

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Examples of Effectiveness and Economic Digital Health Case Studies

JOYCE CRAIG, Associate Project Director  
JUDITH SHORE, Research Consultant  
JOEL RUSSELL, Research Consultant

25 February 2019

**Project Name:** Evidence Standards Framework for Digital Health Technologies  
**Project Number:** RX195  
**Start Date:** 21 September 2018  
**Completion Date:** 25 January 2019

**Correspondence to:** Joyce A Craig  
York Health Economics Consortium (YHEC)  
Enterprise House  
Innovation Way  
University of York  
YORK  
YO10 5NQ  
Tel: +44 (0)1904 323620

**All reasonable precautions have been taken by YHEC to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall YHEC be liable for damages arising from its use.**

# Contents

<a href="#">Acknowledgments</a>	4
<a href="#">Introduction</a>	5
<a href="#">Evidence Effectiveness Case Studies</a>	6
Tier 1:	
<a href="#">MyPreOP</a>	7
<a href="#">S12 solutions</a>	8
Tier 2:	
<a href="#">ChatHealth</a>	9
<a href="#">Health and Care Videos</a>	10
<a href="#">Ieso Digital Health</a>	11
<a href="#">Myhomehelper</a>	12
<a href="#">Owise</a>	13
<a href="#">TIYGA</a>	14
<a href="#">Waitless</a>	15
Tier 3a:	
<a href="#">Drink Less</a>	16
<a href="#">HeLP-Diabetes</a>	17
Tier 3b:	
<a href="#">Ask NHS</a>	18
<a href="#">GDm-Health</a>	19
<a href="#">SEND</a>	20
<a href="#">Space from Depression</a>	21
<a href="#">Economic Evidence Case Studies</a>	22
Basic level:	
<a href="#">Coordinate My Care</a>	23
<a href="#">KiActiv Health</a>	24
<a href="#">Waitless</a>	25
Low financial commitment:	
<a href="#">Monitor</a>	26
High financial commitment:	
<a href="#">HeLP-Diabetes</a>	27

# Acknowledgements

The authors thank the developers of the digital health technologies featured in this report for their willingness to allow their technology to be used as an example of the type of current effectiveness and economic evidence which is required to meet the standards set in NICE's 'Evidence Standards Framework for Digital Health Technologies'. Their co-operation in the drafting process is also appreciated.

We also appreciate the input provided by the NICE Team in selecting and finalising these case studies.



# Introduction

In March 2019, the National Institute for Health and Care Excellence (NICE) published an [evidence standards framework for digital health technologies \(DHTs\)](#). The framework sets out standards for the evidence on effectiveness and on economic impact that should be available for DHTs to demonstrate their value in the UK health and care system. NICE has commissioned this report as one of a range of supporting resources to accompany the framework.

This document provides 15 case studies of the amount and type of evidence which is available for the assessment of effectiveness. The case studies were selected to illustrate most of the combinations of tiers of evidence and functional classifications as described in the NICE framework. In this report the studies are ordered from evidence Tier 1 to Tier 3b.

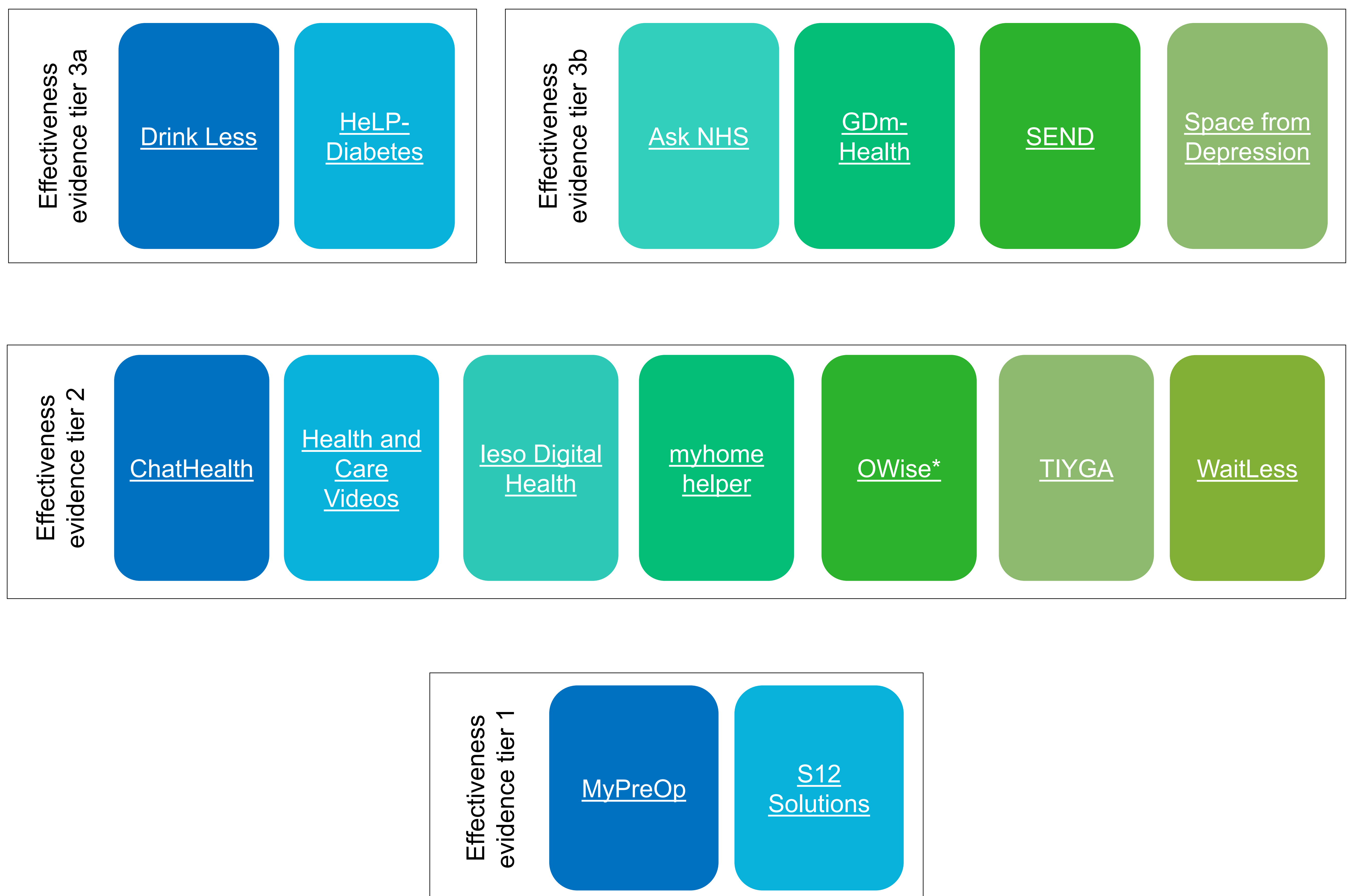
It also contains five economic case studies to demonstrate the type of evidence which is available to assess economic impact. The NICE framework defines three types of economic analyses levels and the examples are ordered from the basic, to low, then high financial commitment levels.

The case studies were selected following interviews conducted with a number of developers by York Health Economics Consortium (YHEC). Notes of the interviews were written up and, once agreed with the developers, shared with NICE. These informed the sample of DHTs selected for further work-up into case studies. The content of each of these case studies has been agreed with the relevant developer. **The following case studies are based largely on information provided by the developer which has not been independently verified.** They are intended to illustrate, using standards relevant to the individual DHT, the evidence available or in-development and therefore demonstrate how the NICE framework could be used in practice.

**The case studies are illustrative and do not represent an evaluation or endorsement of the DHT by YHEC or NICE. In addition, neither YHEC or NICE has assessed the technologies against other relevant standards for DHTs, such as security or information governance.**

# Effectiveness Evidence Case Studies

The case studies are listed according to the effectiveness evidence tier:



**\*OWise has been classified as Tier 3b if it is integrated with electronic patient records**



# Tier 1: Case Study with MyPreOp

Developers: Ultramed Ltd

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

**MyPreOp®** is a patient facing app designed to replace preoperative paper based assessments. Patients requiring an operation can create an account and complete a comprehensive assessment of their general health and medical history via MyPreOp®. Patients can complete the assessment at home prior to their operation. The output includes a clinical summary providing an American Society of Anesthesiologists (ASA) risk grade of 1 to 5 and recommends additional tests the patient may need. This information is then submitted to a nurse from the pre-operative team who reviews the summary and acts on any information provided. Any areas of concern or complex co-morbidities are automatically highlighted to the nurse.

The cloud hosted service can be accessed using a smartphone, tablet or home computer. To date, [more than 5000 patients have used MyPreOp® across 8 UK hospitals](#) (7 NHS hospitals and 1 private hospital).

Figure 1: Screenshot of MyPreOp®

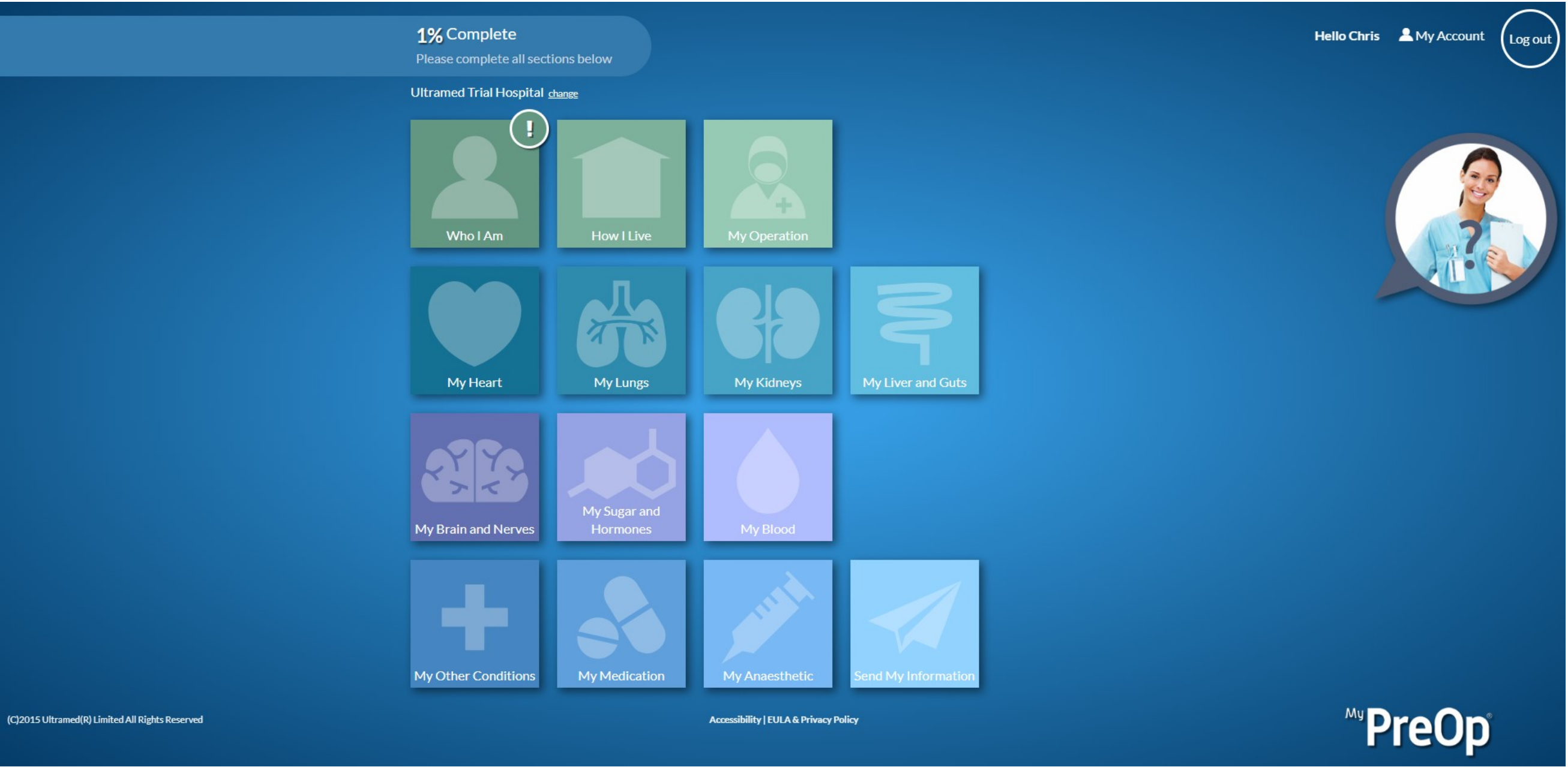


Table 1: MyPreOp® value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Patients can <a href="#">complete their preoperative assessment without a hospital appointment</a>, hence appointments may be freed up.</li><li>One-stop preoperative assessment is facilitated.</li><li>Staff resources can be spent on clinical decision making rather than information gathering allowing staff to process more assessments.</li><li>Information is held online so expenditure on producing and storing patient records and information leaflets may be reduced.</li><li><a href="#">ICD-10 codes for co-morbidities are automatically generated ensuring that hospitals receive expected income.</a></li></ul>	<ul style="list-style-type: none"><li>Authorised staff can <a href="#">access preoperative assessment information electronically</a>.</li><li>May reduce number of cancelled operations due to patients not fit for anaesthesia being identified earlier, enabling the theatre time to be reassigned.</li><li>The reporting capability gives an overview of activity levels of the pre-op service to improve service planning.</li><li><a href="#">Reduced administration time.</a></li><li><a href="#">Shorter appointment times at preoperative clinics</a> because patient has provided their information in advance.</li></ul>	<ul style="list-style-type: none"><li>Fewer appointments in hospital are required as some patients do not need to be seen face-to-face.</li><li>Patients can spend as much time as they need considering their answers to the preoperative assessment at home.</li><li>Web links are provided allowing patients to enhance their understanding around the questions that they are being asked related to their health.</li><li>Patient experience may improve as <a href="#">staff can focus their time on patients with complex needs or concerns.</a></li><li><a href="#">Service can act on patient feedback to improve it.</a></li></ul>

Figure 2: MyPreOp® classification

<b>Expected functional category:</b>	System services
<b>Evidence tier:</b>	Tier 1
<b>Additional Risks:</b>	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology

## CURRENT EVIDENCE

### Tier 1

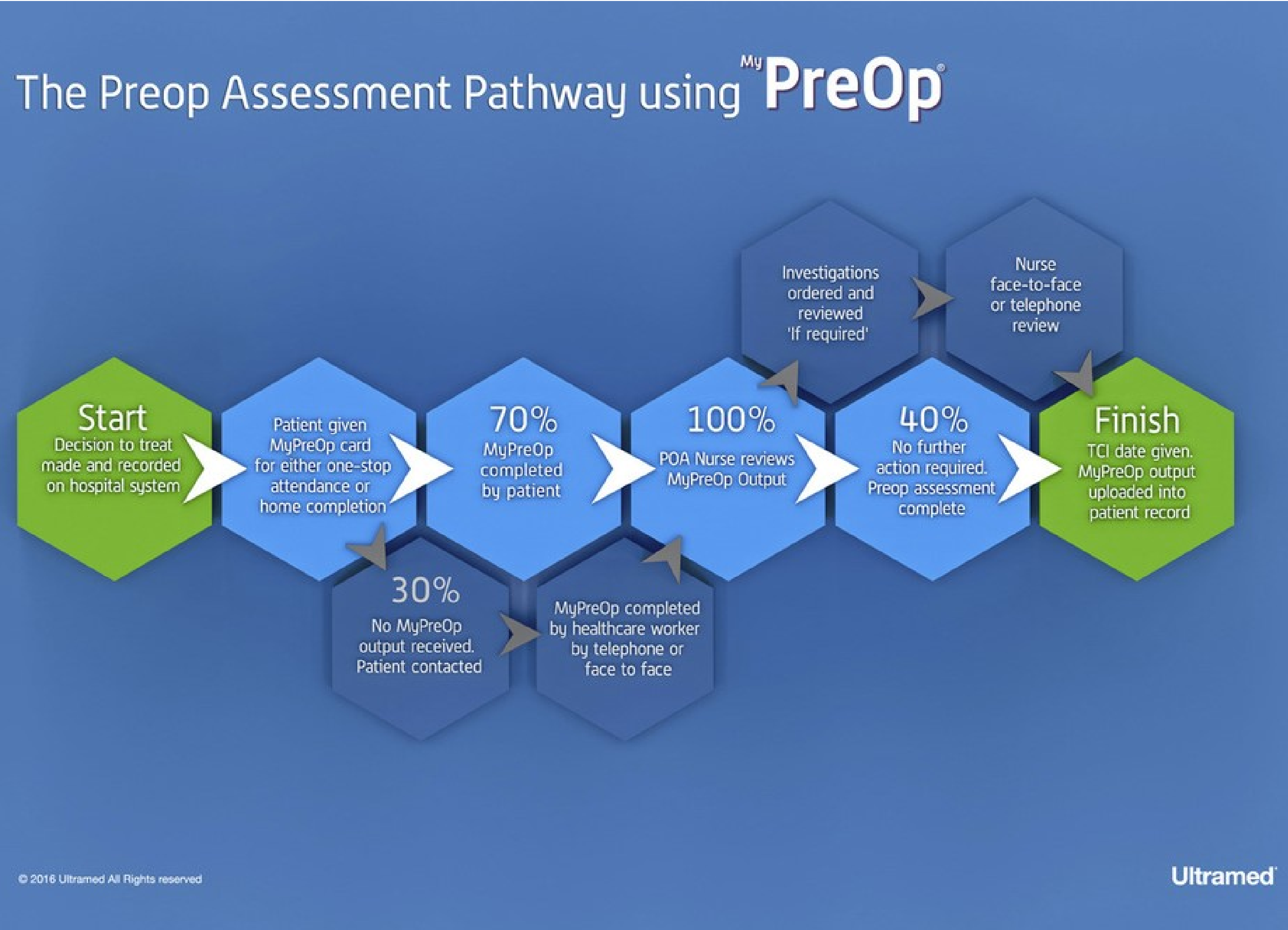
The company has submitted MyPreOp® for inclusion in the NHS apps library, is CE marked and is a registered MHRA class 1 medical device. A retired anaesthetist / medical director developed MyPreOp® by reviewing publicly preoperative questionnaires from multiple hospitals and taking the best aspects from each. Clinical psychologists were involved in developing the app to ensure that patients are asked clear and unambiguous questions. The app is in its 89<sup>th</sup> version, and undergoes continuous development. Its content is reported to be consistent with the [Guidelines from the Royal College of Anaesthetists](#).

