LIVERPOOL REVIEWS AND IMPLEMENTATION GROUP (LRiG)

Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies [HTE10052]: Early Value Assessment final protocol

Confidential until published

This report was commissioned by the NIHR Evidence Synthesis Programme as project number NIHR171847

Completed 28 November 2024

UNIVERSITY OF LIVERPOOL

LIVERPOOL REVIEWS AND IMPLEMENTATION GROUP

A MEMBER OF THE RUSSELL GROUP

Title:	Digital front door technologies to pre-assess people before assessment for NHS Talking Therapies [HTE10052]: Early Value Assessment (EVA) final protocol
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Date completed: 28 November 2024

Declared competing interests of the authors: None

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1 DECISION PROBLEM

1.1 Purpose

Digital front door technologies have been identified by NICE for an Early Value Assessment (EVA). The aim of an EVA is to provide faster access to promising new treatments for patients with serious or life-threatening conditions. The objectives of an EVA are to:

- identify the evidence that is available on the technologies
- explore if technologies have the potential to address the unmet need
- identify important evidence gaps to help direct evidence generation
- determine if technologies should be used while further evidence is generated.

The gathered evidence will help demonstrate whether the expected benefits of the technologies are realised, will inform the final NICE evaluation and help the Committee make recommendations on the possible conditional use of these technologies in the NHS while further evidence is generated.

1.2 Aim

The aim of this EVA is to map the available digital front door technology evidence, assess the potential benefits and costs, and identify evidence gaps to help direct future data collection and further research.

1.3 Objectives

1.3.1 Explore accuracy and acceptability (health care professionals and service users)

- Identify and assess evidence relating to the use of digital front door technologies
- Describe any on-going or planned studies that will provide relevant data
- Report any safety, confidentiality, or equality issues
- Report the evidence gaps, highlighting the data need to fill these gaps

1.3.2 Explore value for money

- Identify and assess economic evidence relating to the use of digital front door technologies
- Develop a conceptual economic model that can be used to inform future data collection and further research
- Describe potential costs and benefits of digital front door technologies
- Describe any on-going or planned studies that will provide relevant economic data
- Report the evidence gaps, highlighting the data need to fill these gaps

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1.4 Population

The population is people over the age of 16 years with suspected common mental health conditions as specified in the NHS Talking Therapies for Anxiety and Depression Manual.[1]

1.5 Intervention

In this EVA, digital front door technologies are online pre-assessment tools that gather relevant information (with or without the use of artificial intelligence [AI]) via a questionnaire and/or via chatbots. Digital front door technologies differ from online referral forms as, in addition to collecting demographic data and information about the person's presenting difficulties, they are dynamic, guiding the user through relevant questions and record information. This information can then be used by the NHS Talking Therapies clinical assessor to inform the initial one-to-one person-centred assessment. Digital front door technologies can also provide relevant information to the service user (e.g., a description of NHS Talking Therapies) to prepare them for the clinical assessment, as well as signpost them to other resources (e.g., free debt counselling services or NHS advice webpages).

In line with the NICE final scope, the focus of the External Assessment Group (EAG) report will be on the information collected by the digital front door technologies. The capacity for digital front door technologies to assign problem descriptors or diagnoses, make treatment decisions, provide remote monitoring or appointment booking will not be considered as part of this assessment.

NICE has identified three digital front door technologies for inclusion in this assessment:
- AskFirst
- Limbic Access
- Wysa Digital Referral Assistant

Summary information about these digital front door technologies is provided in Appendix 1, Section 8.1, Table 3.

1.6 Comparator

This EVA will consider the benefits and costs of current NHS pre-assessment referral practice for NHS Talking Therapies that includes digital front door technologies versus NHS pre-assessment referral practice for NHS Talking Therapies without digital front door technologies. Pre-assessment for NHS Talking Therapies without digital front door technologies includes self-referrals (online forms or by telephone), community or voluntary care referral, primary care referral and secondary care referral (including both mental health and physical healthcare services).

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1.7 Outcomes

Outcomes listed in the NICE final scope are presented in Table 1.

Table 1 Outcomes listed in the NICE final scope

Outcome included in the NICE final scope
Accuracy and acceptability
• Quality and accuracy of the data collected using digital front door technologies • Accuracy of clinical assessment for NHS Talking Therapies • Completion rate of pre-assessment when using digital front door technologies • Inaccessibility to digital front door technologies • Healthcare professional acceptability of digital front door technologies
Resource and system impact
• Administrative resource impact • Time taken to review data collected by digital front door technologies • Time taken to complete clinical assessment • Time saved for the clinician during clinical assessment
Service user reported outcomes
• Ease of access and usability • Information clarity and relevance • Comfort and privacy • Overall satisfaction with pre-assessment process
Economic outcomes
• Costs of the technologies • Initial setup and integration costs • Operational costs (if falling on the NHS rather than the technology provider) such as IT support and cybersecurity • Training costs • Cost of promotion • Costs of applying digital clinical safety assurance DCB0129[2]

1.8 Time horizon

The time horizon for estimating the efficacy and value for money of digital front door technologies will be from referral (any route) until the end of the NHS Talking Therapies assessment only.

