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Validating a measurement instrument for disruptive innovation in retail clinics: A PLS-SEM approach

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Abstract

This study aims to evaluate the validity and reliability of the measurement instrument and the proposed model, titled “Framework of Factors Related to Disruptive Innovation in Retail Clinics,” within the primary healthcare sector in Peru. A quantitative, non-experimental, cross-sectional, and correlational design was employed. Data were collected through a survey instrument comprising Likert-scale items, whose content validity was assessed via expert judgment using Aiken’s V coefficient. Reliability was examined through internal consistency measures such as Cronbach’s alpha. A multivariate analysis was conducted on 101 cases, followed by the application of Partial Least Squares Structural Equation Modeling (PLS-SEM) to evaluate the structural model’s fit, validity, and predictive capacity. The instrument demonstrated validity and reliability, confirming its appropriateness for measuring variables related to disruptive innovation in retail clinics. The model exhibited satisfactory goodness-of-fit indices and predictive capacity, with most hypothesized relationships being statistically significant. The validated measurement instrument and the proposed framework effectively capture the key factors influencing disruptive innovation in retail clinics within the Peruvian healthcare context. The study highlights the importance of evaluating these variables to understand and foster innovation in low-resource healthcare settings. Healthcare policymakers and practitioners can utilize this validated instrument to assess and implement disruptive innovations more effectively. This contributes to improving access, efficiency, and quality of primary healthcare services in emerging economies like Peru.

Keywords: Disruptive innovation in healthcare, PLS-SEM, Structural equation modeling.

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1. Introduction

The deficient primary healthcare system in Peru places an excessive burden on more complex levels of care [1]. The widening healthcare gap exacerbated by economic, geographic, and funding constraints, as well as demographic shifts limits access to basic care and leads to overcrowded hospitals [2]. This pressure necessitates profound systemic changes, where innovative models incorporating disruptive technologies can improve both efficiency and patient engagement [3]. Retail clinics have emerged as a radically valuable alternative, offering convenience, walk-in access, reduced waiting times, and transparent pricing [4]. These clinics represent a cost-effective substitute for traditional primary care and emergency services [5, 6] argue that developing countries, including those in Latin America, constitute ideal markets for disruption. Business models originating in low-income markets can be more profitable, as they provide goods and services to previously unserved consumers those experiencing “non-consumption” who are willing to access simpler and more affordable alternatives than those available in developed markets.

Bamel et al. [7] and Christensen et al. [8] suggests that disruptive innovation in the complex and highly regulated healthcare sector requires a combination of enabling factors: disruptive technologies, innovative business models, value networks, and supportive regulatory frameworks. However, Zhang and Zhu [9] and Williamson et al. [10] highlight that such enablers may differ significantly in developing countries with fragile healthcare systems and limited governmental support for innovation. In this Peruvian context, it becomes essential to identify the key determinants of disruptive innovation in retail clinics and to assess their impact on critical healthcare variables.

Since its conceptualization in the late 20th century, disruptive innovation has evolved from focusing solely on technology to embracing novel business models and service innovations, as highlighted by Christensen and Raynor [11]. Initially, disruptive innovations offer simpler, more affordable, and lower-performing alternatives, appealing to underserved markets before eventually surpassing incumbent products in the mainstream [12, 13]. This contrasts with sustaining innovations, which incrementally improve existing products for leading firms [14], while disruptive innovations redefine market trajectories, enabling new entrants to challenge established players [4, 15]. Disruptive innovations can manifest as low-end disruptions, targeting less profitable customers, or as new-market disruptions, creating entirely new value networks by addressing non-consumers' needs [16]. Disruptive innovation offers a powerful solution to the high costs and limited access prevalent in the healthcare system [3]. Business models providing straightforward, affordable, accessible, and cost-effective solutions for healthcare are crucial. These models are supported by a network of mutually reinforcing, value-creating enterprises and by regulations and standards that facilitate change through norms promoting interactions within the emerging disruptive industry [17].

1.1. Business Model Innovation: Retail Clinics

Retail clinics, categorized as “value-added” disruptive innovations [18] represent a transformative proposition in healthcare. They offer a convenient, high-quality, and low-cost alternative to traditional primary care and hospital emergency services [4]. Driven by private investors, pharmacy chains, and increasingly by hospitals, their main features include basic screening, diagnostic, and treatment services provided in small, low-operating-cost facilities conveniently located. They deliver comfortable, fast, safe, and affordable care with standardized protocols for simple conditions, extended hours, and transparent pricing. Furthermore, retail clinics are evolving to offer more complex services, such as chronic disease management and minor procedures [19], phenomena that collectively underpin the subsequent development of research hypotheses for this study.

Table 1.
Research Hypotheses.

