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Horizon Scanning Report: Neurotechnology for Mental Health, Healthy Ageing and Physical Disability

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Glossary

Health Technology (HealthTech): is defined as an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program, or system (definition from the HTA Glossary; http://htaglossary.net/health+technology).

Medical devices: are any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. Devices intended to diagnose, treat, prevent, or cure a disease or condition are regulated and must undergo a conformity assessment to demonstrate they meet legal requirements to ensure they are safe and perform as intended. In the UK the legal requirements are set out in the Medical Devices Regulations (MDR/2002 (based on the old EU Directives)) which are implemented by the competent authority, Medicines and Healthcare products Regulatory Agency (MHRA).

Neurotechnology: is a technology that enables a direct connection of technical components (e.g., electrodes, computers, or intelligent prostheses) with the nervous system. Neurotechnologies may be invasive (e.g., implanted electrodes) or non-invasive (e.g., electrode caps).

Digital health technologies (DHTs): use computing platforms, connectivity, software, and/or sensors for healthcare and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device.

Summary

Neurotechnology, defined as devices which enable a direct connection between technical components and the nervous system, is a rapidly emerging field with the potential to revolutionise technologies for a range of healthcare conditions. Mental health, healthy ageing, and physical disability are three such areas which neurotechnology innovations may target. The scope of this project encompasses these three research areas.

The aims of this project were to identify and describe neurotechnologies in development, and those that have recently been approved by the US Food and Drug Administration (FDA), and to assess the challenges and opportunities associated with neurotechnology innovation for mental health, healthy ageing, and physical disability. To identify the neurotechnologies in development, a horizon scan was undertaken in March 2024. Clinical trial registries were used as the primary source of information, with complementary searches performed for journal articles, conference abstracts, and news articles. To assess the challenges and opportunities associated with innovation, a literature review of relevant systematic reviews was carried out. Additionally, a survey questionnaire was distributed to contacts (including charities and professional bodies that related to neurotechnology or the included conditions) for advertisement to gain public perspectives on neurotechnologies, including awareness, adoptability, unmet needs, and concerns.

Overall, the horizon scan identified 81 unique neurotechnologies in development, with 23 relating to mental health, 31 to health ageing, and 42 to physical disability. Parkinson's disease, stroke, and depression were the most represented conditions. Considering Parkinson's disease and dementia/Alzheimer's disease specifically, technologies for the former were focused on mild to moderate and advanced/severe stages of disease, whereas those for the latter were focused on mild/early and mild to moderate stages of disease.

The FDA approval status of the identified technologies was ascertained via searching the Devices@FDA database. Less than one quarter of the technologies had received FDA approval. Characteristics of the identified technologies were also analysed. Wearable devices accounted for the majority of the technologies, followed by implantable devices, and most were non-invasive. Few devices had an AI component. Most of the technologies were intended for use in hospital, rather than at home. Treatment was the most common indicated stage of the care pathway, followed by rehabilitation. A range of types of technologies were identified, including various types of stimulation. However, transcranial magnetic stimulation, deep brain stimulation, and brain-computer interfaces were the most frequently identified.

A technology radar was developed to visualise the number of unique technologies for each condition at the different stages of development, both with and without FDA approval. There were 108 unique technology-combinations identified, with the majority of these falling within the earlier stages of development (pilot/early feasibility or traditional feasibility clinical trials) compared to later stages of development (pivotal or post-market clinical trials).

Results from the survey showed that only one third of respondents considered themselves to be at least slightly familiar with transcranial magnetic stimulation, deep brain stimulation, and brain-computer interfaces, despite these being the most common types of neurotechnologies identified in the horizon scan. A lack of trustworthy, digestible information of neurotechnologies was also highlighted. Addressing this challenge could potentially provide an opportunity to increase confidence in adoption of neurotechnologies. Safety was also indicated

as being paramount, reinforcing the need for responsible and ethical development and regulation of these devices.

Introduction

Background

Neurotechnology is an emerging field which has the potential to revolutionise the way we interact with technology and the environment. By 2026, the neurotechnology market is expected to be worth US$17.1 billion globally, with neuromodulation, neuroprosthetics, and neurosensing as the largest segments.[1] Interest and investments in neurotechnology are primarily driven by their perceived scientific, medical, and economic benefits. Neurotechnologies enable a direct connection of technical components (e.g., electrodes, computers, or intelligent prostheses) with the nervous system and may be invasive (e.g., implanted electrodes) or non-invasive (e.g., electrode caps).[2] Neurotechnology can target six of the ten leading causes of disability worldwide, including depressive and anxiety disorders, pain states, hearing loss, and dementias including Alzheimer's disease.[3] Neurotechnologies therefore have the potential to provide significant benefit for both mental and physical health of patients by supporting access and offering new treatments for some of the leading causes of disability. The economic potential of neurotechnology is vast, with applications ranging from enhancing cognitive performance in healthy individuals to developing advanced treatments for neurological disorders. This could lead to significant cost savings in healthcare and generate new revenue streams in consumer markets.

However, there are also some potential risks associated with neurotechnologies. For example, invasive neurotechnologies have the potential to cause infection or nerve damage. Non-invasive neurotechnologies may also cause side effects such as headaches or skin irritation. Additionally, there is a lack of long-term research on the effectiveness of neurotechnologies, which could lead to ineffective or even harmful treatments. Despite the growing interest in neurotechnologies, it is equally important to ensure that any development and regulation of these technologies is carried out responsibly and ethically. For this purpose, a horizon scan of neurotechnologies is required.

The scope of this project encompasses three key research areas:

- Neurotechnology for mental health
- Neurotechnology for healthy ageing
- Neurotechnology for physical disabilities

Neurotechnology for mental health covers conditions such as anxiety and depressive disorders, the latter of which will likely include Transcranial Magnetic Stimulation, a treatment with widespread adoption within the NHS. For healthy ageing, early dementia diagnosis is needed, as well as non-invasive neuropathic pain treatments. Finally, neurotechnologies such as exoskeletons controlled by brain-computer interfaces may provide benefit to patients with physical disabilities. By focusing on these areas, this project aligns to three of the seven healthcare missions defined in the UK Government's Life Sciences vision, linking to neurodegeneration and dementia, ageing, and mental health conditions.[4]

Literature Review

A search of systematic reviews relating to neurotechnology was carried out in Epistemonikos, limited to those published within the last year. The rationale behind this was the large (> 600) number of results returned from initial scoping searches when this date limit was not imposed. 124 records were retrieved and screened in Rayyan by a single screener. Eleven reviews (listed

in Appendix A) were deemed relevant and so data relating to challenges and opportunities associated with neurotechnology innovations for the specified conditions of interest for this project was extracted and synthesised. These reviews covered a range of neurotechnologies and conditions relating to all three of the research areas (mental health, healthy ageing, and physical disabilities). A keyword co-occurrence analysis based on bibliographic data is shown by Figure 1. The analysis, performed in VOSviewer, produced a network visualisation consisting of three clusters containing 19 nodes. The 19 nodes were keywords from the bibliographic references that occurred at least three times. The strongest links were 'human', 'systematic review', 'cognition', and 'transcranial magnetic stimulation'. The relatively strong link of 'transcranial magnetic stimulation' in particular indicates that this specific type of neurotechnology may be highly represented within the literature. One of the clusters contained both 'Alzheimer disease' and 'depression'. Whilst the current project has categorised Alzheimer's disease within healthy ageing and depression within mental health, this cluster may indicate that the literature considers them to be related, perhaps reflecting the fact that depression is common amongst people with Alzheimer's disease.[5]

The neurotechnologies focused on mainly consisted of brain computer interfaces (BCIs), and different types of brain stimulation, including deep brain stimulation (DBS) and transcranial magnetic stimulation (TMS), both of which have been approved by the FDA.[6] Belkacem et al. identified a need for safe and effective treatment with the capability to automatically modify stimulation settings in response to brain activity, based on an increase in work on closed-loop BCI since 2013.[6] Additionally, the market acceptability of brain stimulation was also said to have increased. However, Levett et al. also noted that the implanted technologies included in their review of invasive BCIs for spinal cord injury were not suitable for domestic use due to inconvenient and unsustainable setups, specific training and long experimentation time required.[7]

For both BCIs and TMS, the need for better data was highlighted, in terms of long-term safety, benefits and adverse effects.[6,8,9] For TMS, it was noted that this challenge may lie in the high variability between study protocols which makes efficacy comparisons difficult.[9] Other challenges associated with BCIs which were identified related to the technology itself (algorithms and electrode design), and ethical concerns (the potential for security breaches and mental privacy infringement).[8] One review looked at wearable artificial intelligence (AI) for anxiety and depression and highlighted a lack of use of these devices for treatment purposes, and questioned whether there may be an overreliance within research on diagnostic and predictive data from wearable devices only.[10]

Opportunities associated with BCIs included gaming elements, personalised training, and interactivity. Additionally, these devices were identified as having the ability to be user friendly, affordable, portable, and low risk.[8]

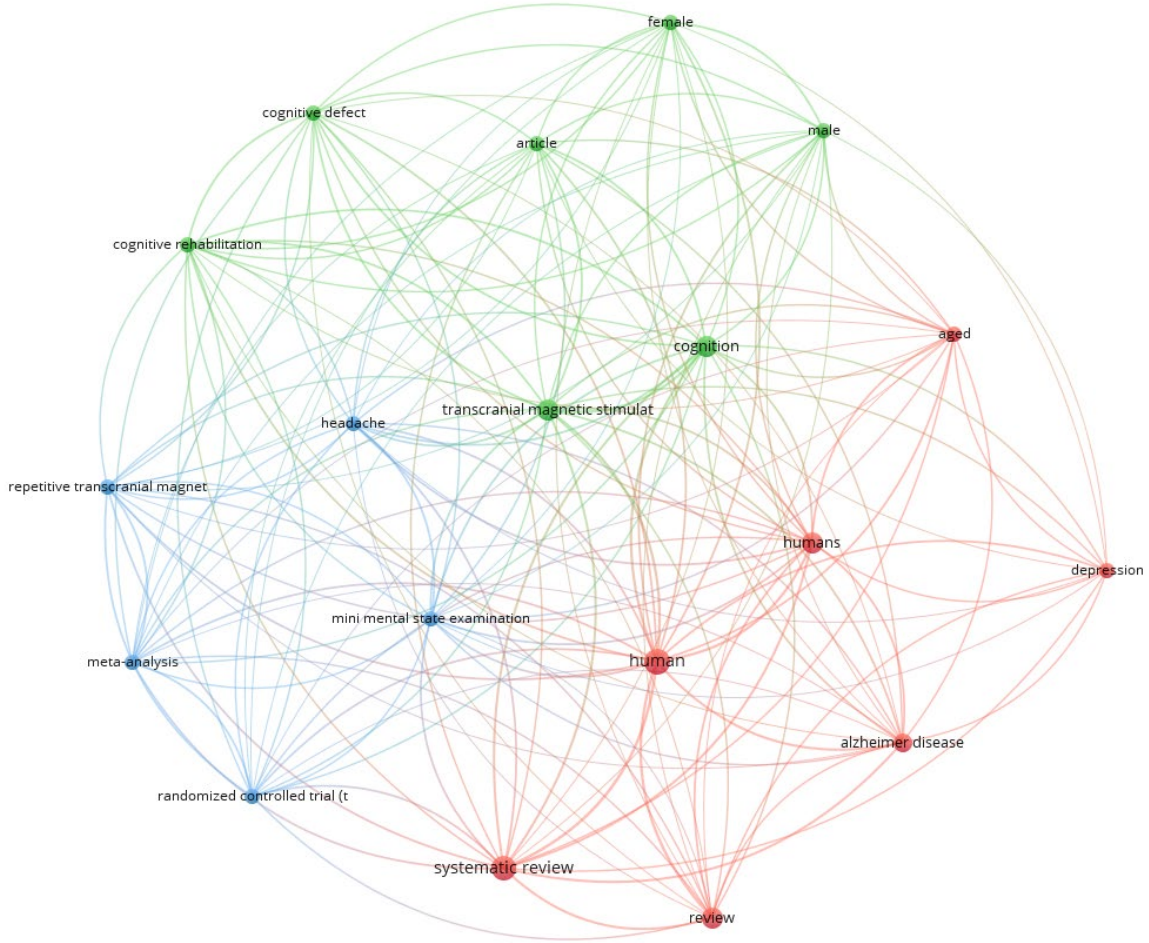

Figure 1. Keyword co-occurrence visualisation map based on bibliographic data of the included reviews.

Aim

The aim of this project was to provide a horizon scan of new neurotechnologies in development and those that have recently been approved to enter the health industry market, along with a rapid literature review to identify challenges and opportunities associated with neurotechnology innovation. The scope of this project covered neurotechnologies for three key research areas: mental health, healthy ageing, and physical disabilities.

