Stakeholder Perspectives on Trustworthy Artificial Intelligence for Parkinson's Disease Management Using a Co-creation Approach: A Qualitative Study

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Abstract

Background: Parkinson's Disease (PD) is the fastest-growing neurodegenerative disorder in the world, with prevalence expected to exceed 12 million by 2040, which poses significant healthcare and societal challenges. Artificial intelligence (AI) systems and wearable sensors hold the potential for PD diagnosis, personalized symptom monitoring, and progression prediction. Nonetheless, ethical AI adoption requires several core principles, including user trust, transparency, fairness, and human oversight.

Objective: This study aimed to gather and analyze the perspectives of key stakeholders, including individuals with PD, healthcare professionals, AI technical experts, and bioethical experts, to inform the design of trustworthy AI-based digital solutions for PD diagnosis and management within the AI-PROGNOSIS European project.

Methods: An exploratory qualitative approach, based on two datasets constructed from co-creation workshops, engaged key stakeholders with diverse expertise to gather insights, ensuring a broad range of perspectives and enriching the thematic analysis. A total of 23 participants participated in the co-creation workshops, including 11 people with PD, six healthcare professionals, three AI technical experts, one bioethics expert, and three facilitators. Using a semi-structured guide, key aspects of the discussion centered on trust, fairness, explainability, autonomy, and the psychological impact of AI in PD care.

Results: Thematic analysis of the co-creation workshop transcripts identified five key main themes, each explored through various corresponding subthemes. AI Trust and Security (Theme 1) was highlighted, focusing on data safety and the accuracy and reliability of the AI systems. AI Transparency and Education (Theme 2) emphasized the need for educational initiatives and

the importance of transparency and explainability of AI technologies. AI Bias (Theme 3) was identified as a critical theme, addressing issues of bias and fairness and ensuring equitable access to AI-driven healthcare solutions. Human Oversight (Theme 4) stressed the significance of AI-human collaboration and the essential role of human review in AI processes. Lastly, AI Psychological Impact (Theme 5) examined the emotional impact of AI on patients and how AI is perceived in the context of PD care.

Conclusions: Our findings underline the importance of implementing robust security measures, developing transparent and explainable AI models, reinforcing bias mitigation and reduction strategies and equitable access to treatment, integrating human oversight, and considering the psychological impact of AI-assisted healthcare. These insights provide actionable guidance for developing trustworthy and effective AI-driven digital PD diagnosis and management solutions. Clinical Trial: na

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Stakeholder Perspectives on Trustworthy Artificial Intelligence for Parkinson's Disease Management Using a Co-creation Approach: A Qualitative Study

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Keywords: Parkinson's disease; artificial intelligence; ethical AI; trustworthiness; co-creation; stakeholder perspectives; digital healthcare solutions; AI-PROGNOSIS

Introduction

Neurological disorders are currently the leading cause of disability, with Parkinson's Disease (PD) emerging as the most common movement disorder, showing the fastest growing prevalence and disease burden [1]. Moreover, PD resulted in 5.8 million disability-adjusted-life years (DALYs) in 2019, an 81% increase since 2000 [2]. Driven by an aging population and increasing longevity, the number of people with PD (PwPD) is projected to exceed 12 million worldwide by 2040, which has been identified as the PD pandemic [3]. Therefore, the societal and economic burden of PD will escalate unless more effective treatments or means of prevention are identified [4].

Recent advances in digital health technologies offer significant opportunities to improve the quality of care of people with neurodegenerative diseases [5]. In particular, artificial intelligence (AI)-based systems based on wearable sensor data have shown potential in several aspects of PD care, from early diagnosis [6] and classification [5] to progression monitoring [7] and outcome prediction [8,9], ultimately aiming to optimize treatment and prognosis.

However, as AI-based technologies rapidly advance, ethical considerations and human rights must guide design, development, and deployment to ensure beneficial impacts on public health and medicine [10]. In this line, the World Health Organization (WHO) outlines six key pillars for ethical AI in healthcare, namely: human autonomy, well-being and safety, transparency and explainability, accountability, inclusiveness and equity, and promoting responsive and sustainable AI [11]. These principles align with other frameworks emphasizing legal data processing, human oversight, bias avoidance, safeguarding vulnerable populations, and ensuring patient involvement [12]. For instance, the High-Level Expert Group on AI has established the Assessment List for Trustworthy Artificial Intelligence (ALTAI) to self-assess the trustworthiness of AI systems. This framework is based on seven key requirements, namely: human agency and oversight, technical robustness and security, privacy and data governance, transparency, diversity and fairness, societal and environmental well-being, and accountability [13]. Furthermore, the need for patient-centered approaches in digital health is reinforced by Riggare et al. [14], noting that PwPD seek tools to manage symptoms, collaborate with healthcare professionals (HCPs) and access information.

The design process of digital health technologies often overlooks the interplay between technology, users, and their socio-economic environment [15]. This oversight can impact effectiveness, as evidenced by high attrition rates in digital health research, estimated at 43% in studies involving people living with chronic conditions [16]. In fact, the adoption rate of digital health technologies has decreased significantly over time, with 32% of users discontinuing their use after 6 months and

50% after more than a year [17].

To address these challenges, research has demonstrated the value of participatory approaches in the design of digital health solutions [16,18]. Co-creation processes actively engage key stakeholders throughout the development process and hold significant potential for improving digital health technologies [19]. A participatory approach is defined by collaboration between diverse participants who contribute with their experiences and expertise across all stages of research, from problem definition to implementation and evaluation [20,21]. Notably, co-created solutions demonstrate 2.1 times higher long-term adoption rates [10], addressing the sustainability challenges observed in digital health technologies. Moreover, a recent study examined the perspectives of citizens and experts on AI ethics in population health, emphasizing the need for greater public involvement. The findings revealed broad agreement for transparent and accessible ways to include the public in AI decision-making [22]. This aligns with efforts to develop socially responsible data contracts that go beyond legal requirements, such as the "Commitments for the Digital Age," a co-created framework that established clear commitments for data stewardship, governance, and accountability in the collection, use and sharing of personal data [23].

Workshops are considered a key component of the co-creation process, enabling active participation and engagement, allowing individuals to contribute with their unique insights, and fostering a sense of ownership. In addition, workshops provide a platform for immediate feedback and iteration, ensuring that solutions are responsive to participants' input and preferences [24]. This iterative approach has been successfully employed in developing mobile health (mHealth) tools, leading to more user-centric and effective interventions [25,26].

Previous studies have also explored participatory approaches in developing digital health solutions for PD. For instance, the development of the eCARE-PD platform involved PwPD, caregivers, and HCPs, leading to the identification of key design principles to address users' needs and expectations [18]. Building on these findings, the iCARE-PD project aimed to improve the usability and acceptability of sensor-based solutions in the context of a community-centered integrated care model [27]. Moreover, Revenäs et al. [28] explored the needs and expectations of PwPD and HCPs that informed a functional eHealth prototype to support PD co-care. Similarly, Kessler et al. [29] analyzed feedback from PwPD, carers, and HCPs regarding medical and self-management approaches to improve the quality of life of PwPD. The findings highlighted the need for a collaborative care model that includes patient engagement and comprehensive support.

This study, part of the AI-PROGNOSIS Horizon Europe research initiative [30], aims to explore the perspectives of key stakeholders, including PwPD, HCPs, AI technical experts, and bioethical experts. The goal is to provide actionable insights for designing ethically sound and trustworthy AI solutions for PD management. These solutions are intended to align with end-users needs, values, and expectations—essential factors for successful implementation and acceptance. Furthermore, the AI-PROGNOSIS project seeks to develop AI-based predictive models for personalized PD risk assessment and prognosis. These models will be informed by digital biomarkers collected from everyday devices such as smartphones and smartwatches. This innovative approach may enable personalized care management and accurate remote monitoring within a comprehensive digital health ecosystem in the future [30]. The present study contributes to this initiative by ensuring that the AI solutions developed are grounded in key stakeholders' real-world needs and preferences, thereby enhancing their practical relevance and potential impact.

