Health Technology Assessment (HTA) of Telehealth intervention in patients with depression

by

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Abstract:

With increased utilization of digital technologies in the healthcare sector, the thesis follows current trends and compares the use of telehealth and in-person treatment. A traditional approach to health technology assessment is utilized and further supported by NICE's Evidence standards framework for digital health technologies. As mental disorders are on the rise, the thesis is focused on patients with depression. Equivalent to the study done by Bounthavong et al. (2016), the efficacy data used are from a randomized clinical trial of *In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression* (Luxton et al., 2015). The data are further adjusted to the UK setting as the NICE framework has been developed by NHS in the UK. Based on the results from cost-effectiveness analyses the study concludes there is little difference between in-person and telehealth treatment from effectiveness perspective. On the other hand, study identified costs as a main factor for treatment decision. Travel cost and technology equipment availability were identified as key drivers of the total cost. These results suggest personalising the treatment decision based on identified key parameters and patient preference.

Key words:

health technology assessment (HTA), digital technologies in healthcare, depression

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Table of Contents

Glossary

Abbreviation	Explanation
BDI-II	Beck Depression Inventory-II
CMA	Cost-minimization analysis
CUA	Cost-utilization analysis
ESF	Evidence Standards Framework
EHR	Electronic Health Record
EMR	Electronic Medical Record
FDA	Food and Drug Administration
HBTBH	Home-based telebehavioral care
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
QALY	Quality Adjusted Life Years
RCT	Randomized Clinical Trial
NEJM	The New England Journal of Medicine
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
WHO	World Health Organization
£	Great British Pound

Introduction

In today's context of the world, digital technologies are on the rise across industries as well as in the healthcare sector. The Covid-19 pandemic has accelerated the growth of digital health, a broad concept that includes solutions for digital health platforms including the use of telehealth (European Parliament, 2021). *Telehealth is defined as the means of providing health care at a distance rather than face to face* (National Health Service, 2022).

At the same time, mental disorders have been increasing as well. Since the start of the Covid-19 pandemic, there has been 25 % increase in the prevalence of anxiety and depression worldwide (WHO, 2022). Depression is a complex disability, which can interfere with work, social and family life. Thus, telehealth makes it easier for both patients and mental health care professionals to proceed with treatment.

To be able to implement the digital health technologies, it is important to thoroughly evaluate them as means of treatment. However, there is little to no information regarding health technology assessment of digital technologies, and even fewer assessing patients with depression. Therefore, aim of the thesis is fill the gap and evaluate telehealth as a means of treatment in patients with depression, comparing telehealth with in-person treatment for depression. Focus is on the key drivers for both costs and health improvements to better evaluate situations, where telehealth brings the highest value to patients. Firstly, the thesis evaluates whether telehealth, as the tool of treatment intervention, has a positive effect on patients with depression. Secondly, the emphasis is on the monetary value of telehealth in treating patients with depression.

The master thesis is conceptualized as descriptive as well as analytical research. Within the theoretical part I provide a literature review for digital technologies in healthcare, depression within the context of mental disorders and health technology assessment with the application on digital technologies. Moreover, I examine the role of telehealth in treating patients with depression.

The analytical part of thesis includes a thorough health technology assessment of telehealth as means of treatment in patients with depression. The economic evaluation (cost-effectiveness evaluation) compares telehealth and in-person treatment – from both perceptive of costs and as well as improvement in health status. The first step in the economic evaluation is updating the model by Bounthavong et al. (2016) by adjusting the data to the United Kingdom setting. Then total costs, costs per patient and incremental costs are calculated. Equivalent to the study done by Bounthavong et al. (2016), the efficacy data (Beck Depression Inventory-II score) used are from a randomized clinical trial of *In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression* (Luxton et al., 2015). Quality adjusted life years compare the differences between two arms of the study and estimate the incremental cost-effectiveness ration (ICER). To then test the robustness of the model, both one-way and probabilistic sensitivity analyses is be performed.

To provide a structured health technology assessment (and support the results from the analytical part), the use of telehealth is assessed using the NICE's Evidence standards framework for telehealth as it is one of the most developed frameworks for HTA for digital health technologies.

Literature Review

In the theoretical part, I first review digital technologies in healthcare, their definition, benefits as well as risks, classification and elaborate on the role of telehealth in treating patients. Second, I define depression within mental disorders and focus on the classifications of depression. Lastly, I examine the Health Technology Assessment (HTA) focusing on HTA for digital health technologies and the NICE's Evidence standards framework for digital health technologies.

Digital Technologies in Healthcare

As digital technologies in general have been on the rise, digital tools are also gaining importance in the healthcare sector. Currently the scope of digital technologies in healthcare includes electronic health records (EHRs), telehealth, wearable devices, mobile health apps, personalized medicine, telemedicine and electronics medical records (EMRs) and more. Hence, various definitions of digital technologies in healthcare are available.

FDA (2021) talks about digital tools as *providers of a more holistic view of patient health through access to data.* WHO (2021) defines digital health as a *broad umbrella term which encompasses e-health, advanced computer science* (e.g., big data, genomics, artificial intelligence). In the Evidence standards framework for digital technologies, NICE (2018) explains *digital health technologies as apps, programs and software used in the health and social care system*, which *may be standalone or combined with other products such as medical devices or diagnostic tests*. Based on these definitions, it can be concluded that digital technologies in healthcare can have various forms and are aimed at improving healthcare.

Potential Benefits & Risks

The digital age of healthcare naturally brings benefits as well as challenges that affect all parties of the healthcare system - be it patients, medical professionals, technology developers or policy makers.

FDA (2021) explains the benefits that data gained from the digital technology tools in healthcare *offer opportunities to improve medical outcomes, enhance efficiency, improve access, increase quality* and overall move towards to an even more personalized healthcare for patients. Additionally, WHO (2021) argues that digital health plays an important role in improving the public health as well as increasing equity in access to healthcare services and aiming for universal health coverage.

To be able to provide objective overview of digital technologies, it is vital to present the potential risks as well. Challenges include data interoperability due to big amount of data from variety of systems, digital literacy of patients raising questions of privacy as well as ethics.

Classification of Digital Health Technologies

To allow for easier navigation within the landscape of digital technologies in healthcare, there are various classifications currently available – by WHO, FDA and NICE. As the core of my thesis is based around telehealth, I categorize telehealth within each of the classification.

The WHO in 2018 published "Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health", which categorizes digital technologies based on the targeted primary user. The categorization includes:

- 1.0 Interventions for Clients,
- 2.0 Interventions for Healthcare Providers,
- 3.0 Interventions for Health System or Resource Managers,
- and 4.0 Interventions for Data Services.

Telehealth then falls under Healthcare Providers, more specifically 2.4 Telemedicine and in terms of my thesis 2.4.1 Consultations between remote client and healthcare provider.

Figure 1: 2.0 Interventions for Healthcare Providers

Source: Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health (WHO, 2018)

The FDA also in 2018 published Digital Health Criteria, which distinguishes health subgroups based on technology used in each product or service: Software as a Medical Device (SaMD), Advanced Analytics, Artificial Intelligence, Cloud, Cybersecurity, Interoperability, Medical Device Data System (MDDS), Mobile Medical App (MMA), Wireless and other Novel Digital Health. According to these criteria, telehealth could fit into multiple groups as the descriptions are not clearly defined. Some of the criteria where telehealth would fall include Software as a Medical Device*; run on a hardware medical device is a SaMD when not part of the intended use of the hardware medical device* and Wireless; *a device or product that uses wireless communication of any form*.

NICE[1] provides a functional classification of Digital Health Technologies (DHT) (2018) based on potential risk to users. This classification is divided into evidence tiers: Tier A: System impact, Tier B: Understanding and Communicating and Tier C: Interventions. Telehealth is part of Tier B: Communicate, because it allows for *a 2-way communication between users and professionals, carers, third-party organizations or peers, where clinical advice is provided by a professional using the DHT, not by the DHT itself* (Unsworth et al., 2021).

Telehealth

If looked at the literature available for digital technologies in healthcare, there are various definitions of telehealth available. Mayo Clinic (2021) defines telehealth as the *use of digital information and communication technologies, such as computers and mobile devices, to access health care services remotely and manage your health*. NEJM Catalyst[2] (2018) describes telehealth as *the delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self-care via telecommunications and digital communication technologies*.

It is also important to describe the difference between telehealth and telemedicine as the two terms have been used interchangeably. The Department of Health and Human Services[3] (2022) defines telehealth as *non-clinical services, such as provider trainings, administrative meetings, and continuing medical education* and telemedicine on the other as only *remote clinical services*. Telemedicine, defined in Oxford Reference (2022), is *the use of the telephone or the Internet in the diagnosis and treatment of patients by seeking advice, or a second opinion, from experts at a distant hospita*l. Based on the definitions above, it can be argued that telehealth is a broader term that encapsulates the term telemedicine.

