Engineering a Clinically Traceable Serious Game for Autism Spectrum Disorder

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Abstract. ***Introduction:*** *Serious Games for Health (SGH) increasingly support clinical and therapeutic interventions, yet developers still rely heavily on ad hoc practices that limit software quality, clinical traceability, and long-term maintainability.* ***Objective:*** *This study presents the construction of a serious game for Autism Spectrum Disorder (ASD) through a Requirements Engineering framework that systematically translates clinical requirements into auditable game mechanics.* ***Method:*** *We grounded the proposed framework around the triad of People, Processes, and Products. The framework organizes development through four iterative stages: elicitation, analysis, specification, and validation. To demonstrate its application, we developed a high-fidelity vertical slice in Unity [1] focused on social-pragmatic training for adults with ASD.* ***Results:*** *The prototype implemented clinically grounded features, including a non-punitive correction loop, sensory-safe interaction design, and structured telemetry export for clinical monitoring. Internal and external evaluators confirmed that the resulting artifact preserved clinical intent, met sensory accessibility constraints, and provided sufficient technical autonomy for reproducible development.* ***Conclusion:*** *The results show that structured requirements artifacts can guide the construction of clinically coherent and technically auditable SGH, supporting more reliable and scalable digital health interventions.*
Keywords *Serious Games; Requirements Engineering; Traceability; Software Governance; Autism Spectrum Disorder (ASD).*

1. Introduction

The development of Serious Games (SG) for healthcare has seen significant growth, yet it remains primarily driven by ad hoc practices [Caserman et al. 2020]. This lack of a structured engineering approach often results in software solutions that fail to provide clinical traceability, making long-term maintenance and institutional validation difficult [Carlier et al. 2023]. In this context of digital games for health, these methodological gaps

[1]https://unity.com/

represent not only a technical debt but a risk to the consistency of clinical interventions [Maxim e Arnedo-Moreno 2025].

Despite the clear necessity for technical rigor, the current state of the art highlights a significant void in the engineering process of these systems. Recent systematic reviews indicate that most SGs for healthcare are developed without the guidance of a Software Engineering (SE) framework or a standardized methodology [Ambros-Antemate et al. 2021, Maxim e Arnedo-Moreno 2025, Fang et al. 2025, Andrew et al. 2023]. The absence of a systematic workflow, which typically includes structured planning, modeling, and iterative feedback cycles [Washizaki 2024]; leads to the creation of "ad hoc" solutions [Tao et al. 2021, Ushaw et al. 2017]. These products frequently overlook essential user experience (UX) principles and fundamental clinical requirements. Consequently, this lack of standardization results in software that is difficult to maintain and often fails to bridge the gap between medical protocols and ludic game design [Souza et al. 2023, Robertson et al. 2021, Caserman et al. 2020].

The motivation for this research stems from the previous development of DiagnosTEA [Barbosa et al. 2024], a serious game designed to assist in diagnosing Autism Spectrum Disorder (ASD). Although it was grounded in a systematic literature review and clinical parameters [Barbosa e Ribeiro 2022], its initial materialization faced critical barriers due to a predominantly ad hoc development approach. A retrospective analysis of the project revealed that the absence of participatory design and a formal requirements engineering methodology created a gap between the implemented mechanics and clinical reality, resulting in a lack of traceability and stability in real-world environments [Barbosa et al. 2025]. These limitations served as the primary catalyst for the creation of a new structured framework, focused on increasing process maturity and ensuring the clinical fidelity of the final product.

To address these challenges, we apply a Requirements Engineering Framework proposed in previous work [Barbosa et al. 2026] and specifically designed for Serious Games in healthcare. The framework bridges the communication gap between health specialists and IT professionals and establishes a clear process for translating clinical requirements into ludic mechanics. The process is composed of an iterative cycle of elicitation, analysis, specification, and validation; transforming subjective clinical needs into auditable technical requirements and preserve therapeutic intent throughout the software life cycle.