Methods

Overall context

The AI-PROGNOSIS project aims to design tools that are meaningful, relevant, and meet the needs of users, industry, and society through an iterative collaboration among stakeholders [30]. By

employing an agile methodology [19,31], the project incorporates three rounds of strategic co-creation workshops, as illustrated in Figure 1. These workshops are integral to the development process, ensuring that stakeholder feedback is continuously gathered and integrated into the project's progression. The present qualitative study describes the findings of the first round of workshops, which focused on Trustworthy AI design and specification. During these workshops, participants engaged in discussions and activities that highlighted the importance of building AI tools that are transparent, secure, and aligned with ethical standards. The insights gained from this initial round of co-creation workshops serve as a foundational step, guiding subsequent iterations and refinements to ensure that the final AI tools are technically robust and socially and ethically sound.

As shown in Figure 1,

following the first round of co-creation workshops, a series of prototyping development sprints will update the initial product backlog, focusing on each tool. This process is based on feedback collected during user research and the insights from the first co-creation workshops. These efforts will lead to the first product increment, featuring early mock-up prototyping and internal testing. The second round of co-creation workshops will focus on each tool's user experience/user interface (UI/UX) design to explore the importance and granularity of the insights, metrics, and symptom-tracking features, engaging the various target audiences. Another round of prototyping sprints, moderated and unmoderated usability testing with a small pool of participants, will result in the alpha version of the AI-PROGNOSIS digital tools. The final round of co-creation workshops focuses on hands-on experience and feedback with the tools from all target audiences to identify and refine the features with the highest value and impact potential and set the final technical and product requirements and necessary modifications. The final round of prototyping and testing sprints of the beta versions of the AI-PROGNOSIS tools will produce the initial Minimum viable products (MVPs). Therefore, we plan to expand the pool of recruited participants as we progress toward more extensive alpha and beta testing of the prototypes (including HCPs, healthcare enablers (e.g., policymakers, hospital managers, head of PD associations), people with/without PD, and expert patients). Overall, co-creation workshops within the AI-PROGNOSIS project are designed to be conducted both in-person and remotely to enhance accessibility. These workshops will utilize appropriate collaborative tools for various activities, such as brainstorming (Miro), creating interactive mock-ups (Figma), and conducting usability testing (UsabilityHub).

Study design

This study adopted an exploratory qualitative design [32] to investigate key stakeholders'

perspectives on integrating trustworthy AI into PD management. In this line, four co-creation workshops were held, each involving different stakeholders. The first two workshops included PwPD, and the third and fourth involved HCPs, with all workshops enriched by technical and bioethics experts from the AI-PROGNOSIS Consortium. Moreover, each workshop was facilitated by three researchers experienced in qualitative methods. They utilized a semi-structured format and open-ended questions to encourage group discussions and elicit participants' opinions and experiences.

Moreover, the following key aspects were discussed during the co-creation workshops: i) factors influencing trust in AI; ii) human autonomy and AI decision-making; iii) fairness and equality; iv) transparency and explainability; and iv) ethical and user-driven concerns around the use of AI in healthcare and self-care.

Recruitment

A patient panel was established using purposive and snowball sampling [32], aiming to ensure diversity across the targeted countries (i.e., France, Germany, Portugal, Spain, Sweden, and the UK) that are part of the AI-PROGNOSIS consortium. Once a participant agreed to join the patient panel, informed consent was obtained and recorded verbally. An onboarding session was conducted with each participant via Zoom platform, covering their diagnosis journey, opinions on AI in healthcare, and expectations regarding the project.

Patient panel members (n=13) were recruited via email from a project member living with PD, who has established a contact network with other PwPD. Inclusion criteria for PwPD were: i) PD diagnosis, ii) residing in one of the six targeted countries (i.e., France, Germany, Portugal, Spain, Sweden, the UK), iii) sufficient English proficiency to participate, and iv) having a basic understanding of AI and eHealth. This process aimed to ensure diversity in age, sex, diagnosis and treatment experiences, employment status, and AI knowledge.

HCPs (n=14) were invited via email through professional networks and healthcare institutions. Inclusion criteria for HCPs were: i) representing primary (i.e., general practitioner) and secondary (i.e., neurologist, movement disorder specialist) HCPs in PD care across France, Germany, Spain and the UK, ii) active involvement in PD care, iii) at least two years of clinical experience, iv) sufficient English proficiency to participate, and v) having a basic understanding of AI in healthcare.

Technical and bioethical experts, being members of the AI-PROGNOSIS consortium, were used as a convenience sample, with direct informal recruitment. Their expertise significantly enriched the co-creation process, enhancing the quality and depth of the discussions during the workshops.

Individuals who showed interest were provided with detailed project information and invited to an online informative session. Those unable to attend received a session recording and could ask follow-up questions. All participants provided verbal informed consent before the informative sessions. Participation was voluntary, and no compensation was provided.

Data collection

Two datasets were created based on data collected through co-creation workshops targeting the perspectives of PwPD (workshops 1 and 2), and the perspectives of HCPs (workshops 3 and 4). These workshops were held in March 2024 and November 2024, respectively. All workshops conducted online via the Zoom platform, allowed for an in-depth exploration of topics, with the HCP workshop lasting about 60 minutes and the PwPD workshop lasting 120 minutes. To ensure comprehensive data capture, both workshops were audio-recorded, transcribed verbatim, and pseudo-anonymized to maintain confidentiality. Participants were informed of the voluntary nature of the study and assured of the confidentiality of the data collected.

Semi-structured scripts guided the workshops with PwPD and HCPs (see Multimedia Appendix). These scripts included open-ended questions designed to explore participants' experiences,

perceptions, and expectations regarding AI in healthcare. Overall, topics covered during the workshops included:

- Diagnosis journeys
- Attitudes toward AI in healthcare
- Factors influencing trust in AI
- Human autonomy and AI decision-making
- Fairness and equality
- Transparency and explainability
- Ethical and user-driven concerns around the use of AI in healthcare and self-care

Data analysis

Data analysis followed an inductive thematic analysis process from a holistic perspective of the AI-PROGNOSIS AI-driven ecosystem, with two independent researchers (BA and SBD) analyzing all qualitative data. After familiarizing the data, an initial set of codes was developed (Figure 2-outer circle). These codes were then organized into themes and sub-themes, which were reviewed for alignment with the data.

The final themes and sub-themes were articulated using clear and precise language, following the methodology outlined by Braun and Clarke [33]. To ensure the credibility and reliability of the analysis, themes were cross-validated. Agreement on code assignment was measured using the Kappa statistic [34], with a threshold of 0.80 considered acceptable [34]. The final themes were established through consensus-building among the researchers. This thorough approach allowed for a comprehensive understanding of the stakeholders' perspectives, ensuring that the analysis accurately reflected their experiences and insights.

Research Participants

Regarding workshop participation, 11 PwPD and six HCPs attended the first and second workshop, respectively. The HCPs included three general physicians, two neurologists, and three movement disorder specialists. Additionally, three technical experts and one bioethics expert attended both workshops, along with the three facilitators/observers. The mean age of PwPD was 54.00 ± 11.19 years, with four females, and an average time since diagnosis of 8.4 ± 5.54 years. The mean age of HCPs was 43.33 ± 14.61 years, with five males, and an average of 15.00 ± 14.63 years of experience working with PD populations (see Table 1).

Table 1. Demographic characteristics of study participants.

Participants / Characteristics	Age (mean ±SD)	Sex (% male)	PD duration (years)	Years of experience	Workshop attendance
PwPD (n = 11)	54.0 ± 11.2	63.6 %	8.4 ± 5.5	n/a	Workshops #1, #2
HCP (n = 6)	43.3 ± 14.6	62.5%	n/a	15.0 ± 14.6	Workshops #3, #4
Technical Expert (n = 3)	35.7 ± 5.1	100 %	n/a	6.0 ± 4.6	Workshops #1-#4
Bioethics Expert (n = 1)	35.0	100 %	n/a	6.0	Workshops #1-#4

Ethics Approval

Ethical approval was granted by the Swedish Ethical Review Authority, Sweden (Dnr 2023-05949-01). Participants gave informed consent to participate in the study before taking part.