MyPreOp® has undergone incremental improvements based upon feedback from patients and clinicians. Feedback from patients is sought using a short questionnaire after preoperative details are completed. The app has accessibility options in that visually-impaired users can select larger text or a choice of background colours. It may improve service access for people in rural areas.

In line with the current paper-based approach, the accuracy and reliability of the app is dependent on user responses. However, with the app conflicting data inputs are flagged to a nurse who reviews all outputs, and the provision of additional information via hyperlinks, may result in better informed and empowered users.

MyPreOp® is hosted on Microsoft Azure (UK server) and can therefore be scaled up to support use in large numbers of patients. [The NHS performs 10 million operations each year.](#)

Figure 3: The MyPreOp® assessment pathway



Please note: All references are provided as hyperlinks. To access these, 7 right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 1: Case Study with S12 Solutions

Developer: S12 Solutions Ltd.

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION OF THE DIGITAL HEALTH TECHNOLOGY

S12 Solutions is an app and website ('platform') that enables Approved Mental Health Professionals ('AMHPs') to use real-time information about doctor availability and location to efficiently assemble a Mental Health Act assessing team. This efficiency is designed to allow AMHPs more time to consider all options for service user care and treatment. By specifying their availability, location and specialisms, doctors can help to make sure that they are only contacted about convenient, appropriate work, while also supporting optimal service user care. The platform also facilitates the claim form process, and captures data about this area of practice, which is absent or collected inconsistently across the country at the moment. The S12 Solutions team checks doctor approval status against the national database every week. S12 Solutions has been adopted in two English health and social care systems, and a further four are preparing to implement the platform in 2019.

Figure 1: Benefits of S12 Solutions for Doctors

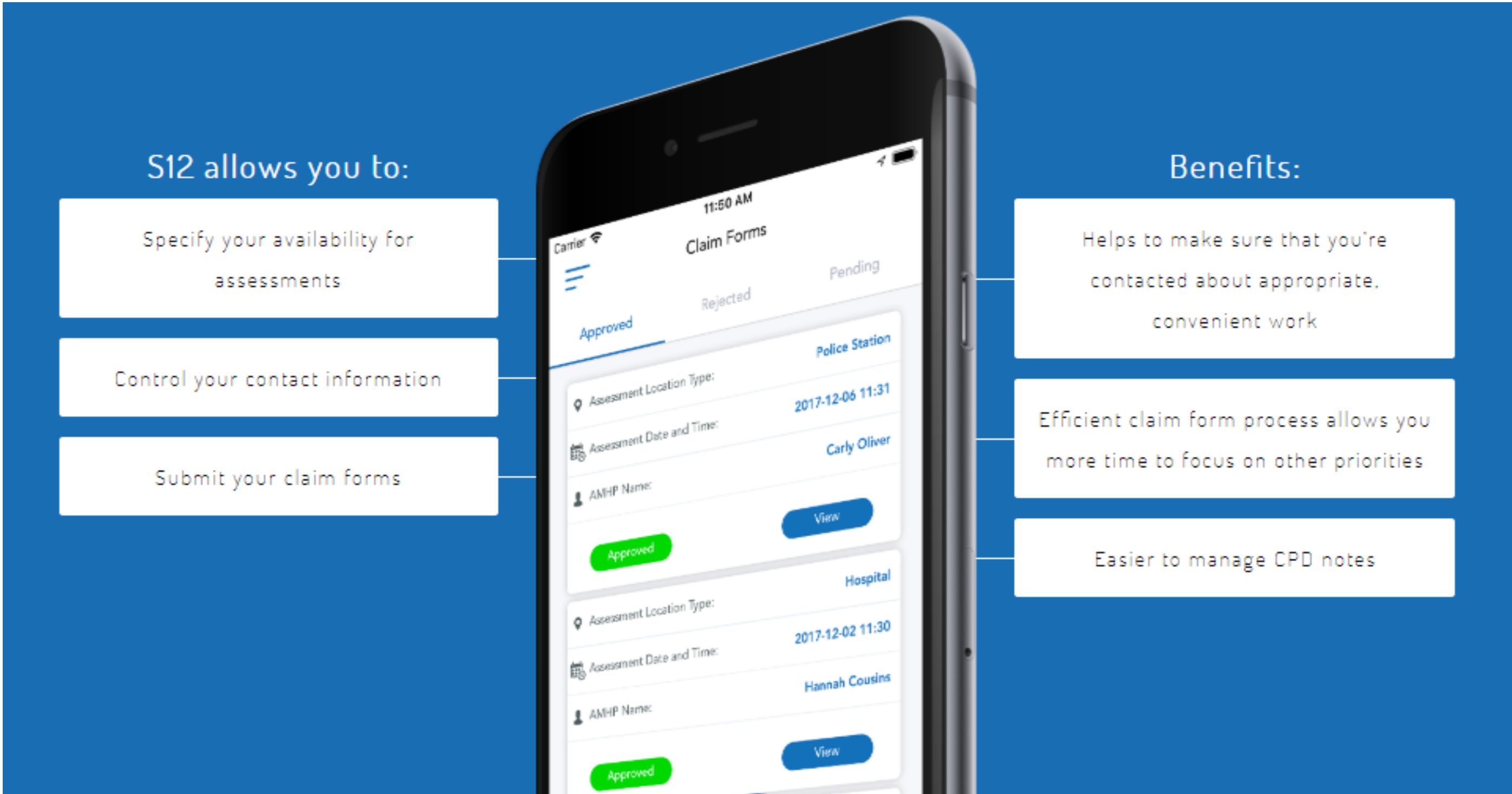


Figure 2: S12 Solutions Classification

Expected functional category:	System Services
Evidence tier:	Tier 1
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Table 1: S12 Solutions Value Proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>S12 Solutions is a platform that allows mental health professionals across England, Northern Ireland and Wales, to quickly and easily assemble Mental Health Act assessing teams, and create and submit claim forms, reducing delays and stress for people and services in this part of the crisis care pathway</li></ul>	<ul style="list-style-type: none"><li>Replaces a paper based system with a digital system, for improved organisation, transparency, communication and ease of use</li><li>Makes on-call arrangements more visible to AMHPs, and enables AMHPs to use one doctor instead of two where clinically appropriate, potentially generating cost savings</li><li>Service providers are more able to <a href="#">monitor and take action to mitigate shortfalls</a> in available s.12 doctors</li><li>Improves throughput at places of safety, where service users wait for assessment</li><li>Reduces strain on public services, such as the police, the ambulance service and A&amp;E departments</li><li>Improves efficiency for claim form administrators</li><li>Data capture can allow service providers to make evidence based decisions</li></ul>	<ul style="list-style-type: none"><li>Facilitates assessing teams that are best suited to the service user's needs</li><li>Reduces potential stress, and increased risk to the service user and community, caused by delayed assessments</li></ul>

## CURRENT EVIDENCE

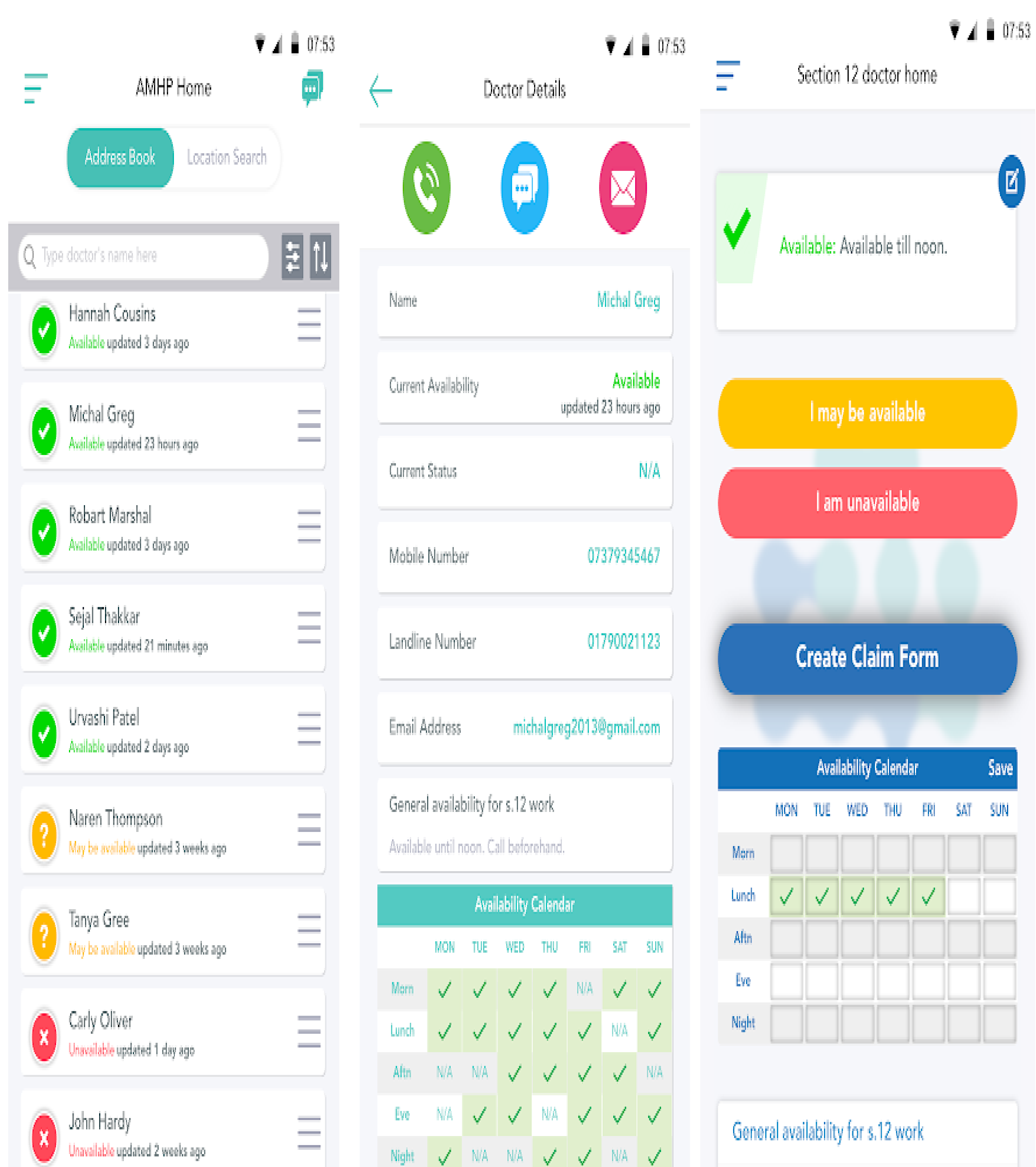
### Tier 1

UK clinical experts were involved in the design, development and testing of the S12 Solutions Minimum Viable Product ('MVP') and version 2 of the platform, which is due to launch in Spring 2019 and builds on the MVP's functionality. The platform has been piloted and commissioned across two health and social care systems. Users were surveyed at the beginning and end of the process to improve the service incrementally. Post-pilot analysis found that [assessments happened sooner than before](#), [more assessments occurred during the day as opposed to out of hours](#), and there was a [reduction in the number of assessments requiring two doctors](#) (where clinically appropriate).

The platform may help improve equity of access to appropriate care because the technology is designed to help people with mental health disorders to be assessed by doctors with the most relevant experience. By comparison, using the paper-based system, AMHPs may resort to cold calling doctors that are not matched as efficiently to the service user. Version 2 of the platform captures data to understand the duration of delays in the system, and the causes of these delays.

Only verified and approved users are given access to the platform. Administrators can be from Local Authorities, Clinical Commissioning Groups and Mental Health Trusts.

Figure 3: IOS Screenshots of the S12 Solutions MVP



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 2: Case Study with ChatHealth

## Developers: Leicestershire Partnership NHS Trust

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[ChatHealth](#) is a free, confidential text messaging service which enables direct contact between predominantly young people aged 11-19 years and healthcare professionals. The child or young person is able to send questions about a range of issues including bullying, self-harm, alcohol and drugs, sex, contraception and relationships and stress and anxiety via text messaging to their School Nursing Team. Normally, each user will receive a reply from a healthcare professional within one working day. The reply from the health care professional may include signposting to additional services that might be of help. Features built into the app include an automated response to acknowledge the text and an automated text if the service is closed suggesting other services. Users can also prevent the school nurse from sending messages their number. Specified people might be informed if there are [safety concerns](#) but usually the nurse would contact the user first.

ChatHealth is used by around 40% of school nursing teams, being available to approximately 1.5 million students. It recently expanded its client base and now serves 10% of health visiting teams in England. It is deployed in more than 30 community service providers. A list of service providers is listed [here](#).

NICE has published a [Medtech innovation briefing](#) on ChatHealth.

### Figure 2: ChatHealth classification

Expected functional category:	Tier 2
Evidence tier:	Communicate, higher
Rationale for higher vs. lower	Contextual questions identify that users of the DHT are in a potentially vulnerable group, hence this is a higher risk technology.

### Table 1: ChatHealth value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>More young people are using their phones in their daily life and so ChatHealth was introduced in order to facilitate a <a href="#">greater uptake</a> of healthcare services by young people.</li><li>The app is <a href="#">free and anonymous</a> and this should similarly promote a greater usage of healthcare services.</li><li>ChatHealth aims to provide <a href="#">timely and convenient advice</a> to those who need it.</li></ul>	<ul style="list-style-type: none"><li>Potential for a more effective allocation of resources as it could <a href="#">allow fewer nurses to serve more schools</a>.</li><li>Potential for a <a href="#">reduction in resource use</a> by answering enquires that were previously made via face-to-face appointments.</li><li>Potential for a <a href="#">decrease in disease burden</a> as a result of earlier intervention, however, there is no current evidence for this.</li></ul>	<ul style="list-style-type: none"><li>Allows young people to receive <a href="#">advice on sensitive issues</a>, if they are not comfortable discussing them face-to-face with a healthcare professional.</li><li>More young people may <a href="#">seek advice and care</a> through an anonymised service which has potential to improve their health.</li><li>ChatHealth can <a href="#">remove potential barriers</a> in the form of transport and geography.</li><li><a href="#">Supplements standard care</a> (face-to-face support from school nurses).</li></ul>

### CURRENT EVIDENCE

#### Tier 1

UK clinical experts were involved in the design, development and testing of ChatHealth. Given the potential vulnerabilities of the young people who might use ChatHealth, there was engagement with the police, National Society for the Prevention of Cruelty to Children (NSPCC), and the Royal College of Nursing. ChatHealth has been implemented successfully since 2014.

A [pilot](#) study of 4,500 service users from 3 colleges in Leicester ran from April 2013 for 12 months to test ChatHealth. This used a variety of methods including focus groups and questionnaires. Also the developer has used mystery shopper, service user satisfaction forms and video interviews to gather user feedback.

Constant gathering of real-time feedback is built into the app. The developer advises that, for example, a health visiting team gathered 1,200 pieces of feedback over 24 months, with 96% rating service at four/five stars. The 1% negative feedback was followed-up to inform service improvement.

ChatHealth can reduce unmet need, particularly where there are insufficient nurses to provide face-to-face care to all who could benefit from it. An Equality Impact Assessment framework was used throughout the development of ChatHealth to address students with protected characteristics. Moreover, text messaging has been shown to [increase access to services](#) in hard to reach groups such as young males.

#### Tier 2

Monthly reporting of number of contacts per month and user feedback is undertaken. Whilst this is not currently in the public domain it can be made available if necessary.

Quality and safeguarding is addressed by employing a qualified clinical lead on the product team, adopting super users to support teams, staff training, having a quality management and audit programme and convening a community of practice monthly. All data are encrypted and a single provider maintains the software to increase reliability.

### Figure 1: [Poster](#) promoting ChatHealth



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 2: Case Study with Health and Care Videos

**Developers:** Health and Care Innovations LLP [www.healthandcarevideos.com](http://www.healthandcarevideos.com) (Health and Care Videos is a trading name of Health and Care Innovations LLP and is a partnership between Torbay and South Devon NHS Foundation Trust and Rocklands Media Limited)

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

Health and Care Videos use video to provide information to patients, carers and staff in primary, secondary and the voluntary/care. Videos are commissioned by and developed with NHS clinicians to ensure the information provided is accurate and relevant. Trusts can create their own videos and scripts or use some of the 1,200 videos and edit them to ensure relevance to their trust and local area. Trusts and primary care organisations are also able to set up their own Health Information Video Library with hundreds of videos available to bolt on to their trust website.

Health and Care Videos is currently in use in over 30 NHS trusts and over 100 GP practices. There has also been wide adoption of inhaler technique videos by clinical commissioning groups (CCGs). Nearly 20,000 people view the videos each month and this number is increasing.