In this paper we show how the framework was implemented to build an ASD-focused serious game and the artifacts that will result from each step, including the Software Requirements Specification (SRS), the Requirements Traceability Matrix (RTM), and the Serious Game Design Document [Vasconcellos e Carvalho 2023]; which will guide the technical implementation while remaining strictly aligned with established clinical protocols. The results show that a structured engineering process can trace every game mechanic back to a clinical requirement, supporting both technical rigor and therapeutic intent.

The remainder of this paper is organized as follows. Section 2 presents the proposed Requirements Engineering framework and describes its core stages and artifacts. Section 3 details the case study and explains how we applied the framework to redesign an ASD-focused serious game through a clinically grounded technical baseline. Section 4

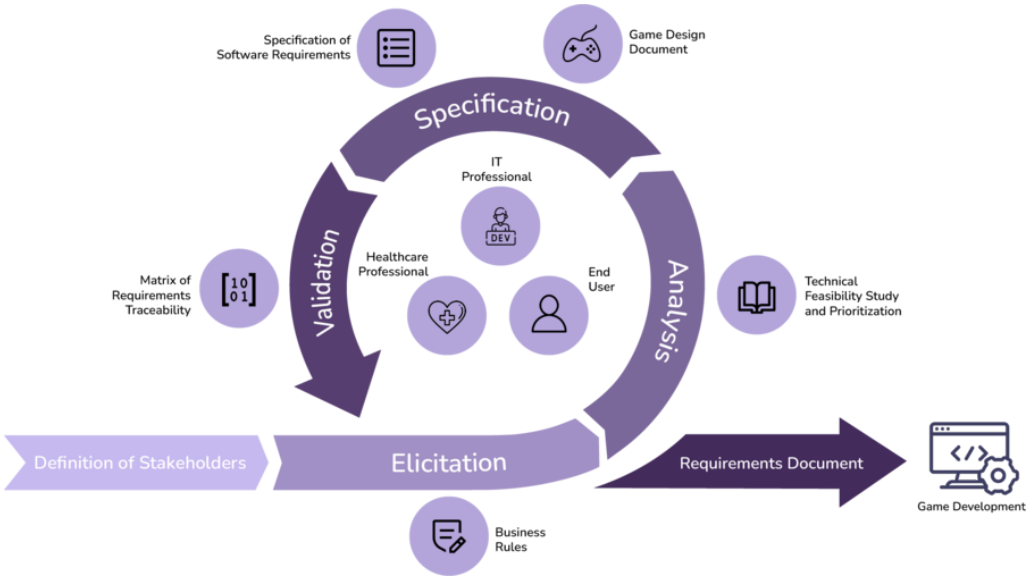

Figura 1. Framework Overview.

describes the implementation of the vertical slice and its main functional components. Section 5 reports the validation results and discusses the implications of traceability, accessibility, and clinical alignment for serious game development in health. Finally, Section 6 concludes the paper and outlines directions for future work.

2. Framework Overview

As illustrated in Figure 1, the proposed framework bridges the gap between clinical needs and game development through a systematic Requirements Engineering (RE) cycle. We ground the framework in the triad of People, Processes, and Products to align to software quality principles. Participatory Design serves as a central pillar of this methodology and promotes the active inclusion of the End User (EU) as a primary stakeholder. This approach ensures that the resulting serious game remains technically sound, clinically effective, and sensitive to the user's specific needs.

We operationalize this methodology through an iterative and incremental cycle structured into four interdependent stages: Elicitation, Analysis, Specification, and Validation. During Elicitation, we capture clinical evidence and stakeholder needs to define business rules and establish a multidisciplinary traceability flow. During Analysis, IT professionals evaluate technical feasibility and prioritize functionalities to ensure that the team can realistically implement clinical requirements. During Specification, the development team formalizes this knowledge into baseline artifacts, such as the Software Requirements Specification (SRS) and the Serious Game Design Document (Serious-GDD) [Vasconcellos e Carvalho 2023], and connects therapeutic intent to technical execution. Finally, Validation closes the loop by elaborating Key Performance Indicators (KPIs) and the Requirements Traceability Matrix (RTM) to confirm that the implemented ludic mechanics remain faithful to the original clinical protocols. This systematic relationship allows each iteration to mature the software while preserving the integrity of the health objectives.