Results

Main findings

Regarding the agreement during the process of thematic analysis across all resolution scales (themes and sub-themes), the two independent researchers (BA and SBD) demonstrated a Kappa statistic of 0.95. In cases of uncertainty, discussions between the researchers led to revisions of the text, ultimately reaching 100% agreement on all themes.

The thematic analysis revealed five major themes: AI Trust and Security (Theme 1), AI Transparency and Education (Theme 2), AI Bias (Theme 3), Human Oversight (Theme 4), and AI Psychological Impact (Theme 5). These themes were further detailed through various subthemes, in particular:

- AI Trust and Security (Theme 1): This theme included subthemes such as data safety, accuracy, and reliability. Participants emphasized the importance of ensuring that AI systems are secure and trustworthy to gain user confidence.
- AI Transparency and Education (Theme 2): This theme encompassed subthemes related to educational needs, transparency, and explainability. Stakeholders highlighted the need for clear and accessible information about how AI systems work and their decision-making processes to foster trust and understanding.
- AI Bias (Theme 3): Examined through subthemes like bias and fairness, and access equity; this theme addressed concerns about potential biases in AI algorithms and the importance of ensuring equitable access to AI-driven healthcare solutions for all individuals.
- Human Oversight (Theme 4): This theme was explored through subthemes including AI-human collaboration and the human review role. Participants discussed the necessity of maintaining human oversight in AI applications to ensure accountability and ethical decision-making.
- AI Psychological Impact (Theme 5): Analyzed through subthemes such as emotional impact and AI perception, this theme highlighted the psychological effects of AI on users, including their feelings of trust, anxiety, and overall perception of AI in healthcare.

The main findings, including themes, subthemes, and corresponding codes, are summarized in Figure 2. These results can help understand the key factors influencing the integration of trustworthy AI into PD management, reflecting the diverse perspectives of stakeholders.

Figure 2 Overview of the main findings derived from the thematic analysis, including themes (inner part of the circle), subthemes (middle part of the circle), and corresponding codes (outer part of the circle).
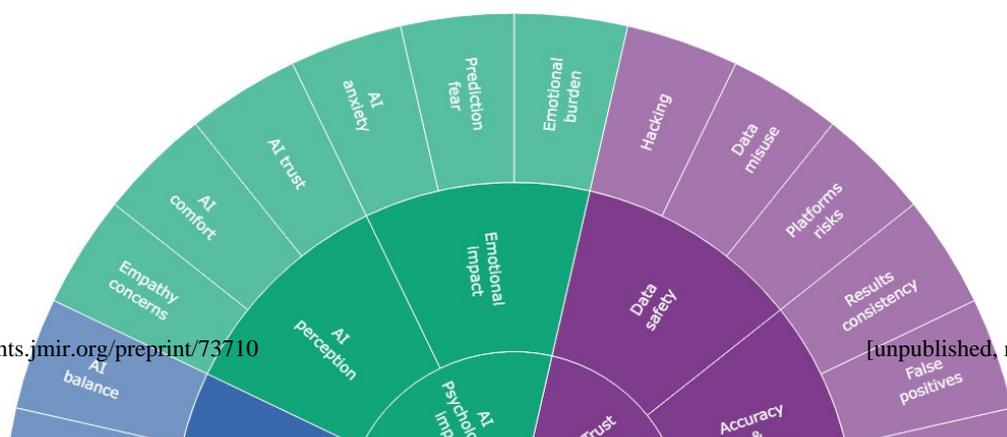
Moreover, the main findings for each theme and subtheme are briefly presented and supported by direct quotations. Participant identifiers (i.e., PwPD = Person with Parkinson's Disease, HCP = healthcare professional, TE = Technical AI Expert, BE = Bioethics Expert) and the respective workshops (workshops #1-#4) in which the quotes were provided are included for context.

Theme 1: AI Trust and Security

Integrating AI in the context of PD diagnosis and management raised several concerns about data security and system reliability. Participants recognized the need to implement robust security measures and clear protocols for data handling as a key factor for building trust in AI systems.

Subtheme 1: Data safety

Participants expressed several concerns about data security and integrity in AI systems, highlighting the potential risks associated with insecure platforms and data misuse. In this vein, ensuring robust security measures to protect patient data from breaches and unauthorized access was considered a critical area of focus for AI systems, as noted:

> "*In terms of what makes it untrustworthy, you would be having insecure platforms for holding the data...if it was in a cloud that anyone could access or hack into, that would be untrustworthy.*" (PwPD#1, workshop #1)

HCPs also acknowledged the risks associated with data collection, storage, and access. The importance of restricted access to prevent privacy concerns was highlighted, as well as the broader implications of data misuse. This scenario could affect insurance coverage, which illustrates the consequences of inadequate data protection in healthcare, as recognized:

> "*There is always a risk in the use of this data, how to collect it, how to store it, and who can access it. This needs to be very clear with strictly restricted access to prevent privacy concerns. (...) This data is very strong and could be used by companies to deny patients insurance.*" (HCP#1, workshop #3)

Subtheme 2: Accuracy and reliability

The accuracy and reliability of AI systems was considered a crucial factor in building trust among users. The importance of avoiding false positives and ensuring diagnostic accuracy was repeatedly mentioned, considering the unnecessary distress it could cause. Whereas one PD patient emphasized the importance of consistency in AI outputs, another highlighted the potential consequences of inaccurate results, as follows:

> "*To me, a trustworthy system would be a system where if you ask twice the same question, it will come with similar answers, not radically different.*" (PwPD#2, workshop #1)

> "*If the process isn't very accurate and it said somebody had Parkinson's when they didn't, a false positive, that can be pretty untrustworthy*." (PwPD#1, workshop #1)

In addition, HCPs expressed the importance of adopting a balanced approach for AI integration into PD management, acknowledging its potential benefits while recognizing its limitations. As highlighted by one participant, clinicians should be properly educated about AI systems to ensure their effective application in clinical practice:

> "*We need to understand how AI works, the data it is based on, and how to interpret its decisions. (…) We should not trust it 100%, but neither should we ignore the additional benefits it provides.*" (HCP#6, workshop #4)

Theme 2: AI Transparency and Education

Transparency and education in AI systems were considered essential for making their processes clear and accessible to all relevant stakeholders. In this line, participants emphasized that these aspects are vital not only for improving understanding and accessibility but also for addressing misconceptions and building confidence in AI-driven solutions.

Subtheme 1: Educational needs

Many participants recognized the need for educational resources to help PwPD and HCPs understand

AI systems and their role in PD diagnosis and management. This was considered relevant in counteracting negative perceptions and fostering informed engagement with AI-driven healthcare solutions, as noted:

> "*There must be a support educational program to inform what AI actually is because the generic opinion about it at the moment is negative.*" (PwPD#3, workshop #1)

Furthermore, HCPs recognized the importance of continuous education on AI advancements, acknowledging that empowered clinicians are more likely to view AI as a supportive tool rather than a replacement, as follows:

> "*Doctors' education must improve to keep up with AI, so they can explain AI-derived solutions to patients. This is an exciting time for evolution in medicine, but everyone needs to be on the same page to provide high-quality care.*" (HCP#4, workshop #4)

> "*Doctors normally are very against things we don't see. (…) If we understand how AI works, we can demystify it. AI shouldn't be seen as something unreachable and incomprehensible.*" (HCP#2, workshop #3)

Subtheme 2: Transparency and Explainability

Overall, participants valued transparency in AI decision-making processes, advocating for the development of Explainable AI (xAI). Understandable and accessible AI decisions can promote trust and acceptance among their users. In this line, technical experts from the AI-PROGNOSIS consortium added the following insights:

> "*We should develop Explainable AI...so that the user can understand, for example, what data went into training a model, why was the data chosen, and did we assess the fairness?*" (TE#1, workshop #1)

> "*In AI-PROGNOSIS, we are developing models related to the risk prediction of Parkinson's disease and the progression, and medication response model. All of them are AI driven, we are aiming to implement models that are not just accurate, but they are trustworthy in a sense of they should have some kind of privacy fairness, closeness, generalization explainability so that our model become trustworthy.*" (TE#3, workshop #2).

