pay.* | Some estimation of how many people have the personal technology required to use the DHT to justify a reasonable user base | Estimate the willingness of users to pay for personal technologies and internet data usage costs to use the DHT or Estimate all personal costs that would have to be reimbursed to the user to use DHT | **A0011/2(1)** |
| Is the DHT limited in platforms, languages, network connectivity, or users' digital literacy?*Discuss whether the DHT usage will be affected (or why not) by limitations in terms of platforms, languages, network connectivity, or users' digital literacy?* | Enough information on limitations and how they affect utilization:* Collect data on users
* Analyze utilization problems, e.g., issues for the less technical, etc.
 | Describe how the DHT is designed to overcome some or all limitation problems | **A0011/2(2)** |
| Is(will) data on DHT usage (be)collected and accessible ongoing? *Has granular data on DHT usage been collected? For example, can this usage data be collected every time the DHT is used or was it difficult to capture, so they only did it in the trial?* | Granular data was presented and analyzed on DHT usage collected in the trial. However, no further evidence provided on how/if usage data is will be collected on an ongoing basis. | Evidence DHT can collect this granular usage data ongoing; e.g., data collection is embedded in the DHT and transmitted to a central database ongoing | **A0011/2(3)** |
| Describe inputs (i.e., image, physiological status, symptoms, etc.), algorithms (i.e., equations, analysis engine model logic, algorithm, etc.), and outputs (i.e., inform, treat, diagnose) of the DHT*Split into two separate items:*  | See below | See below | **F0001** |
| 1. Describe inputs (i.e., image, physiological status, symptoms, etc.) and outputs (i.e., inform, treat, diagnose) of the DHT? | 1. Details the inputs and outputs of the trialed DHT  | 1. Explains why the trialed DHT is better/different from DHT comparators in terms of inputs and outputs | **F0001(1)** |
| 2. Describe the algorithms (i.e., equations, analysis engine model logic, algorithm, etc.) of the DHT | 2. Details the rules and parameters used by the DHT in patient clinical management decisions | 2. Details the engine model logic and algorithms enough to understand limitations and in what circumstances the DHT will and will not work | **F0001(2)** |
| TEC | Investments/ tools required (*EUN*) | Consider device size, battery life/charging method, operating system, connectivity, data access & storage, data security, technical support | Discuss the material investments required to operate in the health system | Discuss how the DHT was designed to minimize these material investments | **B0007** |
| Training/ informationneeded (*EUN*) | Personnel/caregivers/patient/family: Training required/provided on personal data handling, digital skills, and digital health literacy? *(Note: One-off training only on using the DHT is rated as "Poor")*  | Provision of continuous technical support for DHT users | Provision of digital literacy and general digital skills for patients or data handling skills for health care professionals | **B0013/4** |
| Features of Technology (*EUN*) | How well do the DHT and comparator(s) perform in overcoming technical barriers: Interoperability, data extraction, visualization, etc.?*(Note: Mention of technical barriers as a limitation of the trial is rated as "Poor")* | Mention at least one technical barrier that the DHT was designed to overcome and its benefits | Mention more than one technical barrier that the DHT was designed to overcome, and its benefits over DHT comparators | **DHT01** |
| SAF | Quality & safeguarding (*NEW*) | How well are data security and privacy managed? Does it comply with General Data Protection Regulation (GDPR) principles of data minimization/protection by default/design? | Encrypted data transmissions and secure databases controlled by regulated entities; e.g., government departments of health, listed private hospitals, regulated medical device companies | Evidence of compliance with: * GDPR principles (e.g., data minimization); or
* Privacy and data security legislation of the jurisdiction
 | **DHT02** |
| How well is interoperability designed and data quality managed? | Evidence that DHT has processes to support the creation and maintenance of accurate healthcare records that can be integrated with multiple information systems using the relevant patient/ provider identifiers and standard terminologies | DHT is integrated with relevant health system databases | **DHT03** |
| Transparency of risk to the user*How transparent are the DHT risks (e.g., data sharing, conflicts of interest) to the user?*  | Evidence that DHT provides users with accurate information on how their data is collected and protected and clear identification of the DHT's owners and contact information | In addition, evidence the DHT provides users with information on data use and sharing along with funding sources, promotion and sponsorship, and any other possible conflicts of interest | **DHT04** |
| How well is the DHT designed for usability and accessibility? *Evidence that DHT is designed for usability and accessibility?* | Evidence that the DHT is designed to minimize at least one of the barriers associated with hardware, software, data requirements, and platform services, or the language/location, age, culture, and ability of users; e.g., services are compatible with commonly used assistive technologies, meet relevant web page or web application standards  | Evidence that the most relevant/significant barriers have been identified and addressed in the design | **DHT05** |
| Is adequate information disclosed on DHT algorithms to evaluate their risk? | There is enough detail to replicate the process or understand the limitations of the data used, algorithms deployed, and how the outputs were validated. For learning algorithms, adequate disclosure of the characteristics of the training, test, and validation data, the model, and the algorithms to understand how the algorithm controls the clinical decision-making process | In addition, data quality is validated before building and employing algorithms For Artificial intelligence algorithms: Data quality checks are built programmatically to avoid harm | **DHT06** |
| Technical safety (Reliability & stability) (*NEW*) | How technically reliable and stable are the DHT and comparator(s)? *Unlikely to evaluate the comparator, so this has been modified to:* *How technically reliable and stable is the DHT?* | There is evidence of accurate and reliable transmission of unbiased data: Minimal complaints from participants or trial staff of drop-outs/connectivity problems, data inaccuracies, or failure to work on specific platforms/operating systems  | The DHT is designed to: * Alert the user when working suboptimally or experiencing interference, e.g., low or no network connectivity
* Resilient to erroneous data inputs, errors of precision, hardware problems, inappropriate use of devices, changes in other applications, and other interruptions
* Validated for use on multiple platforms
 | **DHT07** |
| How well are updates/continuity of the DHT managed? | Report how: * Platform and operating system updates and patches, service continuity, backup, and recovery mechanisms are managed
* Service changes or interruptions are communicated to users
 | Evidence of a well-managed update and continuity procedure and controls; e.g., participant/patient feedback on DHT service communications on changes | **DHT08** |