As telehealth is quite a wide concept, it can be further divided into many categories, e.g., tele-MAT (medication-assisted treatment through telemedicine), telenursing,

[1]NICE (National Institute for Health and Care Excellence) is an executive non-departmental public body of the Department of Health and Social Care in the United Kingdom. The organization focuses and publishes guidelines in the four following areas: i) clinical practice, ii) public sector workers, iii) social care services and iv) health technologies (2022).

[2]NEJM (The New England Journal of Medicine) *brings health care executives, clinical leaders, and clinicians together to share innovative ideas and practical applications for enhancing the value of health care delivery* (2022).

[3]The Department of Health and Human Services (HHS) of United States of America is to enhance the health and well-being of their citizen (2022).

telepharmacy, teleneurology, teleneuropsychology, telepsychiatry and others. This thesis is focused around telepsychiatry, thus utilizing videoconferencing for patients residing in underserves areas to access psychiatric services, or in other words the use of telemedicine in the psychiatry specialty field.

Depression

According to WHO (2017) mental health conditions are increasing worldwide – there *has been a 13 % rise in mental health conditions in the last decade*. Furthermore, Covid-19 pandemic has contributed to the prevalence in depression (WHO, 2022), increasing the need of access to depression treatment. Defined by Hyman et al. (2006) *mental disorders are diseases that affect cognition, emotion and behavioural control* and substantially *interfere with the ability of adults to function in their families, at work, and in the broader society*. There exist many different mental disorders with various symptoms. These disorders include *depression, bipolar disorder, schizophrenia and other psychoses, dementia, and developmental disorders including autism* (WHO, 2019).

Currently, there are effective strategies for preventing and treating mental disorders – one of the most important things mentioned is the access to healthcare, where telehealth plays a role. The National Alliance on Mental Illness[4] (NAMI) states that telehealth provides an effective way to provide mental health treatment to patients, when the provider is in a different physical location (NAMI, 2022).

Depression is *a common mental disorder and of the main cause of disability worldwide, globally an estimated 264 million people are affected by depression* (WHO, 2019). The National Institute of Mental Health[5] (2021) classifies depression as a serious mood disorder, which *causes symptoms that affect how you feel, think, and handle daily activate, such as sleeping, eating, or working* and last for at least two weeks. It can be therefore assumed that the core of major depression includes emotional (sadness, irritability and loss of interests) and physical (fatigue, multiple aches and pains) symptoms (Hyman et al., 2006).

[4] The National Alliance on Mental Illness, the nation’s largest grassroots mental health organization dedicated to building better lives for the millions of Americans affected by mental illness (2022).
[5] The National Institute of Mental Health (NIMH) is the lead federal agency for research on mental disorders. NIMH is one of the 27 Institutes and Centers that make up the National Institutes of Health (NIH), the largest biomedical research agency in the world. NIH is part of the U.S. Department of Health and Human Services (HHS) (NIMH, 2022).

Classification of depression

To be able to access the level of depression, it is important to define various levels. There are several rating scales of depression available to make this assessment. Scales can be completed by researchers, patients or both.

The Hamilton Depression Rating Scale is used by clinicians to interview patients, the scale includes 21 questions with three to five possible responses that increase in severity (Hamilton, 1960). Another scale used by researchers is the Montgomery-Åsberg Depression Rating Scale that has 10 items to be completed and assess the effect of drug therapy. Furthermore, the Raskin Depression Rating Scale is also used by the clinicians and rates the symptoms of patients in three different areas – verbal, behaviour and secondary symptoms (Raskin, Schulterbrandt & McKeon, 1969).

The most known scale completed by patients is the Beck Depression Inventory, which is a 21-question report that includes symptoms (Beck, 1961). The Patient Health Questionnaire (PHQ) are as well self-reported scales include different number of questions resulting in variations of the questionnaire PHQ-9 and PHQ-2. When a positive response is reported within the questionnaire, the patient is indicated for further testing.

Health Technology Assessment

According to WHO (2011) health technology assessment (HTA) is *the systematic evaluation of properties, effects, and/or impacts of a certain health technology*. Health technology itself is then defined *as the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life* (WHO, 2021). The process of assessment involves a multidisciplinary approach – evaluation of social, economic and ethical issues. The assessment can be used to determine whether the technology is cost-effective and policy makers can make a more informative decision.

HTA for digital technologies

As digital and information technologies and have been on the rise in the healthcare sector, there has also been an increased need to provide evidence for economic effectiveness of these technologies. Digital technologies play both role in the care process (diagnostic treatment, therapy, nursing) and the auxiliary process (e.g., documentation, archiving, appoint making), which makes it difficult for developing a causal relationship between the improvement of efficacy and effectiveness (Luzi, Pecoraro & Tamburis, 2016). Furthermore, digital technologies do not alter the health state itself, therefore benefits must be measured in terms of changes in the health care and management process (Goodman and Ahn, 1999).

When looking for a comprehensive HTA framework for digital technologies, there is not many full economic assessments available. A study done by Haverinen et al. (2019) provides a literature review and based on the collected information created a framework called digi-HTA aimed at Finnish healthcare. The digi-HTA is built as a mini-HTA leaving out ethical, social and legal issues *to provide fast assessment in a rapidly developing technology sector* (Haverinen et al., 2019). On the other hand, the framework is quite comprehensive in the areas of technical stability, cost, effectiveness, clinical safety, data security and protection, usability and interoperability.

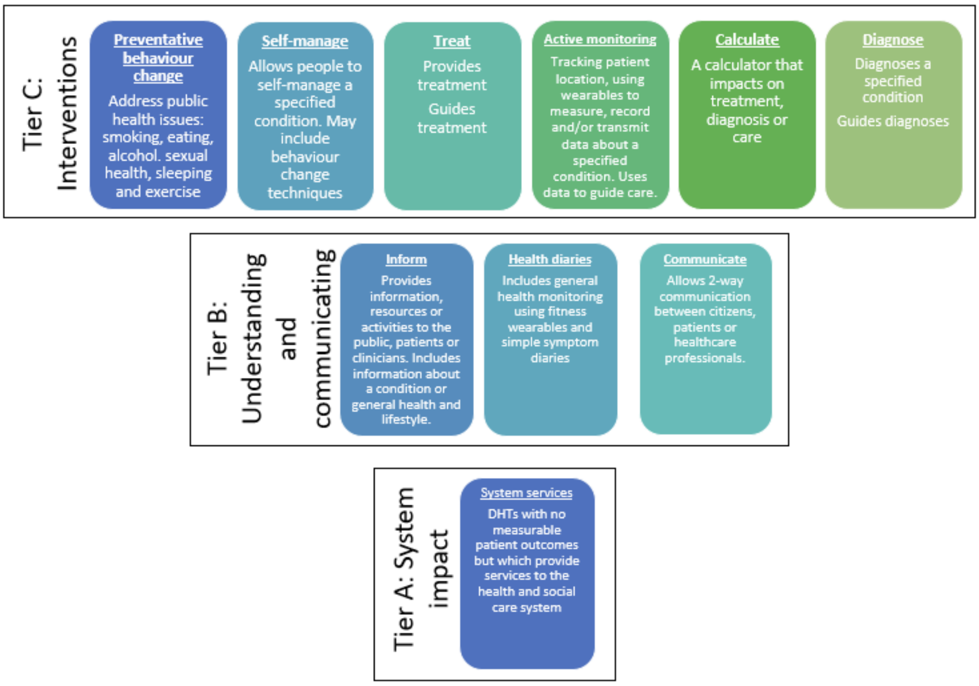
Another framework is The Australian Digital Health Agency's benefits management framework (Biggs, 2019). The framework is divided into workstreams of i) Customer and market insights, ii) Behavioural economics, iii) Data analytics, iv) Impact evaluations, v) Health economics evaluations. Within each of these workstreams are mentioned key benefits to measure and which methods to use. On the contrary, the framework does not consider scalability, enablers and barriers for implementation across various settings (Greenhalgh, 2018).

NICE's Evidence standards framework (ESF) for digital health technologies

The most comprehensive framework for digital technologies in terms of Health Technology Assessment has been developed in the UK. NICE's Evidence standards framework (ESF) for digital technologies improves the assessment, as it was designed to provide missing standardized approach needed for the clinical and economic evaluation of digital health technologies (Unsworth et al., 2021). The framework is intended *to be used by technology developers to inform their evidence development plan, and by decision makers who are considering commissioning a digital health technology* (NICE, 2018).

The framework is divided into two parts – section A of the framework compromises evidence for effectiveness standards and section B compromises evidence for economic impact standards. Section A is further divided into tiers which are proportionate to the potential risk to users from the DHTs in that tier and provided with contextual questions to help guide higher-risk DHTs. The tiers are then provided with evidence categories and provided with minimum evidence standard as well as best practice standards. Section B is separated into three components: i) key economic information, ii) appropriate economic analysis, iii) economic analysis reporting standards. This framework is depicted and utilized in the research part of this thesis.