Furthermore, HCPs noted that receiving AI outputs in an easily interpretable format could not only aid clinical decision-making but also lessen skepticism towards unfamiliar technology. One HCP suggested:

> "*It should be standardized (i.e., figures, graphics) to improve understanding for non-neurologists, so we don't need to interpret different explanations, but rather have consistent information.*" (HCP#3, workshop #3)

Theme 3: AI Bias

Participants expressed significant concern about bias in AI systems, emphasizing the need for equitable treatment and robust bias mitigation strategies. They highlighted examples of racial and gender bias in healthcare algorithms and discussed the challenges posed by incomplete datasets and variability in clinical assessments.

Subtheme 1: Bias and fairness

Concerns about bias in AI models were particularly prevalent among participants, who mentioned examples of racial and gender bias in existing healthcare algorithms. One technical expert noted:

> "*In the United States for example, there are healthcare algorithms that have shown racial bias...the model prioritized patients for high-risk care management programs based on race.*" (TE#2, workshop #1)

The challenge of data collection and its impact on AI model development was also discussed. More specifically, time constraints in clinical practice posed a challenge for a comprehensive assessment and were often associated with incomplete datasets, as acknowledged by one HCP:

> "*Missing data can be a significant issue, if physicians don't have enough time to systematically ask about all symptoms, especially non-motor symptoms.*" (HCP#6, workshop

#4)

In this line, one HCP suggested the implementation of wearable-based remote assessments to address this limitation, emphasizing the practicality of this approach, as follows:

> "*We don't do the complete Movement Disorder Society – Unified Parkinson's Disease Rating Scale (MDS-UPDRS) at each visit. If you want to do it systematically, you need to use something in an ambulatory setting, like an iPhone or a smartwatch, to continuously record data at home. It's not feasible to do this [MDS-UPDRS] during clinic visits because, honestly, we don't have the time.*" (HCP#2, workshop #3).

Moreover, the assessment variability of clinical outcomes could further induce bias in AI models, which must be trained on consistent and reliable data to provide accurate predictions, as suggested by one HCP:

> "*The most challenging values to be gathered by AI would be the normal variability in the physical exam. The pull test is so variable (…) we should find a more reliable way to establish balance. Besides, tremor, rigidity, and bradykinesia are very difficult to measure consistently.*" (HCP#4, workshop #4)

Subtheme 2: Access equity

Some participants suggested that AI could enhance fairness in medical diagnoses by eliminating human prejudices that might influence decision-making. This highlights the potential of AI to provide more equitable healthcare by ensuring consistent and impartial decisions, as noted:

> "*AI will bring more fairness to the diagnosis because it's an algorithm, so it works equally for everybody. There is no prejudice.*" (PwPD#2, workshop #1)

Nonetheless, the bioethics expert highlighted the complex nature of bias in AI systems and the need for continuous monitoring to address potential biases:

> "*A lot of times when we talk about fairness in AI, it's about mitigating bias in the algorithms of the model that you build for the AI.*" (BE, workshop #2)

Furthermore, patient autonomy and informed consent are crucial to ensuring the ethical use of AI in healthcare. These aspects are particularly relevant in the case of AI gathering data that patients may not disclose to doctors and which analysis could uncover sensitive information, as noted by one HCP:

> "*AI could gather data from many sources and make connections that the patient never disclosed to the doctor. This could be very dangerous.*" (HCP#4, workshop #4).

Theme 4: Human Oversight

Participants emphasized the role of human oversight in AI-assisted healthcare and the relevance of human judgment, accountability, and empathy in clinical decision-making. Discussions highlighted the need for AI to complement, rather than replace HCPs, ensuring a collaborative approach that preserves trust, provides reassurance, and supports doctor-patient relationships.

Subtheme 1: AI-Human collaboration

Overall, PD patients strongly preferred AI systems to be overseen by HCPs. This involvement was considered essential for maintaining trust and safeguarding an empathetic therapeutic relationship with HCPs. This perspective shows the need for clear, effective communication from HCPs regarding AI decision-making processes. One PwPD highlighted a common concern about the potential impersonal nature of AI:

> "*It's always good to know that someone is supervising the decision; you're not being treated only by a machine. (…) I think for many people, it would be very scary to know that the health decisions are made by a machine, not a human. It will have to be very well explained.*" (PwPD#2, workshop #1)

Moreover, HCPs emphasized the relevance of human judgment and accountability in AI-assisted decision-making. This reinforces the common perception that while AI can add value to current diagnostic methods, the final interpretation and responsibility lie with the clinician, as stated by one

participant:

> "*The doctor has the final responsibility, and AI is just a tool – like an MRI or CT scan. You would never blame the CT machine, but you would always hold the doctor responsible for interpreting it.*" (HCP#3, workshop #3)

Subtheme 2: Human review role

Several participants acknowledged that human oversight adds a layer of reassurance and accountability, which increases their trust in AI-driven solutions. As expressed by one participant, patients are more likely to trust and engage with technology when human judgment overlays AI systems:

> "*Yeah, I tend to think that AI is getting more and more accurate results, I would give more trust to the to the AI decisions overtime. We tend to give more trust in a human healthcare professional.*" (PwPD#4, workshop #2)

Whereas human oversight was considered essential in maintaining trust and ensuring effective patient care, HCPs recognized the value of AI integration in their practice. This collaborative effort can help mitigate the risks associated with over-reliance on AI while still benefiting from its output, as expressed by one participant:

> "*We can use AI to double-check things, but if something seems off, we shouldn't follow it blindly.*" (HCP#2, workshop #3)

Nonetheless, one HCP noted that AI should not be imposed on clinicians without their consent or understanding, reflecting the need for clear implementation guidelines in clinical settings:

> "*I think the only way AI should be accountable is if it is imposed by your employer, for example, if AI is included in the algorithm of a clinical history at the hospital.*" (HCP#4, workshop #4).

Theme 5: AI Psychological Impact

Participants emphasized the psychological consequences of AI integration in PD care, particularly the potential distress caused by AI-generated diagnoses. There were concerns regarding the risks of false positives, the emotional burden of AI predictions without actionable outcomes, and the fear of losing the human aspect of healthcare.

Subtheme 1: Emotional impact

Participants voiced some concerns about the potential psychological consequences of AI predictions, particularly regarding the anxiety and stress that might result from AI-generated diagnoses. The risk associated with inaccurate predictions, as highlighted by one participant, illustrates the psychological effects of unreliable AI assessments:

> "*If somebody who might have a diagnosis of Parkinson's is then told there's a 75% chance you have got Parkinson's, that could cause some quite disastrous potentially fatal consequences for an individual who fears that their life is over.*" (PwPD#1, *workshop #1*)

Moreover, HCPs stressed the need for thoughtful communication of AI results, discussing the relevance of sharing information that may not lead to actionable outcomes, as follows:

> "*We want to predict if someone will develop PD, but if we can't change the outcome, what is the goal of giving this news now? It's a hard thing to take in.*" (HCP#2, workshop #3)

Subtheme 2: AI perception

Beyond technical accuracy, PD patients' attitudes toward AI tools are influenced by psychological factors, including fear and uncertainty about these technological advancements. One PD patient underlined this perspective, evidencing the need to address existing misconceptions about AI to improve acceptance and trust.

> "*I think there's a lot of fear about AI. And I think it's worth considering where AI is already used, for example for auto segmentation or an MRI scan.*" (PwPD#2, workshop #1)

In addition, HCPs highlighted their role in interpreting and communicating AI outputs in clinical

consultations, ensuring that the human aspect of care is not lost in the integration of technology, as noted:

> "*One of the main roles of a doctor is to guide the patient through their illness, to explain what they are feeling, what they are going through, and to be with them during the process (...). You can use AI as a tool to find the best option, but trust comes from your ability to explain why you're choosing one solution over another.*" (HCP#4, workshop #4)

Another HCP also reinforced the importance of actively involving patients in shared decision-making processes, as follows:

> "*We need to compare the AI data with clinical data and make decisions together with the patient. This approach could increase patient trust in our decisions as they can see the data and understand how we interpret and use it in clinical practice.*" (HCP#1, workshop #3)

Overall, these findings suggest that stakeholders' trust in AI-driven solutions for PD diagnosis and management relies on data security, accuracy, transparency, and human oversight. Concerns about data breaches, biases, and the psychological impact of AI predictions highlight the need for AI tools to be secure, fair, explainable, and sensitive to mental health. Addressing these factors is essential to gain patient acceptance and trust in clinical practice.