| Communicating for safety (*NEW*) | Can the user send critical risk information to the DHT provider? | The DHT provides warning on who should be contacted in an emergency, and there is a contact mechanism for technical support with a fixed response time | The DHT allows the user to communicate critical information to the provider on changes in their condition or risks to the user's health from using the DHT | **DHT09** |
| Processes for correct identification of users in DHT? | Use of user logins and passwords reported  | There are processes for correctly identifying users to match them with appropriate care and provide accurate health records, protecting anonymity where appropriate  | **DHT10** |
| Processes to communicate changes to or transfer of a patient's care? | There are processes to communicate changes in the health care team, stopping of care or transfer of a patient's care through the DHT |  In addition, there is evidence of these processes working from patients/ health care providers | **DHT11** |
| EFF | Patient satisfaction (*EUN*) | Is there evidence that the DHT is usable and accessible for a diverse range of users, including those with disabilities or limited technical ability? Are there obvious design issues hindering usability, e.g., washable, durable, cause skin allergies?*Split into three questions:* | See below | See below | **D0017** |
| 1. Has an analysis been conducted on how effective the DHT is for users with a disability?
 | 1. Report the number of participants with a relevant disability at baseline and discuss any problems/feedback from these users  | 1. Qualitative or quantitative (subgroup) analysis of participants with disabilities | **D0017(1)** |
| 1. Has an analysis been conducted on how effective the DHT is for users with limited technical ability?
 | 2. Report the number of users with limited technical ability at baseline/feedback from users with limited technical ability  | 2. Qualitative or quantitative (subgroup) analysis of participants with limited technical ability | **D0017(2)** |
| 1. For wearables, are design issues to increase usability discussed, e.g., washable, durable, cause skin allergies? (*Is NA if no wearables involved in DHT*)
 |  | 3. Any discussion of wearable issues and designs to overcome them | **D0017(3)** |
| EFF | Demonstrating effectiveness (*NEW*) | Are accepted methods used to overcome common methodological problems in RCTs for DHTs, e.g., achieving blinding, biases from informed consent, high attrition?*(Note: NA if study not an RCT)* | Single blinding; e.g., blinding of assessor | Double blinding | **DHT12(1)** |
| Is it clear whether the DHT was changed (bug fixes, content) during the study?  | State that the DHT had changed during the study to fix technical errors | State whether or not DHT development was frozen during the study. If development is not frozen, report what was changed during the trial and how these changes might impact results. | **DHT12(2)** |
| Was digital literacy an implicit eligibility criterion?*Did they recognize digital literacy was an implicit eligibility criterion or sample population might be biased towards digitally literate people?**(Note: This is NA if it is clear that there were no implicit/explicit digital literacy exclusions in the trial)* | Discussion of potential for selection bias with digital literacy/technical ability exclusions and reporting of how those with less digital literacy/technical ability did in the trial or feedback from the participant survey  | Made active steps in the design of DHT or trial to ensure those with low digital literacy/technical ability were included | **DHT12(3)** |
| Was the comparator group restricted in the DHT to which they had access? | Stated whether or not there were restrictions on DHTs for the comparator group, and if there were, what DHTs were excluded  | Explanation of reason for there being no restrictions or where there are restrictions | **DHT13** |
| Have DHT specific and validated outcome measures been collected: i.e., the intensity of use (dose, exposure), online adherence, engagement  | Use, online adherence, or engagement is measured and reported. These metrics and their methods of collection are described in adequate detail | In addition, validated measures are used.And if surveys of health outcomes are completed online, they are validated for online use | **DHT14** |
| Has data collection embedded in the DHT created systematic bias?  | Independent process to collect health outcomes outside of DHT or acknowledgment of bias from DHT data collection with some estimation of direction and magnitude of bias | Design of DHT data capture to minimize this bias |
| Is reporting of the RCT in accordance with CONSORT E-HEALTH?*Or similar DHT specific reporting standard; e.g., CONSORT AI or MAST**(Note that this question is now covered in the overall summary as a Yes/No answer)* | NA | NA | **DHT15** |
| Reliable information content (*NEW*) | Is the health information provided by DHT accurate, valid, up to date, comprehensive, clear, and tailored to the users' diversity? *(Note: This is NA if it is clear that the DHT provides no* *health information)* | Evidence of a process to ensure this at the time of development of the DHT | In addition, evidence of ongoing process to maintain this standard for the DHT | **DHT16** |
| Use of appropriate behavior change techniques (*NEW*)  | Does the DHT use appropriate and best practice behavior change techniques?Is the mechanism credible? Is the targeted behavior change apparent to the user, and are the appropriate supports in place? | Reference to a peer-reviewed behavior change theory with justification why it applies to the DHT's purpose and evidence the apparent behavior change is evident to the user and the mechanism is credible  | In addition, a description of appropriate supports in place to enable the behavior change and evidence it applies to the target population | **DHT17** |
| External validity/ generalizability (*NEW*) | Has patient identity validation and obtaining off-line contact details to improve follow-up rates jeopardized external validity?*(Note: This is NA if the study is retrospective data analysis*) |  | Discussion of how the processes for the trial are different from the intended operation of the DHT and how that may affect the external validity of the trial | **DHT18** |
| Are results generalizable to settings where telecommunication infrastructure is poor, or there is low network connectivity? | Report number of participants in areas with poor infrastructure/connectivity at baseline, or as a minimum report the number of participants that experience these problems during the study | Qualitative or quantitative (subgroup) analysis of participants in areas with poor infrastructure/connectivity | **DHT19** |
| ECO | Validity of the model(s) (*EUN*) | Are changes in fixed costs for scaling up the DHT known? Is the cost function per patient smooth or stepped?*(Note: Rated "Not reported" if no costing analysis done as yet*) | Some discussion/awareness of this problem  | The cost function is known | **DHT20** |
| Resource utilization (*EUN*) | Consider costs of supporting health care providers in using DHT and costs to use the DHT in the health system (licensing, platforms, hardware, etc.) *(Note: Rated "Not reported" if no costing analysis done as yet*) | Discusses or presents the partial evaluation of costs of supporting health care providers | Detailed evaluation of the additional cost of using in the health system as well | **E0001/2/9** |
| Measurement & estimation of outcomes (*EUN*) | Have DHT-specific outcomes been considered and measured where possible, e.g., self-management benefits, better-connected healthcare professionals?  | DHT specific outcomes considered with feedback from patients/healthcare professionals | Validated self-management measures collected and analyzed | **E0005(1)** |