The objectives were to:

1. Provide an overview of the neurotechnologies that are being developed in the UK and around the world for mental health, healthy ageing, and the treatment of physical disabilities.
2. Identify and describe recently approved neurotechnologies by the FDA, for mental health, healthy ageing, and physical disabilities.
3. Assess the challenges and opportunities associated with neurotechnology innovation for mental health, healthy ageing, and physical disabilities.

These research objectives will enable us to gain a better understanding of the different neurotechnologies that will potentially be available in the near future, as well as identifying areas of greatest need and insights into the process of innovation for neurotechnology.

Methods

Search Strategy

Horizon scanning methodologies were used to search a variety of information sources that could hold signals of research related to neurotechnology.

Data Sources: ClinicalTrials.gov, WHO International Clinical Trials Registry Platform (ICTRP), and Cochrane Central Register of Controlled Trials were searched as primary sources of information. Complementing this was a search conducted in IEEE*Xplore* for conferences and articles in the multidisciplinary science journal Nature's collection, including Nature, Nature Aging, Nature Biomedical Engineering, Nature Nanotechnology, Nature Neuroscience, Nature Reviews Neurology, and Nature Reviews Neuroscience. Additionally, searches were conducted in GoogleNews via GoogleNews Reproducible Search Tool and the MedTech news, including MedTech News, MedTech Dive, Medical Device Network, and MedTech Insight by the News Media Scanning Tool; both tools are currently being developed by the Innovation Observatory.

Search Terms: A comprehensive list of keywords was compiled by the Innovation Observatory's Information Specialist along with concepts provided by the project team from initial conceptualisation. The list was refined through scoping searches, testing, analysis for relevance, and peer review. A search strategy was formulated, translated, and performed within each data source (Appendix B). The search strategy combined key words, synonyms, and where indexing allowed, MeSH terms. Search string combinations in clinical trial searches, IEE*Xplore* and Nature collection comprised terms such as 'neurotechnology' or 'cognitive technology' or 'brain interface' or 'brain computer' or 'brain augmentation'. The general news scan was carried out via an in-house tool that accesses the GoogleNews API utilising search strings 'neurotechnology', 'cognitive technology', 'neurotechnology mental health', 'neurotechnology healthy ageing' and 'neurotechnology disabled adults'. For each MedTech news website, Python tool (Selenium) was utilised for automating web browsers to extract the web elements of the news articles posted before January 1, 2023. The news articles were filtered based on whether they include the search term 'neurotechnology'.

Filters: No limitations or restrictions were placed on the clinical trial searches within ClinicalTrials.gov and WHO ICTRP. Cochrane CENTRAL were restricted to trials within the last two years. The search within *IEEEXplore* was confined to conferences from 2022 to 2024 and the Nature collection was searched in Embase (OVID) restricted to 2023 to current. MedTech news websites and GoogleNews were date constrained for articles published between Jan 1st 2023 and Mar 7th 2024, the oldest relevant article returned by GoogleNews API was published in June 2023.

Searches were performed in March 2024. Searches were combined and deduplicated.

Selection Criteria

Records identified by the search were screened against the following criteria:

- Meets the criteria for being a regulated medical device, digital health technology, or diagnostic as defined by the two new EU regulations (EU Regulation 2017/745 on medical devices (MDR)[11] and EU Regulation 2017/746 on in vitro diagnostic medical devices (IVDR)).[12]
- Is a neurotechnology, defined as HealthTech that enables a direct connection of technical components with the nervous system.
- Is intended for a condition related to one or more of mental health, healthy ageing, or physical disabilities, as defined below.
    - A mental health technology is intended for one or more of the following conditions: anxiety, bipolar disorder, depression, and personality disorders.
    - A healthy ageing technology is intended for one or more of the following conditions: dementia/Alzheimer's disease, Parkinson's disease, sensory impairment, and neuropathic pain. Or the technology is intended for multiple conditions including at least one of those listed.
    - A physical disabilities technology is intended for one or more of the following conditions: stroke, and spinal cord injury. Paralysis was also included where it could be due to stroke or spinal cord injury.
- Has a target population of adults, defined as 18 years and older.
- In English language.
- Geographic trial location of UK, Europe, North America, Latin America, Middle East, Africa, Australia, or multiple sites.

Technologies indicated for any other condition were excluded. Medicinal products were also excluded.

Screening

A pilot was performed for title and abstract screening of the clinical trials and bibliographic searches, where the same 100 records were blindly screened by each of the five screeners. Following resolution of conflicts, the remaining records were split between the five screeners and single screened. Records with a 'maybe' decision were resolved by a second screener.

The included records were split between the five screeners and single screened at full text stage.

Data Extraction

Data extraction was performed on records which were included at the full text screening stage. The following fields were included where relevant:

- Extractor
- Link
- Source
- Author
- Sponsor
- Title
- Publication year
- Trial completion year
- Type of publication

- Study location
- Research area
- Condition
- Manufacturer
- Technology name
- Type of technology
- Type of device
- Invasive (Y/N)
- AI component (Y/N)
- Intended setting
- Stage of treatment
- Stage of development
- FDA approval (Y/N)

Whether the device had received FDA approval was determined by searching the name of the technology and/or manufacturer on the Devices@FDA database. The stage of development of the technology was determined using the criteria outlined in Table 1.

Table 1. Criteria used to determine the stages of development.

Stage of Development	Subjects	Purpose
1: Pilot/early feasibility/first-in-human	10-30	• Small study to collect preliminary safety and device performance data in humans • Guides devices modifications and/or future study design
2: Traditional feasibility	20-30	• Assess safety and efficacy of the near-final or final device design in patients • Guides the design of the pivotal study
3: Pivotal	100's	• Large study to confirm clinical efficacy, safety and risks • Statistically driven
4: Post-market	1000's	• Monitor long term effectiveness, safety and usage in the general population

Public and Patient Engagement

To obtain the views of the public and patient groups in the UK with experience of one or more of the conditions included in the selection criteria, an online survey was developed that captured the participants' thoughts, priorities, and preferences. The opportunity to take part in the survey was directly emailed to specific relevant contacts (including charities and professional bodies that related to neurotechnology or the included conditions) with the ask that they be circulated and advertised through their mailing lists, groups or social media dependant on the standard procedure each organisation followed. The survey was also conducted through the VOICE global platform (https://voice-global.org/), along with a brief

summary of the background of respondents we were seeking for in this project. The survey was available for 3 weeks before the survey closure date.

The opportunity included comprehensive information about the project (introduction, aims and purpose), details to access the survey online, a description of the type of participants we were looking for responses from, and what level of commitment was required. The survey was anonymous, with only basic demographic information collected to verify UK respondents.

The survey was developed using the Qualtrics online survey tool (see Appendix C for the full survey) in order to identify:

- General thoughts of adoptability of Neurotechnologies, both invasive and non-invasive
- People's level of awareness of Neurotechnologies within the space and where they may look for this information
- Priorities for unmet needs in areas where these technologies could make a significant contribution
- People's views on the potential downsides of Neurotechnologies, e.g. how safe they would feel about their data security

When the survey closed, we used Qualtrics and Microsoft Excel to collate the responses. Once collated, the data were reviewed, and responses refined by removing any technologies, unmet needs or outcomes that were:

- Beyond project scope;
- Unclear or ill-defined; or
- Duplications.

Responses were used to feed into the report and assess where topic areas overlapped between the ongoing research and innovations and the public perceived unmet need areas.

The data obtained through the survey was analysed using Qualtrics and Microsoft Excel software. Quantitative data was analysed to allow for comparisons of summary statistics within each individual question. Qualitative responses were reviewed by single reviewer and grouped into 'themes' where each response was touching upon the same point with a matching emotional valence. Where a single response included thoughts on several topics, the same response could be counted in multiple themes to completely cover each response. The figures to represent the survey data were created using Qualtrics and Flourish.

Results

Search Results

The searched identified 7,256 records (trial records/journal articles/abstracts) for title and abstract screening, of which 1,552 were brought forward to full text screening. Additionally, 190 news articles were screened for eligibility. In total, 452 articles were included (420 trial records/journal articles/abstracts and 32 news articles). Figure 2 shows the PRISMA flowchart of identified studies.

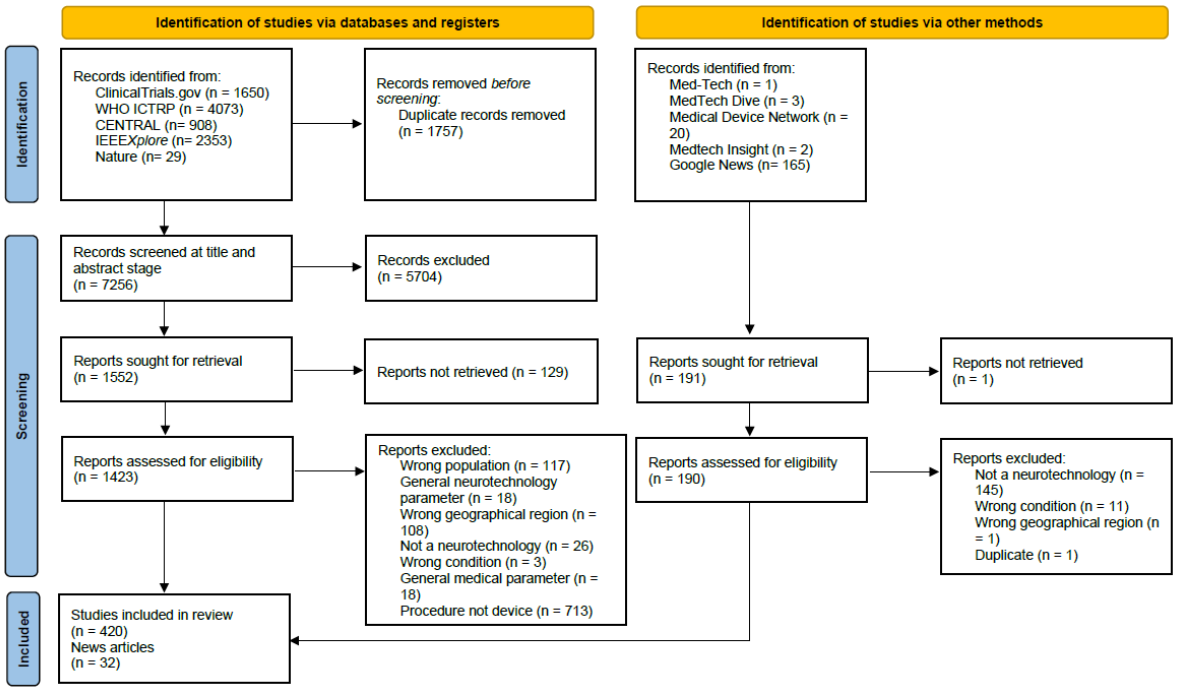

Figure 2. PRISMA flowchart of identified studies.

Overview of Identified Technologies

From the included articles on which data extraction was performed, 81 unique neurotechnologies were identified. This included 23 related to mental health, 31 to healthy ageing, and 42 to physical disabilities. Six of the technologies related to two of the three research areas, and 5 technologies related to all three of the research areas. No technologies were found for anxiety, personality disorders, or sensory impairment (Table 2). Parkinson's disease, stroke, and depression were the most common indicated conditions for the identified technologies (Figure 3).

Table 2. Number of technologies identified for each condition.