3. Case Study: Redesigning an ASD-Focused Serious Game

The redesign of DiagnosTEA served as the primary application of the proposed framework, transforming ad hoc development into a structured engineering process.

This case study details the transition from subjective clinical narratives to an auditable technical baseline [2]. The elicitation phase involved semi-structured interviews with a multidisciplinary team to bridge the gap between clinical reality and technical implementation. In this phase we interviewed Psychiatrists, a Neuropsychologist, and an adult with ASD diagnose:

- EU-01 (End User): Identified critical barriers such as sensory fatigue from aggressive visual stimuli and the difficulty of interpreting subjective social cues.
- PS-01 (Psychiatrist): Emphasized the need for multimodal synchrony (voice, face, and text) and the generation of performance logs for clinical monitoring.
- PS-02 (Neuropsychologist): Highlighted the challenge of "social movement"the dynamic shift in facial expressions and tone—and the necessity of training for social metaphors.
- PS-03 (Psychiatrist): Focused on reducing anxiety through environmental predictability and the effectiveness of modeling-based learning without punitive “Game Over” states.

The Requirements Traceability Matrix (RTM) serves as the backbone of the framework and preserves therapeutic intent across every technical layer. In this study, the RTM also defines the prototype’s vertical slice by selecting a cross-section of functionalities that demonstrates the complete path from elicitation to implementation.

The table 1 summarizes the traceability for the vertical slice.

4. Implementation and Proof of Concept

This section details the technical materialization of the framework through a vertical slice of the generated documentation developed in Unity. The Proof of Concept (PoC) implementation focused on "Dialogues with Expressions and Feedbacks", a core module designed to validate the transition from requirements documentation to functional code

Recognition of Intentions and Pragmatics
REQ-06 (Pragmatic Difficulty) → RN-06 (Social Filter System)

The system manages social-pragmatic training through branching dialogues implemented via `ScriptableObjects`. As shown in Figure 2, the `DialogueNode` structure allows developers to link each dialogue directly to a specific Requirement ID in the Unity Inspector, ensuring every interaction serves a documented clinical purpose and facilitates auditing.

- Implementation: We created scenarios where users must choose between a "Raw Truth"(literal interpretation) and a "Socially Appropriate"response.
- Pedagogical Feedback: As illustrated in the ScriptableObject configuration (Figure 5), when a user selects a literal error, the system triggers a "Pedagogical Explanation"based on clinical modeling.

Correction Loop and Modeling-Based Learning
REQ-03 (Anxiety Management) → RN-01 (Correction Loop)

[2]This study was approved by the Ethics Committee of the participating institution. The details of this approval can be found on the Brazil Platform (plataformabrasil.saude.gov.br) under the Certificate of Presentation for Ethical Review (CAAE) number 8442725.6.0000.5083, with approval opinion number 7.615.894.