Figure 2: The Three Tiers of NICE's Evidence Standards Frameworks



Source: Evidence standards framework for Digital Health Technologies (NICE, 2018)

Parts of HTA

According to Drummond et al. (2015) economic evaluation of technology is the *comparative analysis of alternative courses of action in terms of both their costs and consequences*. Moreover, economic evaluation aims to *identify, measure, value and compare the costs and consequences of the alternatives being considered* (Drummond et al., 2015). To be able to perform the comparative analysis, HTA usually includes cost-effectiveness analysis (CEA), calculation of quality adjusted life years (QALYs), incremental cost effectiveness ration (ICER) and a sensitivity analysis.

Drummond et al. (2015) define cost effectiveness analysis (CEA) as analysis in which *costs are related to a single, common effect that may differ in magnitude between the alternative programs*. Special case of cost-effectiveness analysis is cost-utility analysis (CUA), which *compares the costs and effects of alternative interventions, moreover, measures health effect in terms of both quantity (life years)* *and quality of life* (Drummond et al., 2015). The cost-benefit analysis (CBA) is also a type of CEA and assigns monetary value to a measure of effect (McIntosh et al., 2012). Another case of CEA is the Cost-minimization analysis (CMA) is usually carried out when two or more alternatives that are examined achieve the outcome of the same degree (Drummond et al., 2015). The overview of various cost-effectiveness analyses is available in Table 1.

Table 1: Types of Cost-effectiveness analyses

Type of analysis	**Description**
Cost-effectiveness analysis (CEA)	CEA is a comparative economic analysis that evaluates two or more alternative in terms of their relative costs and outcomes (e.g., life-years gained, diseases averted, etc.).
Cost-utility analysis (CUA)	Type of CEA, where the outcomes are measured by a generic health status, e.g., quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs).
Cost-benefit analysis (CBA)	Type of CEA, where both the costs and outcomes are expressed in monetary terms and reflects the preference of those affected (i.e., the individuals' willingness to pay).
Cost-minimization analysis (CMA)	Type of CEA, where the outcomes are assumed to have equivalent health effects

Source: An Introduction to the Main Types of Economic Evaluations Used for Informing Priority Setting and Resource Allocation in Healthcare: Key Features, Uses, and Limitations (Turner et al., 2021)

Incremental cost-effectiveness ratio (ICER) is *a measure of additional cost per additional unit of health gain produced by one intervention compare by another* (McCabe et al., 2008). ICER is *calculated as the difference in the change in mean costs (ΔC) in the population of interest divided by the difference in the change in mean outcomes (effects) (ΔE)* (NICE, 2022).

$$ICER = \frac{\Delta C}{\Delta E}$$

The most common measure of effect (or outcomes) used is the quality adjusted life years (QALYs). For example, NICE uses QALYs to compare different drugs, devices and other technologies for different conditions. It is a *measure of the state of health of* *a person in which the benefits, in terms of length of life, are adjusted to reflect the quality of life*; moreover, *one quality adjusted life year is equal to one year of life in perfect health* (NICE, 2022).

$$QALYs = Years\ of\ Life * Utility\ Value$$

The parameters above carry with them a certain amount of uncertainty. To test the robustness of these values, sensitive analysis is applied - that is *to change a small number of parameter values and consider the change in results* (Briggs et al., 2006). The most common form of sensitivity analysis is a simple one-way sensitivity analysis, where *uncertain component of the evaluation is varied individually, while the others retain their base-case specifications, in order to establish the separate effect of each component on the results of the analysis* (Briggs, Sculpher & Buxton, 1994). To be able to access more than one parameter at the same time, probabilistic sensitivity analysis *permits to assign ranges and distributions to uncertain variables* (Briggs, Sculpher & Buxton, 1994). Moreover, probabilistic sensitivity analysis is knowns as *formulating uncertainty in the model inputs by a joint probability distribution and then analysing the induced uncertainty in outputs* (Oakley & O'Hagan, 2004).

Methodological Approach

A traditional approach to HTA was applied in the methodology section – a combination of analytical frameworks (QALYs, cost-utility analysis via ICER, one-way and probabilistic sensitivity analysis via Monte Carlo simulation) as well as theoretical framework (NICE's Evidence standards framework for digital health technologies). The target group for performing the analysis were patients with depression – data of the effects (Beck Depression Inventory II scale) were taken from a randomized clinical trial published by Luxton et al. (2015). Costs are coming from various sources tailored to the UK environment. The analysis was carried out using Microsoft Excel Version 16.59.

While building the model I firstly attempted to replicate a study by Bounthavong et al. (2016) published in the Journal of Telemedicine and Telecare[6] that provides *an economic evaluation of home-based telebehavioral health care compared to in-person treatment delivery for depression*. Additionally, the study by Bounthavong et al. (2016) also utilized the data from above mentioned RCT. I then updated the data model to make it suitable for the United Kingdom setting.

Furthermore, I used NICE's Evidence standards framework (ESF) for digital health technologies, which *describes standards for the evidence that should be available, or developed, for DHTs to demonstrate their value in the UK health and social care system* (NICE, 2018). The ESF helps to improve HTA for digital technologies as it was designed to provide missing standardized approach needed for the clinical and economic evaluation of digital health technologies (Unsworth et al., 2021).

Data

Population

The patient population considered in this analysis equivalent to the patient population from a randomized clinical trial. The RCT *In-home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression* (Luxton et al., 2015) was conducted in the USA and sponsored by the National Centre for Telehealth and Technology in 2017. The study was interventional with 121 participants enrolled and consisted of randomized allocation of patients between two arms: i) experimental – at home

[6] Journal of Telemedicine and Telecare is part of the SAGE journal available online.

behavioural activation and ii) active comparator – in-person behavioural activation. The study evaluated the effectiveness of web-based behavioural activation in eight sessions over the approximate course of eight weeks.

Table 2: *Baseline demographics of the home-based telebehavioral health (HBTBH) and in-person (IP) care groups*

	HBTBH (n = 62)	IP (n = 59)	Total (n = 121)
Age (years, SD)	34,76 (12,42)	35,56 (11,76)	35,1 (12,10)
Sex (n, %)			
Male	52 (83,87)	47 (79,66)	99 (81,82)
Female	10 (16,13)	12 (20,34)	22 (18,18)
Race/ethnicity (n, %)			
White, non-Hispanic	44 (70,97)	41 (69,49)	85 (70,25)
Black, non-Hispanic	8 (12,90)	10 (16,95)	18 (14,88)
Asian, non-Hispanic	3 (4,84)	1 (1,69)	4 (3,31)
Native American, non-Hispanic	1 (1,61)	0 (0,00)	1 (0,83)
Hispanic, any race	3 (4,84)	7 (11,86)	10 (8,26)
Other/unknown	3 (4,84)	0 (0,00)	3 (2,48)
Education (n, %)			
High School	13 (20,97)	16 (27,12)	29 (23,97)
Some College	32 (51,61)	24 (40,68)	56 (46,28)
2-Year college	8 (12,90)	13 (22,03)	21 (17,36)
4-Year college	9 (14,52)	6 (10,17)	15 (12,40)

Source: A Randomized Controlled Trial of In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression (Luxton et al., 2015)

The measure of effectiveness used was Beck Hopelessness Scale and Beck Depression Inventory-II on baseline, midpoint in week four, post-treatment in week eight and in three-month follow-up. Baseline and 3-month follow-up data was used for the evaluation.

Table 3: *Measures of effectiveness for HBTBH and IP care*

	Beck Hopelessness Scale		Beck Depression Inventory II	
Timeline	**HBTBH**	**IP**	**HBTBH**	**IP**
Baseline	9,00 (5,12)	10,37(6,13)	27,59 (10,45)	29,71 (11,33)
Midpoint – Week 4	7,04 (5,64)	7,96 (6,26)	19,41 (11,77)	20,21 (13,09)
Post Treatment – Week 8	4,89 (4,63)	4,43 (4,94)	13,82 (12,02)	11,74 (12,08)
3-month follow-up	5,21 (5,10)	5,53 (5,97)	14,76 (12,89)	15,00 (12,61)

Source: A Randomized Controlled Trial of In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression (Luxton et al., 2015)

The utility scores were taken from the study done by Bounthavong et al. (2016), which acquired the results from complete cases in the clinical trial and derived utility scores from the BDI-II mapped to the EuroQol five dimensions questionnaire with three levels (EQ-5D-3L)[7].