Research area	Condition	Number of technologies
Mental health (n=23)	Depression	23
	Anxiety	-
	Bipolar disorder	3 (all bipolar depression)
	Personality disorders	-
Healthy ageing (n=31)	Dementia/Alzheimer's	11 (1 dementia, 10 Alzheimer's)
	Parkinson's	24
	Sensory impairment	-
	Neuropathic pain	4
Physical disability (n=42)	Stroke	24
	Spinal cord injury	15
	Paralysis	6

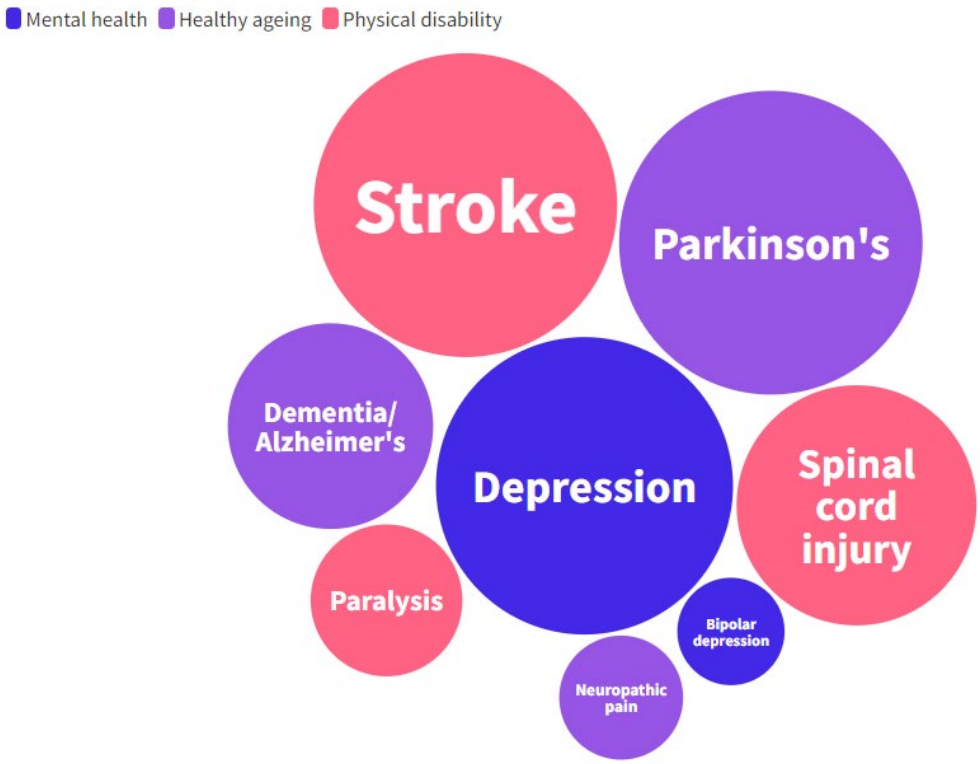

Figure 3. Number of technologies targeting each of the included conditions for mental health, healthy ageing, and physical disability.

The majority of the identified devices were indicated for a single included condition, though 13 targeted more than one of the included conditions (Figure 4).

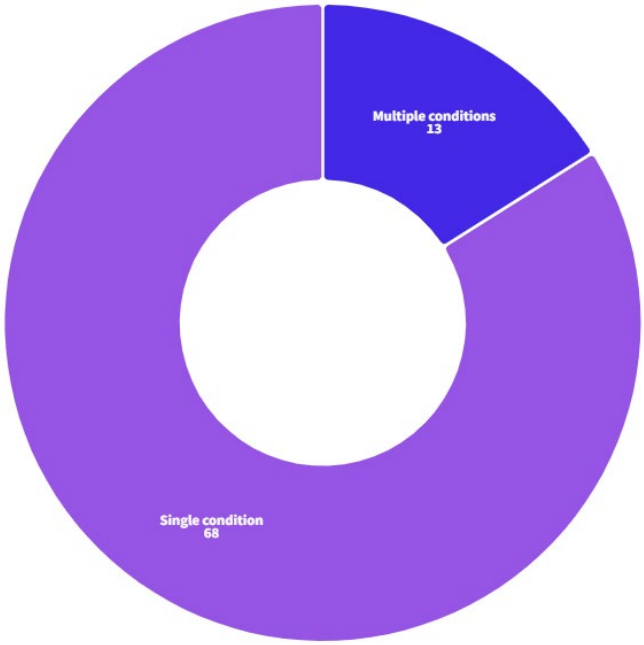

Figure 4. Number of technologies which were indicated for multiple of the included conditions.

For technologies for which the indication was Parkinson's disease and/or dementia/Alzheimer's disease, 17 did not specify a stage of condition, one specified a stage for both Parkinson's disease and Alzheimer's disease, and 12 specified a stage for one condition (Table 3 and Figure 5).

Table 3. Number of identified technologies for different stages of conditions.

	Parkinson's	**Alzheimer's**	**Dementia**
Mild/Early	-	3	1
Mild to Moderate	4	2	-
Advanced/Severe	3	-	-

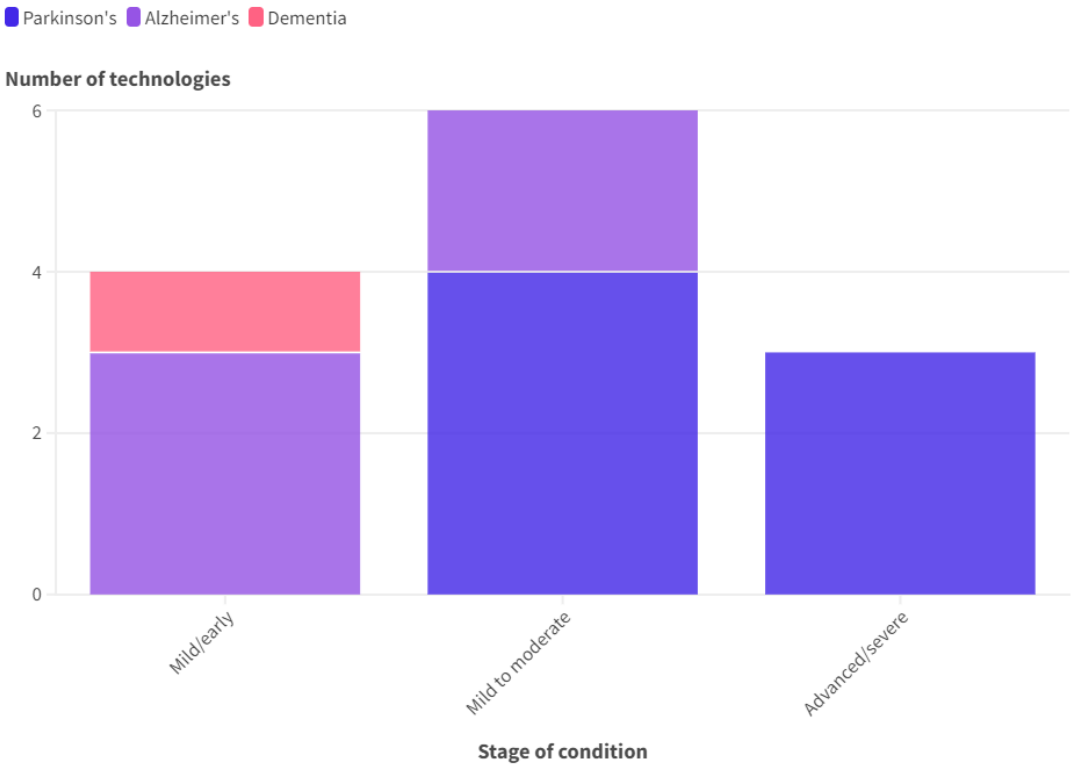

Figure 5. Number of technologies for different stages of Parkinson's disease, Alzheimer's disease, and dementia.

Over three quarters of the identified technologies had not received FDA approval according to the Devices@FDA database (Figure 6).

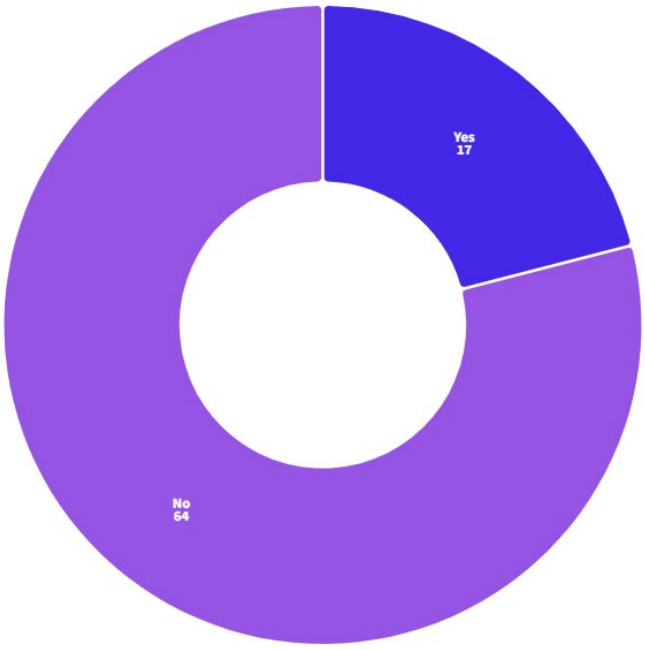

Figure 6. Number of technologies which had received FDA approval.

Wearable devices were the most common type identified, followed by implantable devices (Figure 7). Other categories of identified devices included external devices, software, and surgical devices.

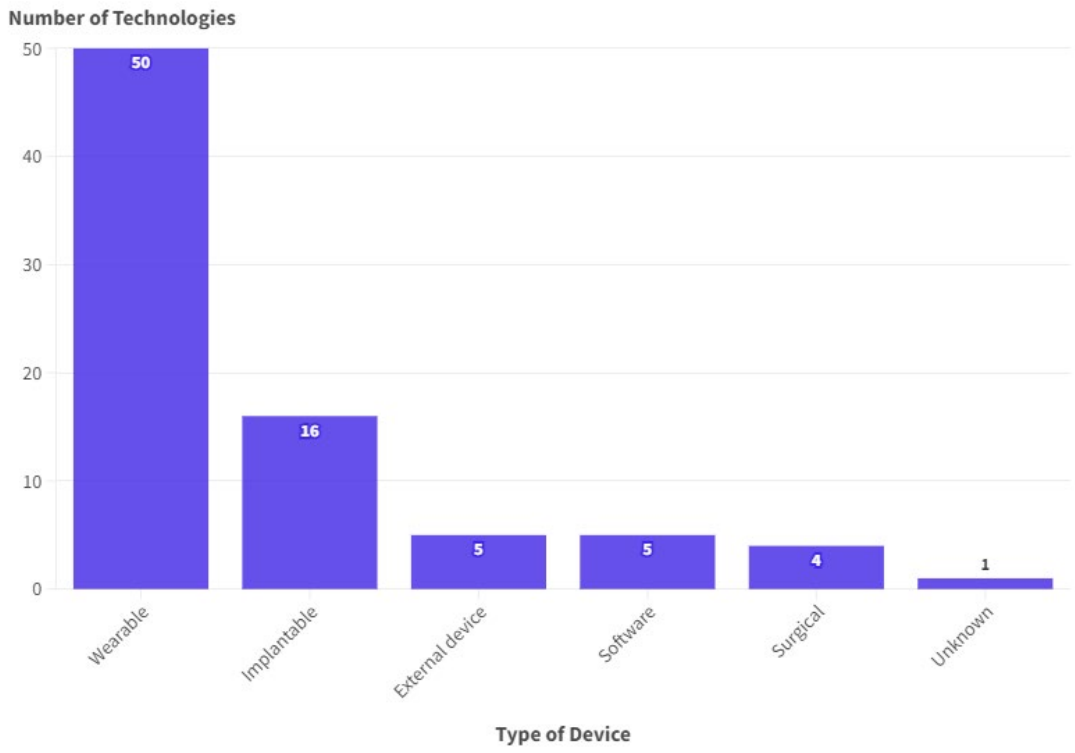

Figure 7. Number of the different types of devices.

Over three quarters of the identified technologies were non-invasive, with the remaining being invasive (Figure 8).

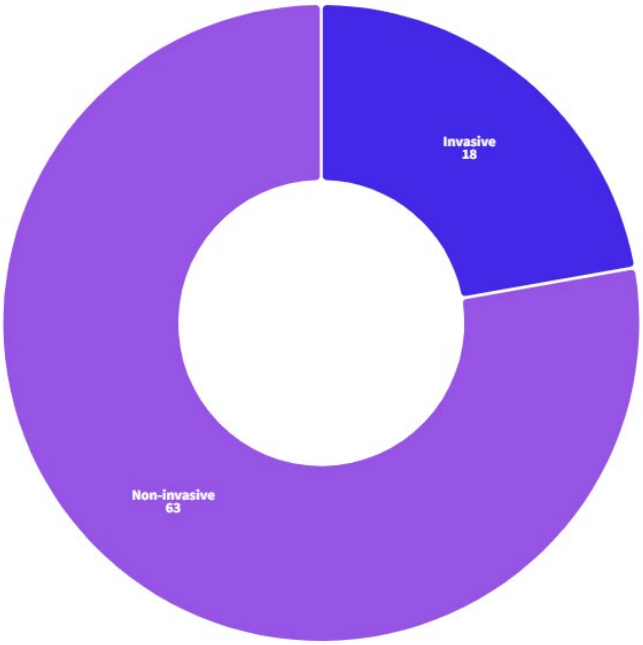

Figure 8. Invasiveness of the technologies.

The majority (77) of the devices did not include an artificial intelligence (AI) component, though three did and one was unknown (Figure 9).