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2 DATA COLLECTION METHODS

Systematic literature searches, conducted using the methods described in Section 2.1, will be designed to identify relevant studies. Inclusion and exclusion criteria will be applied to potentially relevant studies (Section 2.2). The data extraction and quality assessment process will be carried out using standard methods (Section 2.3 and 2.4). Data provided in the included studies will be supplemented with information gathered from other sources (Section 2.5 to 2.6).

2.1 Evidence review: systematic literature search strategy

The following sources will be searched to identify the published and unpublished benefits and costs associated with digital front door technologies for NHS Talking Therapies:

- Electronic databases, including MEDLINE, EMBASE, APA PsycInfo, the Cochrane Library, EconLit and the Cost-Effectiveness Analysis (CEA) Registry
- WHO International Clinical Trials Registry Platform (ICTRP) and the United States National Library of Medicine registry of clinical trials (ClinicalTrials.gov)
- Google Scholar and Lens.org
- Internet resources, including web pages supported by companies and submissions to NICE
- Reference lists of included studies

An example MEDLINE search strategy is provided in Appendix 2 (Section 8.2).

2.2 Evidence review: study selection

Included references will be imported into EndNote and deduplicated. EndNote will also be used to screen titles and abstracts of identified references. Screening will be conducted by one reviewer and a minimum of 20% checked by a second reviewer against pre-specified inclusion and exclusion criteria. After title/abstract screening, full-text versions of all potentially relevant studies will be obtained. Inclusion and exclusion criteria will be applied to these studies by one reviewer and results will be checked by a second reviewer. Discrepancies will be resolved by discussion, with the involvement of a third reviewer, where necessary.

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2.2.1   Evidence review: inclusion and exclusion criteria

Inclusion and exclusion criteria are presented in Table 2.

Table 2 Inclusion and exclusion criteria

Parameter	Included	Excluded
Population	The population is people >16 years with suspected common mental health conditions as specified in the NHS Talking Therapies for Anxiety and Depression Manual.[1]	People aged ≤16 years People without suspected common mental health conditions
Intervention	Digital front door technologies identified in the NICE final scope: • AskFirst (Sensely) • Limbic Access (Limbic) • Wysa Digital Referral Assistant (Wysa)	Any digital front door technology not listed in the final scope issued by NICE
Comparator	Current NHS pre-assessment referral practice for NHS Talking Therapies that does not include digital front door technologies: • self-referral • community or voluntary care referral • primary care referral • secondary care referral (including both mental health and physical healthcare services)	Any other referral routes
Outcomes	Outcomes that occur between referral (any route) and the end of the initial one-to-one person-centred NHS Talking Therapies clinical assessment (see Table 1)	Outcomes occurring the end of the clinical assessment
Studies	Any study type including, but not limited to: • randomised controlled trial • real-world evidence (including quasi-experimental and observation studies and benchmarking against NHS Digital published metrics) • surveys • qualitative studies • evidence based reviews • letters and opinions identifying potential benefits or harms	No study type will be excluded if it provides relevant data
Time horizon	Time period between referral (any route) until the end of the NHS Talking Therapies assessment only	Time period following the end of the clinical assessment

2.3 Evidence review: data extraction strategy

Data will be extracted from included studies into data extraction tables by one reviewer and a minimum of 10% will be checked by a second reviewer. Discrepancies will be resolved by discussion, with the involvement of a third reviewer if necessary. Data points to be extracted include information about the evidence source (including study reference and design), the population and intervention/comparator characteristics, relevant outcomes and their measurement.

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2.4 Evidence review: quality assessment strategy

In line with NICE PMG39[3] (Early Value Assessment interim statement), a full critical appraisal of the identified evidence will not be conducted. However, strengths and weaknesses, and how any potential biases (e.g., how the studies are designed and conducted and how the data are collected and analysed) could affect the key outcomes, will be described. The generalisability of the results to NHS clinical practice will be considered.

2.5 Information provided by the companies

NICE sent the three included digital front door technology companies requests for information. At the time of writing, responses had been received from three of these companies (Limbic and Wysa). Following acceptance of the final protocol by NICE, the EAG (via NICE) will ask the companies to supply any additional evidence they wish to be included in this assessment. If the additional information supplied meet the review inclusion criteria, this information will be considered by the EAG. It may not be possible to include information received after 13 December 2024.