| Given that all the functionalities of DHTs may not be used, and many people may not use the DHT from the outset, are the estimated benefits of the DHT realistic? | Consideration of start-up times and realistic use of DHT functions | Estimates of how long it will take to see full effects and incorporates this into economic evaluation | **E0005(2)** |
| ETH | Benefit-harm balance (*EUN*) | Where are alerts about a patient's health reported? Is real-time data securely transmitted? How does the DHT affect the participant's safety and welfare? *How does the DHT affect the participant's safety and welfare:- Are alerts about a patient's health held securely?- Is real-time data securely transmitted?* | Description of a secure process for data transmissions | Details given about security controls for data transmissions | **F0003(1)** |
| Can the DHT promote a false sense of security or harm patients having access to their data without someone to interpret it?  | Discussion provided or patient feedback reported | Patient feedback on both issues reported | **F0003(2)** |
| Autonomy (*EUN*) | For DHTs targeting behavior change, what controls limit the DHT influencing a person's behavior for purposes other than those stated? |  | Discussion of this risk and controls | **F0004(1)** |
| Is the user always able to make independent and authentic decisions based on an adequate range of options given by the DHT? |  | Discussion of how the range of options have been chosen so user can make independent and authentic decisions and any limitations on decisions | **F0004(2)** |
| Does the DHT use simple and understandable language?  | Discussion of how this was addressed in development **or** patient feedback reported | Discussion of how this was addressed in development **and** patient feedback reported | **F0005** |
| Are any potential conflicts of interest (funding, promotion) disclosed *to the DHT users?* *(Note: Is NA if it is clear that there are no conflicts of interest or funding to disclose)* |  | Yes | **F0006(1)**  |
| *For DHT's providing health information,* is there concise information for the user on how the DHT's contents were selected *and who is responsible for the content?**(Note: Is NA if it is clear that the DHT does not provide health information)* |  | Yes | **F0006(2)** |
| Is the data collected by the DHT, its use, and availability disclosed to the user?*Is the user informed of the data collected by the DHT, its use, and availability to users to extract for their own purposes?* | The user is informed of these details | In addition, the patient can easily extract and use their own data | **F0006(3)** |
| Benefit-harm balance (*EUN*) | Is the DHT designed and used for clearly defined purposes that uphold the health system's social values or society's?*This is a summary question and is unable to determine from primary studies. Therefore, it is not evaluated further.* | NA | NA | **F0011(1)** |
| Is the value of patient data realized but protected from commercial use? |  | Discussion of risks and controls | **F0011(2)** |
| Does the DHT preserve and enhance direct contact between patients and healthcare professionals while supporting them to manage their health? | Some patient or health professional feedback reported on this issue | DHT was designed with this in mind, and qualitative feedback by both patients and healthcare professionals reported | **F0011(3)** |
| Respect for persons (*EUN*) | Does the DHT clearly identify who holds any personal data?  | All data custodians identified for each set of personal data  | In addition, a detailed description of the extent to which third parties may gain access to this personal data is given | **F0101(1)** |
| Is the DHT regularly audited for transmissions with third parties that include linkable identifiers? Is the user informed of this risk? | States that users will be informed of the potential risks of data sharing  | Evidence of regular audits of third-party transmissions with linkable identifiers | **F0101(2)** |
| Justice & Equity (*EUN*) | 1. How does the DHT overcome access barriers, e.g., patients with a lack of economic resources, poor IT skills, digital health literacy?  | 1. Partial evaluation/description of how DHT overcomes one access barrier  | 1. Description of how DHT overcomes multiple access barriers | **H0012(1)** |
| Is the DHT compatible with common assistive technologies and is available in several languages? *Split into two questions:* | See below | See below | **H0012(2)** |
| 2. Is the DHT compatible with common assistive technologies *for the hearing or visually impaired*? |  | 2. Yes, the DHT is compatible with common assistive technologies for the hearing or visually impaired | **H0012(2)** |
| 3. Justification given of the available languages in DHT for the target population or recognition of limitation? *(Note: Is NA if it is clear that the DHT does not have a language restriction)* | 3. Recognise provided languages are a limitation and estimate the impact from restriction | 3. Justify the choice of languages provided for the target population or provide relevant languages | **H0012(3)** |
| ORG | Contextual issues (*NEW*) | Consider all contextual barriers and enablers to DHT uptake: Infrastructure, clinical endorsement, champions of DHT, supplementary payments, etc. | Discussion of barriers and why DHT failed or was successful in this regard | Discussion of how to overcome barriers and use enablers in the new care pathway | **DHT21** |
| Health delivery process (*EUN*) | Are changes to electronic communication, information/reporting systems, face-to-face consultations, and staff communication considered? | Discussion of the changes required |  | **G0004** |
| How does removing the constraints of distance, and sharing patient data, impact staff work methods and the interactions between medical staff, patients, and their carers? | Detail impacts in examples | Provide qualitative/quantitative? evidence on impacts | **G0100** |
| SOC | Social group aspects (*EUN*) | How much does the DHT improve the connectivity between the healthcare team and the patient? Is access improved for remote patients? *Split into two questions:* | See below | See below | **H0201** |
| 1. How much does the DHT improve the connectivity between the healthcare team and the patient?  | 1. Qualitative/quantitative feedback from patients and healthcare providers | 1. In addition, discussion of how the DHT care pathway has been designed to improve connectivity | **H0201(1)** |
| 2. Evidence that access is improved for rural/remote patients? | 2. Report the number of rural/remote participants at baseline or feedback from rural/remote users | 2. Qualitative or quantitative (subgroup) analysis on rural/remote users | **H0201(2)** |
| Communication aspects (*EUN*) | Are expected direct and data usage costs made clear to the user to improve adherence rates? | Direct access costs and data usage costs reimbursed/provided for free | DHT provides service users with clear and transparent information on the: a. Direct costs to access the service, b. Estimated data usage requirements for using the service | **H0203** |
| LEG | Ownership & liability (*EUN*) | Professional liability: Clarify responsible parties, litigation risks, and insurance implications of DHT recommendation or use  | State parties responsible for medical advice; responsible for monitoring and reviewing patient data; and that own the data related to the DHT | Additionally, discuss litigation risks to the healthcare practitioners using or recommending the DHT, how insurance(s) (i.e., professional indemnity, life, health, income) and professional registrations could be affected through use or recommendation of the DHT | **DHT22** |