Figure 1: classification

Expected functional category: Inform	
Evidence tier:	Tier 2
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Table 1: Health and Care Videos value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Health and Care Videos aims to make it easy to share information with patients, carers and staff.</li><li>The videos complement existing methods such as websites, leaflets, appointment letters and consultations.</li><li>Videos can be used to explain anything from how to use medication or what to expect in a procedure, through to training staff on best practice or specific surgeries, therefore reducing burden on the health care system.</li><li>A low cost reliable method of digital information sharing.</li></ul>	<ul style="list-style-type: none"><li>Can be used to reduce the demand for healthcare resources such as nurse and clinician time</li><li>Has been shown to reduce consultation times and prevent the need for an appointment</li><li>Allows clinicians to focus on answering patient questions/concerns rather than explaining procedures/treatments</li><li>Reduces the need to use face-to-face sessions to repeatedly provide information to patients</li><li>Can be used to train staff in best practice procedures and provide information in a standardised way so everyone has access to the same training whilst also reducing the need for face to face sessions.</li></ul>	<ul style="list-style-type: none"><li>Patients are better informed and can easily access information on their condition/treatments/procedures</li><li>Can help to alleviate anxiety associated with receiving or accessing medical treatments</li><li>May allow patients to self-manage their conditions more effectively by providing information on best use of treatments/healthy lifestyles tips specific to their condition.</li></ul>

## CURRENT EVIDENCE

### Tier 1

Videos are [commissioned by, and developed](#) with, NHS clinicians and are reviewed by services on commissioning. The technology has been piloted and implemented in several trusts, CCGs and GP surgeries, and has been implemented in conjunction with service and quality improvement teams to gather feedback from patients and understand impact on demand for health care services. ‘Think aloud’ testing was used to ensure ease of use for users. The platform also includes user surveys and feedback forms to collect continual feedback from users.

Patient facing videos have English subtitles and other language subtitles are available as required. Foreign language voiceovers or sign language can also be added on request. [Videos](#) can contribute to health care organisations’ meeting NHS England’s Accessible Information Standard.

Figure 2: Video library



### Tier 2

The videos are hosted on a specially designed library in a way that is designed to be easy to set up and manage locally. The library allows simple categorisation by way of specialty/treatment pathway and facilitates data capture about usage.

The information content of a video is approved when commissioned by a new trust. Videos are also subject to review every 1 to 3 years dependent on the nature of their content, or more often in response to guidance updates from NICE or Royal Colleges to ensure accurate and reliable information is provided.

Usage and demographic data is captured through the platform and shared annually with trusts/CCGs and more often if required to show who is using the videos and how often they are played. Some of this data is also available [publicly](#) via blogs on the developer website. Audits and evaluations are undertaken with services to identify cost savings, capacity improvements and patient feedback. Hospital data can be used to demonstrate impact on, for example, appointment times before and after introduction of Health and Care Videos.

Figure 3: Video in use example





# Tier 2: Case Study with Ieso Digital Health

## Developers: Ieso Digital health

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[Ieso Digital Health](#) (Ieso) is an online service which delivers one to one, clinically-led cognitive behavioural therapy (CBT) sessions. The [British Association for Behavioural & Cognitive Psychotherapies](#) (BABCP) accredited therapists follow the [NHS IAPT framework](#). [The service is targeted](#) at people with common mental health conditions, such as depression, anxiety, phobias and stress. It can be accessed from any device with internet access, [and it is confidential and secure](#).

Ieso patients are matched with a therapist who initiates the contact and arranges the first appointment. [The appointments](#) are either 30 or 60 minutes long and can be scheduled at any time convenient to the user. Depending on the needs of the patient, it is expected that they will have between 4 and 12 therapy sessions. The therapy is provided through real-time, written conversations; which the [patient has access to](#) even after their sessions have ended. Ieso also adheres to [disorder-specific treatment protocols](#) to ensure patients experience the right CBT for their needs.

Ieso is currently working with 56 [CCGs](#) across England. The 56 CCGs comprise over 12 million patients over the age of 18 who could potentially receive care from Ieso. [From January 2018 to December 2018](#) Ieso received over 16,100 referrals, and over 9,200 patients attended therapy with Ieso therapists. Ieso also works with [children and young people](#) in Oxfordshire, Wiltshire, Buckinghamshire, Bath and North East Somerset and Swindon.

Table 1: Ieso Digital Health value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Ieso enables patients suffering from common mental health conditions – such as anxiety and depression - to <a href="#">access evidence-based treatments</a> at any time or location convenient to patients through any internet-enabled device.</li><li>Online therapy allows researchers <a href="#">to capture interactions and responses</a> between users and therapists. This permits researchers to explore the best patient personalised guidance in order to improve the therapists’ knowledge and to improve the patients’ rate of recovery.</li></ul>	<ul style="list-style-type: none"><li>Reduced <a href="#">waiting times</a> for therapy has likely implications of optimising outcomes and <a href="#">cost savings</a>.</li><li>Increased <a href="#">research</a> from the online platform allows continuous research into patient care. This can improve treatment and facilitate <a href="#">faster recovery rates</a>, reducing the burden on the NHS.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Confidential service</a> allows users to talk freely, for example by <a href="#">removing the pressures</a> of face to face appointments.</li><li>A convenient and flexible service should lead to increased <a href="#">access</a> to therapy, <a href="#">particularly for those</a> where access to treatment is scarce and travel to and from appointments are logistically challenging.</li><li><a href="#">A virtual location</a> allows the user to choose a time and location convenient to them. This meets demand for ‘out of office hours’ appointments and can also aide access to therapy for those with mobility or social anxiety issues.</li><li><a href="#">Increased recovery rates</a> for patients compared to other providers.</li></ul>

### CURRENT EVIDENCE

**Tier 1**  
UK clinical experts and patients were involved in the design, development and testing of Ieso. Ieso has been implemented successfully in several UK health and social care systems. Patient evaluation questionnaires are collected for every patient and metrics used across IAPT are also collected. User acceptance has been [demonstrated by engagement](#), which has been well adopted.

Ieso aims to help patients overcome geographical and social barriers to entry. For example, 37% of patients live in rural areas, and 25% of patients have co-morbidities so may prefer not to visit the GP or hospital repeatedly for help with their mental health as well as their other health conditions. The treatment allows patients to access care out of work hours which increases accessibility and flexibility to the patient.

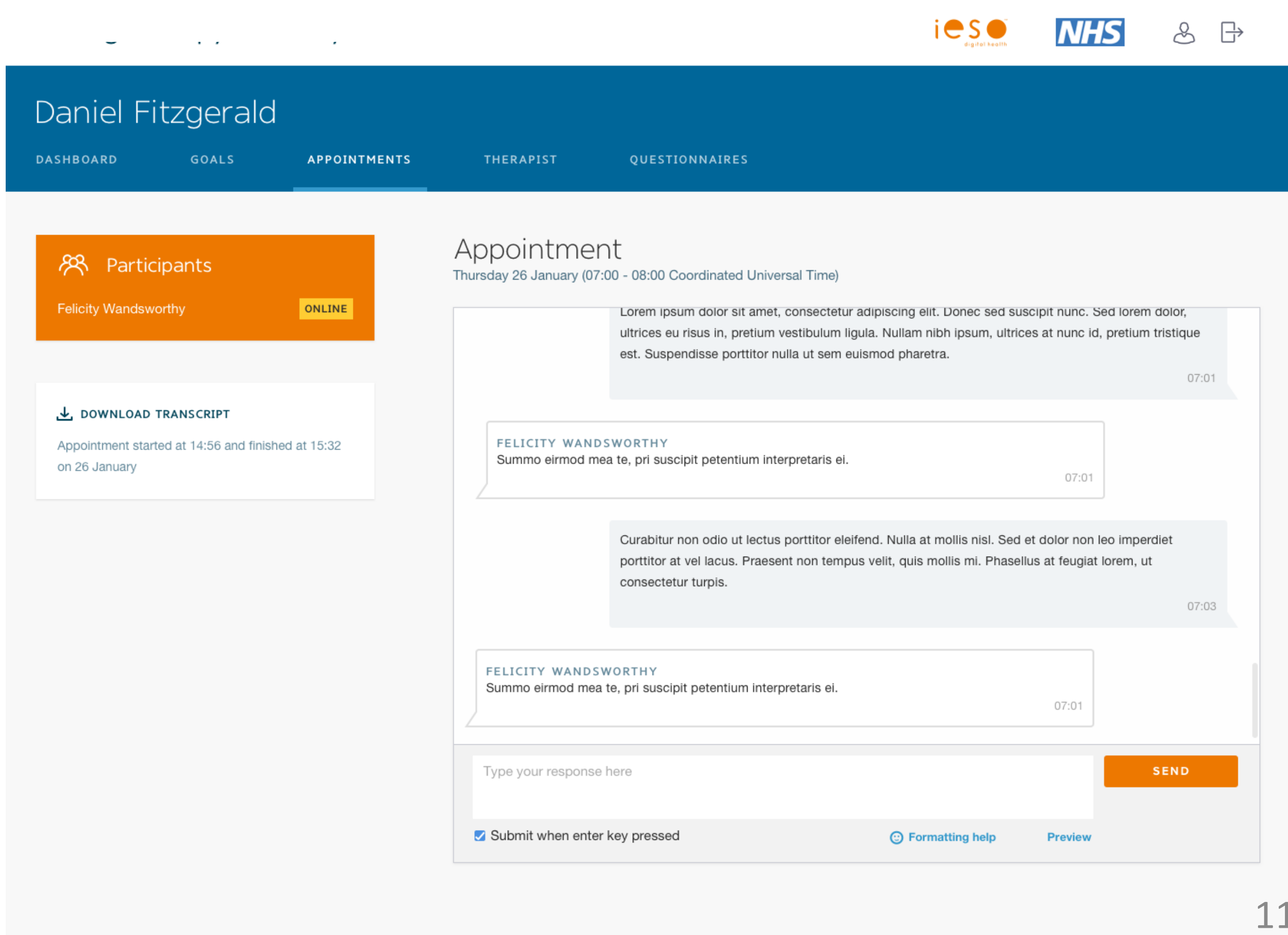
**Tier 2**  
All information is provided by [accredited therapists](#) and data usage is collected and reported to commissioners. The IAPT outcomes framework requires that Ieso report outcomes to NHS Clinical Commissioning Groups. Ieso supports communication with the therapist and all regulations, such as the [Caldicott Principles](#) are followed. There are clear risk escalation protocols in place.

In addition, a [randomised controlled trial](#), funded by the BUPA Foundation, was conducted where 297 patients were allocated to the intervention group compared to a waiting list control group of 148 patients who received usual GP care. The trial reported that at 4 months follow-up, CBT delivered online by a therapist [can be clinically effective](#), improving quality of life measures and functional health status.

Table 2: Ieso Digital Health classification

<b>Expected functional category:</b>	Communicate, higher.
<b>Evidence tier:</b>	Tier 2
<b>Additional Risks:</b>	Contextual questions identify that users of the DHT are in a potentially vulnerable group, hence this is a higher risk technology.

Figure 1: Screenshot of Ieso Digital Health



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 2: Case Study with myhomehelper

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

Developers: Simpla Solutions

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

myhomehelper is a tablet-based aid to independent living, typically used by people with conditions such as dementia, brain injury and learning difficulties. Features include reminders, diaries, news headlines, auto-answer video calling and instant messaging. Use of the technology is intended to reduce anxiety and isolation for the user, whilst providing peace of mind for family members and carers. No interaction is required from the user, as the technology can be set-up and managed by the primary carer or family via a secure web control panel which can be accessed from anywhere.

Purchase of the technology includes a specifically configured tablet, which comes pre-installed with the myhomehelper software, and accompanying tablet stand. Also included in the price is a 12-month warranty and online technical support service.

All current contracts are with councils or private companies. The majority of users (or most often, their families/ carers) purchase the technology directly.

Figure 1: [Screenshot of myhomehelper](#)



Table 1: myhomehelper value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Reduces the emotional burden felt by carers.</li><li>Increases independence in target population which reduces need for step increase in social care support and prevent or delay admission to residential care.</li></ul>	<ul style="list-style-type: none"><li>Could free up hospital beds and social care facilities, by enabling users to remain living independently in their own homes for longer.</li></ul>	<ul style="list-style-type: none"><li>Users gain independence and can have more control over their daily lives.</li><li>Reduced feelings of depression, anxiety and isolation.</li><li>Allows those who struggle with technology to keep in touch with loved ones.</li><li>Peace of mind for those in caregiving roles.</li></ul>

Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.

Figure 2: myhomehelper classification

Expected functional category:	Communications
Evidence tier:	Tier 2
Additional Risks:	The technology is used by vulnerable groups and for this reason it is higher risk.

## CURRENT EVIDENCE

### Tier 1

myhomehelper was, and continues to be developed through an iterative process of constant evaluation and feedback. The technology has been piloted twice by Barnsley Council in collaboration with the [Alzheimer's Society](#), with evaluation carried out by the [University of Sheffield](#). As well as Barnsley Council, Wrexham County Borough Council have had positive results from providing myhomehelper to their service users [\[4\]](#). myhomehelper has also been [successfully piloted in a community setting, by Sheffield NHS in 2013](#).

The tablet interface has been designed with user acceptability in mind, with colour and text size options for the visually impaired as well as a text-to-speech feature. The technology is scalable.

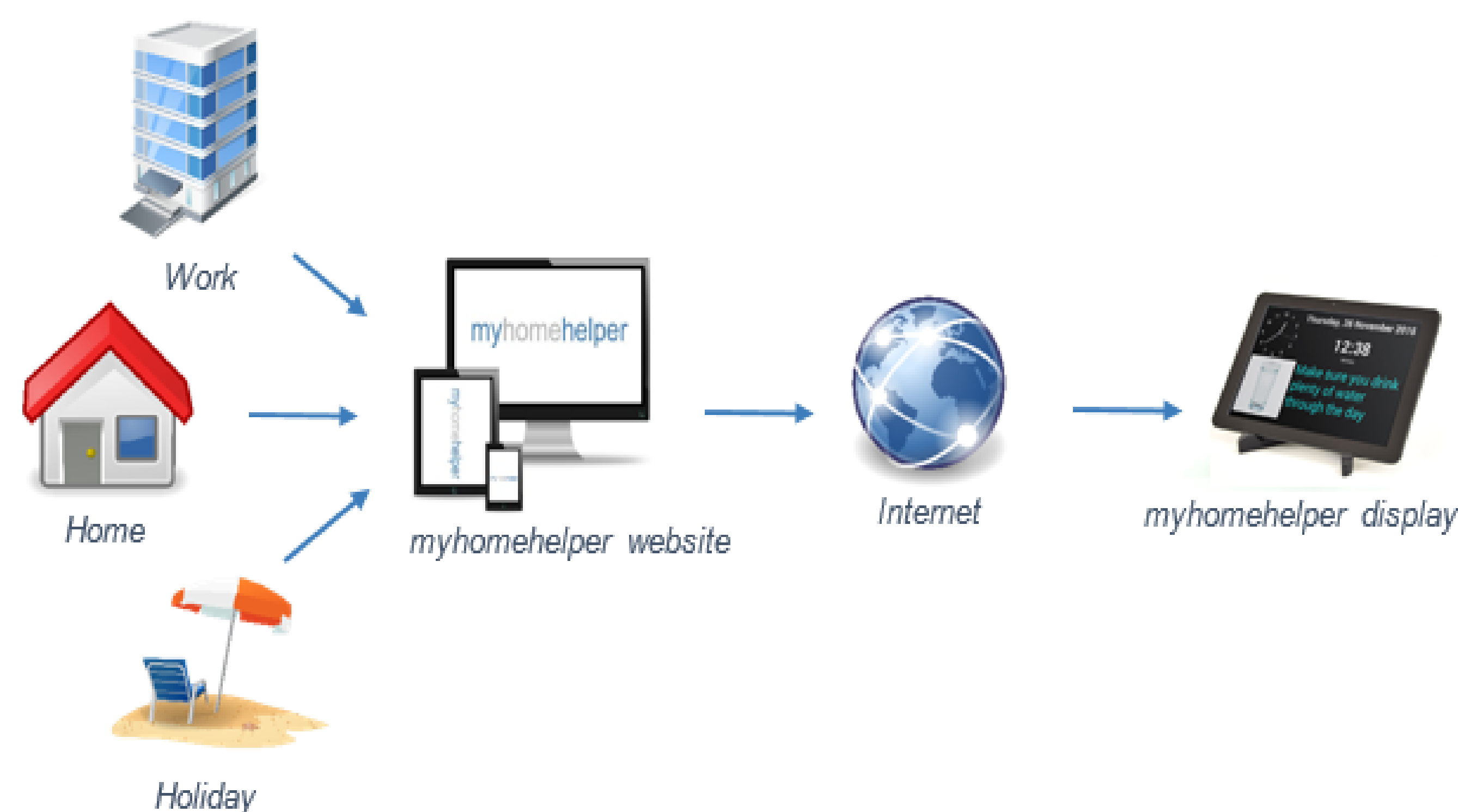
### Tier 2

Since all content is input by the carer/family of the user via the control panel, there are no issues with ensuring reliable information and advice.

Capturing changes in meaningful outcomes is problematic due to the heterogeneous populations who use myhomehelper. Evidence of benefit to the user is often anecdotal, e.g. family members noticing a significant reduction in anxious phone calls.

The currently accessible usage statistics include time of last update and the status of each device (online/offline). However, these records are only kept on the server for 36 hours. All information uploaded by family/carers or entered by user is stored, encrypted, both on the server and on the tablet. This data can only be unencrypted with specific software.

Figure 3: [The myhomehelper system pathway](#)





# Tier 2: Case Study with OWisE

## Developers: Px HealthCare

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[OWisE breast cancer](#) is a website and mobile app that allows people with breast cancer to access to a range of tools and useful information about their condition in one place. The app allows users to access their personal and treatment details wherever they are. Further, users can record how they feel, note down questions, keep a record of medical treatments and read information about treatment options within the app. [OWisE](#) is also designed to provide practical support with the aim of allowing people with breast cancer to have more control over their circumstance.

OWisE is included in the NHS apps library and is free to download. It is also part of the NHS Innovation Accelerator programme. The app is used broadly across the UK. In one area the OWisE patient self-reported outcome data are integrated into the electronic medical record held on TrakCare.