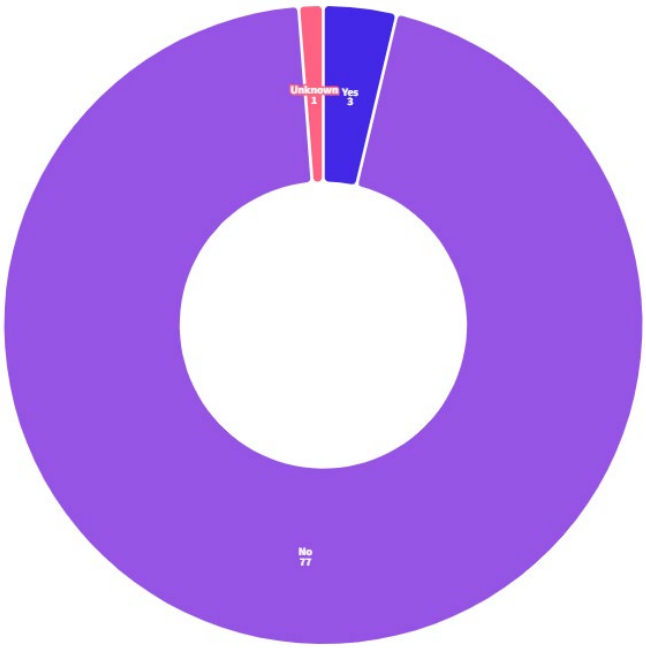

Figure 9. Number of technologies with an AI component.

The intended setting was hospital for the majority (58) of the technologies, with the other 23 intended for home use (Figure 10).

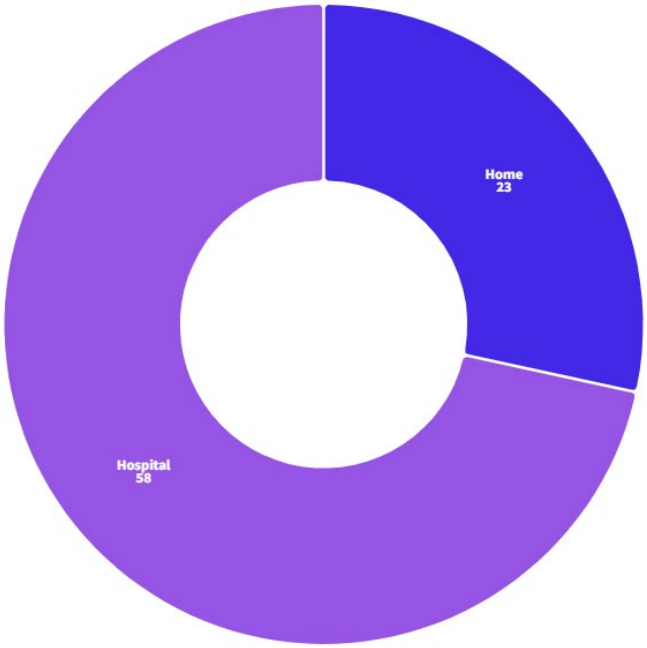

Figure 10. Intended setting of the technologies.

In terms of the care pathway, treatment was the most common stage, followed by rehabilitation (Figure 11).

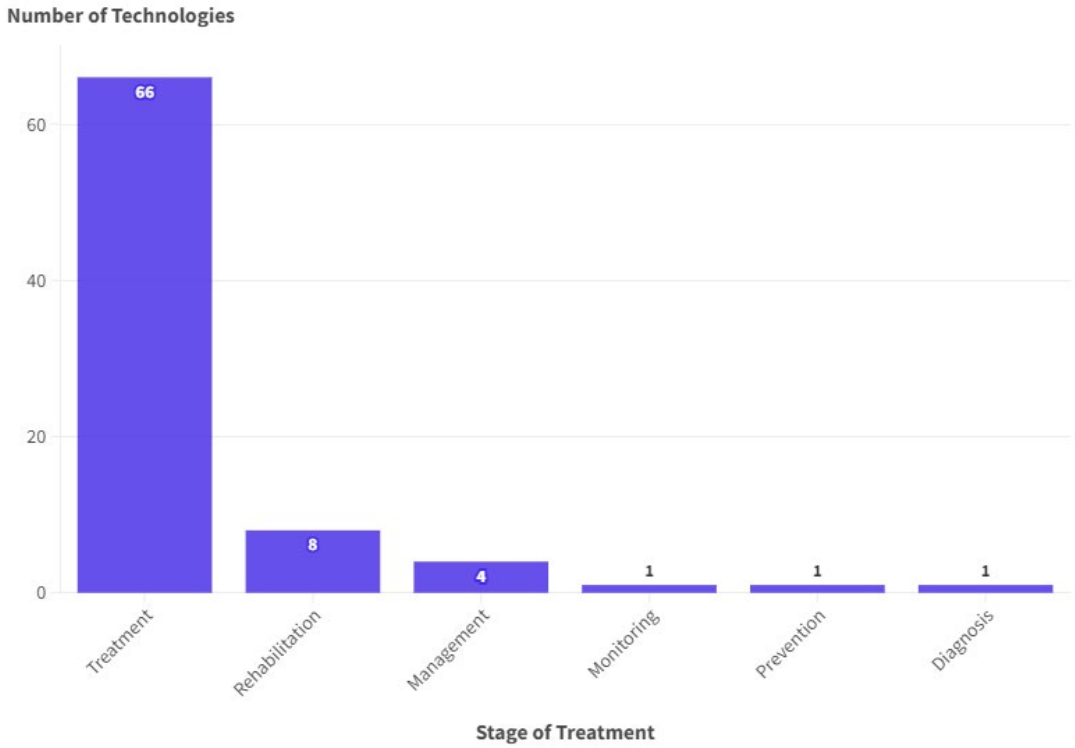

Figure 11. Stage of treatment for the technologies.

The following broad categories were identified to classify the types of technologies: brain computer interface (BCI); deep brain stimulation (DBS); electroencephalography (EEG); electromagnetic stimulation (EMS); transcranial magnetic stimulation (TMS); transcranial direct current stimulation (tDCS); transcranial pulse stimulation (TPS); transcranial ultrasound stimulation (TUS). For TMS in particular, this could then be broken down further to include repetitive TMS (rTMS), single-pulse TMS (sTMS), and theta-burst stimulation (TBS). EMS included extremely low-frequency electromagnetic stimulation (ELF-EMS). BCIs, TMS, and DBS were the most common types of technologies (Figure 12).

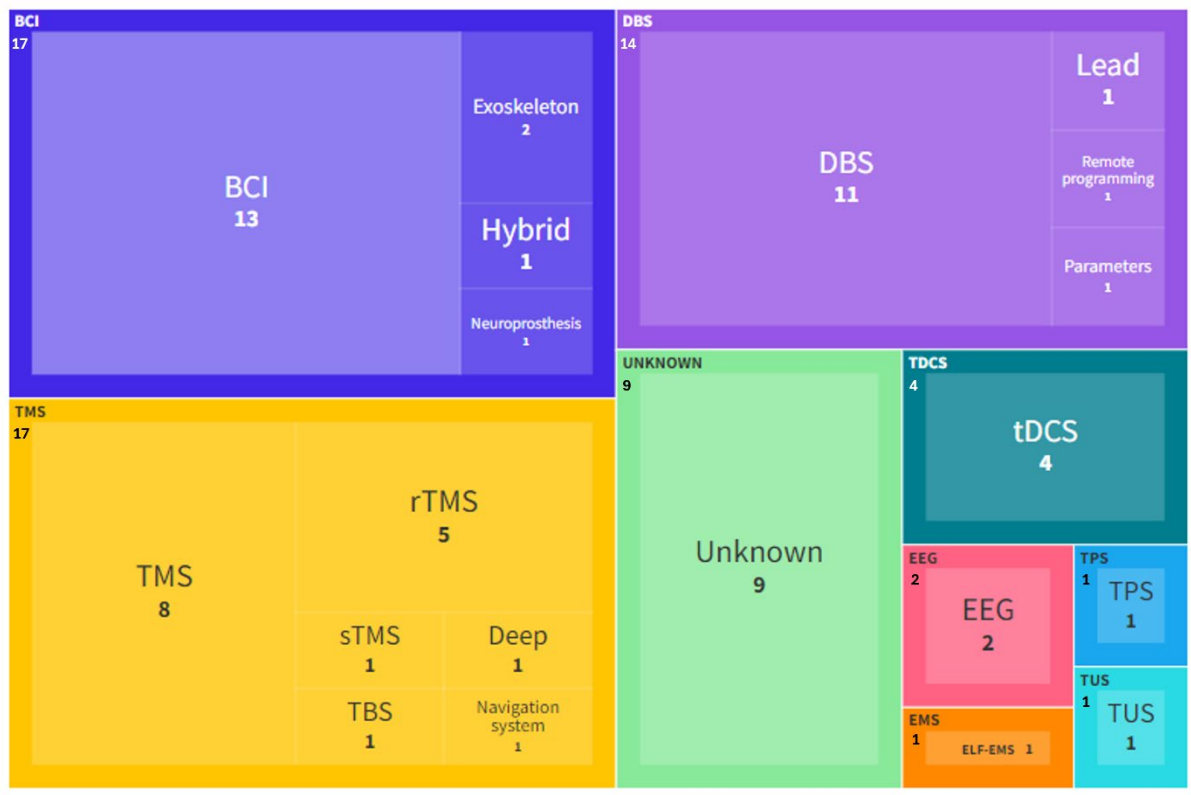

Figure 12. Number of the different types of technologies identified.

Figure 13 shows a technology radar, which represents the number of identified technologies at each stage of development for the different conditions included. Fifteen of the identified technologies and indications did not have an associated stage of development due to the technologies having been identified from sources other than clinical trials (i.e., news articles, journal articles, or conference papers). Of the remaining indication-specific technologies, 35 were at stage one (pilot/early feasibility), 37 were at stage two (traditional feasibility), 14 were at stage three (pivotal), and seven were at stage four (post-market).

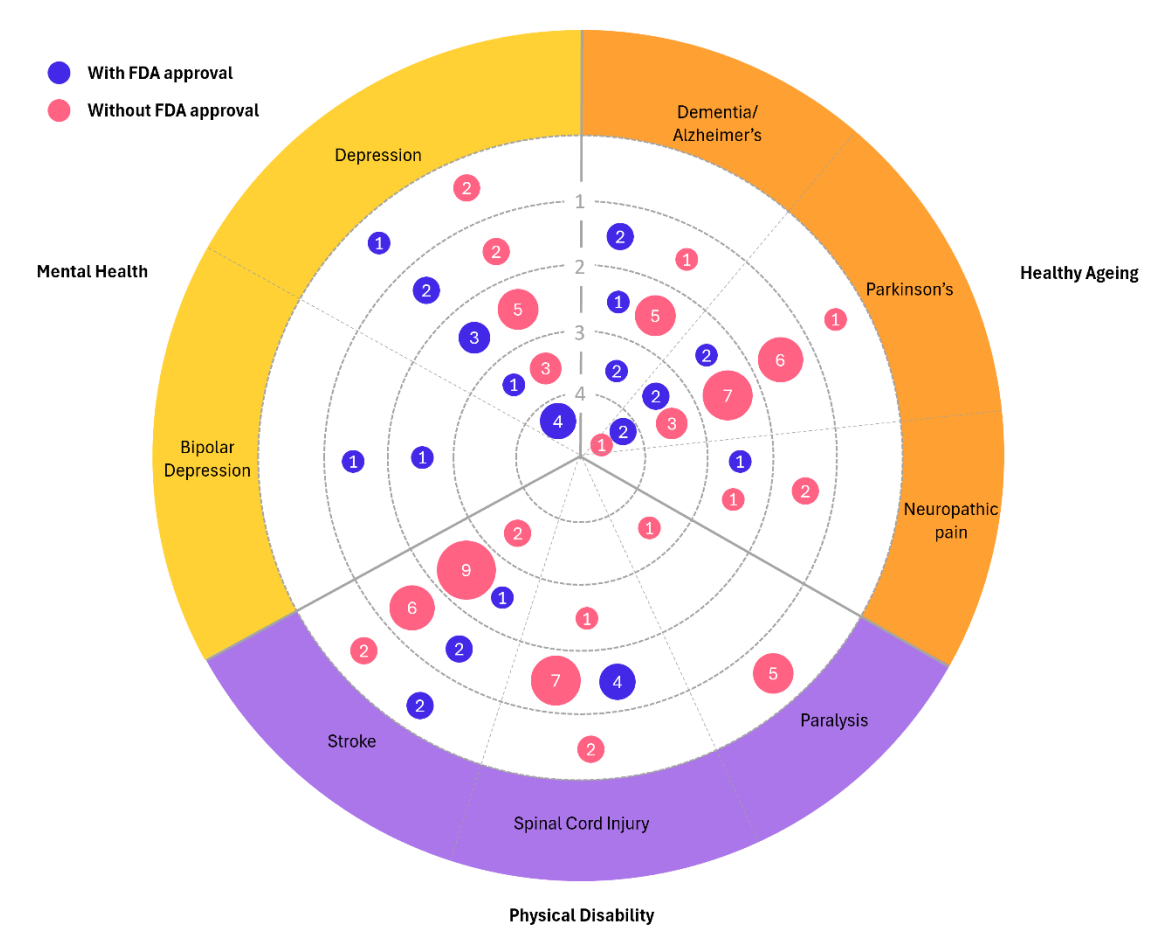

Figure 13. Technology radar showing the stage of development of the identified technologies for each different indication.