| **Checklist 2: Content common to digital and non-digital technologies, but essential for Health Technology Assessments (HTAs) of Digital Health Technologies (DHTs)** |
| --- |
| **HTA****Domaina** | **Topica** | **Issue content (***Modifications***)** | **"Fair" coverage** | **"Good" coverage** | **Issue IDa** **(Item No.)** |
| CUR | Current management of the condition | What DHT do those with the condition already have available to them? | Background on other DHT trials and some comparison of the features between DHTs | Discuss current market products and why this DHT is an improvement/different | **A0018** |
| TEC | Features of the technology | Is there evidence that the DHT is relevant to the health system and can perform to the expected number of users (e.g., is the server size adequate)? | Evidence of being tested in the healthcare system | And that it can handle a large number of patients | **B0003(1)** |
| As DHTs often develop rapidly, is the DHT in a steady state to perform a robust economic analysis? *i.e.,* *no more development planned?**(Yes = No more development planned,* *No = More development planned,**Not covered = Unable to tell)**This question is moved to summary table* | NA | NA | **B0003(2)** |
| SAF | Risk management  | Are there defined parameters to identify and respond to a patient's acute deterioration?  | Some discussion of the process  | Parameters are given, and detailed processes discussed | **C0062** |
| EFF | Patient satisfaction | Is there evidence to show relevant stakeholders were involved in the design and satisfied with the DHT? | Evidence that patients were consulted in the design stage (focus groups/useability and feasibility testing) | In addition, qualitative survey or multiple quantitative questions on patient satisfaction in the design stage and changes to the design made if required | **D0017(4)** |
| Is ongoing data collected on user satisfaction that will be acted upon and available to decision-makers?*Has/will data be collected on user satisfaction that will be acted upon and available to decision-makers?*  | Evidence of patient satisfaction data being collected and analyzed in an effectiveness trial  | There are processes in place to collect data ongoing that are extractable and available | **D0017(5)** |
| Has qualitative data been collected and analyzed to evaluate the mode of action, differences between recipients and sites, and identify barriers to uptake or implementation? | Some presentation of qualitative data  | Qualitative data was collected and analyzed on most of these points | **D0017(6)** |
| Does the DHT create additional burdens on the patient or caregiver that may affect uptake or adherence? | Feedback from patients or caregivers on caregiver burden  | Validated caregiver burden surveys were done and results presented | **D0017(7)** |
| ECO | None noted |  |
| ETH | Benefit-harm balance  | What will be done with any incidental findings?*(Note: Is NA if it is clear that the DHT does not do any testing or only tests for the disease targeted)* |  | Any ethical discussion of how incidental findings should be managed | **F0003** |
| Autonomy | Does the DHT provider: * Identify the diversity of service users, or groups of users, at higher risk of harm and adapt the DHT accordingly?
* Have systems to minimize the risk for children and young people to be harmed?
* Identify those with suicide ideation in depression treatments?
 | Risk segmentation of users and adaptation of DHT with regards to targeted disease only |  Risk segmentation of users and adaptation of DHT for those users with regards to all potential risks from using the DHT | **F0005** |
| Justice & Equity | Show evidence of the DHT being used in hard-to-reach populations | Define hard-to-reach populations and report participants at baseline | And show evidence of use in these populations | **H0012** |
| ORG | Culture | Does the DHT have credibility with health care professionals? i.e., is there published or publicly available evidence documenting the relevant health care experts' role in the design, development, testing, or sign-off of the DHT? | Any evidence of relevant health care experts' role in the design, development, testing, or sign-off of the DHT | And qualitative/quantitative feedback from healthcare professionals | **G0010** |
| Health delivery process | Describe the steps in the proposed new care pathway or pathways incorporating the DHT intervention for the relevant population and setting | A detailed description of the intervention care pathway versus the usual care pathway in the trial setting | A detailed description of how the DHT care pathway would work in relevant population and setting | **G0100(1)** |
| Detail any infrastructure and service-level changes needed to existing pathways and associated systems to implement, operate and maintain the new pathway |  |  Any discussion of infrastructure/service-level/systems changes to implement and operate new care pathway | **G0100(2)** |
| SOC | None noted |  |
| LEG | None noted |  |