Figure 1: [Screenshot of OWisE](#)



Figure 2: [OWisE classification](#)

<b>Expected functional category:</b>	Inform (non-integrated version) Inform, Self-manage & Active Monitoring (integrated version)*.
<b>Evidence tier:</b>	Tier 2 (non-integrated version) Tier 3b (integrated with electronic patient record)*.
<b>Additional Risks:</b>	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

\*Functional category and evidence tier will depend upon the level of service commissioned

Table 1: [OWisE value proposition](#)

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Appointments may be shorter.</li><li>Calls to helplines may be reduced as a result of patients being less anxious about their condition.</li><li>The app can provide a record of signs and symptoms of adverse events, hence potentially allowing them to be spotted more quickly thus reducing their severity.</li><li>Recording symptoms can make it easier to tell whether a patient is well enough to receive chemotherapy doses, thus avoiding inappropriate treatment.</li></ul>	<ul style="list-style-type: none"><li>The recording function offered by the app allows <a href="#">patients to record conversations with clinicians without extended consultation time.</a></li><li>Patients and clinicians can share information.</li></ul>	<ul style="list-style-type: none"><li>Patients may be <a href="#">better informed and in greater control with easy access to all relevant information.</a></li><li>Allows patients to <a href="#">record their consultations with practitioners.</a></li><li>Allows patients to <a href="#">keep a record of their symptoms.</a></li><li>Quality of life may be improved via reductions in inappropriate chemotherapy and adverse events.</li></ul>

### CURRENT EVIDENCE

#### Tier 1

OWisE is published in the NHS apps library and meets the standards set out in the [NHS Digital DAQ tool](#). The app was first developed with people with breast cancer in the Netherlands and then underwent rigorous testing with 50 clinicians and 150 patients over a 6 month period. The app was tailored for use in the UK using clinical guidance and pathways as well as with input from UK clinical experts and patient organisations. The app is endorsed by several UK charities.

The app is an adjunct to current clinical pathways and is well accepted by users. This is monitored through workshops where positive and negative feedback influences changes to OWisE. The app has the potential to reduce inequalities. Studies by [Sprague et al.](#), [Albano et al.](#) and [Nicolson et al.](#) show people with better education tend to get better treatment, leading to better outcomes compared to those with a lower education attainment. Since the app is free to download, and all information is provided through the app, this should decrease inequality as equal access to information is provided. There are plans to introduce speech integration into the app to increase accessibility. Areas with poor digital infrastructure may prevent access for some users in those localities.

The app is scalable in that it has been rolled out across the UK and is established in the Netherlands.

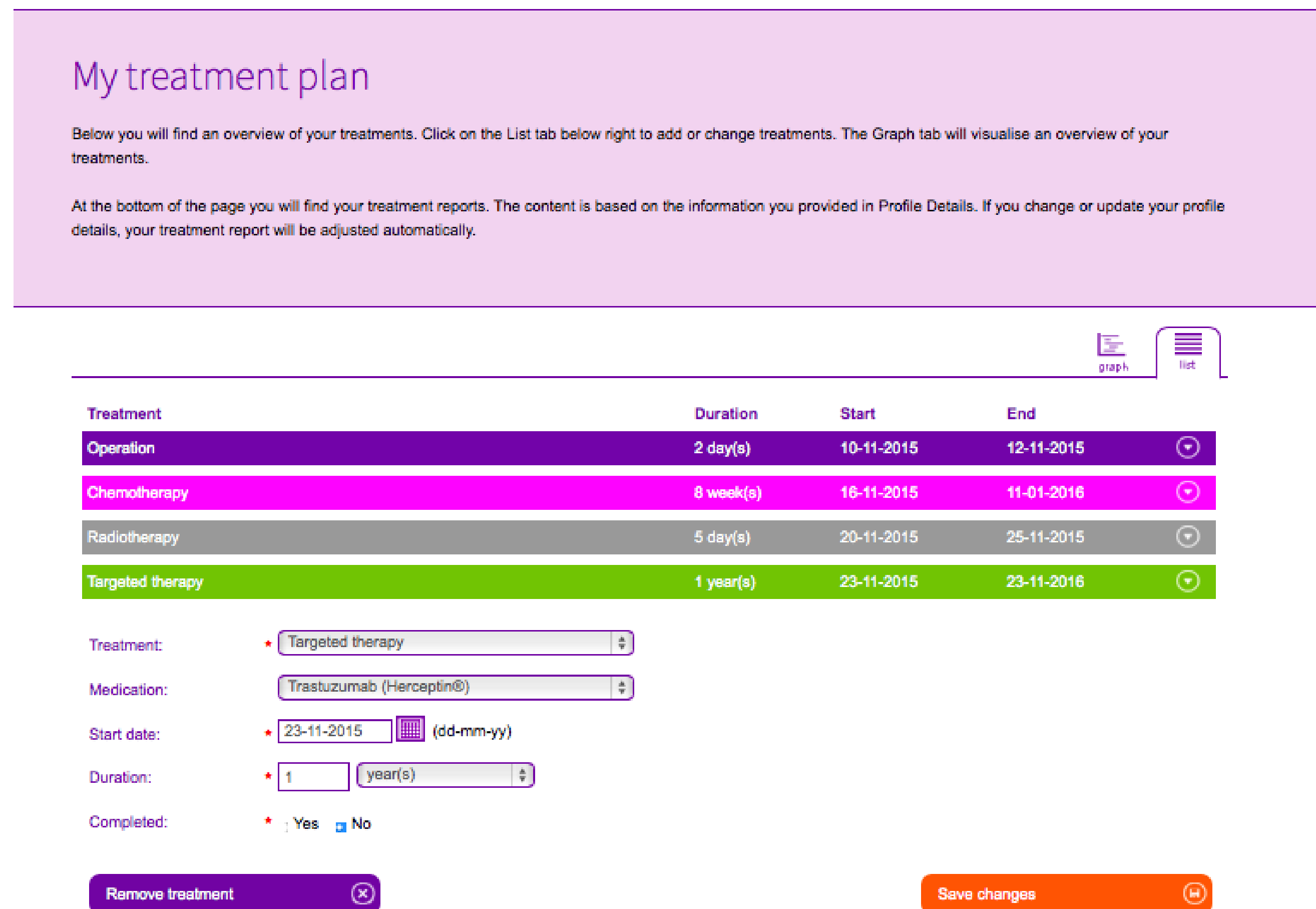
#### Tier 2

Information on breast cancer is provided via hyperlinks to relevant NHS pages and of established UK charities (e.g. Macmillan) and is therefore reliable. User information is provided through Google Analytics. On average, the OWisE is used for 3 months continually in the UK (same as treatment period). The app is used for 8 minutes on average per web-based session, and for 5 minutes on average per app-based session. The developer has no access to patient identifiable data which removes safeguarding concerns but means that the developer cannot report on individuals' changes in outcomes.

#### Tier 3b

A randomised controlled trial will soon be underway to estimate the effectiveness of OWisE and standard care versus standard care alone.

Figure 3: [OWisE treatment plan](#)



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 2: Case Study with TIYGA

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

Developer: TIYGA Health

## DESCRIPTION OF THE DIGITAL HEALTH TECHNOLOGY

TIYGA (Time is your greatest asset) is a DHT designed around the concept of efficiency of time, with multiple potential uses. The main functionality is a patient diary, which can be adapted and tailored to track useful information for many different health and lifestyle needs.

For example, TIYGA can be used on a daily basis for real-time recording of pain symptoms. Users can quickly and easily report symptoms as they occur. Clinicians can access data entered into the DHT and analyse any emerging patterns or trends, leading to more dynamic patient management. TIYGA can also assist with health care appointments, reducing recall bias because patients have a record of their symptoms and activities.

The developer foresees that TIYGA could be used across several NHS pathways, particularly in the management of chronic pain. TIYGA was developed to fit with the NHS Five Year Forward View, and its aims are aligned with those of the recently announced NHS 10 year plan.

TIYGA has been selected for use as an auditing/service evaluation tool by one NHS trust and the app is part of an approved commissioned weight management service in 2 Yorkshire Councils. The developer expects TIYGA to be commissioned in the NHS in 2019.

Figure 1: TIYGA Classification

Expected functional category:	Simple monitoring
Evidence tier:	Tier 2
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Figure 2: [Example screen](#) from TIYGA

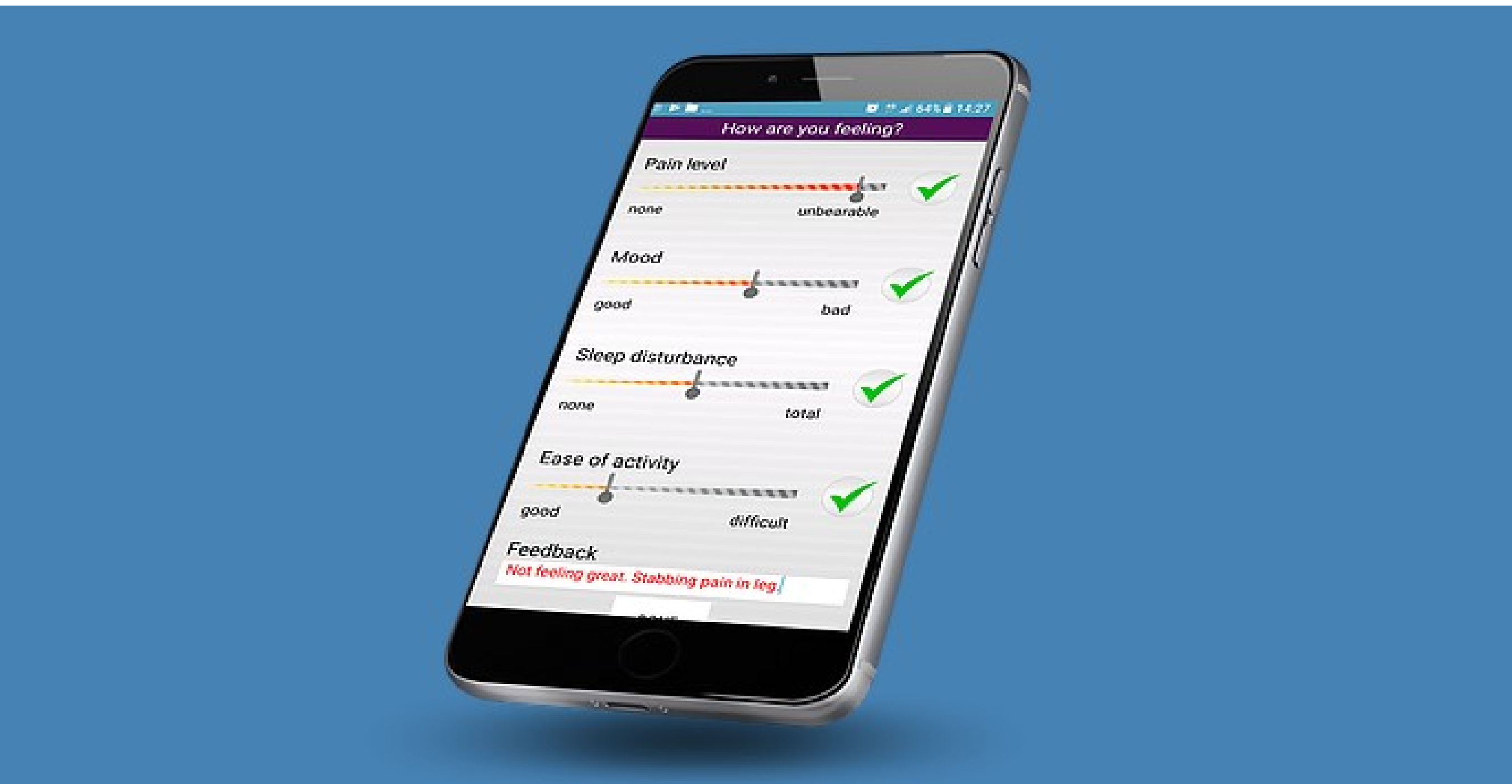


Figure 3: Diagram illustrating the role of TIYGA in doctor-patient interactions



## CURRENT EVIDENCE

### Tier 1

Members of the Northern Ireland Pain Society (NIPS) have trialed TIYGA with their patients and provided feedback to the developer on how the DHT might be used in clinical service. In addition, two UK health and social care professionals (a consultant and a dietitian) are involved in evaluating the technology, and the developer has informally engaged clinical experts to provide advice on acceptability to patients and clinicians.

Qualitative interviews exploring acceptability with users have been conducted by researchers at the University of Manchester. The results were presented as a poster at the NIHR MindTech Symposium in December 2018. Anecdotal feedback from users has been positive and recent studies have shown that around half of users continued using TIYGA after the 90 day research period.

TIYGA has potential to improve access to care for hard-to-reach populations. For example, use of TIYGA is intended in the management of chronic pain, a condition known to disproportionately affect people of lower socio-economic status. The developers also note that TIYGA could appeal to patients who are reluctant to discuss symptoms in detail face-to-face with their doctor and the developer plans to market TIYGA to users who are late adopters of DHTs or lack confidence with digital technology in general.

### Tier 2

Currently, TIYGA is designed for private communication so that the patient only has to tell their story once and that can be seen by a single clinician or, when required, and at the request of the patient, the multidisciplinary team who is treating them.

Clinicians/researchers are able to see when patients last used the DHT, therefore informing usage statistics. All TIYGA users are anonymised, so clinicians reviewing the data cannot see any individual characteristics beyond the information the user has chosen to log.

There are no concerns around reliability of information presented by the DHT. All data are input by the user and TIYGA does not offer any clinical advice.

Table 1: TIYGA Value Proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>TIYGA aims to provide a <a href="#">simple, private and quick platform</a> for patients to keep a diary of any details relevant to their health.</li><li>TIYGA empowers users to become <a href="#">more actively involved in managing their own health</a>.</li></ul>	<ul style="list-style-type: none"><li>TIYGA is designed to <a href="#">enable efficient and timely observation of patient data by clinicians</a>, which could lead to reductions in resource use.</li><li>There is potential for decrease in disease burden because patients can better self-manage their conditions.</li></ul>	<ul style="list-style-type: none"><li>TIYGA helps users to self-manage their condition and feel more in control.</li><li>Users can record symptoms and feelings as they occur, thus saving time and <a href="#">reducing the burden of recalling sequences of events at appointments</a>.</li></ul>



# Tier 2: Case Study with WaitLess

## Developers: Transforming systems.

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[WaitLess](#) is a free, patient-facing app aiming to reduce unnecessary waiting times for patients whilst also alleviating pressures on urgent care services by showing patients the fastest place to access urgent care for minor injuries. The app uses current waiting time feeds from minor injury units and accident and emergency (A&E) departments, drawn from the numerous NHS systems used by the different NHS providers. This is combined with up-to-date travel information using google mapping and geolocation to help patients make an informed decision about where to go to get the quickest treatment for minor injuries.

The service can be accessed using an iOS or Android app.

WaitLess was launched in December 2016. As of January 2018 there were [125,000 users](#) of the app. The app currently provides waiting time information at 8 facilities.

WaitLess has been selected as an NHS Innovation Accelerator fellow and a patient [case study is published](#) on the NHS Accelerator website.

Figure 1: WaitLess classification

Expected functional category: Inform	
Evidence tier:	Tier 2
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Table 1: WaitLess value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Since 2005, A&amp;E units have been struggling to cope with rising demand.</li><li>Many people attending A&amp;E self-present with minor injuries that can often be dealt with at <a href="#">Minor Injuries Unit or Urgent Care Centres</a>.</li><li>People could often be seen sooner by these services instead of waiting in A&amp;E.</li><li>Showing people these options should reduce their waiting times and also alleviate pressures on A&amp;E departments.</li></ul>	<ul style="list-style-type: none"><li>Alleviated pressure across the health care system, particularly in A&amp;E departments during peak times.</li></ul>	<ul style="list-style-type: none"><li>Reduced waiting times.</li><li>Faster care so fewer potential complications from minor injuries.</li><li>User information on the services offered by local Minor Injury Units and Medical Centres.</li><li>Information on health care provider's opening hours.</li><li><a href="#">Directions</a> from the person's location to the chosen health care provider.</li></ul>

Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.

### CURRENT EVIDENCE

#### Tier 1

UK clinical experts and patients were involved in the design, development and testing of WaitLess. WaitLess has been implemented successfully in a CCG since December 2016.

It has proven to be [highly acceptable](#) with users from the feedback gathered via email and comments on the app store. User groups are regularly convened to refine the functionality of the app. Although the app has improved access to healthcare it has been noted by the developers that this may not have reached those who could benefit from it most. Rather, the main users have been familiar with using apps.