1.1. General Hypothesis (H1)		1.2.
The framework of enabling factors is significantly related to Disruptive Innovation in Low-Cost Retail Clinics (N1).		
1.3. Specific Hypotheses		1.4.
Hypothesis H2 (H2)	The variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1) is significantly related to the variable <i>User Satisfaction in Primary Healthcare</i> (N2).	Low satisfaction and delays in primary healthcare services drive the need for innovation. Fast and effective processes attract dissatisfied users [20]. Given the complexity and cost of hospital-based care, disruptive innovation becomes essential to address basic health needs efficiently [3, 21].
Hypothesis H3 (H3)	The variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1) is significantly related to the variable <i>Healthcare Consumerism</i> (N3).	The empowered and well-informed healthcare consumer, with access to technology, demands higher-quality services. This trend impacts the healthcare system and is aligned with the disruption caused by innovative business models that meet these evolving needs [22-24].
Hypothesis H4 (H4)	The variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1) is significantly related to the variable <i>Creation of New and Low-End Demand</i> (N4).	Disruptive innovations generate new markets by turning non-consumers into consumers, overcoming limitations of existing offerings [25, 26]. Low-end disruptions target fewer demanding customers by offering more affordable and lower-performance alternatives in established markets [16, 26, 27].
Hypothesis H5 (H5)	The variable <i>Regulation that Facilitates Disruptive Change</i> (N5) is significantly related to the variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1).	Regulation refers to a set of policy reforms and new industry standards that facilitate or “lubricate” interactions among participants within the emerging disruptive industry. Regulatory frameworks determine which changes are permitted, the influence of institutions, and what enables or limits the co-creation of value and the diffusion of market practices [28, 29].
Hypothesis H6 (H6)	The variable <i>Disruptive Health Technologies</i> (N6) is significantly related to the variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1).	Disruptive technologies, whether as inventions or low-cost, sophisticated innovations applied in healthcare, aim to simplify. They make products or services more affordable and accessible to a broader population and are at the core of disruptive innovation [8, 29-31].
Hypothesis H7 (H7)	The variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1) is significantly related to the variable <i>Competitive Advantage</i> (N7).	Competitive advantage arises from outperforming competitors through superior, unique, lower-cost, or higher-quality value propositions [32]. Disruptive innovation generates a competitive advantage by creating unique, more affordable, and accessible value offerings [20, 33].
Hypothesis H8 (H8)	The strategic variable <i>External Sources of Knowledge</i> (N8) significantly influences the variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1).	An SME's ability to acquire knowledge from external networks (social actors, universities, industry, customers, suppliers) positively affects radical innovation. Increased cooperation with these sources enhances the likelihood of disruptive innovation [9, 34].
Hypothesis H9 (H9)	The strategic variable <i>Low-Cost Business Model</i> (N9) significantly influences the variable <i>Disruptive Innovation in Low-Cost Retail Clinics</i> (N1).	Business models drive organizational transformation through technology and innovation to create value. Low-cost business models simplify offerings and processes, enabling adoption [13]. They foster disruptive innovation by creating markets and improving accessibility and efficiency [35].
Hypothesis H10 (H10)	The strategic variable <i>Low-Cost Business Model</i> (N14) significantly influences the variable <i>Competitive Advantage</i> (N12).	The business model is essential for sustainability and enables SMEs to achieve sustainable growth [36, 37]. An innovative business model predicts competitive advantage and long-term success [38].
Hypothesis H11 (H11)	The variable <i>Regulation that Facilitates Disruptive Change</i> (N5) is significantly related to the strategic variable <i>Low-Cost Business Model</i> (N14).	Business regulation (norms, standards, rules) affects business models by requiring adaptation to regulatory changes. Regulatory dynamics influence economic sectors and SMEs through regulatory and deregulatory processes [39-41].
Hypothesis H12 (H12)	The variable <i>Disruptive Health Technologies</i> (N6) significantly influences the strategic variable <i>Low-Cost Business Model</i> (N14).	Technological disruption drives innovation in business models by reducing costs and creating advantages for new agile players [42]. Disruptive technologies enable innovative low-cost models (e.g., automation, digitization) and scalability (e.g., digital platforms), impacting sectors such as finance, manufacturing, healthcare, and

		logistics [43].
Hypothesis H13 (H13)	The strategic variable <i>External Sources of Knowledge</i> (N8) is significantly related to the strategic variable <i>Low-Cost Business Model</i> (N14).	External knowledge is crucial for the sustainability of the low-cost model, enhancing performance through effective absorption. Access to and efficient use of external sources improve innovation, efficiency, and competitiveness by generating synergies through collaboration [44, 45].

2. Methodology

This is a quantitative study with a hypothetico-deductive approach and a correlational-causal scope, employing a non-experimental, cross-sectional, and correlational design. The sample consisted of managers and/or experts with experience in the management of the primary healthcare sector and/or retail clinics. For the multivariate analysis using Partial Least Squares Structural Equation Modeling (PLS-SEM), a sample of 101 participants was considered, exceeding the recommended minimum of 100 cases to achieve sufficient statistical power [46]. Multivariate statistical analysis was conducted using structural equation modeling with the PLS-SEM technique, applying SmartPLS version 4.0 on a random sample of 101 individuals.