Discussion

Main Findings

Grounded by a co-creation approach, this study explored key stakeholders' perspectives into the challenges and opportunities of integrating trustworthy AI into PD diagnosis and management. As a participatory approach, the added value of co-creation lies in capturing lived experiences and end-user empirical knowledge to ground innovative solutions' development [16]. These efforts aim to promote the acceptability, usability, and effectiveness of the resulting digital technologies, ensuring user satisfaction [19,31].

Driven by the aforementioned perspectives, four co-creation workshops were conducted, actively engaging key stakeholders (i.e., PwPD, HCPs, and technical/bioethics experts). Thematic analysis of the transcripts revealed five main Themes: AI trust and security (Theme 1), transparency and education (Theme 2), AI bias (Theme 3), human oversight (Theme 4), and AI psychological impact (Theme 5), as discussed below.

AI Trust and Security

Overall, participants expressed significant concerns about data privacy and the potential misuse of sensitive health information. In particular, PwPD underlined the risks associated with insecure platforms and unauthorized access, while HCPs emphasized the need for robust data storage to mitigate privacy risks. This reinforces the argument that trust in AI systems is influenced by users' perceptions of AI capabilities and input data quality. However, AI models require large datasets for more accurate outputs, which can lead to privacy issues if not managed properly [35]. These insights contribute to the broader field of AI Trust, Risk, and Security Management (AI TRiSM), highlighting the need for robust data security measures and consistent accuracy in AI systems to build patient trust and ensure effective implementation [36]. Moreover, Reinhardt et al. [37] identified several dimensions of trust in AI, namely interpersonal trust, institutional trust, and trust in technology, emphasizing however that the current understanding of trust and trustworthiness in AI ethics lacks a clear operational framework. In this vein, the WHO [11] also emphasizes that ethics and human rights must be at the heart of AI design, deployment, and use to maximize benefits and minimize risks. This includes ensuring robust security measures to protect patient data and foster confidence among stakeholders.

Transparency and Education

Many participants highlighted the need for clear communication about AI's functionality and decision-making processes. Ethical guidelines mandate clear explanations of AI systems, ensuring they are technically sound and ethically responsible [38]. In addition, PwPD stressed the importance of demystifying AI through accessible educational resources, which aligns with research suggesting that clear explanations of AI processes promote trust by helping users understand its behavior, reducing fear and skepticism associated with unfamiliar technology [39]. Furthermore, HCPs highlighted the relevance of explainable AI (xAI), aligning with the concepts discussed in the literature, aiming to make AI models more interpretable [40,41]. Successful integration of AI in healthcare requires educated and empowered clinicians who view AI as a supportive tool rather than a replacement for clinical expertise [39,42]. Additionally, the WHO report [11] advocates for educating stakeholders on the function of AI systems, including their strengths and limitations, to encourage informed decision-making among providers and patients.

AI Bias

In general, participants raised concerns about bias in AI models, particularly racial and gender disparities. This illustrates the concept of algorithmic bias, which can result in discriminatory outcomes by making decisions based on biased data [43]. The results of Abràmoff et al. [44] reinforced the impact of racial and gender biases in AI healthcare algorithms, highlighting the need for equitable treatment and robust bias mitigation strategies. Moreover, HCPs pointed out the challenges of incomplete datasets due to time constraints in clinical practice and the risks of biased data influencing AI predictions. Data bias, originating from unrepresentative datasets can lead to skewed model predictions [43]. Continuous data collection technology, as recommended by one HCP, aligns with current guidelines for enhancing AI research quality by incorporating diverse data sources and methodologies [45]. Additionally, variability in clinical outcome assessments poses a challenge for AI models, which require consistent and reliable data for accurate predictions. Feeding biased data into AI systems can result in systematically biased outputs and discriminatory practices [46]. Hence, transparency about data sources and clear distinctions between efficacy and effectiveness are essential to prevent, identify, and correct these issues. This aligns with a systematic review of neuroimaging-based AI in PD, emphasizing the importance of addressing data imbalance and using robust methodologies to improve AI quality and applicability in clinical settings [45].

Human Oversight

Overall, PD patients strongly prefer human oversight, which builds trust and ensures empathetic care. Conversely, HCPs emphasized balancing AI's benefits with human expertise to alleviate concerns about AI's impersonal nature and promote accountable, transparent decision-making. This supports the view that AI should support, rather than replace, clinical decision-making [35,42]. The preference for human oversight in AI-driven healthcare aligns with the findings of Laux [47], highlighting its role in addressing institutional distrust towards AI and supporting democratic design principles in AI governance. While AI adds value to diagnostic methods, the final interpretation and responsibility lie with clinicians, ensuring patient safety and effective care. Clear implementation guidelines are needed to ensure that AI is not imposed on clinicians without their consent or understanding, as successful adoption requires clinician buy-in and a comprehensive understanding of AI's benefits [42]. Balancing technology and human expertise, as highlighted by HCPs, helps mitigate risks associated with over-reliance on AI while benefiting from its outputs. Although AI can free up time for clinical consultations, it may limit clinicians' ability to explain decisions, making human oversight crucial [48]. In addition, reliance on AI could lead to gaps in treatment quality for patients who withhold data, creating conflicts between patient consent and the standard of care [49].

AI Psychological Impact

Many participants highlighted concerns about the emotional toll of AI predictions. Particularly, PwPD expressed anxiety and distress caused by false positives or premature diagnoses. Both PwPD and HCPs express concerns that predictions of developing PD should not be communicated to people at risk, since there is nothing to be done to change the outcome. Schaeffer et al. [50] describes

skepticism among PwPD regarding early detection and disclosure of risk. It can however be approved if the individual wishes to know if there were suggested lifestyle changes in regard to the prediction, and with regular follow-up of individuals afterwards. Further, HCPs reinforced the need for sensitive communication of AI-generated results to minimize psychological harm and ensure patient well-being. Thoughtful communication from HCPs regarding the use of AI technologies could alleviate patient concerns, while reaffirming the supportive role of these advancements in PD care, as discussed by Ha and Kim, [39] and Godoy Junior et al. [42]. In this line, Asan et al. [35] suggest that AI outputs must be presented in a way that is sensitive to the patient's emotional and psychological needs, balancing technological innovation with ethical and compassionate care. Clinicians' ability to communicate their rationale behind clinical decisions improves patient understanding and confidence in the treatment approach [42]. This perspective underlines the need for clinicians to be educated to interpret and communicate AI outputs, aiming to improve patient engagement and satisfaction [39]. In this way, patients are more likely to trust the healthcare system and clinical decisions when they are actively involved in their care [42]. Addressing patient mental health in the development and implementation of AI tools in healthcare is crucial. Ensuring thoughtful communication of AI results can reduce stress and support a more human-centered approach to AI integration. In this line, De Freitas [51] suggests that patients' attitudes towards AI tools are significantly influenced by psychological factors, such as fear of inaccurate predictions and the emotional impact of AI-generated results. Addressing these psychological concerns seems crucial for improving patient acceptance and trust in AI technologies.

Implications

This exploratory qualitative study offers valuable insights regarding stakeholder perspectives on the development and implementation of AI-based digital solutions in PD diagnosis and management. From a theoretical standpoint, these findings contribute to a framework for trustworthy AI in PD care, as evidenced by the interdependencies between the emerging themes. For instance, addressing AI bias enhances trust, while effective education supports meaningful human oversight. By considering these aspects, stakeholders can work towards patient-centered AI solutions that are both technically sound and ethically robust. Furthermore, the emphasis on interdisciplinary collaboration, as evidenced by the diverse group of participants, stresses the value of adopting co-creation methodologies in this context. Considering the complex interplay of motor and non-motor PD symptoms, gathering input from key stakeholders is particularly relevant in PD care to develop comprehensive AI-driven solutions, aligning with recent trends in participatory design for health technologies [20,25].