a From EUNetHTA HTA Core Model version 3.0. HTA domains are defined as:

**CUR:** Describes the new technology's target population, target condition and current management, current and expected utilization, and regulatory status

**TEC:** Describes the new technology's features in enough detail to differentiate it from comparators, and the investments, tools, and training required to use it

**SAF:** Identifies unwanted or harmful effects of the new technology important to patients or the decisions of health care providers and policymakers

**EFF:** Provides evidence of comparative effectiveness of the new technology in producing health benefits in the relevant health care setting

**ECO:** Provides information on the new technology's costs, health-related outcomes, and economic efficiency to inform value for money judgments

**ETH:** Considers potential harms to autonomy, respect for persons, justice, and equity from the use of the new technology or from performing the HTA

**ORG:** Identifies resources to mobilized or organized to implement the new technology and the consequences (Intra/interorganizational and health system)

**SOC:** Considers issues related to the new technology relevant to patients, carers, and social groups

**LEG:** Identifies rules and regulations protecting patient's rights and societal interests for consideration when evaluating the new technology

b New topic

c A DHT prefixed denotes a new issue (i.e., *DHTXX*)

*Supplementary Table 3: References for included papers*

|  |  |
| --- | --- |
| **Included papers** | **References** |
| In coverage assessment (i.e., DHT interventions targeting diabetes, cardiovascular disease or both) | (1-130) |
| DHT interventions targeting other chronic diseases | (131-201) |

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*Supplementary Table 4: DHT-specific content to be considered when undertaking a Health Technology Assessment (HTA) of DHTs*