Within the radar, the bubble size indicates the number of technologies. The outer ring represents technologies without an associated development stage (i.e., identified from sources other than clinical trial records), with the rings then moving inwards from stage one (i.e., pilot/early feasibility) to stage four (i.e., post-market).

A comprehensive overview of the identified technologies is given in Table 4 (technologies with FDA approval) and Table 5 (technologies without FDA approval).

*Table 4. Identified technologies with FDA approval. Key: *Conference paper; †Journal article; ††News.*

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
Neuro-Omega System (Alpha Omega Engineering)	Parkinson's disease (2017): Stage 3	DBS	Surgical	✓		Hospital	Treatment
NeuroPort Array (Blackrock Neurotech)	Spinal cord injury (2013): Stage 1	BCI	Implantable	✓		Hospital	Treatment
Vercise (Boston Scientific)	12 trials (2010-2025) Parkinson's disease (2020): Stage 3 Alzheimer's disease (2025): Stage 1 Depression: (2018): Stage 2	DBS	Implantable	✓		Hospital	Treatment
EGI Geodesic N400 System (Electrical Geodesics)	Stroke*	EEG	Wearable			Hospital	Rehabilitation
Rehastim 2 (HASOMED)	Stroke†	BCI	External device			Home	Treatment
SAINT (Magnus)	2 trials (2023-2024) Major depressive disorder (2023): Stage 4	TMS	Wearable			Home	Treatment
Magstim 200[2] (Magstim)	2 trials (2013-2010) Parkinson's disease (2010): Stage 2	rTMS	Wearable			Hospital	Treatment
Magstim Rapid[2] (Magstim)	16 trials (2007-2023) Stroke (2023): Stage 2 Spinal cord injury (2016): Stage 1 Alzheimer's disease (2012): Stage 2 Parkinson's disease (2015): Stage 2 Depression (2012): Stage 2	rTMS	Wearable			Hospital	Treatment

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
	Neuropathic pain (2022): Stage 2 Bipolar depression (2012): Stage 1						
StimGuide (Magstim)	Major depressive disorder (2019): Stage 2	TMS	Wearable			Hospital	Treatment
MagPro R30 (MagVenture)	10 trials (2015-2024) Depression (2024): Stage 3 Bipolar depression (2023): Stage 2 Alzheimer's disease (2023): Stage 3	TMS/TBS	External device			Hospital	Treatment
MagPro X100 (MagVenture)	11 trials (2010-2024) Stroke (2010): Stage 1 Depression (2024): Stage 4 Alzheimer's disease (2023): Stage 3	TMS	External device			Hospital	Treatment
Activa (Medtronic)	20 trials (2005-2017) Depression (2014): Stage 1 Spinal cord injury (2015): Stage 1 Alzheimer's disease (2012): Stage 1 Parkinson's disease (2017): Stage 4	DBS	Implantable	✓		Hospital	Treatment
Percept (Medtronic)	8 trials (2013-2023) Parkinson's disease (2023): Stage 4 Depression (2023): Stage 1 Spinal cord injury (2021): Stage 1	DBS	Implantable	✓		Hospital	Treatment
Relivion (Neurolief)	Major depressive disorder††	Unknown	Wearable			Home	Treatment
NeuroStar TMS (Neuronetics)	4 trials (2011-2020) Major depressive disorder (2020): Stage 4	TMS	Wearable			Hospital	Treatment
NeuroPace RNS System (NeuroPace)	1 trial (2019) Depression (2019): Stage 4	DBS	Surgical	✓		Hospital	Treatment

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
eXimia NBS System (NeuroPace)	1 trial (2009) Stroke (2009): Stage 1	TMS	Wearable			Hospital	Rehabilitation

*Table 5. Identified technologies without FDA approval. Key: *Conference paper; †Journal article; ††News.*

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
LiveAmp Mobile Amplifier + XoMotion (Human in Motion Robotics; BrainProducts)	Paralysis†	BCI	Wearable			Home	Treatment
RECOM	Stroke (2023): Stage 1	BCI	Wearable			Hospital	Treatment
Infinity (Abbott)	3 trials (2019) Parkinson's disease (2019): Stage 4 Depression (2019): Stage 1	DBS	Implantable	✓		Hospital	Treatment
Neurosphere Virtual Clinic (Abbott)	Parkinson's disease (2022): Stage 2	DBS	Software			Home	Treatment
directSTIM System (Aleva Neurotherapeutics SA)	2 trials (2012-2021) Parkinson's disease (2021) Stage 2	DBS	Implantable	✓		Hospital	Treatment
Axem Home (Axem Neurotechnology)	Stroke (2023): Stage 1	Near-infrared Spectroscopy headband	Wearable			Home	Rehabilitation
Picostim DBS System (Bioinduction)	Parkinson's disease (2020): Stage 1	DBS	Implantable	✓		Hospital	Treatment
Combined EEG and fNIRS Device (BioSignal Group; NIRx	Stroke (2017): Stage 1	EEG	Wearable			Hospital	Diagnosis

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
Medizintechnik GmbH)							
Move Again (Blackrock Neurotech)	Paralysis††	BCI	Implantable	✓		Hospital	Treatment
BrainGate Neural Interface System (BrainGate)	Spinal cord injury (2009): Stage 1	BCI	Implantable			Hospital	Treatment
BrainQ (BrainQ)	2 trials (2018-2019) Spinal cord injury (2019): Stage 1	EMS	Wearable		✓	Home	Treatment
H-Coil (BrainsWay)	9 trials (2006-2023) Parkinson's disease (2014): Stage 1 Alzheimer's disease (2010): Stage 2 Depression (2009): Stage 3 Bipolar depression (2014): Stage 2	TMS	Wearable			Hospital	Treatment
ECoG Measuring Implant (Clinatec)	Spinal cord injury (2015): Stage 1	BCI	Wearable			Hospital	Treatment
Headband (Elemind)	Parkinson's disease††	EEG	Wearable		✓	Home	Treatment
The Flow (Flow Neuroscience)	Depression*	tDCS	Wearable			Home	Treatment
recoveriX (g.tec)	Stroke (2019): Stage 1	BCI	Wearable			Hospital	Treatment
Gondola AMPS Device (Gondola Medical Technologies SA)	Parkinson's disease (2021): Stage 2	DBS	External device			Home	Treatment
LG-7500 Digital Muscle Stimulator (LGMedSupply)	Stroke (2010): Stage 3	BCI	Wearable			Hospital	Treatment

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
rTMS Device (Madinatab Iran)	Parkinson's disease (2023): Stage 1	rTMS	Wearable			Hospital	Rehabilitation
Magstim Super Rapid[2] (Magstim)	7 trials (1996-2023) Depression (2015): Stage 3 Alzheimer's disease (2023): Stage 2 Stroke (2015): Stage 2	rTMS	Wearable			Hospital	Treatment
Magstim Rapid[2] Plus[1] (Magstim)	Stroke (2023): Stage 2	rTMS	Wearable			Hospital	Treatment
Cool Coil (MagVenture)	3 trials (2013-2020) Depression (2020): Stage 3	TMS	Wearable			Hospital	Treatment
GENUS Device (Massachusetts Institute of Technology)	3 trials (2019-2025) Alzheimer's disease (2025): Stage 1 Parkinson's disease (2019): Stage 2	Gamma frequency stimulation	Wearable			Home	Prevention
SMARTING Device (mBrainTrain)	Neuropathic pain after spinal cord injury (2020): Stage 1	EEG	Wearable			Hospital	Treatment
MAHI EXO-II (Mechatronics and Haptic Interfaces Lab)	Stroke (2013): Stage 1	BCI	Wearable			Hospital	Treatment
DOT Microstimulator (Motif Neurotech)	Depression††	Unknown	Implantable	✓		Hospital	Treatment
BrainSense EEG Headset	Spinal cord injury*	Unknown	Wearable		?	Home	Treatment
Networked Neuroprosthetic System (National Institute of	Spinal cord injury (2014): Stage 2	Neuroprosthetic	Surgical	✓		Hospital	Rehabilitation

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
Neurological Disorders and Stroke)							
Telepathy (Neuralink)	Quadriplegia††	BCI	Implantable	✓		Hospital	Treatment
Exobots System (Neurobots)	Stroke (2019): Stage 2	BCI	Wearable			Hospital	Treatment
DC Stimulator Plus (NeuroCare)	4 trials (2016-2021) Fibromyalgia depression and neuropathic pain (2016): Stage 2 Parkinson's disease (2021): Stage 3 Alzheimer's disease (2021): Stage 2	TMS	Wearable			Hospital	Treatment
Power Mag (NeuroCare)	1 trial (2022) Alzheimer's disease (2020): Stage 2	rTMS	Wearable			Hospital	Treatment
Starstim tDCS (Neuroelectrics)	1 trial (2021) Parkinson's disease (2021): Stage 1	tDCS	Wearable			Hospital	Treatment
NeuroFUS Device (NeuroFUS)	1 trial (2023) Parkinson's disease (2023): Stage 1	TUS	Wearable			Hospital	Treatment
IpsiHand (Neurolotions)	3 trials (2012-2023) Stroke (2023): Stage: 3	BCI	Wearable			Home	Rehabilitation
Neurow System (NeuroRehabLab)	1 trial (2021) Stroke (2021): Stage 2	BCI	Wearable		✓	Hospital	Treatment
MS and MSD Equipment (Neurosoft)	1 trial (2019) Parkinson's disease (2019): Stage 2	TMS	Wearable			Hospital	Treatment
AlphaDBS (Newronika)	4 trials (2017-2022) Parkinson's disease (2022): Stage 3	DBS	Implantable	✓		Hospital	Treatment

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
LabVIEW Electrical Stimulator (National Institutes)	Stroke/Spinal cord injury*	BCI	Software			Home	Treatment
NeuroCognitive Communictor (Ottawa Hospital Research Institute)	1 trial (2019) Stroke (2019): Stage 1	BCI	Wearable			Home	Management
PD-Monitor (PD Neurotechnology)	1 trial (2022) Parkinson's disease (2022): Stage 3	Monitoring device	Wearable			Home	Monitoring
Layer 7 Cortical Interface (Precision Neuroscience)	1 trial (2023) Severe paralysis (2023): Stage 3	Unknown	Implantable	✓		Hospital	Treatment
Dynamic Environment-Based Visual Interface System	1 trial (2022) Paralysis (2022): Stage 1	Unknown	Software			Home	Treatment
Sapiens (Sapiens Steering Brain Stimulation BV)	1 trial (2012) Parkinson's disease (2012): Stage 1	DBS	Surgical	✓		Hospital	Treatment
M4P-System (SensorStim Neurotechnology GmbH)	1 trial (2021) Parkinson's disease (2021): Stage 2	Unknown	Wearable			Hospital	Treatment
TMS Cap (Seraya Medical Systems)	1 trial (2016) Stroke (2016): Stage 2	TMS	Wearable			Hospital	Treatment
BCI (Smart Wheelchair)	Paralysis*						
Sooma tDCS (Sooma)	Depression (2019): Stage 2	tDCS	Wearable			Home	Treatment

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
tDCS Mini-Clinical Trials System (Soterix)	Depression (2018): Stage 2	tDCS	Wearable			Hospital	Treatment
NEUROLITH TPS (Storz Medical AG)	Dementia (2024): Stage 2	TPS	External device			Hospital	Treatment
Synchron Switch (Synchron)	Paralysis††	BCI	Implantable	✓		Hospital	Treatment
TyroTherapy (Tyromotion)	Stroke (2022): Stage 2	Unknown	Wearable			Hospital	Treatment
Tele-REINVENT (University of Southern California)	Stroke (2021): Stage 1	Unknown	Wearable			Home	Treatment
GHOST	Neuropathic pain (2019): Stage 1	BCI	Wearable			Hospital	Treatment
BCI-NMES	Stroke (2017): Stage 2	Unknown	Implantable			Hospital	Treatment
NEST-1 NeoSync EEG Synchronised TMS (Wave Neuroscience)	Depression (2011): Stage 2	sTMS	Wearable			Hospital	Treatment
H-Coil (Weizmann Institute of Science)	Depression (2007): Stage 2	TMS	Wearable			Hospital	Treatment
The Promotoer	Stroke (2023): Stage 2	BCI	Unknown			Hospital	Rehabilitation
CereGate Software	Parkinson's disease (2024): Stage 2	DBI	Software			Hospital	Treatment
NeuroExo	Stroke (2022): Stage 2	BCI-EEG	Wearable			Home	Rehabilitation
Libra Implantable DBS System	2 trials (2013-2016) Depression (2016): Stage 1	DPS	Implantable	✓		Hospital	Treatment
RoBIK	Spinal cord injury (2018): Stage 1	BCI	Software			Hospital	Management

Technology (Manufacturer)	Number of Trials (Date Range of Trial) Condition (Year of Latest Trial): Development Stage	Type of Technology	Type of Device	Invasive?	AI Component?	Intended Setting	Place in Pathway
MoreGrasp	Spinal cord injury (2018): Stage 1	BCI-neuroprosthesis	Wearable			Home	Management
Mind Extender (MindEx)	Spinal cord injury (2024): Stage 1	BCI	Wearable			Home	Management

Questionnaire Responses

The questionnaire received a total of 365 responses which were analysed, though not all respondents chose to answer every question.