Table 4: *Utility scores for HBTBH care and IP care estimated from the Beck Depression Inventory II*

	Utility scores	IP care n	IP care Proportion	IP care Expected utility	HBTH care n	HBTH care Proportion	HBTH care Expected utility
Baseline depression state							
Not depressed	0,199	3	0,083	0,017	3	0,071	0,014
Mild depression	0,168	5	0,139	0,023	8	0,190	0,032
Moderate depression	0,139	9	0,250	0,035	15	0,357	0,050
Severe depression	0,067	19	0,528	0,035	16	0,381	0,026
3-month post-depression state							
Not depressed	0,199	15	0,417	0,083	12	0,286	0,057
Mild depression	0,168	5	0,139	0,023	10	0,238	0,040
Moderate depression	0,139	7	0,194	0,027	10	0,238	0,033
Severe depression	0,067	9	0,250	0,017	10	0,238	0,016

Source: A complete case analysis done by Bounthavong et al. (2016)

Costs

The analysis considered the costs associated with the cost of technical support for technical issues, cost of equipment, labour inputs and travel costs. All costs data are summarized in Table 5. The costs are calculated from a societal perspective, meaning the total costs include time costs, opportunity costs and community preferences (Garrison et al., 2010). As the time horizon of the analysis is three months, discounting future costs was not necessary.

The cost of technical support was taken from Glassdoor UK (2022), where the yearly salary of A/V technician of IT support is £27 066, therefore £14,07/hour for on-site or remote support. The range low is set at minus 20 % at £11,25 and range high plus 20 % at £16,88/hour. In this analysis IT support is considered as remote, therefore no travel reimbursement of IT services is factored in. Bounthavong et al. (2016) estimated that *there would be on average 3,19 sessions with technical issues requiring 30min of audio-visual technician's time*, with the range low and high set minus / plus 20%.

[7] EQ-5D-3L is a measure that generates a single index value for health-related quality of life; essentially consisting of two pages, i) descriptive system where self-evaluation is performed in regard to mobility, self-care, usual activities, pain/discomfort and anxiety/depression with each dimensions having three possible level; and ii) visual analogue scale where overall health is accessed by the individual on a scale 0-100 (EuroQol, 2022).

The cost of laptop was taken from Amazon website (2022) - all new laptops that had a built-in front camera were sorted according to the average customer review. Then the average price of first 10 laptops was taken with the resulting price of £689 per laptop. The range low and the range high was set minus, plus 20 %. Compared to the study done by Bounthavong et al. (2016) the cost of webcam was not taken as separate item.

According to a report published by Statista[8] (2019) there is 88 % of households with access to a computer in the United Kingdom. The range low and the range high was set minus, plus 10 %; at 0,79 range low and at 0,97 as range high.

The average annual salary for full-time workers was £31 285 from Statista (2021). Range low was taken as the lowest average annual salary in UK region, which was North East UK at £27 515 and range high was taken as highest average annual salary in UK regions, which was London at £39 719 (Statista, 2021). The study by Bounthavong et al. (2016) took a different approach, with range low and range high as minus, plus 20 % consequently. The hourly wage for UK was calculated by dividing the annual salary by 52 weeks and then dividing by 37 hours per week. This provides an average wage of £16,26/hour, range low of £14,30/hour and range high £20,64/hour.

Another aspect that was factored in the model are travel costs. According to NimbleFins[9] (2022) the average cost per mile was 47p. The range low and range high was taken as minus, plus 20% at 38p and 56p respectively. The average length of a car trip in the UK was taken as 8.4 miles per trip from NimbleFins (2021). Therefore, the mileage per round trip of 16,8mi was considered. To set the range low and high, average car trip distance in the UK from NimbleFins (2021) was considered - range low was set at 7,0mi and range high at 9,2mi, for round trip 14,0mi and 18,4mi consequently. Furthermore, trip time was considered – according to Jerry[10] (2022) it takes on average 1min and 45seconds to travel one mile, therefore round-trip took

[8] Statista is a *German company specializing in market and consumer data, according to the company, its platform contains more than 1,000,000 statistics on more than 80,000 topics from more than 22,500 sources and 170 different industries, and generates a revenue of about €60 million (*Statista, 2022).
[9] NimbleFins *is a personal finance website that conducts in-depth research & analysis on a variety of topics from insurance and credit cards to everyday spending and household budgets* (NimbleFins, 2022).
[10] Jerry is an *American insurance company, their mobile app allows users to compare and buy insurance, primarily for vehicle insurance but also home insurance using artificial intelligence* (Jerry, 2022).

29,4 minutes. The range low and range high was set as minus, plus 20 % at 23,5 minutes and 35,3 minutes consequently.

Table 5: *Variables considered in the model*

Variable inputs	Mean	Range low	Range high	Distribution	Source
HBTBH and IP inputs					
HBTBH sessions per patient	8,00				RCT
IP sessions per patient	8,00				RCT
HBTBH total number of sessions	472,00				RCT
IP total number of sessions	496,00				RCT
Number of sessions w/ tech. issues	3,19	2,55	3,83	beta	RCT
Cost of tech. support (per hour)	£14,07	£11,25	£16,88	normal	Glassdoor (2022)
Equipment inputs					
Cost of laptop	£689,00	£551,20	£826,80	normal	Amazon (2022)
Prop. w/ access to computer	0,88	0,79	0,97	normal	Statista (2021)
Labour Inputs					
Average wage (per hour)	£16,26	£14,30	£20,64	normal	Statista (2021)
Travel cost					
Cost per mile	£0,47	£0,38	£0,56	normal	NimbleFins (2022)
Number of miles (round-trip)	16,80	14,00	18,40	normal	NimbleFins (2021)
Trip time in minutes (round-trip)	29,40	23,40	35,28	normal	Jerry (2021)

Source: Various input sources

Analyses

The first step in conducting a wholistic HTA was a replication of study done by Bounthavong et al. in 2016, which provides an *economic evaluation of home-based telebehavioral health care (HBTBH) compared to in-person (IP) treatment*. The study compared overall QALYs for IP and HBTBH care, followed by cost utility analysis via ICERs and one way and probabilistic sensitivity analysis for the input variables. Variable names used in the equations are depicted in Appendix Table 1.

Quality Adjusted Life Years (QALYs)

The QALYs for IP and HBTBH care were calculated from expected utility for baseline (start of the study) and for three-month post treatment. The study by Bounthavong et al. (2016) used a trapezoidal method assuming the two different time points (baseline and three-month follow-up) are connected by a straight line, therefore calculated the sum for baseline and three-month total. Then QALY was calculated as an average of the sum of expected utilities.

$$QALY_{AVG} = \frac{\sum_{states} E[U_{base}] + \sum_{states} E[U_{3months}]}{n_{states}}$$

To account for different baselines between treatment arms, I decided to go with the difference approach of calculating QALYs.

$$QALY_{DIFF} = \sum_{states} E[U_{base}] - \sum_{states} E[U_{3months}]$$

Furthermore, I calculated QALYs for reach of the depression states using the difference approach.

$$QALY_{DIFF} = E[U_{base}]_{dep.state} - E[U_{3months}]_{dep.state}$$

Calculation of IP & HBTBH costs

When calculating the costs of IP and HBTBH various costs were considered. For IP care labour inputs and travel expense were considered, for HBTBH labor inputs, cost of equipment and cost of technical support were considered.

IP costs

$$C_{labor} = N_{IPsess.} * W_{hourly}$$

$$C_{travel} = N_{IP\ sess.} * ((C_{mile} * N_{miles}) + (W_{hourly} * \frac{t_{travel}}{60}))$$

$$C_{IP_{total}} = C_{labor} + C_{travel}$$

HBTBH costs

$$C_{labor} = N_{HBTBHsess.} * W_{hourly}$$

$$C_{equip.} = \frac{N_{HBTBHsess.}}{N_{HBTBHsess._{per\ patient}}}(1 - prop_{HBTBH_{PC}}) * C_{laptop}$$

$$C_{tech.sup.} = N_{HBTBHsess._{tech.issues}} \frac{C_{tech.sup._{hour}}}{2} * \frac{N_{HBTBHsess.}}{N_{HBTBHsess._{per\ patient}}}$$

$$C_{HBTBH_{total}} = C_{labor} + C_{equip.} + C_{tech.sup.}$$

Cost-utility analysis (CUA)

Cost utility *analysis compares the cost of different procedures with their outcomes measured in "utility based" units* (Robinson, 1993), meaning units that are related to a person's wellbeing. In this analysis, quality-adjusted life-years (QALYs) were considered as utility measure when estimating the cost effectiveness rations (ICERs). To be able to calculate the ICER, difference in costs and QALYs were calculated.

$$ICER = \frac{C_{HBTBH_{total}} - C_{IP_{total}}}{QALY_{HBTBH_{total}} - QALY_{IP_{total}}}$$

Additionally, ICER was calculated for each of the depression states using the QALYs of various states for the effect and the above costs.

One-way sensitivity analysis

One-way sensitivity analysis was carried out for each of the variables entering the model. First the calculation of "Low" and "High" results was done for IP and HBTBH care using range low for each of the variable separately, and then using range high for each of the variables separately. The number for low and high range was taken from the table Variables considered in this model (Table 5). Then the difference for "Low" between IP and HBTBH care and the difference for "High" between IP and HBTBH care was calculated for each of the variables. This result then entered the difference with base case scenario, which served as a basis for creating a tornado diagram.