Building on these theoretical insights, several practical implications can also emerge from the identified themes. The "AI Trust and Security" Theme reinforces the need for robust security measures and trustworthy algorithms in AI applications for PD care. This is particularly relevant considering the sensitive nature of the data, which may include detailed motor assessments and personal health information. Research suggests that users are more likely to engage with technologies they perceive as secure [52], aligning with findings from studies on trust in AI-based health information technologies [35,37]. Moreover, the "AI Transparency and Education" Theme highlights the importance of developing educational resources to promote trust and acceptance among users. These results are consistent with the findings of Dias et al. [53], suggesting that tailored educational resources improve technology acceptance in the context of wearable neurofeedback for students' stress and anxiety management. As such, these findings could inform the development of ethical guidelines and policies governing AI deployment in PD care settings, providing actionable insights for policymakers and healthcare organizations.

From a managerial perspective, the "AI Bias" Theme reinforces the need for protocols to ensure fair and equitable access to AI-driven PD care across diverse patient populations. Healthcare organizations should implement bias mitigation strategies in AI systems, such as diverse data

collection and regular algorithmic audits, to address disparities in AI model performance across patient subgroups [54]. This is particularly important in PD care, where age and gender biases in symptom recognition could impact diagnosis and the course of treatment [45]. The "Human Oversight" Theme emphasizes the critical role of HCPs in AI integration. Considering the pathophysiology of PD, with symptom fluctuations and variable treatment responses, human oversight is crucial for interpreting AI outputs in the context of individual patient needs. Therefore, organizations should develop clear protocols for AI-human collaboration, including defined roles for HCPs in reviewing and interpreting AI outputs, to effectively integrate AI into clinical workflows while maintaining accountability.

Lastly, the "AI Psychological Impact" Theme stresses the need for support systems addressing the emotional aspects of AI interaction in PD care. The support system could involve developing AI interfaces that are sensitive to cognitive and emotional states common in PD, such as anxiety, depression, or cognitive fluctuations. In this context, the MoveONParkinson study [55] pointed out the relevance of incorporating behavior change and self-management principles into digital solutions for PD care. In line with these findings, AI interfaces could be designed to include conversational agents (CAs) that provide personalized support and encourage patient autonomy. This approach was implemented by Macedo et al. [56], outlining the potential of CAs in providing personalized support and motivation for exercise adherence in PwPD. Furthermore, the user-centered design principles employed in these studies align with adopting a co-creation approach in this study, highlighting the relevance of stakeholder engagement in this field.

Overall, by ensuring AI systems are not only technically sound but also acceptable, usable, and responsive to the needs of PwPD, we can potentially improve engagement, reduce anxiety, and improve PwPDs' experience with AI-driven care solutions.

Limitations

While this study provides valuable insights, there are a few limitations to consider. The small sample size and specific demographic characteristics may not fully represent the broader stakeholder population, yet they offer a focused perspective. The voluntary nature of participation could have introduced a form of engagement bias, as participants might have been more informed and enthusiastic about AI. Additionally, the requirement for English proficiency and a basic understanding of AI could have led to some selection bias. Nonetheless, these criteria ensured that participants could fully engage in the discussion, contributing meaningfully to the findings.

Future research

This study described the findings of the first round of co-creation workshops within the AI-PROGNOSIS project approach. Following this, several prototyping sprints are planned to update the product backlog based on user feedback and workshop insights, leading to early mock-ups and internal testing. The second round of workshops will focus on UI/UX design, exploring insights, metrics, and symptom-tracking features with target audiences, resulting in alpha versions through usability testing. The final round will gather hands-on audience feedback to refine features and set final requirements, resulting in beta versions and initial minimum viable products. This integrated process of co-creation activities would allow the optimization of the tools produced by the AI-PROGNOSIS project and would, thus, provide smooth integration of the stakeholders' voices, incorporating ethical considerations in all aspects of AI use. Further validation and insights are anticipated from planned extension of the sample size to larger groups, e.g., via a survey of the actual users of the AI-PROGNOSIS ecosystem across Europe.

Conclusions

This study offers valuable insights into stakeholder perspectives on integrating AI into PD diagnosis

and management. Primary concerns include the need for robust data security to protect sensitive information, the risk of perpetuating bias and fairness issues within AI systems, and the necessity for transparency in AI decision-making processes. Additionally, PwPD emphasize the importance of human oversight to complement AI's support and worry about the potential psychological impact on their sense of autonomy and human connection. Addressing these issues is crucial for developing AI systems that are secure, fair, transparent, and supportive of patient well-being. Focusing on these areas can enhance the trust and efficacy of AI in healthcare, ultimately improving patient outcomes and satisfaction. By addressing these concerns and leveraging AI's benefits, AI can be ethically and effectively designed and implemented to improve PD care.

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Data Availability

The datasets generated and analyzed during this study are not publicly available, but they can be accessed upon reasonable request from the corresponding author.

Authors' Contributions

BA, AS, and SBD contributed to the study conceptualization and design; SR, and TSD collected the data; BA, GA, and SBD contributed to project administration. BA, GA, SBD contributed to data curation and formal analysis; LJH and SBD contributed to funding acquisition; BA, GA, SR, TSD,

AS, DML, CC, IG, SH, LJH, and SBD contributed to methodology; BA and SBD contributed to writing the original draft; BA, GA, SR, TSD, AS, DML, CC, IG, SH, LJH, and SBD contributed in reviewing and editing the paper; all authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

None declared.

Abbreviations

AI: Artificial intelligence
BE: Bioethics Expert
CA: Conversational Agent
HCPs: Healthcare professionals
MDS-UPDRS: Movement Disorder Society – Unified Parkinson's Disease Rating Scale
PD: Parkinson's Disease
PwPD: People with Parkinson's Disease
TE: Technical AI Expert
WHO: World Health Organization

Multimedia Appendix

Semi-structured guide scripts for co-creation workshops conducted with persons with Parkinson's disease (PwPD) and healthcare professionals (HCPs).