Two thirds of respondents (n=129) who answered indicated that they were not familiar at all with any of the neurotechnology devices mentioned in the survey (these being: transcranial magnetic stimulation, deep brain stimulation and brain-computer interfaces). Thirty-four per cent n=66) of respondents said that they were slightly or moderately familiar with these technologies, and only 1 individual considered themselves to be extremely familiar.

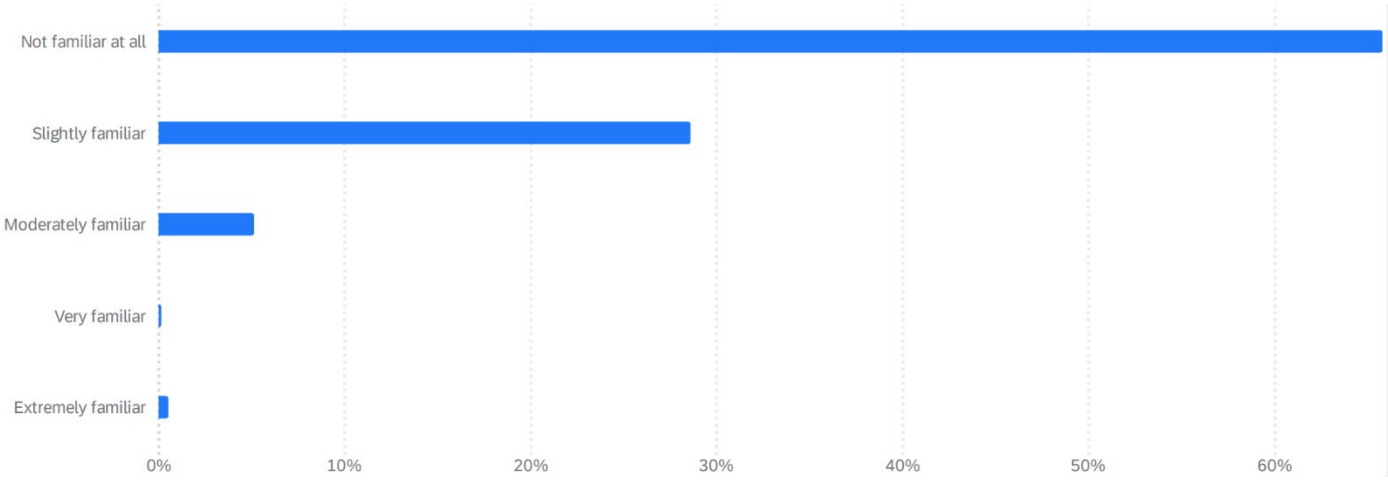

Figure 14. The levels of familiarity with the neurotechnologies included in this research (transcranial magnetic stimulation, deep brain stimulation and brain-computer interfaces) indicated by survey respondents.

When discussing their priorities for hypothetically considering a neurotechnological intervention for a condition, 'physical safety' was stated to be an essential criterion by the most people (n=97), followed closely by 'how well the technology helps your treatment/symptoms' (n=86) and 'costs to the user' (n=82). These criteria also received the highest average weighting for priorities in the same order. The criterion that deemed to be the least important by the respondents was 'how noticeable would the technology be to others' which received the most responses indicating that it was not a priority (n=28) and the fewest for it being an essential part of a hypothetical neurotechnology (n=26).

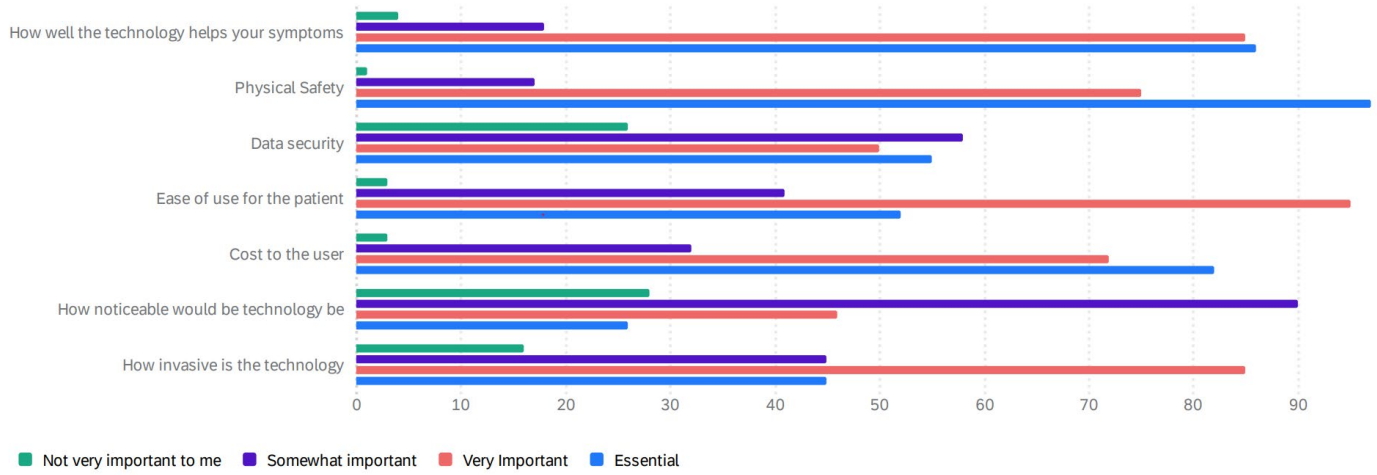

Figure 15. Survey respondent's reported priorities when considering which criteria they would consider most influential on how comfortable they would feel adopting a hypothetical neurotechnological device.

Respondents were split on how acceptable they found the idea of a surgically implanted neurotechnology; 68 individuals responded that they would find a surgically implanted neurotechnology unacceptable, with 5 responses stating the ideas was not at all acceptable and 63 saying only as a last resort. In total 68 respondents also found an implanted neurotechnology to be acceptable, with 62 people indicating that they found the idea quite acceptable and 6 responses indicating that this would be their preference for treatment. 30% of people (n=59) responded as feeling 'fairly neutral' on the topic of acceptability.

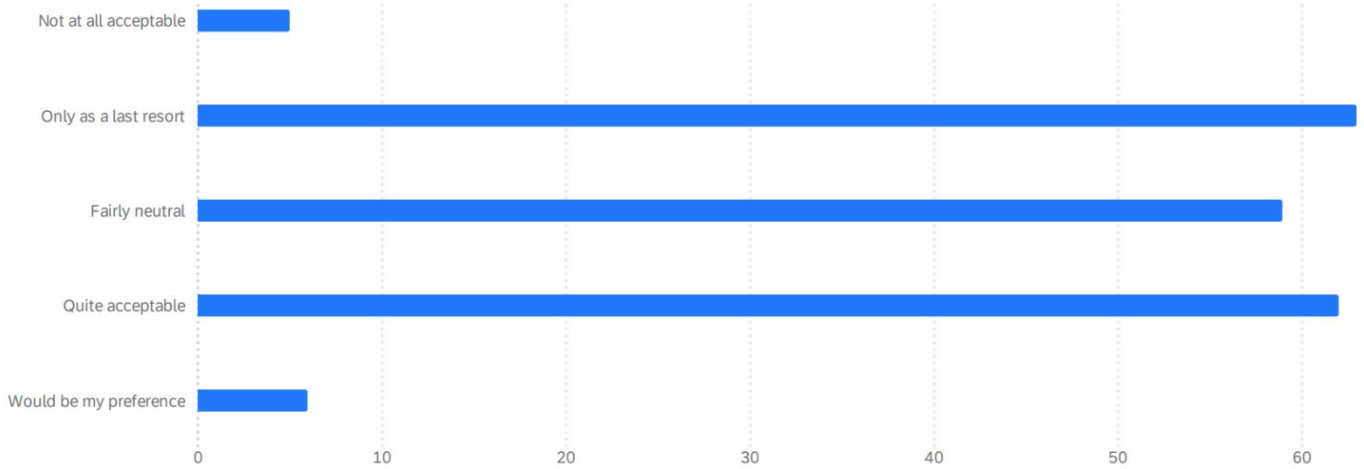

Figure 16. The acceptability of a surgically implanted neurotechnology reported in the survey responses.

When considering potential concerns around the use of neurotechnological devices in healthcare, the most concerns were shown for the risk of outside interference with the device (n=56), how much the device had been tested (n=48) and the possibility of side effects (n=38). In general, responses indicated that most people's concerns could be reduced to the point

where they would be willing to try a technology if they could discuss their concerns with a health care practitioner and receive information and reassurances about their concerns. This was the case for all three of the most highly ranked concerns. People were most comfortable with the idea that a technology may collect data or monitor data as part of its normal functioning.

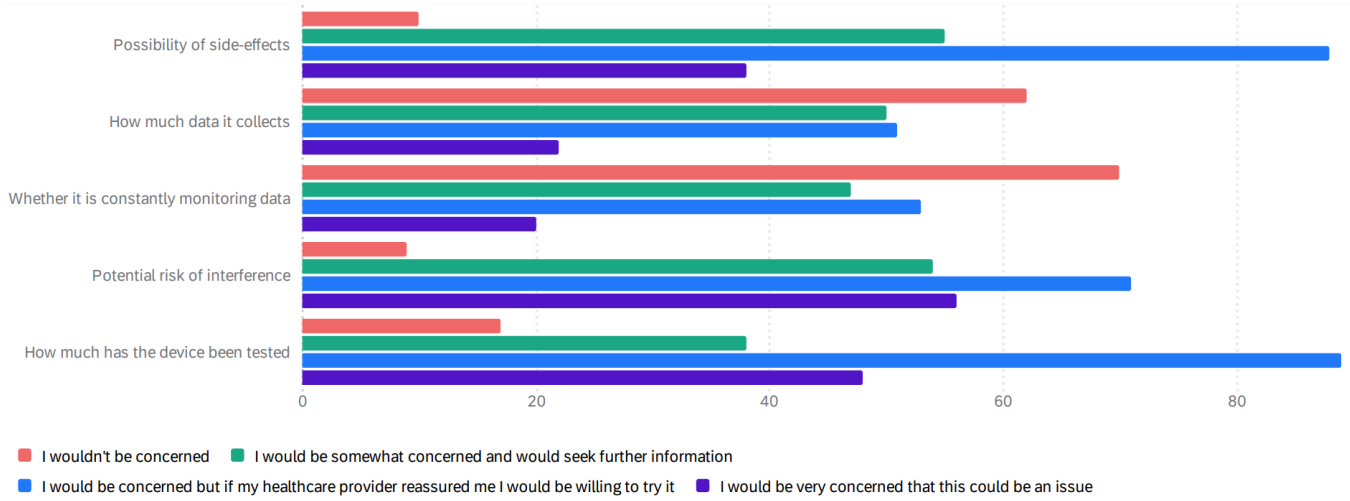

Figure 17. The levels to which certain features of a neurotechnological device would, or would not, cause concern for survey respondents when considering their hypothetical treatment options.

When asked what where respondents would be likely to look for reliable and trustworthy sources of information on neurotechnology, there was an even split in the most common responses of health care providers and internet sources (sites such as NHS, NHS digital and Google were mentioned by several people). There were also responses referring to peer-reviewed journals and charities, but many people indicated that they would be unsure of where to obtain information on neurotechnology.