Tabela 1. Prototype Implementation Traceability Matrix

ID	Clinical Origin (Stakeholder)	Technical Component (Unity)	Mechanic / Ludic Implementation
REQ-01 / RN4	Multimodal synchrony and coherence (PS-01/PS-02)	*NPCFaceController* and *BlendShapes*	NPC emotional reactions synchronized with speech for training subjective cues.
REQ-06 / RN-06	Difficulty with figurative language (PS-02)	*ScriptableObjects* and *DialogueManager*	Branching dialogues focused on metaphors and sarcasm.
REQ-07	Need for predictability (PS-03)	*SceneManager* and Continue Button	User-controlled flow; manual scene transition to reduce anxiety.
REQ-08	Profiling (PS-03)	Data structure in *TelemetryManager*	Individualized identification (Name, ASD Level, and Scenario) in clinical logs.
RN-01	Need for error tolerance (PS-03/UF-01)	State logic in *DialogueManager*	Correction Loop: Prevents Game Over and allows re-attempts.
RN-02	Sensory Safety (UF-01/PS-01)	*Low Poly* and *URP*	Environment with neutral colors and prohibition of aversive visual stimuli.
RN-05	Modeling-based learning (PS-03)	*UI Explanation Panel*	Display of objective pedagogical feedback after a literal error.
RF-02	Speech processing support (UF-01)	*TextMeshPro*	Dynamic high-contrast subtitles with opaque background.
RF-03 / KPI-06	Cognitive Flexibility monitoring (PS-01)	*TelemetryManager*	Detailed report export (.csv) with metaphor hit rate.
RF-04	Social hesitation monitoring (PS-02)	*TelemetryManager* (C# Singleton)	Capture and export of response latency in .csv format.
RNF-05	Sensory overload prevention (PS-02/UF-01)	*Universal Render Pipeline* (URP)	Low Poly scenario with low background stimulus density.
STK-REQ-04	Progress monitoring (PS-01/PS-03)	C# Dictionaries and *System.IO*	Consolidation of hits and errors per specific dialogue in the final report.
GDD (Narrative Dim.)	Setting and Contextualization (PS-03)	*Office Scenario*	Simulation of everyday situations for social skills training in a work environment.
GDD (Visual Dim.)	Support for reading subjective cues (UF-01)	*NPC Face and HUD*	Use of avatarization and visual indicators to materialize emotional intentions.
GDD (Procedural Dim.)	Social Filter System (PS-02)	*Dialogue Tree*	Choice between "Raw Truth"and "Socially Appropriate"with ludic feedback.

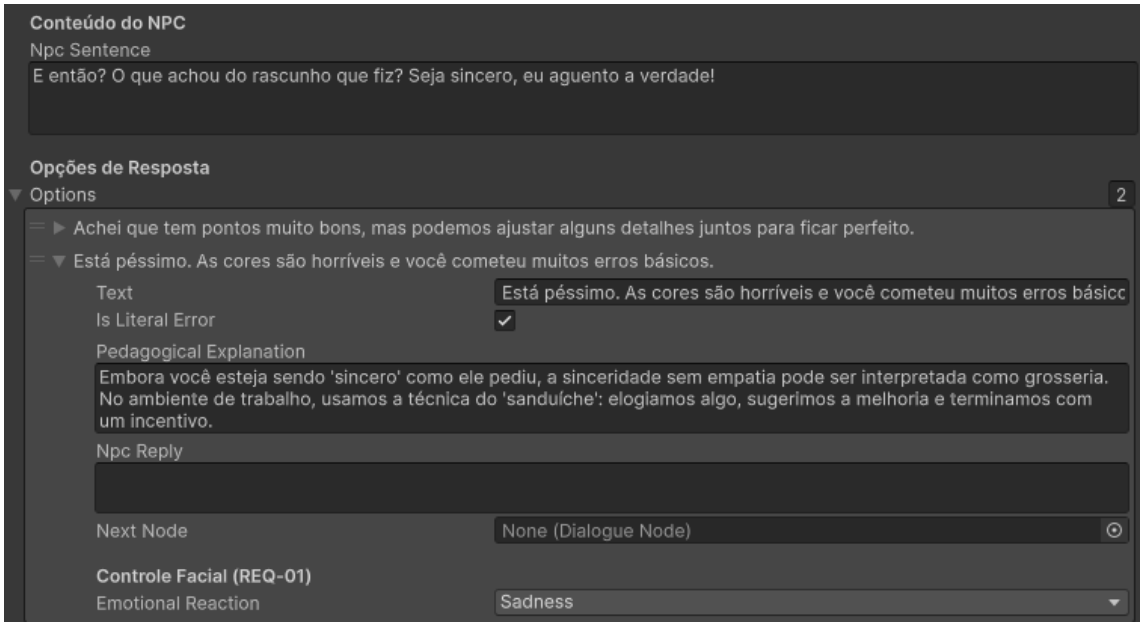

Figura 2. Unity Inspector view of a `DialogueNode` showcasing the traceability link to REQ-06.

To replace the traditional "Game Over" state, which can trigger frustration and anxiety in users with ASD, we implemented a Correction Loop (Figure 3).

- Implementation: When a user selects a social dialogue option deemed inappropriate for the context, the game does not terminate.
- Mechanism: Instead, the NPC provides immediate feedback (e.g., a facial expression of confusion), and the system triggers a "Pedagogical Explanation"panel.
- Clinical Goal: This allows for immediate re-attempt of the scenario, utilizing Modeling-Based Learning to help the user understand social nuances without the punishment of losing progress.