The calculation below illustrates the calculation of for <u>Number of sessions with technical issues:</u>

1) Calculation of low (LR) and high result (HR) for HBTBH care

$$(LR)C_{HBTBH_{per\ patient}} = (C_{labor} + C_{equip.} + (RL)N_{HBTBHsess._{tech.issues}} \frac{C_{tech.sup._{hour}}}{2} * \frac{N_{HBTBHsess.}}{N_{HBTBHsess._{per\ patient}}})/N_{HBTBHpatients}$$

$$(HR)C_{HBTBH_{per\ patient}}$$

$$= (C_{labor} + C_{equip.} + (RH)N_{HBTBHsess._{tech.issues}} \frac{C_{tech.sup._{hour}}}{2} * \frac{N_{HBTBHsess.}}{N_{HBTBHsess._{per\ patient}}})/N_{HBTBHpatients}$$

2) Calculation for both low and high result for IP care is the same – number of technical issues does not enter the equation.

$$(LR)C_{IP_{per\ patient}} = (C_{labor} + C_{travel})/N_{IPpatients}$$

$$(HR)C_{IP_{per\ patient}} = C_{labor} + C_{travel}/N_{IPpatients}$$

3) Calculation of the differences between low results for IP and HBTBH care and between high results for IP and HBTBH care.

$$LR_{diff} = (LR)C_{HBTBH_{per\ patient}} - (LR)C_{IP_{per\ patient}}$$

$$HR_{diff} = (HR)C_{HBTBH_{per\ patient}} - (HR)C_{IP_{per\ patient}}$$

4) Comparison with the base case scenario results.

$$(LR)BC_{diff} = (C_{IP_{per\ patient}} - C_{HBTBH_{per\ patient}}) - LR_{diff}$$

$$(HR)BC_{diff} = (C_{IP_{per\ patient}} - C_{HBTBH_{per\ patient}}) - HR_{diff}$$

5) Results for each of the variables then enter the tornado diagram for one-way sensitive analysis.

Probabilistic sensitivity analysis

Probabilistic sensitivity analysis was carried out using Monte Carlo simulation for 1000 repeats. Normal distribution was applied to cost of technical support per hour, cost of laptop, proportion with access to a computer in HBTBH group, labour inputs, cost per mile, number of mile and trip time in minutes. Beta distribution was applied to number of sessions with technical issues. Distribution used for each of the variables that entered the probabilistic sensitivity analysis are also summarized in Table 5. For normal distribution, "norminv" and for beta distribution, "betainv" function was utilized in Microsoft Excel. Standard deviation was also calculated for the variables with normal distribution to be able to perform the analysis. After repeating the calculation 1000 times, costs and cost differences were calculated with the values and then visualized via histogram.

The syntax below illustrates the formula in Excel for beta distribution.

$$BETAINV(probability, alpha, beta, [A], [B])$$

If looking at a specific example, <u>number of sessions w/ technical issues;</u>

$$BETA.INV(RAND(); N_{HBTBHsess._{tech.issues}}; (8 - N_{HBTBHsess._{tech.issues}}); 0; 8)$$

where “rand” represents the probability associated with the distribution, alpha and beta expressions are parameters of distribution (in this case number of sessions with technical issues) and zero and eight represent the lower and upper bound of the interval (8 as there is eight number of sessions).

The syntax below illustrates the formula in Excel for normal distribution.

$$NORMINV(probability, mean, standard\_dev)$$

If looking at a specific example, <u>cost of tech support per hour;</u>

$$NORMINV(RAND(); C_{tech.sup._{hour}}; st.dev_{C_{tech.sup.}})$$

where “rand” represents the probability associated with the distribution, mean is the cost of technical support per hour and standard deviation was calculated for the cost of technical support.

Results

In the analytical framework of the I evaluated QALYs, calculated costs and cost differences, analyse cost-utility by estimating ICERs and performed one way and probabilistic sensitivity analysis of the costs. I then utilized NICE's Evidence standards framework for digital health technologies to further evaluate the use of telehealth in patients with depression.

Deterministic analyses

Results for Quality Adjusted Life Years (QALYs) did not differ much for IP and HBTBH care when using the QALY average approach as in Bounthavong et al. (2016) – IP care had 0,004 lower QALY than HBTBH care. However, using average approach can lead to biased results when having different baselines in treatment arms. To account for different starting points, the QALY difference approach was utilized, which resulted in IP care having a higher QALY by 0,015 (Table 6).

Table 6: *Utilities calculated for IP and HBTBH*

Utilities	IP	HBTBH
Total exp. utility at baseline	0,110	0,121
Total exp. utility at 3-month	0,150	0,146
QALY Average	0,130	0,134
QALY Difference	0,040	0,025

Source: Own analysis

In the deterministic cost analysis approach (using mean values from Table 5), the total cost of IP care was higher than the cost of HBTBH care (the total cost of IP care was £15 934 compared to HBTBH care £13 877). The incremental difference in cost was £2 057 higher for IP care, which translates to £46 higher cost in IP care per patient (Table 7).

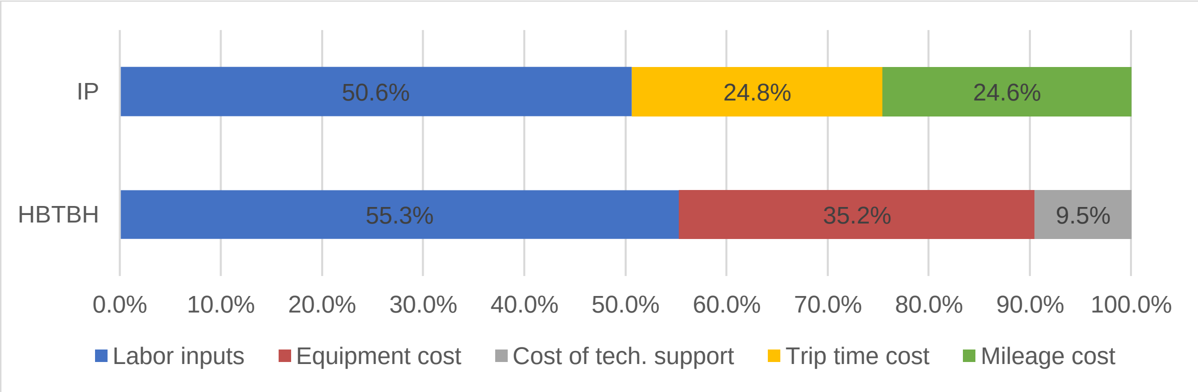
Table 7: *Summary of total costs and costs per patient (£)*

Strategy	Total cost for strategy	Difference in total cost	Total cost per patient	Difference per patient
IP	£15 933,50	£2 056,64	£270,06	£46,24
HBTBH	£13 876,85		£223,82	

Source: Own analysis

Figure 2 shows that for both treatment arms, care costs were mainly driven by labor inputs. For IP care trip time cost, along with mileage cost had similar effect on the overall total cost. For HBTBH care the second largest driver were the equipment costs required to deliver the treatment, while the cost of technical support was relatively small.

Figure 3: *Proportion of costs for each treatment arm*



Source: Own analysis

The cost-utility analysis was completed using the QALYs difference approach together with the total cost per patient for IP and HBTBH care. The results were considered for estimating the incremental cost-effectiveness ratio (ICER). The ICER between IP and HBTBH was £3 016, meaning the difference in costs per additional QALY gained is equal to £3 016 per patient (Table 8).

Table 8: *Results from cost-utility analysis*

Strategy	Total cost per patient	Difference in costs	Total QALYs	Difference in QALYs	ICER
IP	£270,06	£46,24	0,040	0,015	£3 016,44
HBTBH	£223,82		0,025		

Source: Own analysis

Furthermore, cost-utility analysis was performed for various depression states. The costs within each of the health states stayed the same, while the QALYs (difference approach) varied according to utility scores for HBTBH care and IP care. Utility scores were estimated from the complete case analysis of BDI-II scores done by Bounthavong et al. (2016) (Table 4). The difference in cost per patient together with the difference in QALYs were then considered for estimating the incremental cost-effectiveness ratio (ICER) (Table 9).