2.6 Gathering evidence from SCMs and other key stakeholders

It is anticipated that only a limited number of studies will be identified for inclusion in the literature review. Therefore, the EAG will contact Specialist Committee Members (SCMs) and other key stakeholders to:

- understand current referral pathways into NHS Talking Therapies (with and without digital front door technologies)
- explore the impact that the introduction of digital front door technologies has on resources required to complete the pre-assessment and assessment process
- estimate the costs associated with implementing and operating a digital front door technology
- identify quantitative and/or qualitative data relating to accuracy of information provided for the pre-assessment and clinical assessment
- describe the equality considerations associated with adopting digital front door technologies.

Questions will be sent via email to the SCMs and key stakeholders identified by NICE, with the option to participate in a follow-up interview via Zoom or MS Teams. SCMs and stakeholders will be asked to identify any colleagues with relevant expertise or experience who might also wish to provide share information.

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3 METHODS OF ANALYSIS AND SYNTHESIS

3.1 Evidence of benefits and costs identified

Data (from all relevant sources) describing benefits and costs will be tabulated and narratively synthesised. The generalisability of findings to NHS pre-assessment referral practice to NHS Talking Therapies will be considered. The EAG will identify important evidence gaps and help direct future data collection and further research.

3.2 Economic evidence identified

Economic data (from all relevant sources) will be tabulated and narratively synthesised. The generalisability of findings to NHS pre-assessment referral practice to NHS Talking Therapies will be considered. The EAG will identify important evidence gaps and help direct future data collection and further research. Any studies carried out from the UK NHS perspective and the Personal Social Services (PSS) perspective will be presented in detail.

3.2.1 Cost consequence analysis

The EAG will carry out a cost consequence analysis (CCA). The CCA will capture as many relevant **costs** as practically possible; these may include costs to the NHS, to patients and to others. The CCA will capture as many relevant **consequences** as practically possible; these may include broader health effects, non-health effects and non-patient effects.

The costs and consequences associated with NHS pre-assessment referral pathways to NHS Talking Therapies that include digital front door technologies will be compared with the costs and consequences associated with NHS pathways that **do not** include digital front door technologies. Costs and consequences will be reported in a simple, disaggregated format. Sensitivity analyses will be used to explore how sensitive cost estimates are to variations in healthcare utilisation patterns and unit cost assumptions. Nationally representative unit costs for each resource item will be identified from sources including NHS Cost Collection[4] and the Personal Social Services Research Unit (PSSRU).[5] If unavailable, estimates will be derived through consultation with SCMs and key stakeholders. If data are available, a budget impact assessment will be also be carried out.

3.2.2 Conceptual economic model

The EAG will identify the key cost and benefit parameters that will be needed to populate an economic model that could be used to assess the cost effectiveness of digital front door technologies. An outline structure of this model will be developed in alignment with NICE PMG39[3] (Early Value Assessment interim statement). Available data that could be used to populate such a model will be presented. Data gaps and suggested methods required to

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collect these data will be described. Once populated, this model will generate information that will help NICE decision makers assess the cost effectiveness of digital front door technologies for NHS Talking Therapies services.

3.3 Gap analysis

Identified evidence gaps relating to clinical and economic evidence will be summarised in tabular and narrative form. If appropriate, a 'traffic light' scheme will be used to highlight the relative importance of gaps. Key areas for evidence generation will be summarised in tabular form. Narrative text will also address missing clinical evidence, such as population, setting and comparators.

3.4 Other considerations

The NICE final scope refers to under-represented groups who access NHS Talking Therapies (from NHS Talking Therapies Manual v7,[1] Section 10.1). Where possible, evidence presented will consider the potential impacts of outcomes on under-represented and other groups.

4 COMPETING INTERESTS OF AUTHORS

None.

5 HANDLING CONFIDENTIAL INFORMATION

Any 'commercial in confidence' data provided and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided and specified as such will be highlighted in yellow and underlined in the assessment report. Any 'depersonalised data' provided and specified as such will be highlighted in purple and underlined.

If confidential data are included in the conceptual model, then a version of the conceptual model that is populated with dummy data, or publicly available data, in place of the confidential data will be provided.

6 MILESTONES

Milestone	Date to be completed
Submission of final protocol	28.11.2024
Submission of progress report	09.01.2025
Submission of draft Diagnostic Assessment Report	28.01.2025
Submission of final Diagnostic Assessment Report	11.02.2025

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8 APPENDICES

8.1 Appendix 1 Digital front door technologies included in this EVA

Summary information about the digital front door technologies sourced from NICE requests to the companies for information and NICE and EAG scoping searches is provided in Table 3.