Clinical Telemetry and Data Persistence
REQ-04 (Clinical Monitoring) → RF-03/RF-04 (Telemetry Module)

For the game to serve as a diagnostic support tool, data collection must be transparent and structured (Figure 4).

- **Implementation:** We used `ScriptableObjects` to decouple dialogue content from game logic and enable modular updates to clinical content.
- **Mechanism:** The TelemetryManager (C# Singleton) monitors every interaction, including response latency and the number of attempts within the correction loop.
- **Clinical Export:** At the end of each session, the system exports these metrics to a .csv file, allowing health professionals to import logs into data analysis software for long-term clinical tracking.

Sensory Design and Accessibility
REQ-02 (Sensory Safety) → RNF-01/RNF-02 (Accessibility Requirements)

We prioritized cognitive and sensory accessibility to prevent sensory overload (meltdowns). 5.

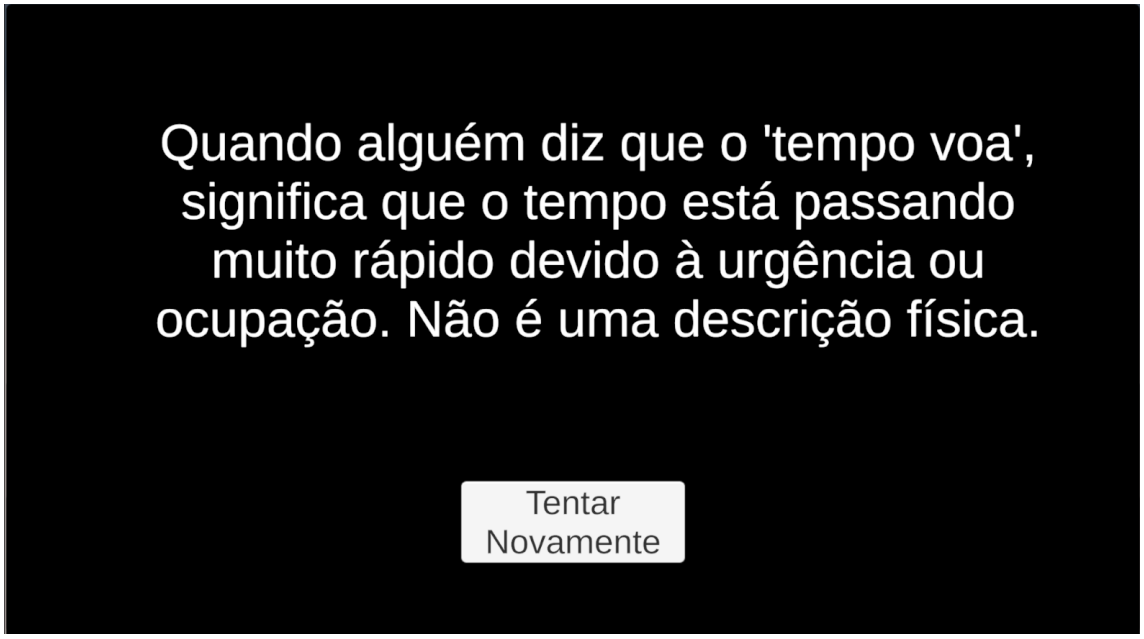

Figura 3. Interface of the non-punitive Correction Loop (RN-01) displaying pedagogical explanations after a literal error.