Table 9: *Results from cost-utility analysis*

Depression state	Total cost per patient	Difference in costs	QALYs	Difference in QALYs	ICER
Not depressed					
IP	£270,06	£46,24	0,066	0,024	£1 952,58
HBTBH	£223,82		0,043		
Mild depression					
IP	£270,06	£46,24	0,000	-0,008	-£5 734,01
HBTBH	£223,82		0,008		
Moderate depression					
IP	£270,06	£46,24	-0,008	0,009	£5 280,24
HBTBH	£223,82		-0,017		
Severe depression					
IP	£270,06	£46,24	-0,019	-0,009	-£5 112,11
HBTBH	£223,82		-0,010		

Source: Own analysis

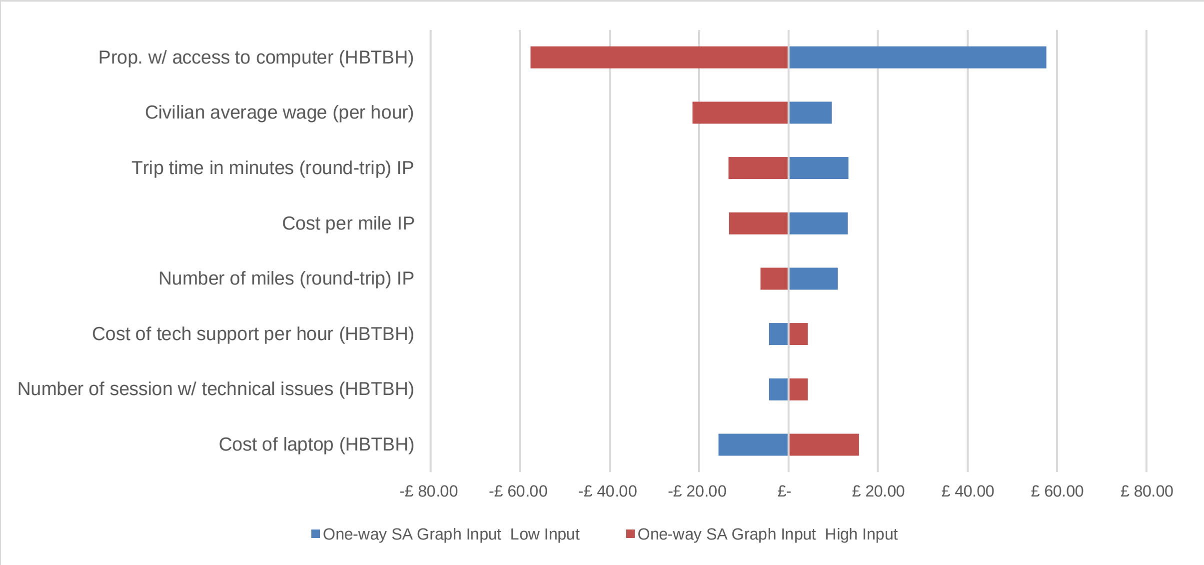
Based on the cost-utility analysis for each of the depression states, ICER is positive for not depressed and for moderate depression states. Meaning, the cost per additional QALY gained is £1 953 for not depressed state, £5 280 for moderate depression respectively. In mild depression and severe depression, ICER is negative, meaning HBTBH care is dominant. However, the difference in QALYs is small, therefore it’s difficult to draw conclusions and patient level data would be needed to provide more precise results.

Sensitivity analyses

Bounthavong et al. *claim that the differences in behavioural health outcome were not expected to be different based on the results of the HBTBH clinical trial program* (2016). Sensitivity analyses were therefore done by cost-minimization approach, meaning utilities (QALYs) for the two treatment arms are considered the same and only costs are further analysed.

One-way sensitivity analysis was performed to test the robustness of the model assumptions, meaning how each of the variables effect the difference in cost per patient between the treatment arms. Based on the results, the cost difference is most sensitive to proportion with access to computer, cost of laptop and civilian average wage, while cost of technical support and number of sessions with technical issues seem to have relatively low effect on the difference in costs (Figure 3).

Figure 4: *Tornado diagram for One-way Sensitivity Analysis of costs per patient*



Source: Own analysis

Probabilistic sensitivity analysis was performed to evaluate how the variables effect the total cost for both strategies, total difference in cost between the strategies, total price per patient for both strategies as well as total difference in cost per patient. The incremental difference in total costs between IP care and HBTBH was £ 2 015 (95% CI: -£2134–£6089), which translates to £46 (95% CI: -£21,02–£112,74) difference in cost per patient (Table 10).

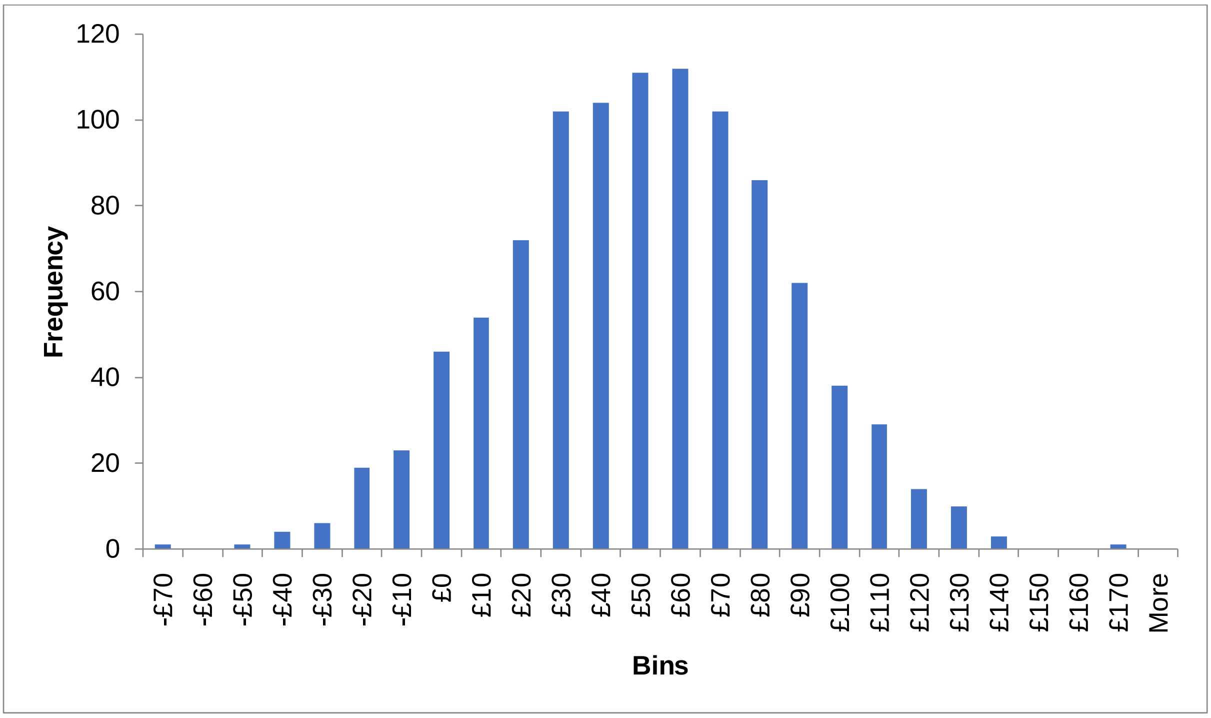
Table 10: *Results from Probabilistic Sensitivity Analysis*

Strategy	Total cost for strategy	Difference in total costs	Total cost per patient	Difference per patient
IP	£15 935,50 *(95% CI: £12746,63–£19350,24)*	£2 014,50 *(95% CI: -£2134,35–£6088,79)*	£270,09 *(95% CI: £216,04–£327,97)*	£45,56 *(95% CI: -£21,02–£112,74)*
HBTBH	£13 921,00 *(95% CI: £9505,67–£18215,54)*		£224,53 *(95% CI: £153,32–£293,80)*	

Source: Own analysis

The confidence interval for the difference in total cost (as well as per patient) includes zero, meaning difference in cost is not statistically significant from zero (on 95% CI). However, as visible in Figure 5, based on probabilistic sensitivity analysis of cost difference per patient, HBTBH care was less expensive in 90 % of the cases in comparison with IP care.

Figure 5: *Histogram for Probabilistic Sensitivity Analysis of cost difference per patient*