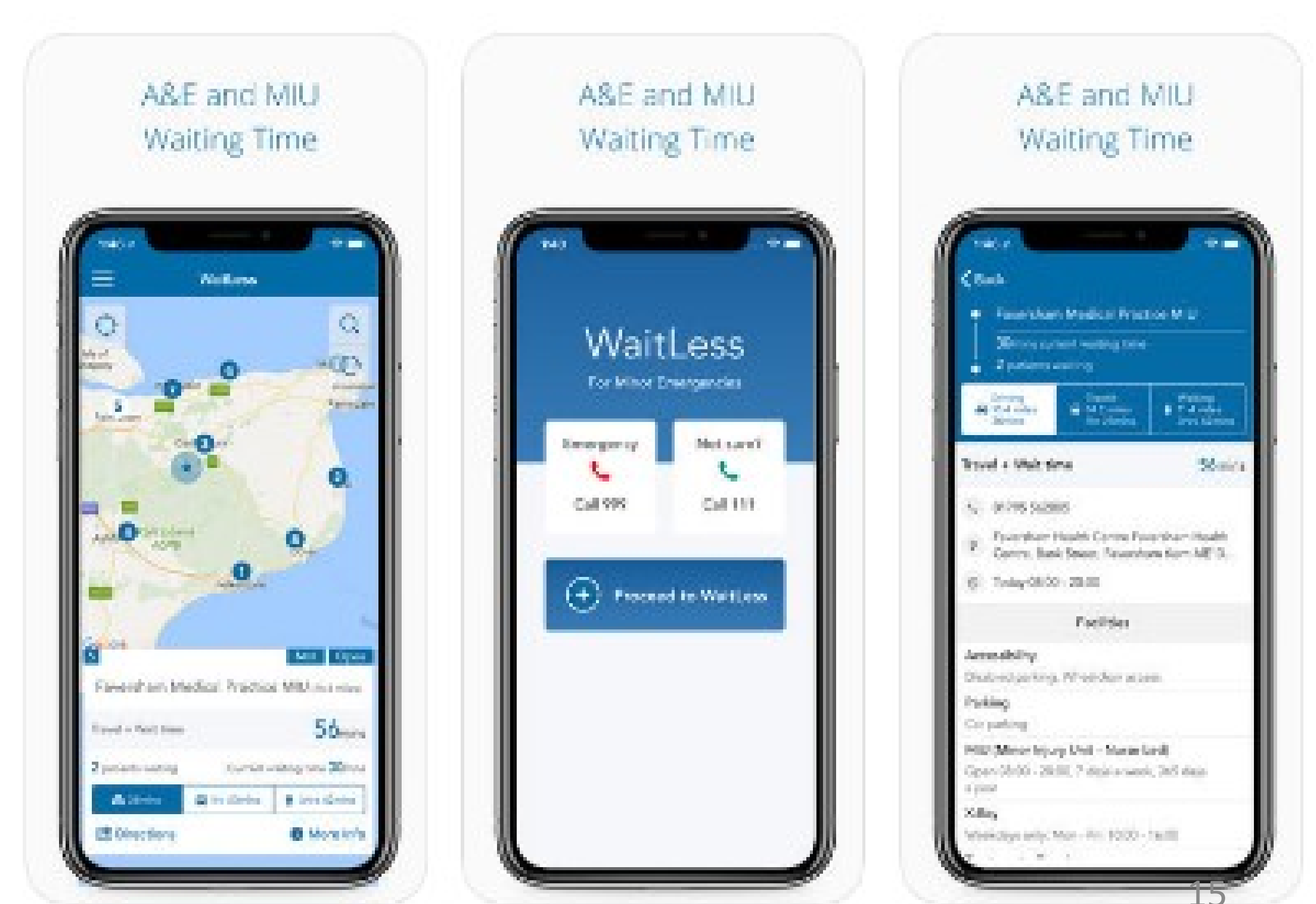
Waiting time data is taken directly from live feeds in A&E departments, urgent treatment centres and minor injuries units. Any technical problems faced are usually caused by facility-level problems, and not the app itself. To ensure these are accurate, developers and facility reception staff are made aware if a facility has not updated data for 45 minutes. If it is still not updated after an hour the facility is shown as closed on the app to ensure that the data is never more than one hour out of date.

#### Tier 2

To ensure information content in the app is reliable and reflects current practice, providers are requested to sign off on the quality of their data to ensure the data is robust and as accurate as possible before the app is released to the public app stores.

Data from the app is collected on an on-going basis. Pseudo-anonymised data is held by developers on activity and usage of the app, and usage statistics are reported online. In order to demonstrate the value of WaitLess in line with the value proposition, WaitLess collect data on A&E attendance profiles. This data and usage data were used to evaluate the impact of WaitLess, which was found to have a statistically significant benefit. The use of [WaitLess](#) was associated with an 11% reduction in minor injuries activity in A&E, specifically during the busiest times of day and a 5% reduction in minor injuries activity across all facilities.

Figure 2: Screenshot of WaitLess iOS





# Tier 3a: Case Study with Drink Less

Developers: University College London

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the particular digital healthcare technology.

## DESCRIPTION OF DIGITAL HEALTHCARE TECHNOLOGY

[Drink Less](#) is an app designed to help people reduce their alcohol consumption. Researchers at University College London developed the app on the basis of behavior change theory and multiple sources of evidence, which has been detailed in [publications](#). The app features a drinking diary whereby different types of alcoholic beverages can be recorded. It also includes a dashboard to show how drinking habits change over time, and techniques to help the user reduce alcohol consumption including goal setting, normative feedback, action planning and cognitive bias re-training. Anonymous data are collected from the app for use in scientific research and to improve the app. The app can be downloaded for free from the Apple App Store.

The app is used by people to change their behaviour and as a preventative tool. To date, it has not been evaluated within the health and social care system.

Figure 1: [Screenshots of Drink Less](#)



Figure 2: Drink Less classification

Expected functional category:	Preventative behaviour change
Evidence tier:	Tier 3a
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology

Table 1: Drink Less value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>The app has potential to reduce resource usage as a result of a reduction in short and long term alcohol related problems.</li><li>The app is downloaded directly by the user, with no cost to the user or the NHS, and so any later reduction in health and care resources will lead to cost savings.</li></ul>	<ul style="list-style-type: none"><li>A reduction in alcohol consumption may help to prevent short and long term alcohol related problems that result in usage of healthcare resources, such as <a href="#">accidents and injuries, heart disease, stroke and various types of cancer</a>.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Alcohol consumption can be logged easily</a>.</li><li>The app provides evidence-informed techniques to help with cutting down on alcohol.</li><li>Reduction in alcohol consumption have health benefits and may <a href="#">help improve mood</a>.</li></ul>

## CURRENT EVIDENCE

### Tier 1

Healthcare professionals were not involved in the original development because the intent was for the app to be a standalone intervention. The [current research project](#) to optimise the app includes three collaborators from Public Health England. The app has not yet been trialled in an NHS setting. However, discussions are underway with a Clinical Commissioning Group that may be interested in trialling the app as part of a nurse-led alcohol intervention.

Information on user testing, ongoing acceptability and user engagement is available in the public domain from four sources([1](#), [2](#), [3](#), [4](#)). Anonymised data continue to be collected from the app along with user feedback to improve the app on an ongoing basis. Within the usability studies, 50% of respondents were from disadvantaged backgrounds. This may have helped to produce an app that is [appealing to, and effective for, users from different socioeconomic groups](#).

### Tier 2

Drink Less provides reliable information content (e.g. via signposting to UK drinking guidelines) and relevant, up-to-date advice for further support. The app is constantly reviewed and updated. Anonymous usage data are collected and used both to improve the app and for research. These data are not currently published on an ongoing basis. Data collected on change in alcohol consumption and usability ratings as part of a factorial trial have been [published](#) and a secondary analysis of the factorial trial data on users' engagement with the app has also been [published](#). Over the summer in 2018, Drink Less experienced a spike in usage following a reference to it in a [BBC2 documentary](#). The developer is planning an analysis of the differences between this group of users compared with the previous user cohort (the analysis will not be framed as a trial).

### Tier 3a

A [factorial RCT](#) was conducted to assess the effectiveness of Drink Less. The factorial trial, guided by the Multiphase Optimization Strategy (MOST), allowed multiple intervention components and their interactions to be evaluated simultaneously, without requiring a large sample size (n=672). A full RCT is planned to compare the Drink Less app against a comparator to evaluate the effectiveness and cost-effectiveness of the app.

The approach taken to develop the app has been [published](#). This approach comprised a Delphi study with behaviour change experts to identify the components of the intervention and engagement strategies and a scoping literature review of behaviour change theories to identify factors associated with excessive alcohol consumption that could be targeted by intervention components in an app.

Please note: All references are provided as hyperlinks. To access these, <sup>16</sup> right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 3a: Case Study with HeLP-Diabetes

Developers: University College London

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[HeLP-Diabetes](#) (Healthy Living for People with Diabetes) is a web-based self-management programme designed to allow people with type 2 diabetes learn about their condition and provide support to them, both physically and emotionally. The website offers behavior change support tools on healthy eating, increasing physical activity, weight loss, smoking cessation, alcohol moderation and managing medication as well as tools to improve mood and manage the strong negative emotions associated with having diabetes. Users are able to send themselves reminders, the content and frequency of the reminders is decided on by the user. [Engagement](#) with the website is encouraged through regular email updates and newsletters.

The website is currently suspended as NHS England has taken over HeLP-Diabetes in order to roll it out across England.

Figure 1: HeLP-Diabetes classification

Expected functional category:	Self-manage, lower.
Evidence tier:	Tier 3a
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Table 1: HeLP-Diabetes value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Diabetes affects over <a href="#">3.1 million people</a> in England and accounts for <a href="#">10% of total</a> health resource expenditure</li><li>People with poorly-controlled diabetes have a higher risk of developing cardiovascular &amp; kidney disorders, neuropathy and blindness than others.</li><li>These problems are often <a href="#">preventable</a> if people self-manage their condition.</li><li>NHS provided educational programmes to encourage self-management have <a href="#">a low take-up</a>.</li><li>University College London has developed a web-based educational tool for people with type 2 diabetes to help them <a href="#">improve control</a>.</li></ul>	<ul style="list-style-type: none"><li>People who use the service should have <a href="#">better control</a>, <a href="#">reducing medication use</a>, <a href="#">disease complications</a>, <a href="#">health services use and costs</a>.</li><li>The intervention is low-cost and has been shown to be <a href="#">cost-saving</a>.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Access to education is enhanced</a> using the medium of the website which is an anonymised service which can appeal to some users.</li><li>RCT evidence shows HeLP-Diabetes can <a href="#">lower average blood glucose</a> (HbA1c) levels over 12 months.</li><li>There is evidence that HeLP-Diabetes <a href="#">reduces distress</a>, particularly when people are first diagnosed.</li></ul>

## CURRENT EVIDENCE

**Tier 1**  
The website was developed using participatory design principles involving UK clinical experts and users in the design, development and testing of HeLP-Diabetes. HeLP-Diabetes has been implemented successfully in several UK health and social care systems. There was extensive user [testing](#) with health care professionals and patients. Development followed [best practice](#) for ensuring accessibility to people with low literacy / health literacy skills, including extensive use of video and personal stories, and following national guidelines to ensure the text was suitable for those with poor vision.

Data shows around half of usage is outside of working hours, demonstrating the potential increase in access to information and support for those working full time, who might not otherwise receive educational support.

**Tier 2**  
The content is reported to align with NICE guidelines and is regularly reviewed and updated. Data were collected to show usage of HeLP-Diabetes when it was implemented across Clinical Commissioning Groups. As the website supports self-management it was difficult to routinely collect data to demonstrate the value of HeLP-Diabetes. Hence a randomised controlled trial (RCT) was conducted.

**Tier 3**  
In 2014-16, an [RCT](#) (n = 374) was undertaken in primary care, comparing HeLP-Diabetes to a simple information website. The co-primary outcomes were diabetes control [as measured by glycated haemoglobin (HbA1c) levels] and diabetes-related distress [as measured by the Problem Areas in Diabetes (PAID) scale]. A health economic analysis was included. The RCT reported some positive patient outcomes, it was also cost-saving and more effective than the control (simple information website). Limitations included that at baseline the participants had better control of diabetes and less distress compared to the general type 2 diabetic population. In a distressed population, [a single-arm, pre-post study](#) demonstrated a reduction in distress amongst users. An implementation study has been published which reported that the HeLP-Diabetes programme could be [successfully implemented](#) in primary care and used by a [wide demographic](#).

Figure 2: Screenshot of HeLP-Diabetes



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 3b: Case Study with Ask NHS

## Developers: Sensely

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[Ask NHS](#) is an all-in-one integrated platform for accessing local NHS services which launched in the UK in 2016. The app provides advice for urgent, but non-life threatening, emergencies and routes patients to the correct care pathway (via virtual health assistant “Olivia”). Further, the app provides self-care (via NHS website advice), appointment booking services and the opening times and locations of local healthcare services. Finally, remote monitoring of common, high cost conditions allows clinicians to remotely monitor a person’s health, well-being and environment around the clock via notifications provided by the app (monitoring module). Ask NHS is integrated with NHS systems such as EMIS and 111 service providers. It is compliant with cyber security and safeguarding.

Ask NHS is currently used by around 185,000 users within the NHS. This includes GP practices using the app for primary care online consultations and one Trust is using it to monitor patients with early onset dementia. Ask NHS is the preferred digital access point for a region with a population of 4.5 million to support 111 demand.

Figure 1: The [services](#) provided by Ask NHS

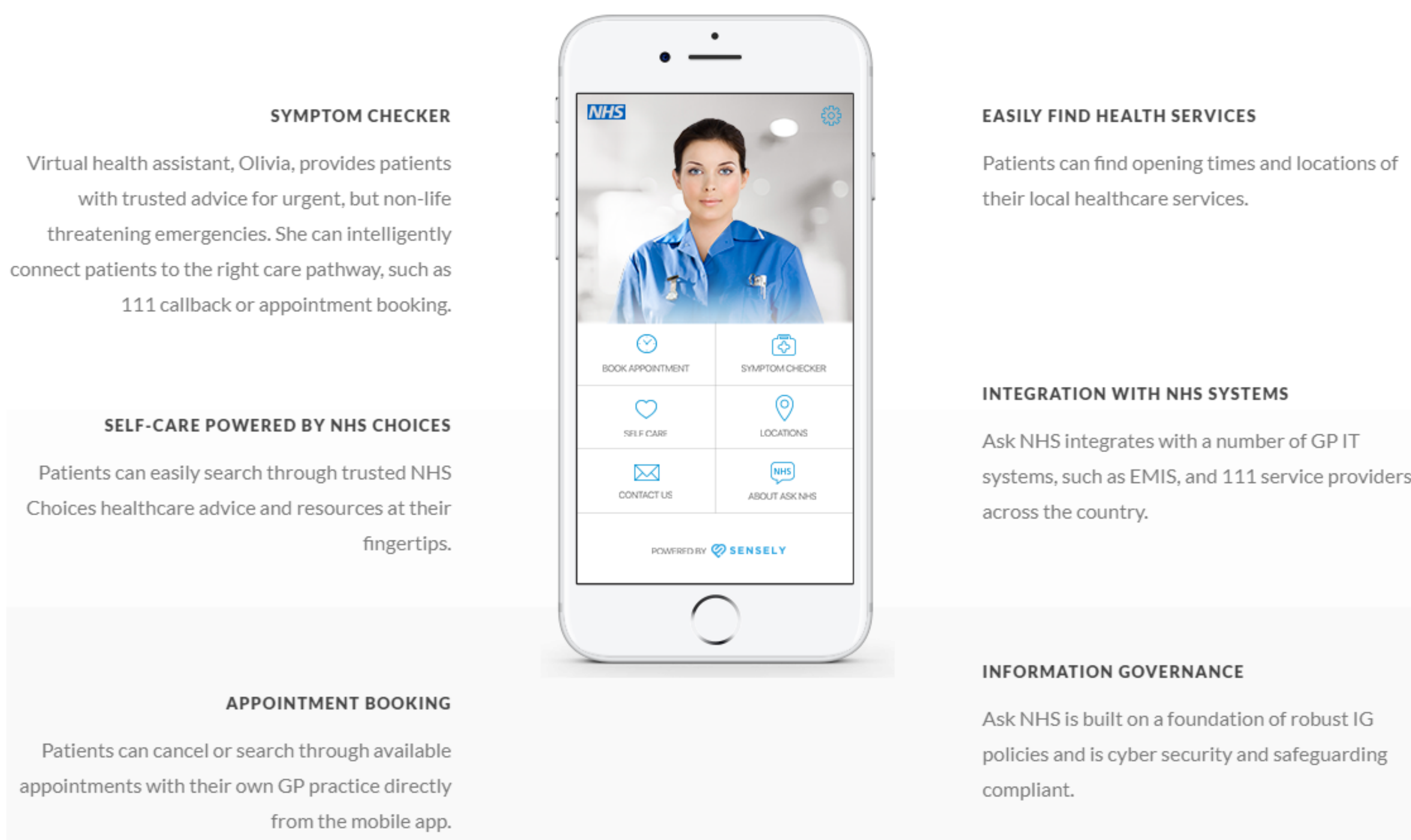


Table 1: Ask NHS value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Informing people about the correct clinical pathway for their condition will allow them to be seen by the most relevant service, potentially freeing up unnecessary health care visits.</li><li><a href="#">Digital interactions may help to reduce demand on NHS 111.</a></li></ul>	<ul style="list-style-type: none"><li>The information provided on Ask NHS may allow for more people to self-care or seek appropriate clinical care reducing unnecessary health care visits.</li><li>Monitoring allows clinicians to intervene, where required, before the user is in a state of emergency or before their condition deteriorates.</li></ul>	<ul style="list-style-type: none"><li>Monitoring allows clinicians to step in and offer support where required.</li><li>Users have access to information and local services in one place.</li><li>Users are informed about the correct care pathway for their current condition.</li></ul>

Figure 2: Ask NHS classification

<b>Expected functional category:</b> Active monitoring	
<b>Evidence tier:</b>	Tier 3b
<b>Additional Risks:</b>	Contextual questions identify that users of the DHT are in a potentially vulnerable group, hence this is a higher risk technology.

### CURRENT EVIDENCE

#### Tier 1

UK clinical experts and users were involved in the design, development and testing of Ask NHS. Feedback from clinicians and users informed iterative updates of the app and such feedback loops are ongoing. Ask NHS contributes to challenging health inequalities and promoting equity in people who may, or may not, be hard to reach. Technical evidence is collected about the app to demonstrate that numerical, text, audio, image-based, graphic-based or video information are not changed during transmission.