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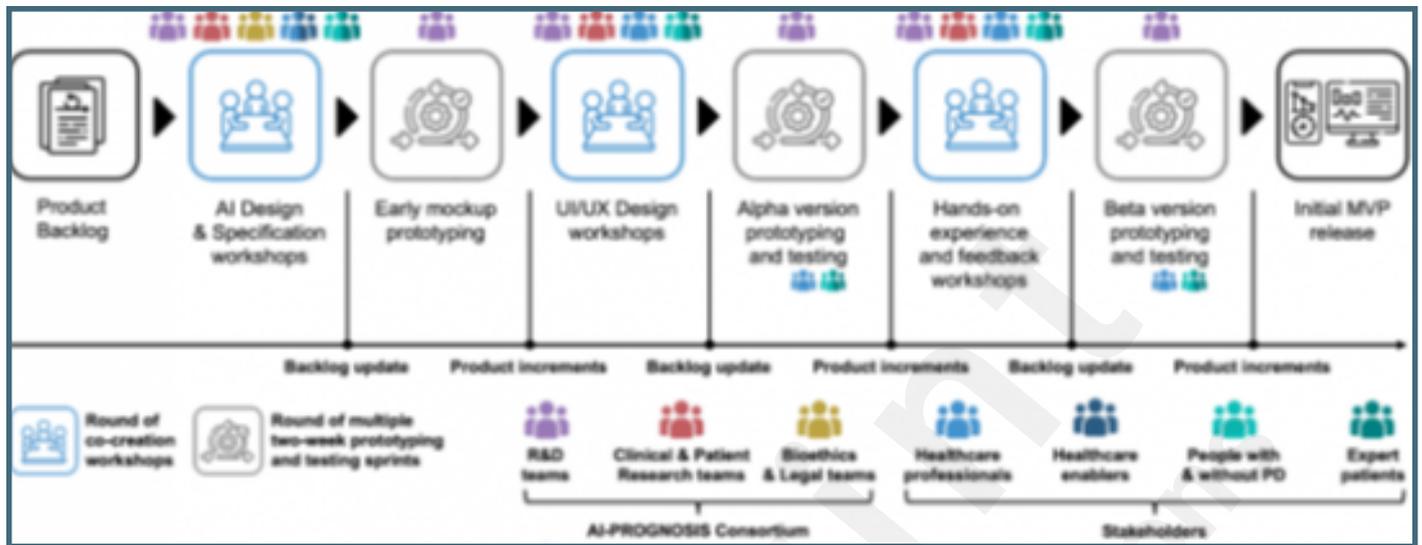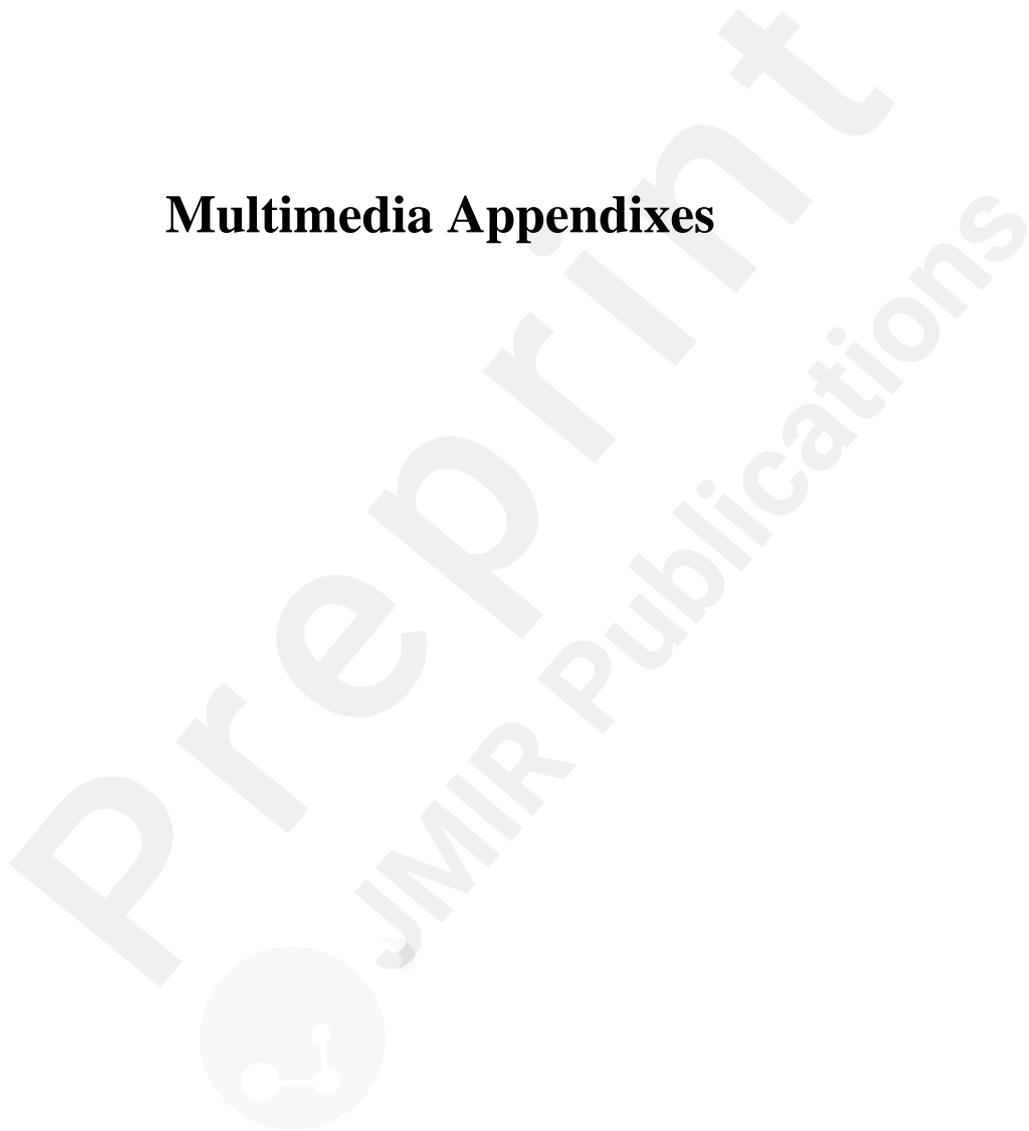
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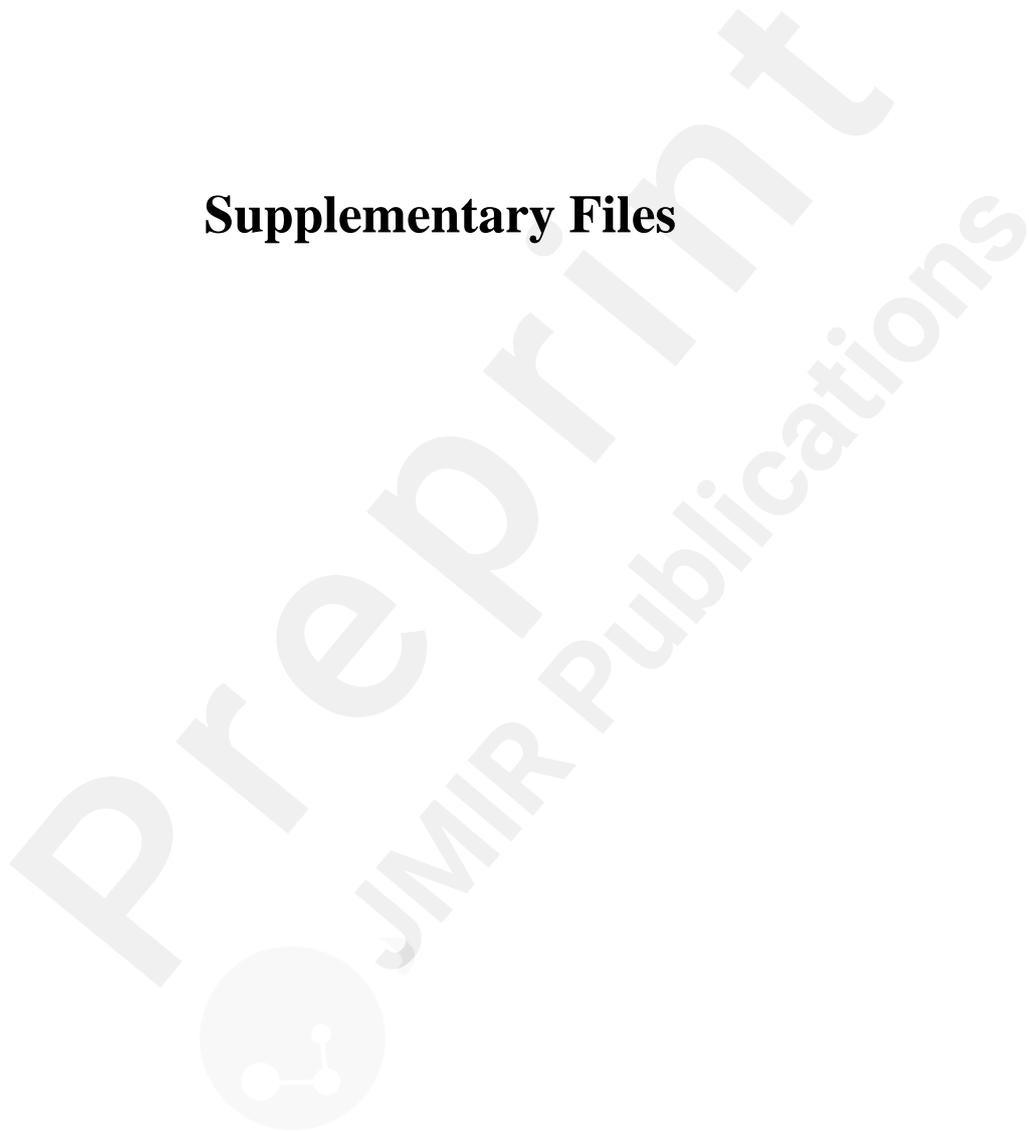
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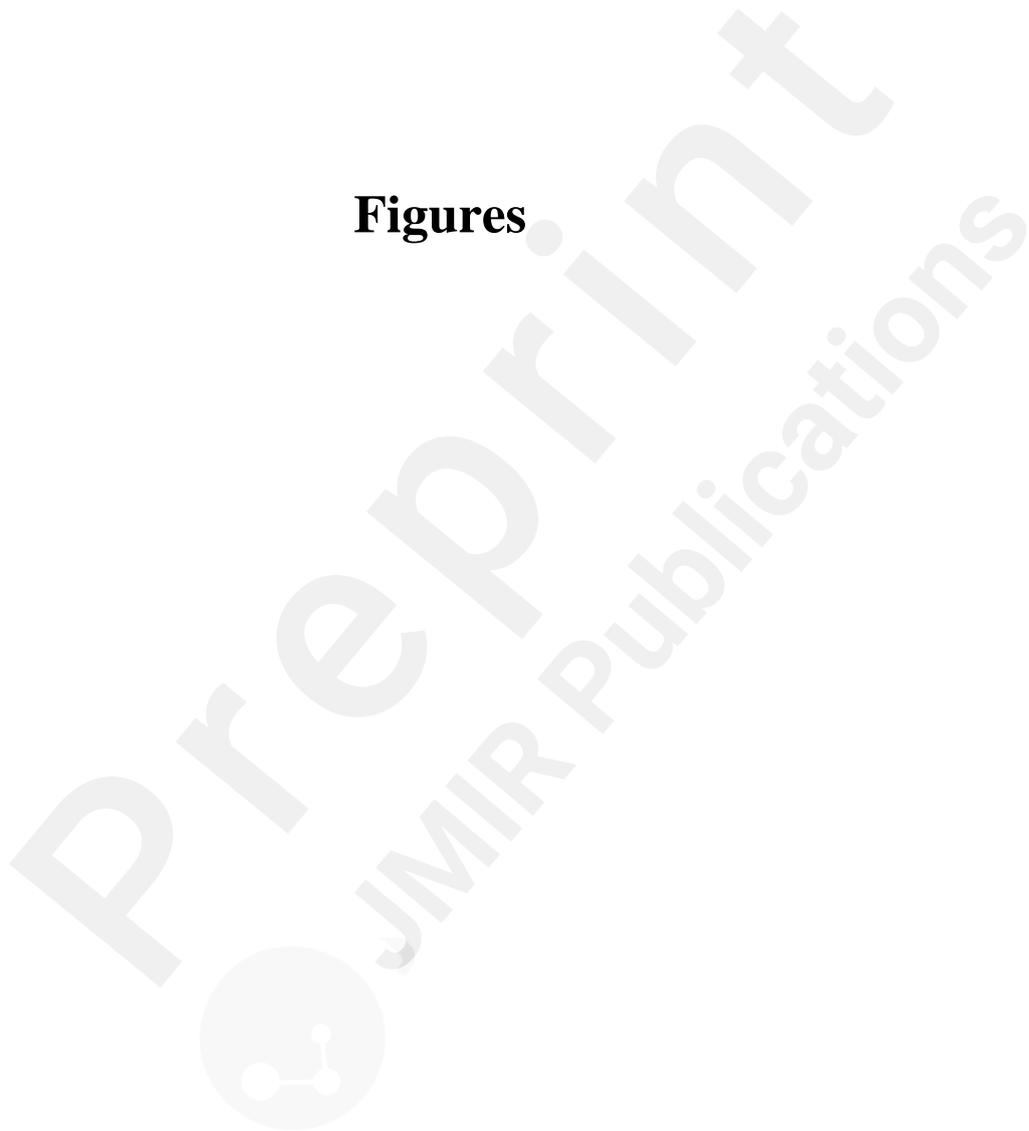
Co-creation approach for Minimum Viable Products in the AI-PROGNOSIS project. AI: Artificial Intelligence; UI: User Interface; UX: User Experience; R&D: Research and Development; MVP: Minimum Viable Product.