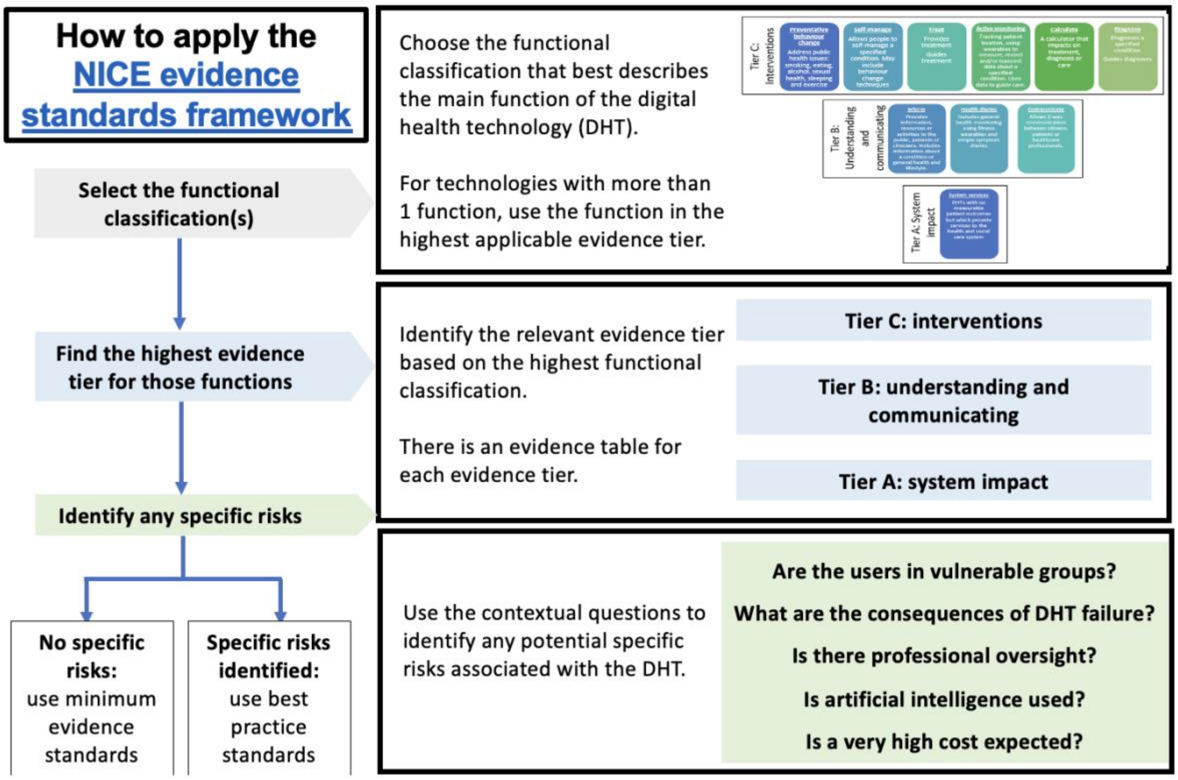


Source: Own analysis

NICE's Evidence standards framework for digital health technologies

To further evaluate the use of telehealth in patients with depression in a more structured way, I utilized the Evidence standards framework for Digital health technologies developed by NICE (2018). The framework is divided into two sections: Section A: Evidence for effectiveness standards and Section Evidence for economic impact standards. The diagram below (Figure 6) illustrates how the framework should be applied, which was followed within the discussion.

Figure 6: *How to apply the NICE evidence standards framework*



Source: NICE's Evidence standards framework for DHT (2018)

Section A: Evidence for effectiveness standards

The first step is selecting the functional classification that best describes the main function of the DHT within Section A. Two of the evidence tiers could be applied to telehealth: Tier B: Understanding and communicating and Tier C: Interventions. According to the guidance the function in the highest applicable evidence tier should be applied, therefore I selected Tier C Interventions, more specifically the functional classification "Treat". According to the framework, it is described *as providing treatment for a diagnosed condition (such as cognitive behavioral therapy for anxiety),* *or guides treatment decisions* (NICE, 2018). The example of DHTs in this functional classification specifically mentions treating mental health, which is how telehealth was used in the assessed clinical trial – *cognitive behavioural activation for depression* (Luxton et al., 2015).

Identifying higher risk DHTs according to the five contextual question was the second step of the analysis. If the question determines the DHT as higher risk, then instead of using minimum evidence standard, best practice standards should be used within the evidence category. It can be argued that due to the first question *Are the intended users of the digital health technology (DHT) considered to be in a potentially vulnerable group such as children or at-risk adults*?, telehealth in this context is considered as higher-risk DHT. NHS England defines “at-risk adults” as *adults who may need community care services by reason of mental or other disability, age or illness; and who is or may be unable to take care of him or herself, or unable to protect him or herself against significant harm or exploitation* (NICE, 2018). This statement is further supported by the definition of depression, which includes suicidal attempts along with self-mutilation (Mayo Clinic, 2022). Second question – evaluating the consequences of DHTs failure – is arguable since the cognitive behavioural activation in the RCT has been done on a predetermined basis, therefore no immediate risk of life is associated with the DHT failing to perform as described. Third question – professional oversight – the sessions are done with a clinical professional, therefore could be considered as lower risk. Fourth question – use of artificial intelligence – is not applicable in this case as no artificial intelligence was considered in this RCT. Final question – expectation of high cost – is again arguable and dependent on various factors (size of the population, proportion with access to telehealth). Based on these assumptions, telehealth, in the context of *A Randomized Controlled Trial of In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression*, is categorized as a high risk DHT, therefore best practice standards should be utilized.

Next step in the Section A is to apply Tier C evidence standards to DHTs that function as interventions. Evidence categories that are relevant for the thesis analysis are:

- Demonstrating effectiveness for treat, active monitoring, calculate or diagnose functions
- Use of appropriate behaviour change techniques

- Ongoing data collection to show usage and value of DHT
- Quality and safeguarding
- Credibility with UK health and social care professionals
- Relevance to current care pathways in the UK health and social care system
- Acceptability with users
- Equalities considerations

In the evidence category Demonstrating effectiveness for treatment, best practice standard is *a high-quality randomized controlled study in a setting relevant UK health and social care system, comparing the digital health technology (DHT) with a relevant comparator and demonstrating consistent benefit including in clinical outcomes in the target population, using validated condition-specific outcome measures* (NICE, 2018). The RCT utilized within this thesis is done in USA, therefore, to be able to make a more accurate analysis, the RCT would have to be done in UK.

Considering the evidence category Use of appropriate behaviour change techniques, it can be argued that telehealth in the sense of behavioural activation for depression is used appropriately. A systematic review done by Palylyk-Colwell & Argáez (2018) claims that telehealth is a viable option for delivery of psychotherapy to patients with depression.

In category Ongoing data collection to show usage of DHT and to show the value of DHT, the data collection was ongoing throughout the assessed RCT. Data collection happened for the number of sessions that happened via telehealth, number of sessions with technical issues as well as the change in depression scales (Luxton et al., 2015). Furthermore, *treatment completers indicated high overall satisfaction with the treatmen*t (Luxton et al., 2015).

For Quality and safeguarding evidence category, the sponsor of the RCT provided study participants with high level security software and hardware (Luxton et al., 2015). However, if patients were to use their own technology, safeguarding measures would have to be put in place.

In terms of Credibility with UK health and social care professionals along with Acceptability by users, both participants and health care professionals were administered with pre-assessment encounter which briefed both sides on how to use the technology (Bounthavong et al., 2016).

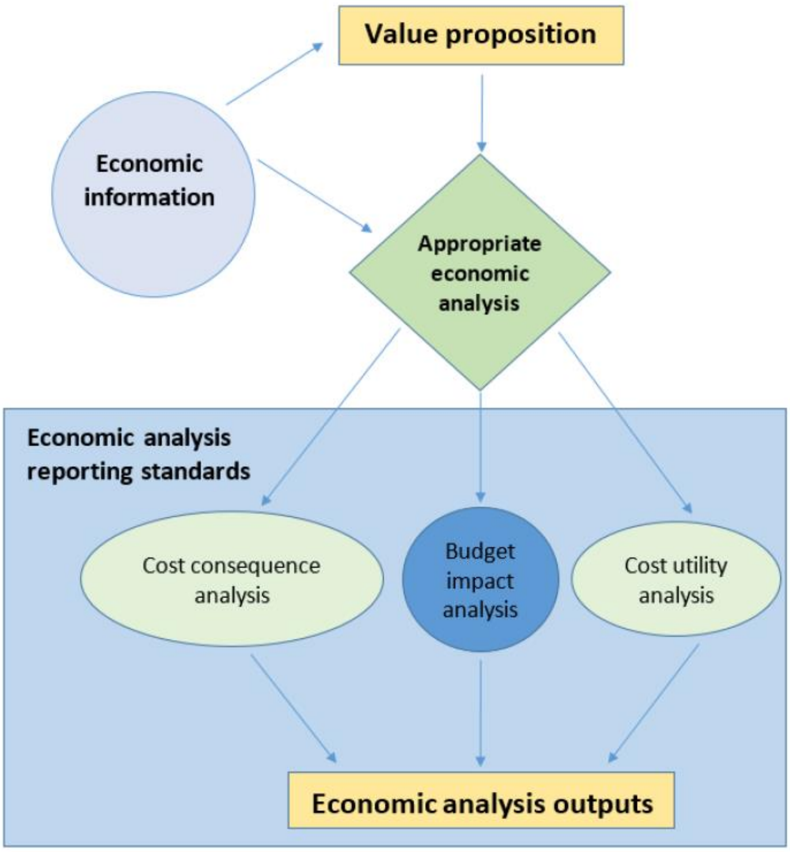
In the evidence category Relevance to current care pathways in the UK health and social care system – as mentioned above, the RCT has been conducted in the USA, therefore further study would have done in the UK. Nonetheless, the care pathways for treating depression are similar in the USA and UK (Link et al., 2011), therefore it could be argued that the design of the RCT is applicable for UK setting.

For the evidence category Equalities considerations - *show evidence of the DHT being used in hard-to-reach populations, or that its use reduces health inequalities* (NICE, 2018). The use of telehealth could reduce health inequalities in the sense that treatment can be delivered even to those living in rural areas. However, for telehealth to reduce inequalities, it also means to have the technology available for everyone.