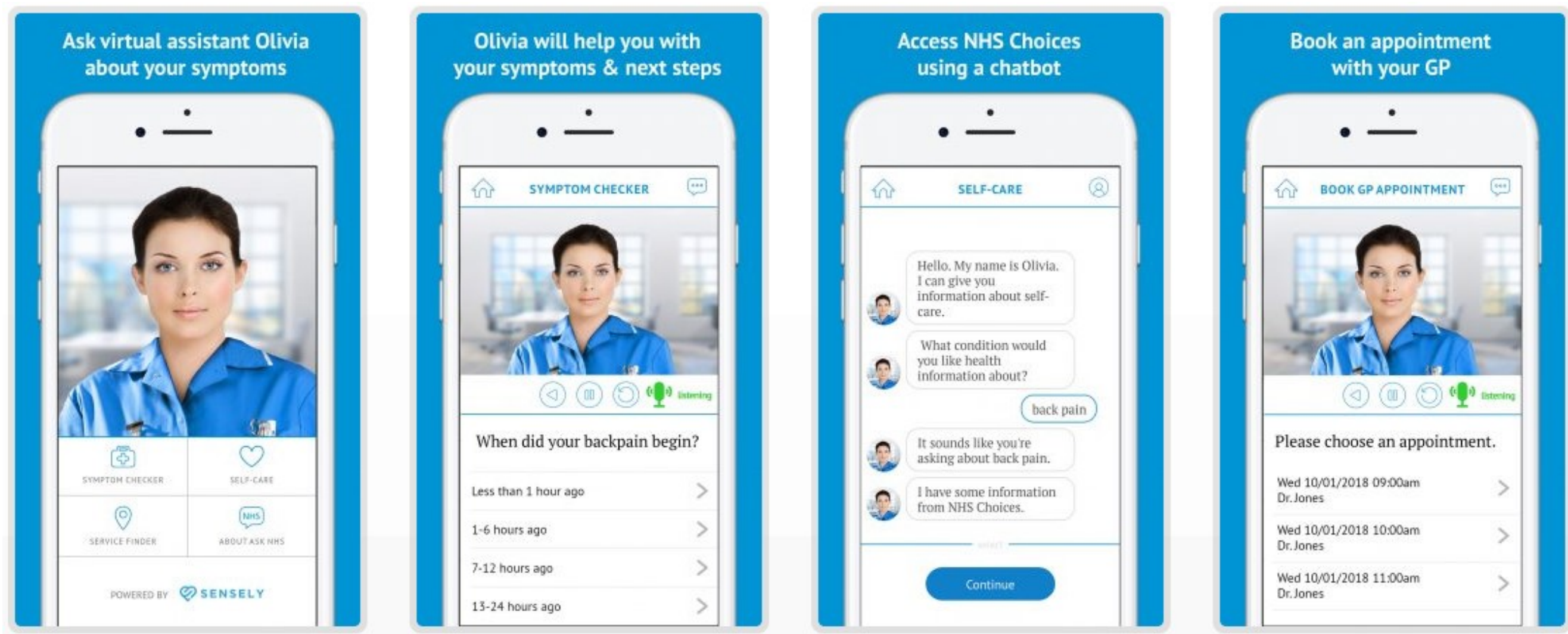
#### Tier 2

Reliable information content is provided by Ask NHS as it links to the NHS website and its clinical content has been accredited by NICE. Ongoing data collection on the use of the app takes place and is shared with local commissioners. A [case study regarding performance](#) is available in the public domain. Sensely (the app developer) is focused on demonstrating value for money with Ask NHS and works with clinical commissioning groups to prepare business cases. Some such [value propositions are in the public domain](#). Further, the company undertakes audits to ensure that quality standards are met and monitors outcomes in an attempt to compare these to what a user would have done without the app.

#### Tier 3

A [randomised controlled trial](#) is underway for monitoring of people with dementia using technology integrated health management via Ask NHS. This study began in Autumn 2016.

Figure 3: [Screenshot](#) of Ask NHS



Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 3b: Case Study with GDm-Health™

Developers: Sensyne Health plc.

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[GDm-Health](#) is a medical device which is free to download for the management of gestational diabetes at home. The app was launched by Sensyne Health plc. in August 2018 and enables monitoring, management and communication between pregnant women with gestational diabetes mellitus and health care providers.

[GDm-Health](#) is a Class 1 CE marked medical device for women with gestational diabetes that allows accurate self-recording of blood glucose measurements, which are then automatically uploaded to a secure server. Health care professionals access these measurements via a secure interface with alerts for prioritisation. A simple interface allows 2-way communication between women and health care professionals; information on the condition and advice on exercise and diet are also provided.

[GDm-Health](#) is currently used in 7 NHS Trusts with an anticipated wider roll-out. Data from the University of Oxford's prototype has been extensively evaluated. There have been multiple publications, oral presentations and posters published on GDm-Health, an exhaustive list can be found at <https://www.sensynehealth.com/gdm>. NICE has also published a [MedTech innovation briefing](#) on the technology. The briefing noted that GDm-Health may result in efficiency savings from reducing face-to-face clinic appointments.

Figure 2: GDm-Health classification

Expected functional category:	Active Monitoring.
Evidence tier:	Tier 3b
Additional Risks:	Contextual questions do not reveal any factors of high risk and hence this is a lower risk technology.

Table 1: GDm-Health value proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>GDm-Health has been specifically designed for the management of gestational diabetes, and can also be used by women with pre-existing diabetes.</li><li>GDm-Health <a href="#">provides patient data</a> in a user friendly format, facilitating the decision-making and communication between health care professionals and women.</li><li>The app was created as a direct response to manage the increasing workload arising from an increase in the incidence of gestational diabetes.</li><li>GDm-Health was designed by clinicians to be faster and more efficient than standard care, which is delivered predominantly through face-to-face appointments.</li></ul>	<ul style="list-style-type: none"><li>Allows clinicians a broad oversight of their patients.</li><li>Allows clinicians to see, at a glance, near real-time BG readings and then prioritise patients most in need.</li><li>It should allow efficiency savings as a result of the reduction in face-to-face appointments.</li><li>GDm-Health <a href="#">improves efficiency</a> by increasing the communication between healthcare professionals and patients.</li><li>Team-based care is also enhanced through communication between healthcare professionals on the patient's GDM tailored digital record.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Improves communication</a> between women and their diabetes care team which can lead to higher patient satisfaction.</li><li>A trial reported a <a href="#">significant reduction in caesarean sections</a> for women using the GDm-Health app compared to standard care.</li><li>Reduces the need for women to attend face-to-face appointments saving time and money for patients.</li><li>Enables women to observe effects of diet and medication adjustments as they occur allowing for better self-management.</li></ul>

Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.

## CURRENT EVIDENCE

### Tier 1

UK clinical experts were involved in the design, development and testing of GDm-Health. GDm-Health has been [successfully piloted](#) in the UK health and social care systems. GDm-Health has also been [clinically evaluated in over 1,000 patients](#). User satisfaction was measured throughout the development of the app and continues using a validated questionnaire sent out to users. [Mackillop et al](#) (2014) and [Hirst et al](#) (2015) both reported high degrees of patient compliance and satisfaction. GDm-Health facilitates the improved care of pregnant women. Pregnancy is a protected characteristic under the 2010 Equalities Act. In addition, smartphones can be supplied to pregnant women with no current access to them. Inequalities are also addressed by allocating longer times in clinics to vulnerable women who do not use the app.

Accuracy of measurements relies partly on the blood glucose monitor being used. The app uses limited graphics and is predominantly text-based to ensure data is transmitted accurately.

### Tier 2

When a patient logs in to the app they are provided with [information](#) on diet, exercise, weight management and the Glycemic Index. This information is linked to the NHS website to facilitate reference to the most up-to-date guidance. Usage information and monitoring are continuous.

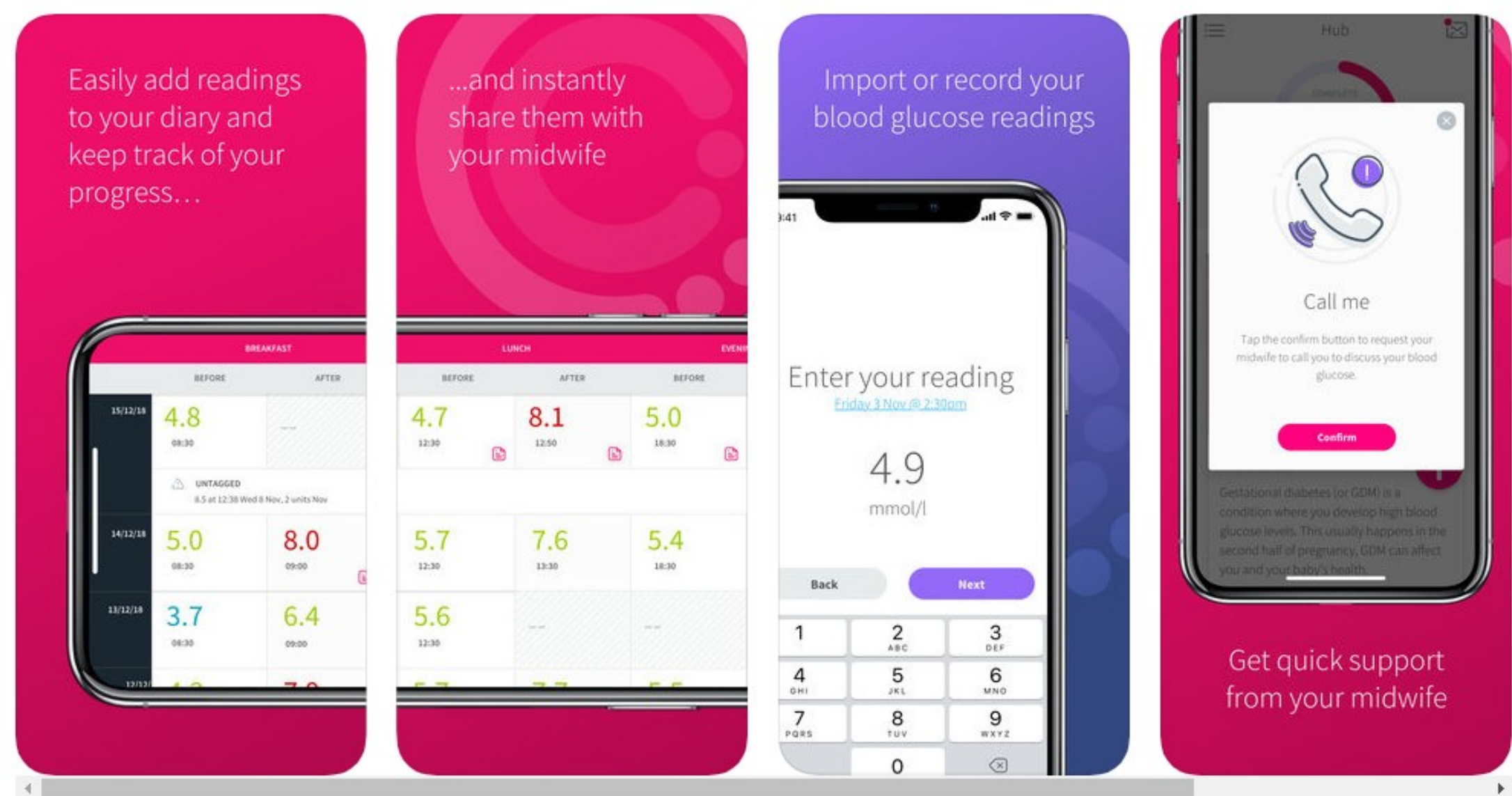
Anonymised outcomes for baby and mother are routinely collected facilitating local audit. Metrics regarding usage, outcomes and administration metrics are collected and compared pre and post-implementation of GDm-Health at each Trust. All data from the app is owned by the NHS and this is explained in the terms and conditions which the users agree to when they download the app. Access to the cloud-based server is limited to NHS staff who are responsible for providing care. Sensyne Health plc. have access to anonymised data for the purpose of medical research.

### Tier 3

An [RCT](#) (n=203) was conducted which compared the rate of change of blood glucose in pregnant women using the app and standard care. Other end points were user satisfaction, clinical outcomes and system costs. Women using GDm-Health had higher satisfaction with care (p=0.049). The RCT reported that GDm-Health improved BG measurement compliance compared with the paper system: 78 of 98 women in the intervention group and 52 of 85 women in the control group recorded at least 67% of the expected number of readings (p<0.001). Preterm births and cesarean deliveries were less common in the intervention group (p=0.005 for reduced cesarean deliveries compared to those women receiving standard care). Costs per patient were also lower by £1,044.

Real world data from a Trust which changed their pathway to maximise the benefit of GDm-Health reported that [clinical visits reduced](#) by 26%.

Figure 1: Screenshot of GDm-Health iOS





# Tier 3b: Case Study with: SEND™

Developer: Sensyne Health plc

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION OF THE DIGITAL HEALTH TECHNOLOGY

SEND (System for Electronic Notification and Documentation) is an evidence-based, digital charting system for vital-signs observations in hospital and for the automatic calculation of Early Warning Scores (EWS). A patient’s vital signs are inputted by the health care professional [HCP] (typically a nurse) and each is scored for risk, and from these the patient’s overall risk score is calculated. The appropriate next steps to manage the patient are then shown to the HCP (according to Trust protocol) through the user interface. HCPs can see the patient’s history of vital signs and risk scores as well as the advice that has been given.

SEND has been implemented successfully in several NHS trusts, and has been used in the care of over 200,000 patients to date.

Figure 1: SEND Classification

Expected functional category:	Calculate
Evidence tier:	Tier 3b
Additional Risks:	Contextual questions identify that there are potentially serious consequences to the user if the DHT fails to perform as described, hence this is a higher risk technology.

Figure 2: [The SEND data entry hardware, and an example screenshot of the patient monitoring screen](#)



Table 1: SEND Value Proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>SEND is <a href="#">designed by clinicians to be faster than pen and paper, with at-a-glance information so clinicians can prioritise care to patients most in need</a></li><li>The design of SEND is intended <a href="#">to minimise barriers to data entry</a> and <a href="#">facilitate viewing of current and historical observations</a> at the point of care whilst releasing time to enable the HCP to focus on the quality of care.</li></ul>	<ul style="list-style-type: none"><li>SEND is consistent with the pathway and recommendation set out in <a href="#">NICE clinical guideline 50</a>.</li><li>An <a href="#">observational study showed a 30% reduction in time to undertake a set of vital-sign observations</a>.</li><li>Claimed increase in patient safety.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Improved patient safety e.g. by enabling positive patient ID with patient wristband barcodes linked to HCP ID and patient record</a>.</li><li><a href="#">Can prioritise patients with highest risk scores</a>.</li></ul>

## CURRENT EVIDENCE

**Tier 1**  
UK clinical experts were involved in the design, development and testing of SEND. The software is consistent with NICE Clinical Guideline 50 and has been successfully implemented in the English NHS. The platform has a testing plan, and there is a validation process in place to show the accuracy of calculations. User feedback informs product development. [SEND is CE marked as a Class 1 Medical Device](#).

**Tier 2**  
Information and advice from SEND is based on an escalation protocol, which is developed internally in each Trust. The Trust is responsible for ensuring this is up to date. There are strict regulations over the data collected and made available for analysis, which are contractually agreed with each Trust upon implementation of the technology which grants the rights to analyse the Trust’s anonymised data governed by a Data Processing Protocol. Any analysis of anonymised patient data (and hence the Company’s access to it) for medical research purposes must be pre-approved for each programme on a case-by-case basis by relevant NHS Trusts.

**Tier 3**  
Clinicians and Academics have carried out an [observational study](#), and a [usability assessment](#). They have also published a [protocol for a non-randomised stepped wedge study](#) comparing charting on paper and charting using SEND.

Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Tier 3b: Case Study with Space from Depression

Please note: This case study is intended to demonstrate how the evidence for effectiveness framework could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

Developer: SilverCloud

## DESCRIPTION OF THE DIGITAL HEALTH TECHNOLOGY

Space from Depression is part of a suite of over 30 internet delivered cognitive behavioural therapy (CBT) programmes developed by SilverCloud. The programmes can be accessed on multiple devices through its responsive website or a dedicated mobile app. Programmes are available for a range of mental and behavioural health issues including anxiety, depression, stress, eating issues, and chronic illness. This specific case study is for Space from Depression, a CBT intervention for helping users treat depression.

Space from Depression has incorporated key elements of iCBT (internet delivered cognitive behavioural therapy) through seven consecutive programme modules. Firstly, the programme provides information to the user about depression and users are encouraged to chart their own difficulties with depression. The modules progress to mood assessment, noting and tracking negative thoughts, challenging negative thought patterns, and assessing core beliefs to alter thoughts. The final module requires the user to collate the skills and ideas learned through the modules to create a plan for staying well and for spotting warning signs for depression. Weekly reviews by a trained supporter provide guidance, feedback and motivation to the user.

Space from Depression launched in the UK in 2012. It has been implemented successfully in several UK health and social care systems.

Figure 2: Space from Depression Classification

Expected functional category:	Treatment
Evidence tier:	Tier 3b
Additional risks:	Contextual questions identify that users of the DHT are in a potentially vulnerable group and the DHT is not necessarily intended to be used with clinical support, hence this is a higher risk technology.

Table 1: Space from Depression Value Proposition

Value proposition	Benefits to health and care system	Benefits to patients
<ul style="list-style-type: none"><li>Space from Depression has been <a href="#">developed specifically to address historical difficulties with engagement in internet-delivered interventions</a>. Thus improves access to effective interventions.</li><li>Seeks to deliver internet interventions <a href="#">that are as effective as face-to-face therapy, but at a much lower cost</a>.</li></ul>	<ul style="list-style-type: none"><li><a href="#">Proven to reduce depression symptoms and anxiety symptoms. Also produces reductions in work and social adjustments.</a></li><li>Can be integrated into care delivery pathways.</li><li><a href="#">Reduces costs and releases clinical time.</a></li></ul>	<ul style="list-style-type: none"><li>In a 2016 study, the <a href="#">majority of respondents reported satisfaction (68%) with Space from Depression</a>.</li><li>Embeds a number of features designed to improve engagement, which have previously been categorised as <a href="#">Social, Interactive, Personal, and Supportive</a>.</li><li>Space from Depression continues to evolve in line with best practice technology &amp; human-centred design to ensure a continued excellence of user experience</li></ul>

## CURRENT EVIDENCE

### Tier 1

[Space from Depression was founded on 10 years of clinical research in iCBT](#), with 7 years of research on technology to support the treatment of mental health issues leading to a 3- year transnational research project. UK clinical experts were involved in the design, development and testing of Space from Depression. The platform offers proven scalability, with a current 200,000+ users across several countries.