A	B	C	D	E	F	G
Data	Paciente	Cenario	ID_Requisito	Sentenca_NPC	Resultado	Tentativas
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	E então? O que achou do rascunho que fiz? Seja sincero, eu aguento a verdade!	Necessita Treino	2
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	Achei que tem pontos muito bons, mas podemos ajustar alguns detalhes juntos para ficar perfeito.	Dominado	1
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	Acho que 'estou carregando o mundo nos ombros' esta semana.	Necessita Treino	2
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	Parece que está com muita carga de trabalho. Posso ajudar em algo?	Dominado	1
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	Puxa, estou super atrasado com este relatório, não posso parar para conversar agora!	Necessita Treino	4
2026-04-06 15:21	Bruna Mota	Cenario02	REQ-06	Entendo perfeitamente. Quando você fizer uma pausa, podemos conversar rapidinho?	Dominado	1
2026-04-06 15:22	Bruna Mota	Cenario01	REQ-06	Fulano, você fez um ótimo trabalho no relatório. Você realmente matou a cobra e mostrou o pau!	Necessita Treino	5
2026-04-06 15:22	Bruna Mota	Cenario01	REQ-06	Fulano, precisamos desse código pronto até as 17h. O tempo voa quando estamos no final do projeto!	Necessita Treino	5
2026-04-06 15:22	Bruna Mota	Cenario01	REQ-06	Uau, Fulano! Chegar 20 minutos atrasada na segunda-feira... que belo começo de semana, hein?	Necessita Treino	2
2026-04-06 15:22	Bruna Mota	Cenario01	REQ-06	Estou muito sobrecarregada com esses novos requisitos. Você poderia me dar uma mão com essa documentação?	Dominado	1
2026-04-06 15:22	Bruna Mota	Cenario01	REQ-06	Sua apresentação foi boa, mas sinto que você encheu muita linguiça na introdução.	Dominado	1

Figura 4. Clinical report generated by the `TelemetryManager` logging patient performance metrics

- **Low Poly Aesthetics:** We used simplified 3D models with neutral color palettes (saturation below 60%) to reduce visual sensory load.
- **High-Contrast Subtitles:** We implemented subtitles with TextMeshPro and opaque backgrounds to ensure legibility and support speech processing.
- **Audio Control (REQ-02):** The prototype includes granular audio mixing, allowing independent adjustment of voice-overs and sound effects (FX) to accommodate auditory hypersensitivity.

4.1. Technical Justification

We validated every element of this vertical slice through the Requirements Traceability Matrix (RTM). By linking dialogues directly to REQ-06 within the Unity Inspector, developers ensure that every line of code serves a documented clinical purpose and supports both technical maintenance and clinical auditing.

5. Results and Validation

The PoC validation phase focused on verifying whether the framework's structured approach yielded a prototype that balanced technical quality with clinical efficacy. This stage utilized the Key Performance Indicators (KPIs) established during the RE process phase to measure the success of the implemented vertical slice.