Section B: Evidence for economic impact standards

The economic impact standards of the NICE's framework are separated into three major components: i) *key economic information,* ii) *appropriate economic analysis and* iii) *economic analysis reporting standards* (NICE, 2018).

Figure 7: Overview of relationship between components for economic impact



Source: NICE's Evidence standards framework for DHT (2018)

For the key economic information, user population size, current and proposed pathways and parameters of the economic model are comprised. The population size has been thoroughly defined within the RCT. On the other hand, if the telehealth treatment was to be scaled as a standard of treatment, the whole UK population with depression would have to be considered. Current and proposed care pathways would be the same even after the implementation of telehealth, as both treatment arms have the same lengths and number of sessions. In terms of parameters for the economic model – intervention parameters, cost parameters, resource use parameters and utilities were considered.

In terms of appropriate economic analysis, since a randomized clinical trial was evaluated, it can be assessed as pilot study. A pilot study bares a low economic risk to the payer (NICE, 2018) and the economic analysis level is evaluated as basic. However, when attempting to scale the digital health technology to national level, high level of economic risk is perceived together, which mean high financial commitment at economic analysis level (NICE, 2018).

For economic analysis reporting standards, following components were considered: i) economic perspective – a societal perspective was taken in the analysis as some of the costs are bared by the patient, ii) time horizon of three months was evaluated, therefore no discounting considered, iii) sensitivity analyses were performed for the cost inputs, iv) critique of the economic analysis – mentioned in the discussion.

According to the NICE’s Evidence standards framework for digital technologies a thorough analysis have been executed based on data from *A Randomized Controlled Trial of In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression* (Luxton et al., 2015). Telehealth demonstrates its value in terms of efficacy and costs. However, to further evaluate the use of telehealth as means of treatment for depression in the whole population, further analyses is needed along with a RCT performed within the setting of NHS.

Discussion

As the Covid-19 pandemic accelerated the development and adoption of digital technologies across industries, adoption of telehealth has also increased within the healthcare sector. Unfortunately, the Covid-19 pandemic also contributed to increased prevalence of depression (WHO, 2022). This thesis therefore evaluated the use of telehealth compared to in person care in patients diagnosed with depression.

Telehealth provides new opportunities for both treatment and diagnosis of patients. Additionally, telehealth enables to provide care to people with limited mobility or to those living in rural areas. In the context of the thesis, telehealth, was taken as a means of treatment for patients with depression.

To be able to implement novice digital health technologies, it is imperative to evaluate these technologies and demonstrate their value (both in terms of efficacy and cost). However, there is few frameworks providing coherent guidance on health technology assessment of digital technologies. Furthermore, there is very few studies available that evaluate digital technologies in healthcare (in both efficacy and cost). The thesis therefore aims to fill the gap and provide a comprehensive health technology assessment of telehealth.

Health technology assessment (HTA) was performed following the evaluation done by Bounthavong et al. (2016). Moreover, the data was tailored to the UK settings as NICE's Evidence standards framework for digital health technologies was utilized. For the efficacy, similarly to the study by Bounthavong et al. (2016), the data was taken from a Randomized Controlled Trial of *In-Home Tele-Behavioural Health Care Utilizing Behavioural Activation for Depression* (Luxton et al., 2015).

Based on the results from the analysis, result for calculated QALY is negligible and both treatment arms are comparable without any large differences (difference in QALY was 0,015). It can be argued that there is little significant difference in efficacy for the two strategies (IP and HBTBH). The calculated ICER between IP and HBTBH was £3 016, meaning the difference in costs per additional QALY gained is equal to £3 016 per patient. The calculated ICER value is relatively low for IP and HBTBH, meaning the willingness to pay value can be low as well.

In cost minimization analysis (CMA), efficacy is assumed to be similar between HBTBH and IP care (Bounthavong et al., 2016). Therefore, to further illustrate the value of telehealth, cost-minimization analysis (CMA) was performed. The analysis showed that the incremental difference in cost was £2 057 higher for IP care, which translates to £46 higher cost in IP care per patient.

Sensitivity analyses (one-way and probabilistic sensitivity analysis) were performed to test the robustness of the model. The cost difference per patient was most sensitive to proportion with access to computer, cost of laptop and civilian average wage, while cost of technical support and number of sessions with technical issues seem to have relatively low effect on the difference in costs Based on probabilistic sensitivity analysis, HBTBH was less expensive in 90 % of the cases suggesting that HBTBH could be less expensive. It could be argued that if a patient has access to a videoconference technology, it makes sense from a cost perspective to follow the telehealth strategy. Therefore, telehealth could become an alternative for patients with depression.

As with all the studies, assumptions were a source of limitation for the analyses. Major perceived limitation is no access to patient level data. Likewise, depression scores (Beck Hopelessness Scale and BDI-II scores) did not differ between the two treatment groups, which was the reason for opting for CMA. This further affects that no sensitivity analysis was done for the utilities. One of limitations related to the data might be too few participants in the available clinical trial results. Another perceived limitation could be the number of sessions for which the treatment was evaluated – as the horizon the of the study is only three months, it would be beneficial to assess longer term of telehealth treatment.

Even though, the study has various limitations, there are strengths associated with the assessment as well. One of the perceived strengths of the study is providing comprehensive economic evaluation according to the NICE's Evidence standards framework for digital health technologies. I believe an improvement was made to the study done by Bounthavong et al. (2016) by utilizing the difference approach for calculating QALYs, which accounts for various efficacy baselines.

An implication from this analysis, would be constructing a decision tree which would consider the ownership of technology allowing for telehealth treatment, as well as distance (and time) needed to travel for the appointment (cost of travel). In a hypothetical scenario, it could make sense for a patient that is living far from the clinic where treatment is executed, to undergo the treatment via telehealth. On the other hand, if the patient is living in a proximity to the clinic and does not have access to the technology, from cost perspective it could make more sense for them to undergo the treatment in person. Another important aspect that should be considered is patient’s preference to create a personalized treatment.

It can be concluded that telehealth demonstrates its value according to the NICE’s Evidence standards framework for digital technologies. However, to make the decision whether to implement telehealth treatment as a standard of care in patients with depression, further analysis would have to be done. More precisely a randomized clinical trial would have to be tailored to the British setting.

Conclusion

The thesis evaluated the difference between telehealth and in-person treatment in patients with depression. Based on the results it can be argued that treatment strategies are very similar in terms of treatment effectiveness. Therefore, the focus of the analysis was more on the cost, specifically on the main drivers of cost difference among the two treatments. It was found there is no statistically significant difference between costs for telehealth and in-person treatment. However, results of probabilistic sensitivity analyses demonstrate that home-based telebehavioral care was cheaper in 90 % of simulations. From a cost perspective, this means home-based telebehavioral care is the preferred option in most cases. A deep dive cost analysis would allow to construct a decision tree, which would use identified key parameters (technology ownership, travel distance and travel time for the appointment) to decide the treatment based on individual situation and needs. This would help to access patient's preferences and create a personalized treatment. In a hypothetical scenario, patients with access to the digital technology with a lengthy traveling time (and distance) would prefer home-based behavioural care treatment. On the other hand, patients living near the clinic could undergo treatment in-person, especially if they would not possess video-conferencing device.

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Appendix

Ap. – Table 1: *Variable abbreviations*

Variable inputs	Variable abbreviation
HBTBH and IP inputs	
HBTBH sessions per patient	$N_{HBTBHsess.per\ patient}$
IP sessions per patient	$N_{IPsess.per\ patient}$
HBTBH total number of sessions	$N_{HBTBHsess.}$
IP total number of sessions	$N_{IPsess.}$
Number of session w/ technical issues	$N_{HBTBHsess.tech.issues}$
Number of session w/ technical issues – range low	$(RL)N_{HBTBHsess.tech.issues}$
Number of session w/ technical issues – range high	$(RH)N_{HBTBHsess.tech.issues}$
Cost of tech support per hour	$C_{tech.sup.hour}$
Equipment inputs	
Cost of laptop	C_{laptop}
Prop. w/ access to computer HBTBH	$prop_{HBTBHpc}$
Labour Inputs	
Average wage (per hour)	W_{hourly}
Travel expense	
Cost per mile	C_{mile}
Number of miles (round-trip)	N_{miles}
Trip time in minutes (round-trip)	t_{travel}
Costs	
Cost of labor	C_{labor}
Cost of travel	C_{travel}
Cost of equipment	$C_{equip.}$
Cost of technical suport	$C_{tech.sup.}$
Cost of IP total	$C_{IPtotal}$
Cost of HBTBH total	$C_{HBTBHtotal}$
QALY calculation	
Total exp. utility at baseline	$E[U_{base}]$
Total exp. utility at 3-month	$E[U_{3months}]$
QALY calculated on Average	$QALY_{AVG}$
QALY calculated on Difference	$QALY_{DIFF}$
Number of depressed states	N_{states}
QALY for HBTBH total	$QALY_{HBTBHtotal}$
QALY for IP total	$QALY_{IPtotal}$