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Table 3 Summary information about the digital front door technologies

Feature	AskFirst (Sensely)	Limbic Access (Limbic)	Wysa Digital Referral Assistant (Wysa)
Type of tool	Online consultation platform developed in partnership with the NHS	AI chatbot for conversational referral and clinical decision support	AI-supported e-triage tool (chatbot)
CE Mark	Information not found from scoping searches	Class IIa	Class I
NHS integration	Integrates with GP IT systems and 111 service providers	Interoperable with any cloud-based EHR system, meaning data can be immediately accessed from or imported into the record system	Transfers data to EHR to local NHS Talking Therapies; clinical contact is created directly within the EHR, where data fields exist
Description	• Triage function with symptom checking and routing to pathways like NHS Talking Therapies • Self-assessments including PHQ-9 and GAD-7	• Streamlines referral and triage process (e.g., triages mild, moderate, and severe cases of depression) • As a minimum, information is collected relating to: ○ Eligibility criteria ○ Contact details ○ Demographic information • Additional clinical information collected includes information about the patient's presenting symptoms (MDS), such as the PHQ-9, GAD-7, WSAS and a selection of additional screening questions • Generates a clinical report with presenting concerns, risk levels, clinical notes, assessment scores, disorder-specific measures and diagnoses predictors to aid clinician's assessment • Captures all activity in a dashboard with visibility into engagement, demographics, referrals, conversion rates, and staff hours saved	• Collects data based on questions from the referral form for NHS Talking Therapies services: ○ Referral: Demographic questions ○ Clinical: GAD-7, PHQ-9 and WSAS as default, along with all other MDS The referral questions are asked initially and if referral accepted, clinical are asked • Provides immediate alternative signposting to patients who are not eligible for an NHS Talking Therapies clinical assessment because they do not meet the age criteria or because their GP location is not within the services' catchment area • Cases flagged as too complex for NHS Talking Therapies, are recommended for secondary care • Provides report for clinician, with summary

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Feature	AskFirst (Sensely)	Limbic Access (Limbic)	Wysa Digital Referral Assistant (Wysa)
Risk flagging?	Information not found from scoping searches	Sends an alert to clinical staff so they can take appropriate action	Self-harm or domestic violence risk identified in free text using a combination of NLP techniques and rule-based matching to risk-related phrases
Online booking possible?	Yes	Yes	Yes
Other features which may be beyond what a digital front door should provide	Remote monitoring	Information not found from scoping searches	• Users engage with mindful exercises as the patient completes the eTriage • 24/7 conversational care including access to therapeutic self-help exercises, daily check-ins, and clinical outcome monitoring during waits, treatment and post discharge • AI-based app for people with mild to moderate depression and anxiety with a collection of CBT based self-help programmes that are designed to be used with practitioner or therapist support
Training for staff required	Information not found from scoping searches	Training is typically run as 3 x 1-hour sessions	Requires no more than 30 minutes of training for staff
Usage within NHS	Information not found from scoping searches	Used by ~40% NHS Talking Therapies services	Live in several NHS Talking Therapies Services including Dorset, Coventry and Warwickshire, and Lancashire and South Cumbria

AI=artificial intelligence; API=application programming interface; CBT=cognitive behavioural therapy; EHR=electronic health record; GAD-7=General Anxiety Disorder-7; EAG=External Assessment Group; GP=general practitioner; IT=information technology; MDS=minimum data set; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; NLP=natural language processing; PHQ-9=Patient Health Questionnaire-9; PTSD=post-traumatic stress disorder; RFI=requests for information; SPA=Single Point of Access; WSAS=Work and Social Adjustment Scale
Source: NICE scope, NICE scoping workshop, Wysa RFI responses (all unpublished sources provided to the EAG by NICE); company's digital front door technology websites;[6-9] Wysa online webinar;[10] Rollwage 2023[11]

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8.2 Appendix 2 Example MEDLINE search strategy

Example search strategy for Ovid MEDLINE(R) ALL

1	limbic.af. and (mental health* and (app or ai or artificial intelligence or chatbot* or etriag* or e triag* or talking therap*)).tw.
2	WYSA.af.
3	(((askfirst or ask first) and nhs) or ask nhs or mediktor or sensely or "sense.ly").af.
4	or/1-3
5	mental health*.tw.
6	IAPT.af.
7	(counselling or counseling or cbt or cognitive behavio?r therapy or psychotherap* or psychological therapy or psychological therapies or talking therapy or talking therapies).tw.
8	or/5-7
9	((triage or triaging or symptom checker*) and (app or apps or ai or "artificial intelligence" or chatbot* or chat bot* or digital or machine learning or online or electronic or technology)).tw.
10	(etriage or e triage or auto triage or autotriage or automated triage or smart triage or intelligent triage).tw.
11	digital front door*.tw.
12	or/9-11
13	8 and 12
14	4 or 13
15	limit 14 to english language
16	animals/ not humans/
17	15 not 16

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