| **HTA Domain** | **Topic (EUN)/(NEW)** | **Issue ID (modifier)** | **Issue content** | **N=112** |
| --- | --- | --- | --- | --- |
| **n (%)** |
| **Good** | **Fair** | **Poor** | **Not covered** | **NR** | **NA** |
| CUR | Utilization (EUN) | **A0011/2(1)** | Provide evidence of whether health workers/patients do or will invest in the personal digital technologies required to use the DHT? Estimate current investment by workers/patients, detail direct and add-on costs, and user willingness to pay | 5(4) | 17(15) | 4(4) | 86(77) |  |  |
| **A0011/2(2)** | Discuss whether the DHT usage will be affected (or why not) by limitations in terms of platforms, languages, network connectivity, or users' digital literacy?  | 4(3) | 10(9) | 12(11) | 86(77) |  |  |
| **A0011/2(3)** | Has granular data on DHT usage been collected? Can this usage data be collected every time the DHT is used or was it difficult for them to capture so they only did it in the trial?  | 39(35) | 34(30) | 4(4) | 35(31) |  |  |
| **F0001(1)** | Describe inputs (i.e., image, physiological status, symptoms, etc.) and outputs (i.e., inform, treat, diagnose) of the DHT? | 34(30) | 72(64) | 5(5) | 1(1) |  |  |
| **F0001(2)** | Describe the algorithms (i.e., equations, analysis engine model logic, algorithm, etc.) of the DHT?  | 7(6) | 51(46) | 15(13) | 39(35) |  |  |
| TEC | Investments/tools required (EUN) | **B0007** | Considerations of device size, battery life/charging method, operating system, connectivity, data access & storage, data security, technical support  | 3(3) | 16(14) | 6(5) | 87(78) |  |  |
| Training/information needed (EUN) | **B0013/4** | Personnel/caregivers/patient/family: Training required/provided on personal data handling, digital skills, and digital health literacy? | 4(4) | 18(16) | 25(22) | 65(58) |  |  |
| Features of Technology (EUN) | **DHT01** | Discussion of how well the DHT and comparator(s) perform in overcoming technical barriers: Interoperability, data extraction, visualization, etc.?  | 9(8) | 32(29) | 8(7) | 63(56) |  |  |
| SAF | Quality & safeguarding (NEW) | **DHT02** | How well are data security and privacy managed - Does it comply with GDPR principles of data minimization/protection by default/design?  | 5(4) | 14(13) | 7(6) | 86(77) |  |  |
| **DHT03** | How well is interoperability designed and data quality managed?  | 10(9) | 9(8) | 6(5) | 85(76) |  | 2(2) |
| **DHT04** | How transparent are the DHT risks (e.g., data sharing, conflicts of interest) to the user? |  | 1(1) | 1(1) | 110(98) |  |  |
| **DHT05** | Evidence that DHT designed for usability and accessibility? | 8(7) | 18(16) | 6(5) | 80(72) |  |  |
| **DHT06** | Is adequate information disclosed on DHT algorithms to evaluate their risk? |  | 11(10) | 4(3) | 97(87) |  |  |
| Technical safety (Reliability & stability) (NEW) | **DHT07** | How technically reliable and stable is the DHT? | 2(2) | 21(19) | 5(4) | 84(75) |  |  |
| **DHT08**  | How well are updates/continuity of the DHT managed? |  | 5(4) | 1(1) | 101(95) |  |  |
| Communicating for safety (NEW) | **DHT09** | Can the user send critical risk information to the DHT provider? | 6(5) | 12(11) | 3(3) | 91(81) |  |  |
| **DHT10** | Processes for correct identification of users in DHT? | 1(1) | 5(4) | 2(2) | 104(93) |  |  |
| **DHT11**  | Processes to communicate changes to or transfer of a patient's care |  | 5(4) |  | 107(96) |  |  |
| EFF | Patient satisfaction (EUN) | **D0017(1)** | Has an analysis been conducted on how effective the DHT is for users with a disability?  | 2(2) | 9(8) | 3(3) | 98(87) |  |  |
| **D0017(2)** | Has an analysis been conducted on how effective the DHT is for users with limited technical ability? | 5(4) | 13(12) | 3(3) | 91(81) |  |  |
| **D0017(3)** | For wearables, are design issues to increase usability discussed, e.g., washable, durable, cause skin allergies? | 1(1) |  | 3(3) | 51(45) |  | 57(51) |
| Demonstrating effectiveness (NEW) | **DHT12(1)** | Are accepted methods used to overcome common methodological problems in RCTs for DHTs, e.g., achieving blinding, biases from informed consent, high attrition  | 3(3) | 49(44) | 24(21) | 8(7) |  | 28(25) |
| **DHT12(2)** | Is it clear whether the DHT was changed (bug fixes, content) during the trial?  | 2(2) | 5(4) |  | 105(94) |  |  |
| **DHT12(3)** | Did they recognize digital literacy was an implicit eligibility criterion or sample population may be biased towards digitally literate people?  | 6(5) | 7(7) | 6(5) | 64(57) |  | 29(26) |
| **DHT13** | Was the comparator group restricted in the DHT to which they had access?  |  | 10(9) |  | 102(91) |  |  |
| **DHT14(1)** | Have DHT specific and validated outcome measures been collected: i.e., the intensity of use (dose, exposure), online adherence, engagement? | 2(2) | 47(42) | 6(5) | 57(51) |  |  |
| **DHT14(2)** | Has data collection embedded in the DHT created systematic bias or confounding? | 3(3) | 52(46) | 1(1) | 56(50) |  |  |
| Reliable information content (NEW) | **DHT16**  | Is the health information provided by DHT accurate, valid, up to date, comprehensive, clear, and tailored to the users' diversity?  | 2(2) | 25(22) | 1(1) | 36(32) |  | 48(43) |
| Use of appropriate behavior change techniques (NEW) | **DHT17** | Does the DHT use appropriate and best practice behavior change techniques? Is the mechanism credible? Is the targeted behavior change apparent to the user, and are the appropriate supports in place? Is it relevant for the target population?  | 19(17) | 9(8) | 2(2) | 37(33) |  | 45(40) |