Overview of the main findings derived from the thematic analysis, including themes (inner part of the circle), subthemes (middle part of the circle), and corresponding codes (outer part of the circle).
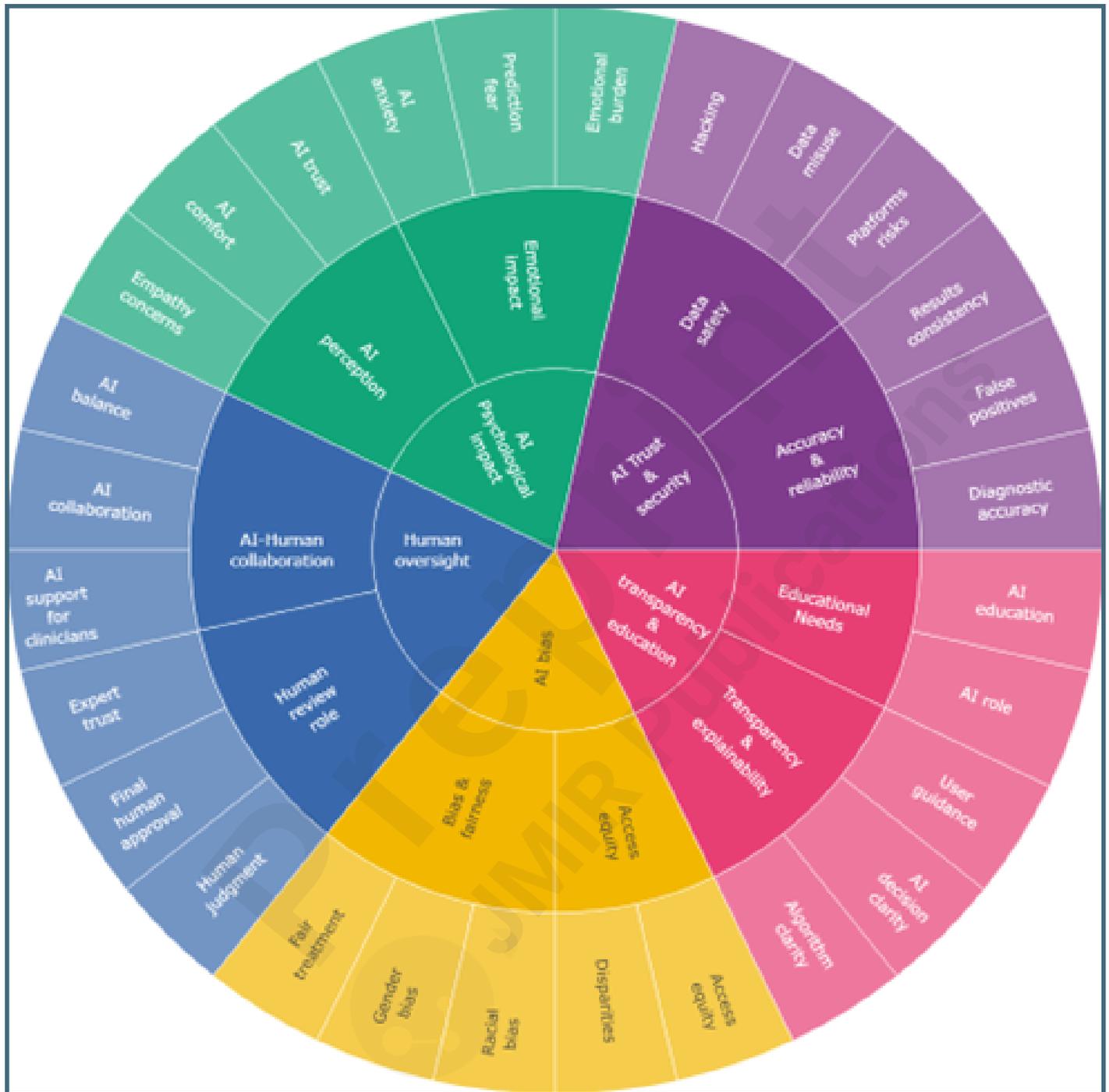
Multimedia Appendixes

Semi-structured guide scripts for co-creation workshops conducted with persons with Parkinson's disease (PwPD) and healthcare professionals (HCPs).
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