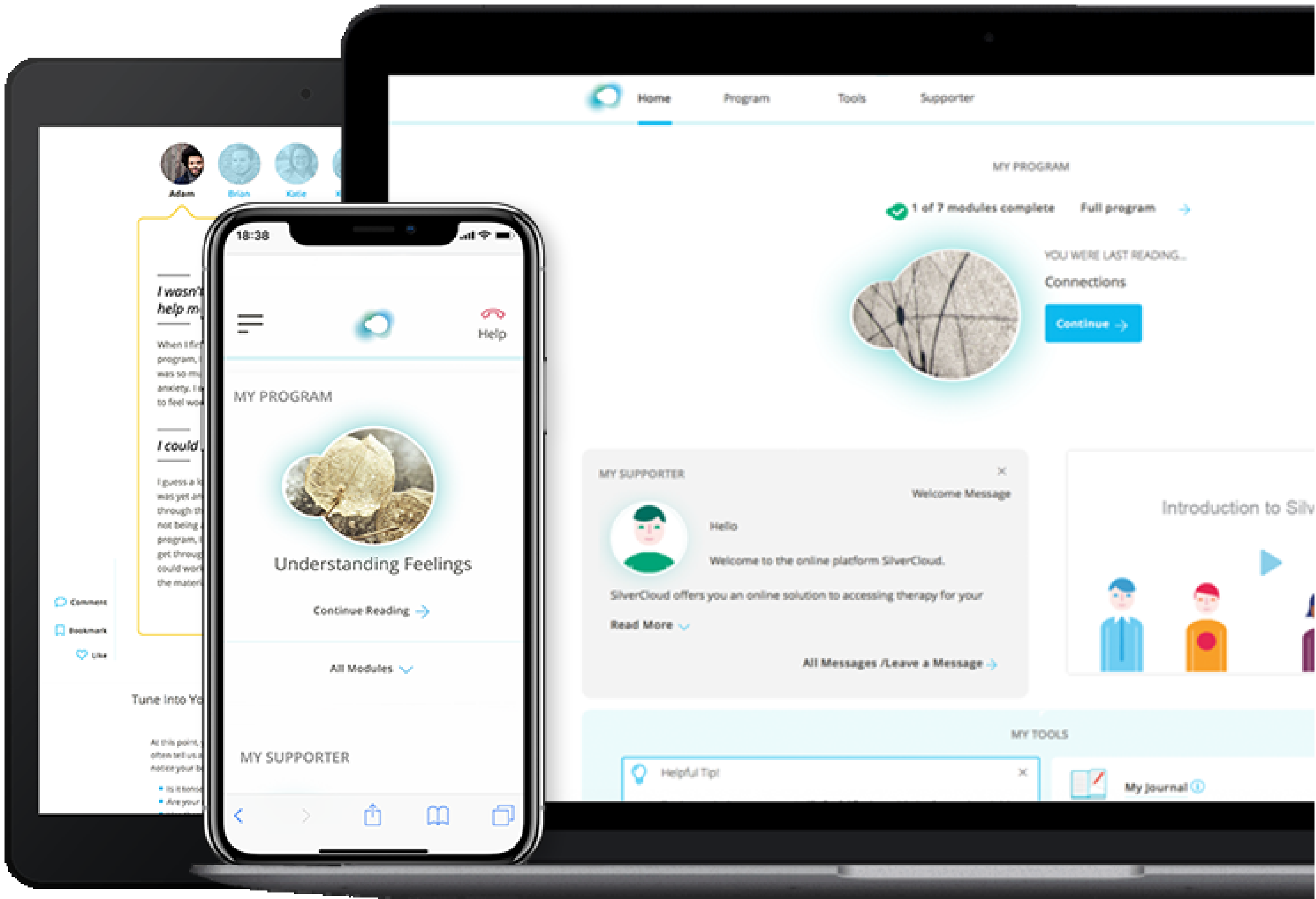
### Tier 2

Content aligns closely with IAPT content and is updated as and when needed. User engagement (both patients and psychological wellbeing practitioners) is always measured. Peer support functions are limited and anonymous. For example users can like content and others can see number of users liking content but not names. Outcomes have been demonstrated, [with over 30 research studies on the programmes](#).

### Tier 3

Space from Depression has previously conducted a [non-randomised control trial in a student population](#), and a [randomised control trial \(RCT\) in a community setting using a waiting list control](#). It is currently undertaking an RCT to evaluate the immediate and longer-term impact on patient outcomes, service provision aspects, and the cost effectiveness of internet-delivered interventions for depression and anxiety. [There are two recently published protocols for this work](#).

Figure 1: User Interfaces of Space from Depression

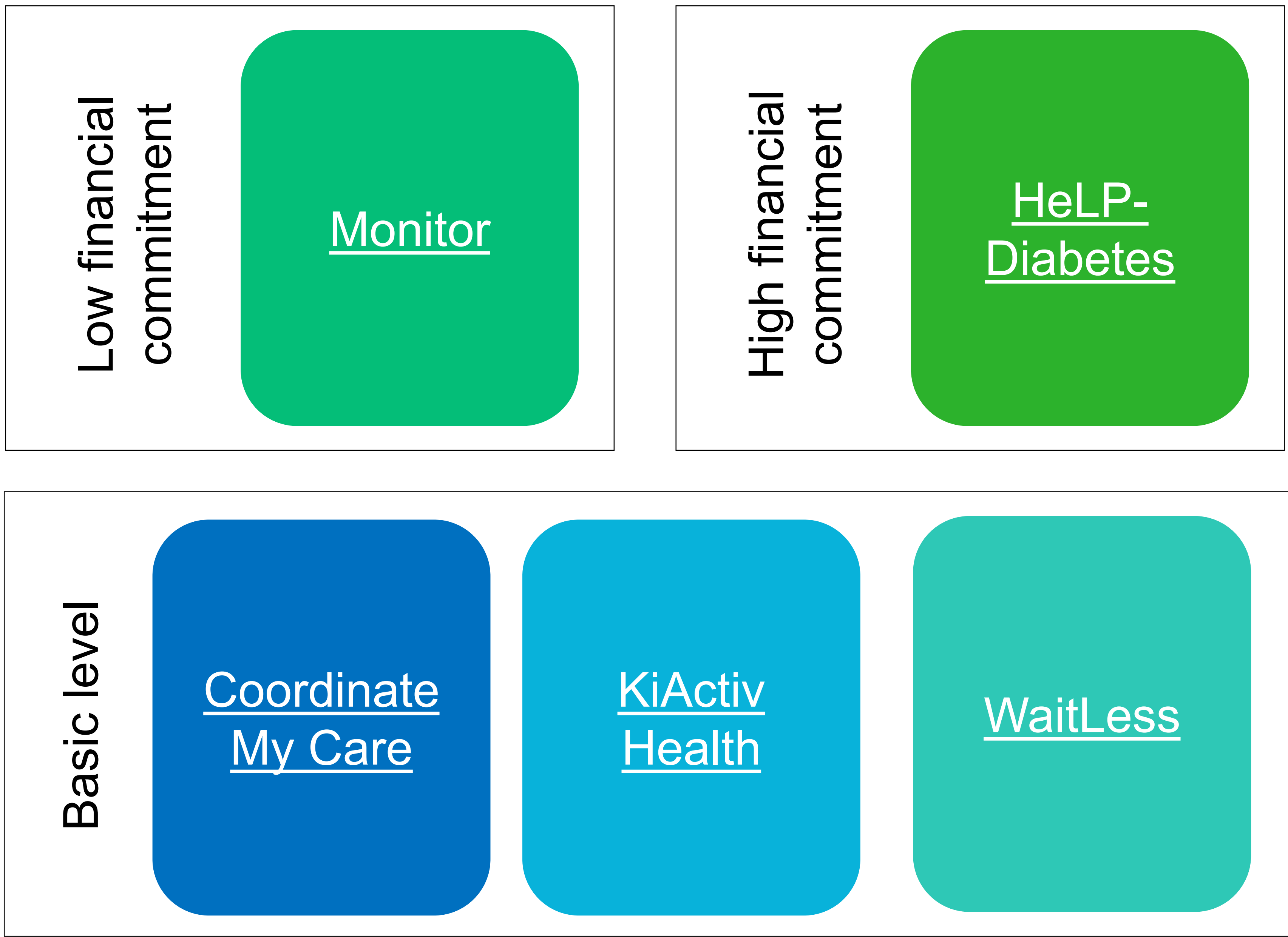


Please note: All references are provided as hyperlinks. To access these, right click on the hyperlinked text and choose 'open hyperlink'.



# Economic Impact Evidence Case Studies

The case studies are listed according to the economic analysis requirements.





# Basic level: Case Study with Coordinate My Care

## Developers: Coordinate My Care

This case study is intended to demonstrate how the evidence for economic impact section of the evidence standards framework for digital health technologies could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[Coordinate My Care \(CMC\)](#) is an NHS clinical service commissioned by the 32 London Clinical Commissioning Groups (CCG). The service enables a patient and their care professionals to jointly create and maintain an electronic urgent care plan that lists the patient's wishes and care preferences. It also can include practical information (e.g. where a patient keeps medicines, or who to contact in an emergency). A care plan can be created on the CMC system by a doctor or nurse or initiated by a patient via myCMC, the CMC patient portal and then completed and approved on CMC by a clinician. Care plans are collaborative and can be accessed by all health and social care professionals caring for the patient. Clinically approved care plans can be viewed by urgent care services, such as NHS 111, out-of-hours GPs, the ambulance service and emergency departments (ED).

CMC has Information Sharing Agreements that govern how care plan information is used and protected with all of its partner organisations. Associated staff, who are authorised to access the system, are able to sign up to an Acceptable Use Policy when logging in to the system.

The CMC care plan is not a legally binding document. A clinician who chooses a method of care that is not in the plan can support their decision-making with sound clinical reasoning.

CMC was launched in 2010 and there are now over 61,550 urgent care plans on the system. Monthly reporting, including CMC usage, is available by service and at individual CCG level. CMC was selected for the [NHS Innovation Accelerator programme](#).

#### Figure 1: CMC classification

<b>Expected functional category:</b>	Communicate, lower risk
<b>Evidence tier:</b>	Tier 2, lower risk
<b>Economic analysis level:</b>	Basic level

CMC was piloted within a London CCG and subject to independent evaluation . The evaluation team collected data on usage of healthcare services for 3 groups. Group 1 (n = 83, mean age 85 years and 36% male) used CMC and died in 2011/12; Group 2 (n= 75, mean age 82 years and 43% male) did not use CMC and also died in 2011/12 and Group 3 (n= 75, mean age 84 years and 41% male) were non-CMC users and died in 2010/11. Resource use was captured for 5 main categories: A&E, hospital inpatient care, general practice (GP), community palliative care and other services and hospice care.

The analyses showed that CMC patients had fewer hospital admissions, a shorter mean length of stay (LoS) and fewer attendances at emergency and unplanned care services. For example, the mean number of hospital inpatient attendances was 1.7 for CMC patients, with a mean LoS of 10.7 days; and 2.3-2.6 attendances, with a mean LoS of 12.6 to 13.7 days for non-CMC patients. CMC patients also made greater use of community services, e.g that group had 15.5 GP surgery attendances compared with 10.0 to 10.4 for non-CMC patients. Most differences were statistically significant.

### ECONOMIC EVIDENCE

Frontier Economics conducted a cost minimisation analysis (CMA) of the CMC service compared to usual care. The analysis applied unit costs to the service use data collected during the pilot study.

An NHS perspective was adopted. The time horizon is not stated but is judged no more than 1 year and hence discounting was unnecessary.

All consultations with GPs, community services including palliative care teams, hospices, EDs, and GP out-of- hours were recorded by the evaluation team running the pilot. Ambulance use in the control groups had to be obtained directly from the providers. A separate exercise was undertaken to ascertain the duration of appointments with GPs (18.8 minutes).

Unit costs were taken from 3 national databases: [NHS Reference Costs](#), [NHS Tariff Costs](#) & PSSRU [Unit Costs of Health and Social Care](#). Hospice costs were estimated by the evaluation team. The unit costs were applied to the resource use data for each service and the resulting costs per service were summed to give the total cost for all services used by each Group.

No data on quality of life or other patient outcomes were collected.

Sensitivity analysis on the estimation approaches on GP time, ambulance usage and hospice costs were undertaken.

The total costs were £7,113 per patient in Group 1 (using CMC), £9,215 and £8,464 for patients in Groups 2 and 3 respectively. Savings ranged from £1,350 to £2,102 per patient. Patients in the CMC group had, on average, lower costs from ED attendances, hospital admissions, use of ambulance and GP out-of-hours services but higher costs from non-hospital resources: GP in-hours, hospices, and community palliative care and other services.

The results of the sensitivity analysis reported that the savings per patient from using CMC may vary by + £34 to -£10, using different methods to estimate the costs of the 3 parameters. No other sensitivity analyses were undertaken.

This is the only published economic evaluation. There is no budget impact analysis but one could be informed by the CMA results.

#### Figure 2: Summary of economic evaluation

<b>Type of analysis:</b>	Cost minimisation analysis
<b>Developed by:</b>	Frontier Economics
<b>Data sources: clinical and patient outcomes</b>	Only resource use modelled and values taken from pilot study. This consistent with CMA.
<b>: resource use</b>	
<b>: unit cost</b>	<a href="#">NHS Reference Costs</a> , <a href="#">NHS Tariff Costs</a> & PSSRU <a href="#">Unit Costs of Health and Social Care</a> .
<b>Results:</b>	Savings with CMC ranged from £1,350 to £2,102 per patient
<b>Sensitivity analyses:</b>	Limited sensitivity analysis on intervention costs only reported savings could vary by +£34 to -£10 per patient

1Frontier Economics Evaluation Report. End-of-life care – CMC pilot cost analysis. Final Report June 2013 (unpublished).

2 CMA assumes clinical and patient outcomes are the same between the comparators.

23



# Basic level: Case Study with KiActiv® Health

**Developers:** KiActiv® (Ki Performance Lifestyle Ltd)

This case study is intended to demonstrate how the evidence for the economic impact section of the evidence standards framework for digital health technologies could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[KiActiv® Health](#) is a web-based app that provides personalised, data-driven feedback for everyday physical activity, measured in multiple dimensions, to empower sustainable behavioural change in the context of the user’s health. The app integrates proven behavioural science and uses proprietary algorithms to evaluate physical activity data from an accurate movement tracker. The platform is supported by a trained health coach who helps to guide the user for enhanced wellbeing and health-related outcomes. The programme has a 12-week duration.

**Figure 1: KiActiv® Health classification**

<b>Expected functional category:</b>	Self-manage, lower risk
<b>Evidence tier:</b>	Tier 3a, lower risk
<b>Economic analysis level:</b>	Basic level

## Existing clinical evidence

The clinical effectiveness of KiActiv® Health was measured in the [Mi-PACT](#) randomised controlled trial (planned n = 216). The [study protocol](#) advises patients are aged 40 to 70 years and at medium or high risk of cardiovascular disease and/or type II diabetes (T2DM). The comparator is usual care from GPs plus standardised messages about physical activity for health. The primary outcome is physical activity, measured at baseline, 12 weeks and 12 months. Secondary measures include weight loss, fat mass, and markers of metabolic control, motivation and well-being. Four papers have been published [[1,2,3,4](#)], with the results due to be released shortly.

An unpublished longitudinal cohort study, supported by an Academic Health Science Network, recruited 179 patients from 3 GP practices to start the KiActiv® Health 12-week programme. Mean age was 64 years, 64% were men, 89% had T2DM and 11% type 1 diabetes (T1DM). Results included that 97% of patients improved physical activity, which was objectively measured in dimensions of physical activity known to be independently important to health. Daily moderate activity improved by a mean of 44 minutes; Daily sedentary time reduced by a mean of 1 hour and 29 minutes; Weekly moderate bouts improved by a mean of 2 hours 36 minutes; Daily calorie burn increased by a mean of 294 kcals. About 90% of patients reported being confident in managing their physical activity to improve health, whilst 60% achieved physical activity levels shown in an [unrelated study](#) to reduce haemoglobin A1c (HbA1c) by 0.9%. Medicine use also declined. Mean weight loss was 2.7 kg in the 43 patients who reported their weight. These findings are reported in an unpublished evaluation report written by the developer.

**Figure 2: Summary of economic evaluation**

<b>Type of analysis:</b>	Return on investment (RoI)
<b>Developed by:</b>	KiActiv®
<b>Data sources: clinical and patient outcomes</b>	Cohort study for change in physical activity; other published studies for impact on clinical events & quality of life
<b>: resource use</b>	
<b>: unit cost</b>	<a href="#">Published cost of illness study</a>
<b>Results:</b>	RoI for every £1 spent by year 10: £43.40
<b>Sensitivity analyses:</b>	Nil

## ECONOMIC EVIDENCE

The developer conducted an economic evaluation of KiActiv® Health which is described briefly in the unpublished evaluation report, with supporting notes on the methodology, assumptions and references. This presents the return on investment (RoI), expressing all savings in monetary terms. This form of analysis is consistent with the guidance in the Technical Report for the [NICE Physical Activity RoI Tool](#).

The clinical effectiveness component of the economic evaluation uses the results of the cohort study. The objectively measured change in physical activity was treated as a surrogate endpoint for diabetes self-management and assumed to be correlated with a 0.9% improvement in HbA1c ([evidenced from an unrelated study](#)) and hence improved diabetes related outcomes, cost savings from reduced medication, and fewer microvascular complications. The improved HbA1c was assumed to result in a 33% risk reduction in microvascular complications at year 10 ([evidenced from an unrelated study](#)), and the potential to avoid second and third line prescribing costs, which were calculated from national and local data.