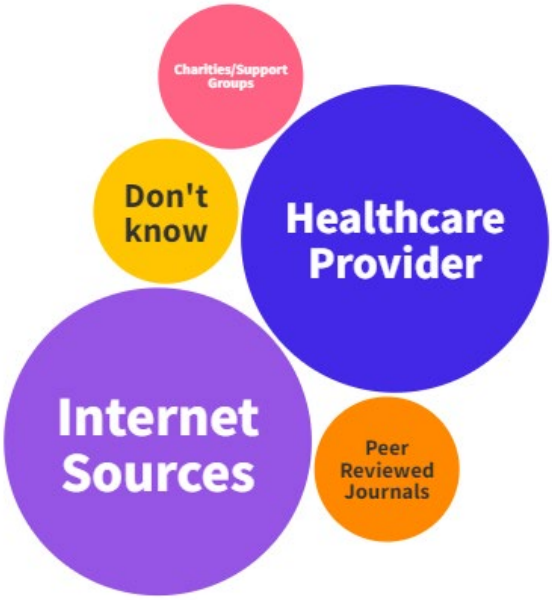

Figure 18. Number potential sources of information mentioned positively by survey responders when asked where they would consider searching for reliable information on innovative neurotechnologies.

Respondents were invited to highlight any key areas relating to neurotechnology that had not yet been covered, the most common area mentioned was safety followed by the idea of a technology being easy to use. Individuals also highlighted areas such as equity of access to neurotechnologies, that potentially innovative treatments should not be solely accessible by the wealthy, and the potential for neurotechnological devices to have negative environmental impacts.

Discussion

This horizon scan identified 81 unique neurotechnologies in development or recently approved, targeting a range of conditions within the areas of mental health, healthy ageing, and physical disability. When considering specific conditions also, there were 108 unique technology-condition combinations identified in total (as 13 of the technologies targeted more than one included condition). A survey was also conducted to gather opinions on neurotechnologies in terms of familiarity, priorities, acceptability, and information sources. In general, there was a relatively low level of familiarity and, likely linked to this, a lack of accessible information on neurotechnologies.

Survey

The results of the survey showed that only one third of those questioned considered themselves to be slightly familiar (or more) with transcranial magnetic stimulation, deep brain stimulation and brain-computer interfaces. This would suggest that most people, even within a group selected for their interest and experience with conditions relating to neurotechnology, are still relatively naïve to these types of intervention. This may be due, in part, to the frequency

at which these interventions are currently used leading to many people never knowing someone personally to receive a neurotechnological intervention, but also to the apparent lack of reliable lay information on these interventions. This was supported when individuals were asked to comment on where they would look for trusted sources of information on neurotechnology, with most people trusting mostly in their healthcare providers or searching for information on the internet, and several people stating that they wouldn't know of anywhere they could find information they could digest and trust. As the implementation and adoption of these interventions becomes more common, it is likely that people's awareness of the technologies will also increase; however, it could also be that some accessible and digestible information on these intervention types could increase confidence and adoption of certain innovative technologies.

Unsurprisingly, the survey suggested that the public considered physical safety paramount when discussing their priorities for any neurotechnology, followed closely by the efficacy of the technology and the costs (if any) to the user. Most people considered the way the technology may be outwardly perceived to others, as well as the idea that the technology may be consistently monitoring and recording data, to be low priorities. This indicates that the likelihood of an individual adopting a technology is much more heavily weighted in favour of everyday practicality than more social concerns such as having the technology visible or identifiable. The idea of costs to users being a high priority may be influenced by the fact that the majority of respondents come from the UK, where free national healthcare is the norm.

Interestingly there was an equal split in those who found the idea of having a neurotechnological intervention surgically implanted into their body to be acceptable or unacceptable. This is perhaps unsurprising given the number of extenuating circumstances that would factor into someone's willingness to have a surgical implant. However, this does indicate that there would be a considerable number of individuals who would at least consider an implantable device as a treatment option if there were significant benefits to be gained from an implantable device. Rather than dismissing the idea of invasive surgery altogether, many people would at least consider it as a treatment option.

This survey would suggest that there is no well known about, trusted and accessible repository for members of the public to learn about neurotechnologies. Most people indicated that they would look online for information or would want to speak to a health care practitioner. Should the prevalence of neurotechnologies being used to treat and manage areas such as physical health, mental health and healthy aging, there may be a need for an accessible resource to inform members of the public about these types of devices, their uses, and their relative safety, in order in increase public confidence in their use and therefore increase their acceptability to patients and potential patients.

Overview of Identified Technologies

Parkinson's disease, stroke, and depression were the most commonly indicated conditions for these technologies. Given that depression and stroke are included amongst the 10 leading causes of disability worldwide, combined with the ageing population expected to increase the prevalence of age-related conditions such as Parkinson's disease, it follows that these conditions may be targeted.[1,3,13] While the majority of technologies identified were targeted at a single condition, 13 targeted multiple conditions, suggesting that the technologies may be applicable in some instances across multiple conditions. Among those technologies that did indicate more than one condition included, a combination of all these conditions (Parkinson's

disease, Alzheimer's disease, depression, stroke, spinal cord injury, neuropathic pain, and bipolar depression) was observed, with one technology targeting all 7. Of the three research areas, physical disability comprised the largest set of neurotechnologies, with 42 targeting at least one condition falling within this category, while 31 were for healthy ageing, and 23 were for mental health. This may provide an insight into the healthcare research areas being prioritised by neurotechnology developers, though it should also be noted that only select conditions were included within each of the three research areas.

For the technologies which were indicated for Parkinson's disease and/or dementia/Alzheimer's disease, the stage of disease (e.g., early stage or late stage) targeted by the technology was analysed. Although most of the technologies did not specify a stage of disease, the majority of those which did were for mild to moderate disease, followed by early/mild disease, and finally advanced/severe disease. In the case of dementia/Alzheimer's disease, all the technologies specified were for early/mild or mild to moderate disease, and none were for advanced/severe disease, whereas in the case of Parkinson's disease, three technologies did explicitly specify that they were to be used for advanced/severe disease. This suggests that early treatment of these conditions is reflected in these technologies.

The majority of the identified indication-specific technologies were classified as being at stage 1 (n = 35) or stage 2 (n = 37) of development, with fewer being at stage 3 (n = 14) or stage 4 (n = 7). This indicates that the technologies are mostly in earlier stages of development, with few having reached the post-market stage. The technologies which were classified as stage 4 comprised four technologies for depression and three for Parkinson's disease. The fact that these two conditions are represented in the latest stage of development is not surprising given that they were also two of the three most common conditions found to be targeted by the technologies identified in this horizon scan.

Wearable devices were the most common type identified, with 50 technologies falling into this category, followed by 16 implantable devices. Aligned with this, over three quarters of the technologies were non-invasive, rather than invasive. With the questionnaire responses indicating that public opinion on the acceptability of invasive neurotechnologies was split, the predominance of non-invasive technologies perhaps reflects public preference in that they may appeal to a larger proportion of people.

BCIs, TMS, DBS were the most common broad types of technologies identified. These types were all represented within the technologies with FDA approval also. For the devices with FDA approval (n = 17), TMS (n = 8) and DBS (n = 5) in particular were frequently represented. These types of technologies therefore appear to be the most established, though other types of stimulation were identified within the non-FDA approved technologies in development.

Most of the identified technologies were intended for use in hospital (n = 58), however there was a proportion that were for home use (n = 23). Those that were intended for home use included a range of types of devices/technologies and conditions which they were targeting. Given that the majority of the identified technologies were for treatment (n = 66), compared to other stages of the care pathway such as rehabilitation (n = 8), which home treatments may be beneficial in terms of ease of use and equity of access, two points which were raised by the questionnaire respondents. It has been argued that neurotechnologies should be viewed not only as treatments, but also as potential approaches for diagnosis, prognosis, and classification, as well as the prediction of treatment responses.[3] There is therefore scope for neurotechnology innovations for earlier stages of the treatment pathway such as diagnosis, which may be of particular relevance for conditions such as Alzheimer's disease where early

detection is of importance.[14] Additionally, although few technologies were identified with an AI component, this is an area which could aid in predicting treatment responses.

Only 3 of the technologies had an AI component, compared to 77 which did not. Within the literature review, a lack of wearable AI technologies for mental health (specifically depression and anxiety) was also highlighted.[10] Of the technologies which did have an AI component, all 3 were wearable devices, though the conditions they were targeting differed with one each for Parkinson's, stroke, and spinal cord injury. Previous literature has suggested the gradual merging of AI with neurotechnology, and suggested the potential for AI to enhance user experience and functionality of neurotechnologies such as BCIs.[15,16] However, few technologies with an AI component were identified in this horizon scan, with those that were being in earlier stages of development (one at stage 1, one at stage 2, and one without an ascertained stage). As both AI and neurotechnology continue to advance, more AI-enabled neurotechnologies may be seen in the future. However, there are several ethical challenges associated with neurotechnologies, including safety, data security, privacy, and equitable distribution.[8,16] The questionnaire responses indicated that most people are comfortable with the idea of a device collecting data as part of its normal functioning, which could indicate that AI-enabled neurotechnologies may be generally accepted by the public. However, safety and risk of outside interference with the device were also concerns raised by the respondents, again highlighting the importance of responsible and ethical development and regulation of these devices. Given that neurotechnologies are still emerging, there is an opportunity for pre-emptive action to ensure the ethicality and safety before potential issues arise.[15]

From the technologies identified, fewer had achieved an FDA licence while others were still in development with no FDA regulatory status identified yet. Regulatory approval is crucial for any technologies prior to being marketed for use in human subjects.[17] The approval is generally given following a clinical trial evaluating the efficacy and safety profile of the technology. The relatively few approved technologies reported may potentially be due to a number of factors, including technologies being at different stages of clinical trial, restricted access to approval record status, or falling under other regulatory jurisdictions. Only the FDA approval status was reported as there was difficulty in assessing approval records for medical device in other regulatory agencies.

Conclusions

This horizon scanning project sought to identify technologies in development for mental health, healthy ageing, and physical disability. We searched clinical trials, bibliographic, and news sources and identified 81 unique neurotechnologies and 108 unique technology-condition combinations. Parkinson's disease, stroke, and depression were the most commonly indicated conditions. The most frequently identified types of technologies were TMS, DBS, and BCIs. However, the survey indicated that only a minority of the population were at least slightly familiar with these types of neurotechnologies. Despite this, a substantial proportion of survey participants would consider invasive devices, with accessible information a challenge which, if overcome, could provide an opportunity to increase confidence in adoption of neurotechnologies. Safety was unsurprisingly highlighted as being of high priority, reenforcing the need for responsible and ethical development and regulation of these devices, particularly as the neurotechnology field continues to advance.

References

1 Neurotech Reports. *The Market for Neurotechnology: 2022-2026*. Available from: https://www.neurotechreports.com/pages/execsum.html#:~:text=Neurotech%20Reports%20projects%20that%20the,reach%20%2417.1%20billion%20in%202026 [Accessed 26 Jun 2024].

2 Müller O, Rotter S. Neurotechnology: Current developments and ethical issues. *Frontiers in systems neuroscience*. 2017;11:93. Available from: https://doi.org/10.3389/fnsys.2017.00093.

3 Ploner M, Buyx A, Gempt J, Gjorgjieva J, Müller R, Priller J, et al. Reengineering neurotechnology: placing patients first. *Nature Mental Health*. 2023;1(1):5-7. Available from: https://doi.org/10.1038/s44220-022-00011-x.

4 GOV.UK. *Life Sciences Vision*. 2021. Available from: https://www.gov.uk/government/publications/life-sciences-vision.

5 Alzheimer's Association. *Depression*. Available from: https://www.alz.org/help-support/caregiving/stages-behaviors/depression [Accessed 23 Jul 2024].

6 Belkacem AN, Jamil N, Khalid S, Alnajjar F. On closed-loop brain stimulation systems for improving the quality of life of patients with neurological disorders. *Frontiers in Human Neuroscience*. 2023;17. Available from: https://doi.org/10.3389/fnhum.2023.1085173.

7 Levett JJ, Elkaim LM, Niazi F, Weber MH, Iorio-Morin C, Bonizzato M, Weil AG. Invasive Brain Computer Interface for Motor Restoration in Spinal Cord Injury: A Systematic Review. *Neuromodulation: Technology at the Neural Interface*. 2024;27(4):597-603. Available from: https://doi.org/10.1016/j.neurom.2023.10.006.

8 Mitsea E, Drigas A, Skianis C. Digitally Assisted Mindfulness in Training Self-Regulation Skills for Sustainable Mental Health: A Systematic Review. *Behavioral Sciences*. 2023;13(12):1008. Available from: https://doi.org/10.3390/bs13121008.