| External validity/ generalizability (NEW) | **DHT18** | Discuss whether patient identity validation and obtaining off-line contact details to improve follow-up rates has jeopardized external validity?  |  | 6(5) |  | 96(86) |  | 10(9) |
| **DHT19** | Are results generalizable to settings where telecommunication infrastructure is poor, or there is low network connectivity?  | 1(1) | 6(5) | 3(3) | 102(91) |  |  |
| ECO | Validity of the model(s) (EUN) | **DHT20** | Are changes in fixed costs for scaling up the DHT known? Is the cost function per patient smooth or stepped? | 3(3) | 8(7) | 1(1) | 31(27) | 69(62) |  |
| Resource utilization (EUN) | **E0001/2/9** | Consider costs of supporting health care providers in using DHT and costs to use the DHT in the health system (licensing, platforms, hardware, etc.) | 4(4) | 8(7) | 5(4) | 26(23) | 69(62) |  |
| Measurement & estimation of outcomes (EUN) | **E0005(1)** | Have DHT-specific outcomes been considered and measured where possible, e.g., self-management benefits, better-connected healthcare professionals? | 19(17) | 13(12) | 9(8) | 71(63) |  |  |
| **E0005(2)** | Given that all the functionalities of DHTs may not be used, and many people may not use the DHT from the outset, are the estimated benefits of the DHT realistic? | 3(3) | 5(4) | 1(1) | 103(92) |  |  |
| ETH | Benefit-harm balance (EUN) | **F0003(1)** | How does the DHT affect the participant's safety and welfare? - Are alerts about a patient's health held securely?- Is real-time data securely transmitted? | 2(2) | 15(13) |  | 95(85) |  |  |
| **F0003(2)** | Can the DHT promote a false sense of security or harm patients by having access to their data without someone to interpret it? |  | 13(12) | 1(1) | 98(87) |  |  |
| ETH | Autonomy (EUN) | **F0004(1)** | For DHTs targeting behavior change, what controls limit the DHT influencing a person's behavior for purposes other than those stated? |  |  |  | 93(83) |  | 19(17) |
| **F0004(2)** | Is the user always able to make independent and authentic decisions based on an adequate range of options given by the DHT? |  |  |  | 112(100) |  |  |
| **F0005** | Does the DHT use simple and understandable language? | 3(2) | 12(11) | 1(1) | 96(86) |  |  |
| **F0006(1)** | Are any potential conflicts of interest (funding, promotion) clearly disclosed to DHT users?  |  | 1(1) |  | 106(95) |  | 5(4) |
| **F0006(2)** | For DHT's providing health information, is there concise information for the user on how the DHT's contents were selected and who is responsible for the content?  | 4(4) | 5(4) |  | 66(59) |  | 37(33) |
| **F0006(3)** | Is the user informed of the data collected by the DHT, its use, and availability to users to extract for their own purposes?  | 1(1) | 3(3) |  | 108(96) |  |  |
| Benefit-harm balance (EUN) | **F0011(2)** | Is the value of patient data realized but protected from commercial use? |  |  |  | 112(100) |  |  |
| **F0011(3)** | Does the DHT preserve and enhance direct contact between patients and healthcare professionals while supporting them to manage their health? | 4(3) | 10(9) | 2(2) | 96(86) |  |  |
| Respect for persons (EUN) | **F0101(1)** | Does the DHT clearly identify for the user who holds any personal data?  |  | 3(3) | 2(2) | 107(95) |  |  |
| **F0101(2)** | Is the DHT regularly audited for transmissions with third parties that include linkable identifiers?  |  | 1(1) |  | 111(99) |  |  |
| Justice & Equity (EUN) | **H0012(1)** | How does the DHT overcome access barriers, e.g., patients with a lack of economic resources, poor IT skills, digital health literacy?  | 9(8) | 13(12) | 15(13) | 75(67) |  |  |
| **H0012(2)** | Is the DHT compatible with common assistive technologies for hearing and visually impaired?  | 1(1) |  |  | 111(99) |  |  |
| **H0012(3)** | Justification is given for the available languages given the target population, or there is recognition of the limitation | 5(4) | 2(2) | 4(4) | 49(44) |  | 52(46) |
| ORG | Contextual issues (NEW) | **DHT21** | Discussion of contextual barriers and enablers to DHT uptake: Infrastructure, clinical endorsement, champions of DHT, supplementary payments, etc.  | 10(9) | 15(13) | 10(9) | 77(69) |  |  |
| Health delivery process (EUN) | **G0004** | Are changes to electronic communication, information/reporting systems, face-to-face consultations, and staff communication considered?  |  | 14(13) | 6(5) | 92(82) |  |  |
| **G0100** | How does removing the constraints of distance, and sharing patient data, impact staff work methods and the interactions between medical staff, patients, and their carers | 4(4) | 12(11) | 6(5) | 90(80) |  |  |
| SOC | Social group aspects (EUN) | **H0201(1)** | How much does the DHT improve the connectivity between the healthcare team and the patient?  | 11(10) | 11(10) | 6(5) | 81(75) |  |  |
| **H0201(2)** | Evidence that access is improved for rural/remote patients? | 6(5) | 4(4) | 2(2) | 100(89) |  |  |
| Communication aspects (EUN) | **H0203** | Are expected direct and data usage costs made clear to the user to improve adherence rates?  | 5(4) | 12(11) | 1(1) | 94(84) |  |  |
| LEG | Ownership & liability (EUN) | **DHT22** | Professional liability: Clarify responsible parties, litigation risks, and insurance implications of DHT recommendation or use  |  | 1(1) | 4(4) | 107(95) |  |  |