The objectively measured changes in physical activity were also used to model the reduction in risk of co-morbidities (such as heart disease, colorectal cancer and dementia), and the associated cost savings, using the [Sport England Moves Tool \(v2.0\)](#). This [tool](#) was also used to value the improved quality adjusted life years (QALY) in monetary terms. The economic evaluation also included productivity gains, using a societal perspective. These are both reported separately and can be removed to give a NHS and social care perspective, consistent with the NICE [reference case](#).

The mean cost of KiActiv® Health was included at £139.99 per patient and 500 patients were modelled. Costs and savings were discounted at 3.5% per year as per [Treasury guidance](#). Table 1 presents the results at 1, 5 and 10 years, showing the KiActiv® system had a positive rate of return by the end of year 1. Assuming the improved physical activity is maintained in subsequent years, the return increases to over £40 for every £1 spent by year 10. No sensitivity analysis were conducted.

The developer notes these estimates may be conservative because the existing models do not adequately account for the positive impact of all types of physical activity, and rather focus on exercise alone. For example, by also including the impact of reduced sedentary time, which is known to be an independent risk factor, the reduction in risk of co-morbidities and associated QALYs may be higher.

**Table 1: Economic benefit of KiActiv® for 500**

Benefits	Year 1	Year 5	Year 10
Medicine reduction	£51,074	£238,675	£439,633
Microvascular complications reduction	£-	£-	£204,068
Healthcare savings from fewer co-morbidities	£18,865	£157,178	£463,696
QALY benefits from fewer co-morbidities	£12,000	£254,000	£1,112,000
Productivity gains from improved wellbeing	£95,065	£444,248	£818,294
Total economic benefit	£177,005	£1,094,102	£3,037,691
Net economic benefit	£107,010	£1,024,107	£2,967,696
RoI for every £1 spent	£2.53	£15.63	£43.40

Other economic analyses of KiActiv® have been conducted for different patient cohorts. No budget impact analysis is available.



# Basic level: Case Study with WaitLess

## Developers: Transforming systems.

This case study is intended to demonstrate how the evidence for economic impact section of the evidence standards framework for digital health technologies could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

### DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[WaitLess](#) is a free, patient-facing app aiming to reduce unnecessary waiting times for patients whilst also alleviating pressures on urgent care services by showing patients the fastest place to access urgent care for minor injuries. The app uses current waiting time feeds from minor injury units and accident and emergency (A&E) departments, drawn from the official NHS system. This is combined with up-to-date travel information using google mapping and geolocation to help patients make an informed decision about where to go to get the quickest treatment for minor injuries. The service can be accessed using an iOS or Android app.

WaitLess was launched in December 2016. As of January 2018 there were [125,000 users](#) of the app. The app currently provides waiting time information at 8 health care facilities. WaitLess has been selected as an NHS Innovation Accelerator fellow and a patient [case study is published](#) on the NHS Accelerator website.

### Figure 1: WaitLess classification

Expected functional category:	Inform, lower risk
Evidence tier:	Tier 2
Economic analysis level:	Basic level

### Existing clinical evidence

WaitLess has been implemented successfully in a Clinical Commissioning Group (CCG) since December 2016 and subsequently commissioned by other CCGs. It has proven to be [highly acceptable](#) with users from the feedback (patient satisfaction rate of 99.6%). User groups are regularly convened to refine the functionality of the app.

Data from the app is collected on an on-going basis. Pseudo-anonymised data is held by developers on activity and usage of the app, and usage statistics are reported online. In order to demonstrate the value of WaitLess data are collected on A&E attendance profiles. These data and usage data were used to evaluate the impact of WaitLess, which was found to have a statistically significant benefit. In a pilot study, the use of [WaitLess](#) was associated with an 11% reduction in minor injuries activity in A&E, specifically during the busiest times of day and a 5% reduction in minor injuries activity across all facilities.

### Figure 2: Summary of economic evaluation

Type of analysis:	Cost minimisation (commissioner perspective)
Developed by:	An Academic Health Science Network
Data sources: clinical and patient outcomes	None (consistent with cost-minimisation analysis)
: resource use	<a href="#">Pilot study</a>
: unit cost	<a href="#">National Tariff Payment System</a>
Results:	Annual savings of £40.5m if all England ( 202 CCGs) are modelled based on assumption that 11% reduction in Tier 1& 2 A&E cases per month move from A&E to a cheaper centre.
Sensitivity analyses:	A reduction in 2% or more in Tier 1 & 2 A&E attendance will generate some cost savings and outweigh the annual cost of WaitLess.

### ECONOMIC EVIDENCE

An Excel economic modelling tool was developed by an Academic Health Science Network to enable commissioners to model the expected impact of WaitLess on their health systems. The tool adopts a health care commissioner perspective. It reports the potential savings to a commissioning body, deducts the cost of WaitLess and gives a net saving from using the app. The tool uses a cost minimisation approach (CMA) which appears appropriate for the needs of commissioners.

Within the tool the user can select the population size for the NHS Trusts selected. The tool is pre-populated with A&E attendance data (from March 2018) for each Trust from [Unify2](#). The tool uses clinical effectiveness rates measured by change in A&E self-presenters at the busiest times, observed in a [pilot study](#) with independent evaluation, of WaitLess (proposed reduction of 11%). Users can override this value with their own rates. The tool uses these values to estimate the number of cases directed away from A&E to other, less busy, treatment centres. The unit tariff for each centre is selected by the user and includes various health resource group codes (HRG) for emergency medicine by department type (i.e. types 1, 2 or 3). The tool uses HRG codes from the [National Tariff Payment System](#) for 2018/19 to populate unit costs.

The total ‘expected’ tariff payment without WaitLess and the total ‘new’ tariff payment with WaitLess are then calculated and reported by the tool. The ‘expected’ tariff payment is the sum of the expected tariff payments for each treatment centre (number of attendances multiplied by unit tariff) assuming WaitLess is not used. The total ‘new’ tariff payment is the sum of the expected tariff payments for each treatment centre (number of attendances multiplied by unit tariff) assuming WaitLess is commissioned. The difference between the two gives a measure of the gross savings to the NHS; the cost to the NHS of acquiring and operating WaitLess is then deducted to give the forecast net NHS savings.

No sensitivity analyses around input parameters are included within the tool. However, the user can select from various options or redefine input values to test scenarios. The tool uses a maximum time horizon of 1 year and hence no discounting of future costs is required in the analysis.

The results from the analysis are dependent on the options selected by the user. If the tool is set up to include all A&E attendances within England and 202 CCGs (the maximum permitted to be selected) then estimated annual cost savings are £40.5m, equating to around £200,800 per CCG per year. This assumes that 126,693 cases per month (11%) move from an ‘expected’ tariff of £93 (Tier 1&2: Emergency Medicine, Category 1 Investigation with Category 1-2 Treatment) to a ‘new’ tariff of £63 (Tier 3: Emergency Medicine, Category 1 Investigation with Category 1-2 Treatment). The Under this scenario, scenario, a 2% reduction in tier 1&2 A&E visits is required to be cost neutral; further reductions would generate cost savings outweighing the annual cost of WaitLess.

There is no budget impact analysis but one could be informed using the CMA results.



# Low financial commitment: Case Study with Monitor

Developers: Message Dynamics.

This case study is intended to demonstrate how the evidence for economic impact section of the evidence standards framework for digital health technologies could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[Monitor by Message Dynamics](#) is a telehealth service with several modules designed to reduce hospital admissions, improve adherence, measure patient outcomes. The Monitor service automatically contacts users at pre-determined intervals and takes user responses to pre-set questions to evaluate their state of health. Patients record their symptoms or physiological readings by responding to a series of questions. Using this data, Monitor automatically alerts the clinician if a user's health has deteriorated, beyond a given threshold, using a clinician developed algorithm. The technology can be used in several clinical areas as the questions are set by relevant clinicians and answers allocated to the relevant user group. Examples of use to date include asthma, heart failure, diabetes and gynaecology.

Message Dynamics' services were launched in 2011 and have been implemented in multiple NHS Trusts. The service is estimated to cost around £1 per patient per week.

Figure 1: Monitor classification

Expected functional category:	Self-manage, higher risk
Evidence tier:	Tier 3A
Economic analysis level:	Low financial commitment

## Existing clinical evidence

Clinical evidence of Monitor comprises a [single arm pilot study](#) undertaken by Thames Valley Health and [a comparative study](#) with historical controls by the London School of Economics. The [single arm study](#) used Monitor in people with chronic obstructive pulmonary disease (COPD) (n=36) for 9 months. The system was well received and judged to contribute to patients' ability to self-manage their condition and better adhere to treatment. This resulted in fewer Accident and Emergency (A&E) units and GP surgery attendances as well as fewer hospital admissions and home visits. As a result, Monitor expanded the clinical capacity of staff allowing them to focus on the highest risk patients.

The [comparative study](#) involved the use of Monitor within a Gynaecology Department at the Royal Free Hospital London, which aimed to reduce the follow-up outpatient appointments, reduce "did not attends" and increase the rate of patients receiving test results by letter. Three subgroup analysis were undertaken and findings compared to historical controls. In gynaecology (n=47) there was a statistically significant reduction in the number and cost of follow-up visits and the rate and cost of "did not attends". In the treatment of vulval disease (n=48) there was no significant difference (at p=0.05) in the elapsed time between follow-up appointments and the small sample size meant that the rate of "did not attends" could not be tested. In hysteroscopy (n=72) more patients received test results by letter.

Figure 2: Summary of economic evaluations

Type of analysis:	Two cost minimisation analyses (Trust perspective)
Developed by:	(1) Thames Valley Health & (2) LSE
Data sources: clinical and patient outcomes	None (consistent with cost-minimisation analysis)
: resource use	Taken from (1) <a href="#">COPD</a> & (2) <a href="#">gynaecology</a> studies
: unit cost	(1) Unclear & (2) <a href="#">NHS Tariff Costs</a> , <a href="#">PSSRU</a> and <a href="#">National Audit Office</a>
Results:	(1) Cost savings estimated at £1,546 per patient per year. (2) Cost savings associated with a reduction in follow-up visits and reduction in "did not attends".
Sensitivity analyses:	(1) None undertaken. (2) Results were not sensitive to a change in cost of Monitor (between £0 and £10).

## ECONOMIC EVIDENCE

Two cost minimisation analyses (CMA) were undertaken alongside each clinical evaluation reported in the previous section.

Within the [Thames Valley evaluation](#), a CMA was undertaken to assess if there were any savings attributable to the use in Monitor in people with COPD. Cost savings were estimated over a 1 year time horizon and hence discounting was not applied. A NHS trust perspective was adopted. An unpublished report of the evaluation provided more detailed information additional to that reported below.

Resource use information was obtained from both patient questionnaires and healthcare professionals involved in the pilot. The source for unit costs inputs is unclear. The cost savings estimated include those associated with a reduction in primary care home visits and in unplanned admissions. The reduction in the number of occurrence of each activity (resource use) was multiplied by the unit cost of each activity. The total was the sum of savings across all activities.

The total financial benefit to the trust was estimated at £1,546 per patient per year. This deducted the operating cost of the Monitor service (£26 per patient per year) from the cost savings associated with reduced home visits and hospital admissions. Cost savings associated with reduced GP and A&E visits were considered separately. The analysis excluded the cost of any staff time by the respiratory team resulting from the use of Monitor and the cost to acquire and implement the system. No sensitivity analyses were undertaken.

The CMA conducted by the [London School of Economics](#) (LSE) considered 2 populations separately: gynaecology and the management of vulval disease. In both populations the cohort in the evaluation was compared with a historical cohort. The costs included within the analysis were follow-up visits (both scheduled and completed) and "did not attends". The analysis is described as a cost consequence analysis but no outcomes other than those included in the cost analysis were reported. The time horizon of the analysis was 9 months and hence discounting of future costs was unnecessary. An NHS perspective was adopted.

Information on resource use (being number of follow-up visits and number of did not attends) were obtained from the data collected during the evaluation and the historical control patients. The unit costs of appointments and "did not attends" used within the analysis were from [NHS Tariff Costs](#), [PSSRU](#) and [National Audit Office](#). The cost of the delivery of Monitor in these populations was estimated as £5 per patient, based on a discussion with an expert. This cost was varied between £0 to £10 per patient in a sensitivity analysis. No further sensitivity analyses were carried out.

Within the reported results the total cost per patient both with Monitor and before its use are reported. These are broken down such that the costs associated with follow-up visits (both scheduled and competed) and "did not attends" are reported separately with no total provided. It is unclear whether these results can be combined or if this would result in double counting. Incremental costs or cost savings are not reported but can be calculated, by element, based on the information presented. The paper concludes that in both populations (gynaecology and vulval disease) the use of Monitor was estimated to generate cost savings from a reduction in follow-up appointments and in fewer "did not attends" up to a cost of Monitor of at least £10 per patient.

There is no budget impact analysis of Monitor but one could be informed using the CMA results.



# High financial commitment: Case Study with HeLP-Diabetes

Developers: University College London

This case study is intended to demonstrate how the evidence for economic impact section of the evidence standards framework for digital health technologies could be used in practice. It is not intended to represent an evaluation or endorsement of the digital healthcare technology.

## DESCRIPTION of DIGITAL HEALTHCARE TECHNOLOGY

[HeLP-Diabetes](#) (Healthy Living for People with Diabetes) is a web-based self-management programme designed to allow people with type 2 diabetes learn about their condition and provide support to them, both physically and emotionally. The website offers behavior change support tools on health eating, increasing physical activity, weight loss, smoking cessation, alcohol moderation and managing medication as well as tools to improve mood and manage the strong negative emotions associated with having diabetes. Users are able to send themselves reminders, and the content and frequency of the reminders is decided on by the user. [Engagement](#) with the website is encouraged through regular email updates and newsletters, which users can opt out of.

The [website](#) is currently suspended as NHS England has taken over HeLP-Diabetes in order to roll it out across England.

### Figure 1: HeLP-Diabetes classification

Expected functional category:	Self-manage, lower risk
Evidence tier:	Tier 3a, lower risk
Economic analysis level:	High financial commitment

### Existing clinical evidence

UCL conducted [a series of related studies to evaluate the clinical and cost-effectiveness](#) of HeLP-Diabetes for people with Type 2 diabetes at any stage of their illness journey and to determine how best to integrate the programme into routine care.

Patient and health-care professionals’ requirements informed the development of this online self-management programme. [A randomised controlled trial \(RCT\)](#) and health economics analysis were conducted. The RCT was set in primary care, recruiting 374 people with type 2 diabetes who were randomised to HeLP-Diabetes and treatment as usual (TAU) or an information-only website and TAU. Participants in HeLP-Diabetes arm (n = 185) received training, follow-up telephone calls, discussion of patient’s self-management goals in routine practice appointments and routine care. The control group (n = 189). received routine care and had access to the information-only website.

The mean age of participants was 65 years and 80% were white British. Baseline diabetes control was good (mean haemoglobin A1c (HbA1c) level = 56 mmol/mol in the intervention arm and 57 mmol/mol in the control) & participants had low self-reported levels of distress. No sub-groups were analysed. Outcomes were collected at 3 and 12-months follow-up. The trial ran from 2014 – 16. Full data and analyses are available in a [health technology assessment report](#) and a summary is reported in a [recent paper](#).

The economic evaluation used two primary outcomes (HbA1c levels and diabetes-related distress, as measured by the Problem Areas in Diabetes scale) from the RCT plus the resource use and quality of life outcomes using the [EuroQol-5 Dimensions](#) [EQ-5D]) collected throughout its duration. Baseline data were collected from patients’ records and follow-up data were collected online where possible.

## ECONOMIC EVIDENCE

[UCL conducted a cost-utility analysis of HeLP-Diabetes using data collected during the RCT](#). An NHS and social care perspective was adopted & a 12-months time horizon so no discounting was needed. This methodology is consistent with the [NICE reference case](#).

The resources modelled included all consultations in the pathway being with GPs, practice nurses, clinics, A&E and hospital attendances, prescriptions & use of social services.

Unit costs were taken from 2 national databases; [NHS Reference Costs](#) & PSSRU [Unit Costs of Health and Social Care](#). These were applied to the resource use data. The cost of developing, delivering, maintaining, and updating the intervention and related staff costs for training and facilitating access were also calculated, with full details provided in the [assessment report](#).

For the economic analysis, the EQ-5D scores were converted into utilities using [tariff values](#) obtained from the UK population ([see user guide](#)). This is consistent with [the NICE guidance on measuring and valuing health effects](#).

The incremental cost for the intervention was £41 per person (£4 operating costs; £21 training practice nurses and £16 for nurse-led facilitation). In comparison the control was assumed to cost £0 per patient. Savings from lower use of health care resources resulted in net savings of £111 per person at 12 months. Quality adjusted life years were higher by 0.02 per person. Hence HeLP-Diabetes dominated the control being cheaper and improving quality of life. One way sensitivity analysis on the cost of the intervention, and a scenario analysis using data from people with complete datasets only, confirmed HeLP-Diabetes was dominant.

The probabilistic sensitivity analysis (PSA) reported that under the existing NICE willingness to pay threshold of [£20,000 to £30,000 per QALY gained](#), the probability of the intervention being cost-effective, compared with the control, was over 97%. The results from the sensitivity analyses show that, despite considerable uncertainty around the point estimates, the overall conclusion that the intervention is cost-effective is likely to be robust.

### Figure 2: Summary of economic evaluation

Type of analysis:	Cost utility analysis
Developed by:	UCL
Data sources: clinical and patient outcomes : resource use	RCT
: unit cost	NHS Reference Costs and PSSRU
Results:	HeLP-Diabetes was dominant, with lower costs and higher utilities than usual care
Sensitivity analyses:	Dominance was reported in the one way sensitivity analysis and PSA reported a 97% probability that HeLP-Diabetes was cost-effective.

UCL did not do a budget impact analysis. Currently, NHS England is developing one but it is not yet publicly available.