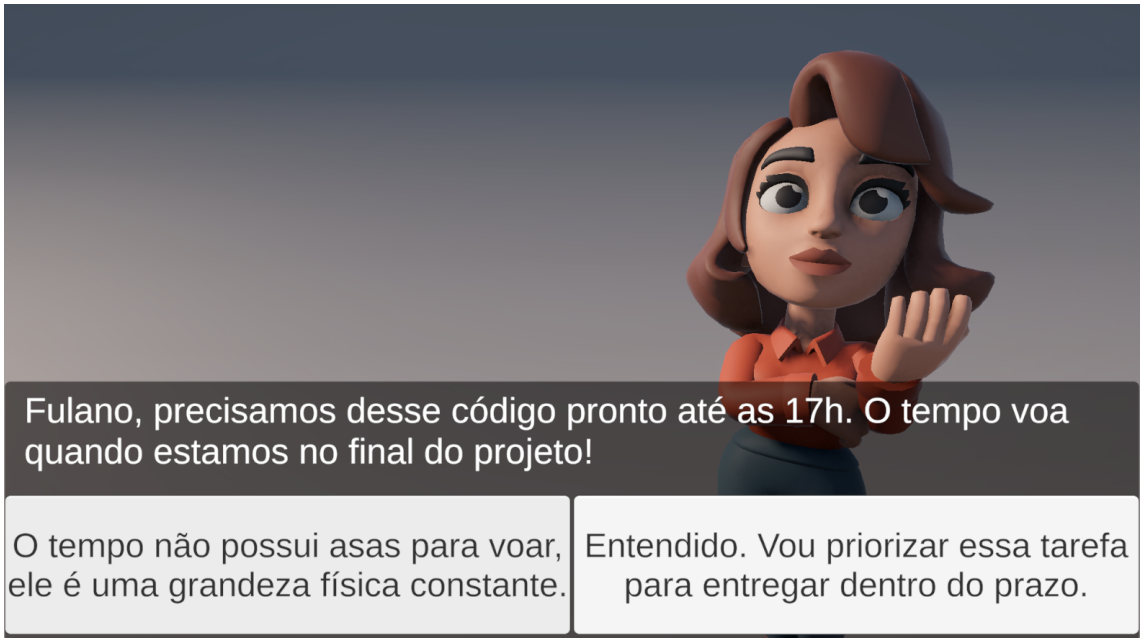

Figura 5. Gameplay vertical slice demonstrating Low Poly aesthetics (RNF-05) and multimodal synchrony (RN-04).

5.1. KPI Achievement and Performance Metrics

The analysis of the results demonstrated high levels of satisfaction and compliance across all multidisciplinary axes:

- **Sensory Comfort (KPI-02):** Achieved 100% agreement from the end user (EU-01), validating that the neutral color palette and controlled stimuli prevented sensory overload.
- **Pedagogical Flow (KPI-03):** The "error $\rightarrow$ explanation both internal and external health professionals fully validated $\rightarrow$ re-attempt"protocol as an appropriate modeling-based learning tool.
- **Social Understanding (KPI-06):** The end user demonstrated success in understanding metaphors and nuances, confirming the effectiveness of the visual support systems.
- **Data Integrity (KPI-05):** Clinical specialists confirmed that the telemetry generated by the system provided high-quality data for therapeutic planning.

5.2. External Audit and Framework Autonomy

To evaluate the maturity and autonomy of the framework, we submitted the project to external evaluators who were not involved in the initial development:

- **DEV-External:** The technical evaluator confirmed that the documentation (SRS, GDD, and RTM) provided sufficient clarity for a developer to start the project from scratch, validating the framework's autonomy.
- **PS-External:** The external health professional confirmed the clinical value of the telemetry and the correction loop and noted that the artifacts supported therapeutic intervention regardless of prior software knowledge.
- **Scalability:** External auditors confirmed that the ScriptableObject-based architecture supports scalability and reduces dependency on the original clinical specialist once the baseline is established.

5.3. Discussion: The Hierarchy of Accessibility

The results support a critical finding regarding the development of serious games for ASD: Sensory Safety is a prerequisite for Pragmatic Training. By treating Non-Functional Requirements (NFRs) as mandatory constraints, the system ensured a non-aversive interface, allowing users to allocate the cognitive resources required to process social nuances and metaphors (REQ-06) without interface interference. Furthermore, the system's traceability directly benefited from the 1:N relationship mapped within the Requirements Traceability Matrix (RTM), which proved essential as a single clinical goal, such as "Monitoring Evolution,"unfolded into multiple technical layers of telemetry and data persistence. In summary, the transition to a structured engineering process allowed the project to evolve from an ad hoc experiment to an auditable, high-maturity digital health tool.

6. Conclusion

This study demonstrated how a structured Requirements Engineering framework can transform the development of serious games for healthcare from an empirical, ad hoc activity into a mature and auditable engineering process. By integrating triad of People, Processes, and Products, we bridged the historical communication gap between clinical specialists and IT professionals. The redesign of the prototype served as a proof of concept, demonstrating that formal documentation and technical discipline can align software quality with therapeutic intent.

A central contribution of this work is the evidence that 1:N traceability, which links a single clinical need to multiple technical requirements and game mechanics, is not merely a documentation task but a fundamental safety requirement for digital medical devices. This level of rigor ensures that clinical evidence justifies every interaction within the game environment and allows auditors to assess safety and efficacy.

The resulting vertical slice demonstrates that a serious game for ASD can preserve clinical intent, support sensory accessibility, and operationalize therapeutic interaction through auditable mechanics. By translating structured requirements into playable systems, this study shows that serious games for health can move beyond exploratory prototypes and evolve into clinically coherent digital interventions. Future work will expand this approach to broader clinical domains and evaluate its impact in real therapeutic settings.

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