9 Semyachkina-Glushkovskaya O, Penzel T, Poluektov M, Fedosov I, Tzoy M, Terskov A, et al. Phototherapy of Alzheimer's disease: photostimulation of brain lymphatics during sleep: a systematic review. *International Journal of Molecular Sciences*. 2023;24(13):10946. Available from: https://doi.org/10.3390/ijms241310946.

10 Abd-Alrazaq A, AlSaad R, Aziz S, Ahmed A, Denecke K, Househ M, et al. Wearable artificial intelligence for anxiety and depression: scoping review. *Journal of Medical Internet Research*. 2023;25:e42672. Available from: https://doi.org/10.2196/42672.

11 EUR-Lex. *Regulation (EU) 2017/745 of the European Parliament and of the Council*. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424 [Accessed 09 Jul 2024].

12 EUR-Lex. *Regulation (EU) 2017/746 of the European Parliament and of the Council*. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0746-20170505 [Accessed 09 Jul 2024].

13 Hindle JV. Ageing, neurodegeneration and Parkinson's disease. *Age and Ageing*. 2010;39(2):156-61. Available from: https://doi.org/10.1093/ageing/afp223.

14 Ning S, Jorfi M, Patel SR, Kim DY, Tanzi RE. Neurotechnological approaches to the diagnosis and treatment of Alzheimer's disease. *Frontiers in Neuroscience*. 2022;16:854992. Available from: https://doi.org/10.3389/fnins.2022.854992.

15 Berger S, Rossi F. The Future of AI Ethics and the Role of Neurotechnology. In: Workshop on Adverse Impacts and Collateral Effects of Artificial Intelligence Technologies; 2021: CEUR-WS; 2021.

16 Pulicharla MR, Premani V. AI-powered Neuroprosthetics for brain-computer interfaces (BCIs). *World Journal of Advanced Engineering Technology and Sciences*. 2024;12(1):109-15. Available from: https://doi.org/10.30574/wjaets.2024.12.1.0201.

17 Department of Health & Social Care. *Report on regulations made under sections 2(1), 10(1), 15(1) and 19(1) of the Medicines and Medical Devices Act 2021*. 2024. Available from: https://www.gov.uk/government/publications/medicines-and-medical-devices-act-report-2024/report-on-regulations-made-under-sections-21-101-151-and-191-of-the-medicines-and-medical-devices-act-2021#operation-of-regulations.

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Appendix A. Reviews Included in Literature Review

Citation	Title
Abd-alrazaq (2023)	Wearable Artificial Intelligence for Anxiety and Depression: Scoping Review
Belkacem (2023)	On closed-loop brain stimulation systems for improving the quality of life of patients with neurological disorders
Chen (2023)	High-frequency repetitive transcranial magnetic stimulation (HF-rTMS) impacts activities of daily living of patients with post-stroke cognitive impairment: a systematic review and meta-analysis
Chen (2023)	Transcranial pulse stimulation in Alzheimer's disease
Dawar (2022)	A Scoping Review of Recent Advancements in Intervention and Outcome Measures for Post-Stroke Cognitive Impairments
Jaiswal (2023)	Continuum of Care for Older Adults With Concurrent Hearing and Vision Impairment: A Systematic Review
Levett (2023)	Invasive Brain Computer Interface for Motor Restoration in Spinal Cord Injury: A Systematic Review
Li (2024)	Unlocking the Potential of Repetitive Transcranial Magnetic Stimulation in Alzheimer's Disease: A Meta-Analysis of Randomized Clinical Trials to Optimize Intervention Strategies
Mitsea (2023)	Digitally Assisted Mindfulness in Training Self-Regulation Skills for Sustainable Mental Health: A Systematic Review
Pan (2023)	Effects of low-frequency rTMS combined with antidepressants on depression in patients with post-stroke depression: a systematic review and meta-analysis
Penev (2023)	Therapeutic Effectiveness of Brain Computer Interfaces in Stroke Patients: A Systematic Review
Semyachkina-Glushkovskaya (2023)	Phototherapy of Alzheimer's Disease: Photostimulation of Brain Lymphatics during Sleep: A Systematic Review

Appendix B. Search Strategy

ClinicalTrials.gov

Search date: 20/03/2024

#	String	Results
1	"deep brain stimulation" OR neuroprosthetic OR photostimulation OR "transcranial magnetic stimulation" OR "transcranial electric stimulation" OR "brain–computer interfaces" OR "brain interface" OR "brain augmentation" OR "brain computer" OR neurotechnology OR cognitive technology OR (brain AND prosthetic)	1650

WHO ICTRP

Search date: 20/03/2024

#	String	Results
1	"deep brain stimulation" OR neuroprosthetic OR photostimulation OR "transcranial magnetic stimulation" OR "transcranial electric stimulation" OR "brain–computer interfaces" OR brain interface OR brain augmentation OR "brain computer" OR neurotechnology OR cognitive technology OR (brain AND prosthetic)	4073

CENTRAL

Search date: 20/03/2024

#	Search	Results
#1	("neuroprosthetic"):ti,ab,kw	13
#2	((brain AND prosthetic)):ti,ab,kw	47
#3	(Photostimulation):ti,ab,kw	153

#4	(“Brain–computer interfaces”):ti,ab,kw	140
#5	(Brain interface):ti,ab,kw	599
#6	(Brain augmentation):ti,ab,kw	435
#7	(“Brain computer”):ti,ab,kw	401
#8	MeSH descriptor: [Brain-Computer Interfaces] this term only	105
#9	(Neurotechnology):ti,ab,kw	32
#10	(Cognitive technology):ti,ab,kw	2133
#11	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 with Cochrane Library publication date in The last 2 years, in Trials	908

IEEE*Xplore*

Search date: 20/03/2024

#	String	Results
1	("Document Title":“deep brain stimulation” OR "Abstract":“deep brain stimulation” OR "Document Title":Neuroprosthetic OR "Abstract":Neuroprosthetic OR "Document Title":Photostimulation OR "Abstract":Photostimulation OR "Document Title":“Transcranial magnetic stimulation” OR "Abstract":“Transcranial magnetic stimulation” OR "Document Title":“Transcranial electric stimulation” OR "Abstract":“Transcranial electric stimulation” OR "Document Title":“Brain–computer interfaces” OR "Abstract":“Brain–computer interfaces” OR "Document Title":Brain interface OR "Abstract":Brain interface OR "Document Title":Brain augmentation OR "Abstract":Brain augmentation OR "Document Title":“Brain computer” OR "Abstract":“Brain computer” OR "Document Title":Neurotechnology OR "Abstract":Neurotechnology OR "Document Title":Cognitive technology OR "Abstract":Cognitive technology OR "Document Title":Brain AND prosthetic OR "Abstract":Brain AND prosthetic)	20,937
2	Filters Applied: 2022 - 2024	3,403

3	Filters Applied: Conferences	2,353

Nature

Search date: 20/03/2024

Database(s): **Embase** 1974 to 2024 March 19
Search Strategy:

#	Searches	Results
1	(nature or nature aging or nature biomedical engineering or nature nanotechnology or nature neuroscience or nature reviews neurology or nature reviews neuroscience).jn.	131082
2	"Deep brain stimulation".ti,ab,kw.	25484
3	Neuroprosthetic.ti,ab,kw.	913
4	Photostimulation.ti,ab,kw.	1815
5	"Transcranial magnetic stimulation".ti,ab,kw.	27828
6	"Transcranial electric stimulation".ti,ab,kw.	340
7	"Brain–computer interfaces".ti,ab,kw.	33
8	Brain interface.ti,ab,kw.	462
9	Brain augmentation.ti,ab,kw.	18
10	"Brain computer".ti,ab,kw.	8439
11	Neurotechnology.ti,ab,kw.	614
12	Cognitive technology.ti,ab,kw.	41
13	or/2-12	64715
14	1 and 13	221

15	limit 14 to yr="2023 -Current"	29

News Media Scanning Tool

Search dates: Lines #1-3 01/01/2023 – 11/03/2024, line #4 01/01/2023 – 14/03/2024

#	Source	URL	# hits
1	Med-Tech	https://www.med-technews.com	1
2	MedTech Dive	https://www.medtechdive.com	3
3	Medical Device Network	https://www.medicaldevice-network.com	20
4	Medtech Insight	https://medtech.citeline.com	2
5	Medical Device and Diagnostic Industry	https://www.mddionline.com/	0
6	Medical Tech Outlook	https://www.medicaltechoutlook.com/	0
7	MDTechReview	https://www.mdtechreview.com/magazine/	0
8	Today's Medical Developments	https://www.todaysmedicaldevelopments.com/	0
9	Medgadget	https://www.medgadget.com/	N/A*

*URL no longer works

GoogleNews Reproducible Search tool

Search dates: 1/1/23 to 7/3/2024

#	Search	Results
1	Neurotechnology	50
2	cognitive technology	50
3	neurotechnology mental health	20
4	neurotechnology healthy ageing	20
5	neurotechnology disabled adults	13
6	Additional Googles News search (hand searched)	12

Appendix C. Survey

Patient and Public views on Neurotechnology

Q1 Thank you for taking a couple of minutes of to share your views on the topic of neurotechnology. Sharing your views will allow us to provide a public voice on the priorities, hopes and concerns for neurotechnology with our stakeholders, which will allow us to better tailor future research to best suit the needs of patients and the public.

What is this project about?

This project aims to provide a horizon scan of new neurotechnology in development, or that has recently been approved for sale and use. In this work, we are defining neurotechnology as a technology that enables a direct connection of technical components (e.g. electrodes, computers, or intelligent prostheses) with the nervous system. Neurotechnologies may be invasive (e.g. implanted electrodes) or non-invasive (e.g. electrode caps).

For this project we are currently focusing on how neurotechnology can impact on people's mental health (such as depression, anxiety or personality disorders), healthy ageing (such as Alzheimer's and Parkinson's disease), and physical disabilities (for example those that may arise from spinal cord injuries), though many of the challenges and opportunities we hope to identify may overlap with other conditions or diseases.

Why are we asking you these questions?

One of our goals in this project is to identify any potential opportunities and challenges involved in using neurotechnologies. We need to make sure that the neurotechnologies being developed are fit for purpose and are attempting to tackle the issues are most important to the people who need them. To do this, we need to make sure that we're hearing from as many people as possible, to find out how they feel about these potential interventions and what might make a technology appealing, or what may make them hesitant to adopt these technologies into their lives or treatment regimens.

All data collected in this survey will be anonymised with no identifiable information collected or stored. The collected data from all respondents will be used to inform ongoing research and may also be shared with policy and decision makers.

Q4 How familiar are you with neurotechnology devices such as transcranial magnetic stimulation, deep brain stimulation and brain-computer interfaces, which are designed to improve brain function or treat neurological conditions?

- o Not familiar at all
- o Slightly familiar
- o Moderately familiar
- o Very familiar
- o Extremely familiar

Q2 If you were living with a condition mentioned on the previous page and you were discussing the possibility of using neurotechnology as part of your treatment with your healthcare practitioner, how would you prioritise the following when weighing up your treatment options?

	Not very important to me	Somewhat important	Very Important	Essential
How well the technology helps your treatment/symptoms	o	o	o	o
Physical Safety	o	o	o	o
Data security (will it be collecting or sharing data when used and who with)	o	o	o	o
Ease of use for the patient	o	o	o	o
Cost to the user	o	o	o	o
How noticeable would be	o	o	o	o

technology be to others (would the technology stand out or could it be easily concealed in clothing)				
How invasive is the technology (would it require surgery versus being worn)	o	o	o	o

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Q3 How acceptable would you find a neurotechnology put into the body through a surgery?

- o Not at all acceptable
- o Only as a last resort
- o Fairly neutral
- o Quite acceptable
- o Would be my preference

Q8 If you were looking for information on neurotechnology, where would you look for information that you can trust or rely on?

_____

Q6 Are there any concerns that may affect how likely you would be to adopt a neurotechnology that had been approved for use in the UK?

	I wouldn't be concerned	I would be somewhat concerned and would seek further information	I would be concerned but if my healthcare provider reassured me I would be willing to try it	I would be very concerned that this could be an issue

Possibility of side-effects	o	o	o	o
How much data it collects	o	o	o	o
Whether it is constantly monitoring data	o	o	o	o
Potential risk of interference (e.g. picking up a signal from another device connected to the internet)	o	o	o	o
How much has the device been tested for long term effects (e.g. Is there evidence yet to suggest that this will continue to help after 10 years of use?)	o	o	o	o

Q7 Are there any opportunities or concerns you have about potential neurotechnology use for the treatment or management of mental health, healthy ageing, and physical disabilities that we have not touched on in these questions that you would like to highlight?

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