DHT, Digital Health Technology; HTA, Health Technology Assessment; NR, not reported; NA, not applicable.

*Supplementary Table 5: Health technology assessment (HTA) content that is common across DHTs and non-DHTs, but essential for DHT*

| **HTA Domain** | **Topic**  | **Issue ID (modifier)** | **Issue content** | **N=112** |
| --- | --- | --- | --- | --- |
| **n(%)** |
| **Good** | **Fair** | **Poor** | **Not covered** | **NA** |
| CUR | Current management of the condition | **A0018** | What DHT do those with the condition already have available to them?  | 24(21) | 66(59) | 6(6) | 16(14) |  |
| TEC | Features of the technology | **B0003(1)** | Is there evidence that the DHT is relevant to the health system and can perform to the expected number of users (e.g., is the server size adequate)?  | 18(16) | 72(64) | 2(2) | 20(18) |  |
| **B0003(2)** | As DHTs often develop rapidly, is the DHT in a steady-state? i.e., No more development planned? (Yes = No more development planned; No = More development planned; Not covered = unable to tell) | Yes 47(42) | No 53(47) |  | Unable to tell12(11) |  |
| SAF | Risk management  | **C0062** | Are there defined parameters to identify and respond to a patient's acute deterioration? | 17(15) | 32(29) | 2(2) | 61(54) |  |
| EFF | Patient satisfaction | **D0017(4)** | Is there evidence to show that relevant patient stakeholders were involved in the design of the DHT? | 12(11) | 17(15) | 4(4) | 79(70) |  |
| **D0017(5)** | Has/will data be collected on user satisfaction that will be acted upon and available to decision-makers? |  | 32(28) | 2(2) | 78(70) |  |
| **D0017(6)** | Has qualitative data been collected and analyzed to evaluate the mode of action, differences between recipients and sites, and identify barriers to uptake or implementation? | 4(4) | 12(10) | 4(4) | 92(82) |  |
| **D0017(7)** | Does the DHT create additional burdens on the patient or caregiver that may affect uptake or adherence? | 3(3) |  | 2(2) | 107(95) |  |
| ETH | Benefit-harm balance  | **F0003** | What will be done with any incidental findings? | 2(2) |  |  | 34(30) | 76(68) |
| Autonomy | **F0005** | Does the DHT provider identify the diversity of service users, or groups of users, at higher risk of harm and adapt the DHT accordingly? E.g., have systems to minimize the risk for children and young people to be harmed, identify those with suicide ideation in depression treatments, and have procedures for monitoring and responding to acute events. | 3(3) | 4(3) | 2(2) | 103(92) |  |
| Justice & Equity | **H0012** | Is there evidence of the DHT being used in hard-to-reach populations? | 8(7) | 7(6) | 5(5) | 92(82) |  |
| ORG | Culture | **G0010**  | Is there evidence that the DHT has credibility with health care professionals? i.e., Is there published or publicly available evidence documenting the relevant health care experts' role in the design, development, testing, or sign-off of the DHT? | 8(7) | 30(27) | 4(3) | 70(63) |  |
| Health delivery process | **G0100(1)** | Describe the steps in the proposed new care pathway or pathways incorporating the DHT intervention for the relevant population and setting | 11(10) | 64(57) | 13(12) | 24(21) |  |
| **G0100(2)** | Detail any infrastructure and service-level changes needed to existing pathways and associated systems to implement, operate, and maintain the new pathway | 20(18) |  | 4(3) | 88(79) |  |

DHT, Digital Health Technology; HTA, Health Technology Assessment; NA, not applicable.

1. Searches modified for Embase, Econolit, CINAHL, Cochrane [↑](#footnote-ref-1)
2. (1) Search terms used to identify e-Health, m-Health, and digital health modes of health delivery (2) Terms used to identify decision making, funding and health evaluation studies (3) Terms to identify economic evaluation studies (4) Terms used to identify Randomised Controlled Trials (5) Terms used to identify observational studies (6) Terms used to identify Health Technology Assessments (7) Terms used to search for animal not human studies [↑](#footnote-ref-2)
3. All terms were searched using multipurpose (.mp) [↑](#footnote-ref-3)
4. All terms were searched using text words (.tw)

Search string: Limit yr="2015 - Current" ((1) AND ((2) OR (3)) AND ((4) OR ((5) NOT (4)) OR (6) NOT ((4) OR ((5) NOT (4))))NOT (7)); Medline/Embase search conducted on 20 March 2020; CINAHL/Econolit search conducted on 22 March 2020. [↑](#footnote-ref-4)