3. Results

3.1. Questionnaire Validation

Content validity was assessed (Aiken's $V = 0.94$; all item values > 0.7), along with reliability (Cronbach's $\alpha = 0.975$), indicating high internal consistency. After reducing the questionnaire to 9 dimensions and 20 items, the reliability was recalculated (Cronbach's $\alpha = 0.760$), confirming the instrument's adequacy and reliability for measurement purposes.

Table 2.
Selected Dimensions and Variables.

Dimension	Variable	Item
Disruptive Innovation in Low-Cost Retail Clinics	Variable: A1	Disruptive Low-Cost Innovation - Retail Clinic attracts customers who are willing to accept fewer service attributes in exchange for a lower price to meet their essential personal and family primary healthcare needs.
	Variable: A2	"Disruptive low-cost innovation - retail clinics can attract customers interested in acquiring a viable, innovative value proposition characterized by proximity, faster service, and user accessibility.
User Satisfaction in Primary Healthcare	Variable: B1	Users dissatisfied with the limited reliability and responsiveness of current primary care services may be potential clients for alternatives such as the "Disruptive Low-Cost Innovation - Retail Clinic."
	Variable: B5	Users who perceive a lack of empathy, safety, and infrastructure quality in current primary care services may also be potential clients of the "Disruptive Low-Cost Innovation - Retail Clinic."
Healthcare Consumerism	Variable: C1	Emergence of a new type of health consumer, more empowered, informed, and independent, who may become a potential client of the "Disruptive Low-Cost Innovation - Retail Clinic."
	Variable: C2	Emergence of a new type of health consumer seeking greater involvement in their healthcare and who may become a potential client of the "Disruptive Low-Cost Innovation - Retail Clinic."
	Variable: C3	Emergence of a new type of health consumer more inclined to use new technologies and social media to obtain health information and make decisions, and who may become a potential client of the "Disruptive Low-Cost Innovation - Retail Clinic."
New and Low-End Market Demand	Variable: D1	The presence of potential new or low-end consumers (with limited purchasing power) who currently use private primary healthcare services may be attracted by the faster service delivery of the "Disruptive Low-Cost Innovation - Retail Clinic."
	Variable: D2	The presence of potential new or low-end consumers who may be drawn to the geographic proximity of the Disruptive Low-Cost Innovation - Retail Clinic.
Regulatory Environment Enabling Disruption	Variable: E1	Current laws, norms, and regulations are not necessarily positive, but do not obstruct innovation in the healthcare field, particularly for the "Disruptive Low-Cost Innovation - Retail Clinic."

	Variable: E2	Public policies and government programs are considered scarce and ineffective in fostering innovation in healthcare, particularly in primary care and in models like the "Disruptive Low-Cost Innovation - Retail Clinic."
Disruptive Health Technologies	Variable: F1	New (low-cost) healthcare technologies are perceived as enablers that help reduce healthcare process costs and facilitate the "Disruptive Low-Cost Innovation - Retail Clinic."
	Variable: F2	Disruptive health technologies are perceived to improve service accessibility and affordability for a broader population through the "Disruptive Low-Cost Innovation - Retail Clinic."
Competitive Advantage	Variable: G1	The "Disruptive Low-Cost Innovation - Retail Clinic" contributes to achieving sustainable differentiation through its unique business model, thus fostering a competitive advantage.
	Variable: G2	The "Disruptive Low-Cost Innovation - Retail Clinic" contributes to the development of services with high satisfaction levels due to their accessibility and affordability, enhancing competitive advantage.
	Variable: H1	Deep collaboration with universities and research institutions is deemed important and contributes to the success of the Disruptive Low-Cost Innovation - Retail Clinic.
External Knowledge Sources	Variable: H2	Collaboration with users and clients is considered essential and contributes to the development of the "Disruptive Low-Cost Innovation - Retail Clinic."
Low-Cost Business Model	Variable: I1	The proposed low-cost business model offers a unique and differentiated value proposition that supports the "Disruptive Low-Cost Retail Clinic."
	Variable: I2	The proposed low-cost business model has a standardized structure and processes that facilitate the development of the "Disruptive Low-Cost Retail Clinic."
	Variable: I3	The proposed low-cost business model features a viable profitability formula (low margins, high turnover), which contributes to the success of the "Disruptive Low-Cost Retail Clinic."

3.2. Results From the Application of Multivariate Analysis

A multivariate structural equation modeling analysis using PLS-SEM was applied to a random sample of 101 participants. The observed variables were generated using 20 reflective indicators. Finally, the PLS algorithm was calculated using SmartPLS, and the results are presented in Figure 1.

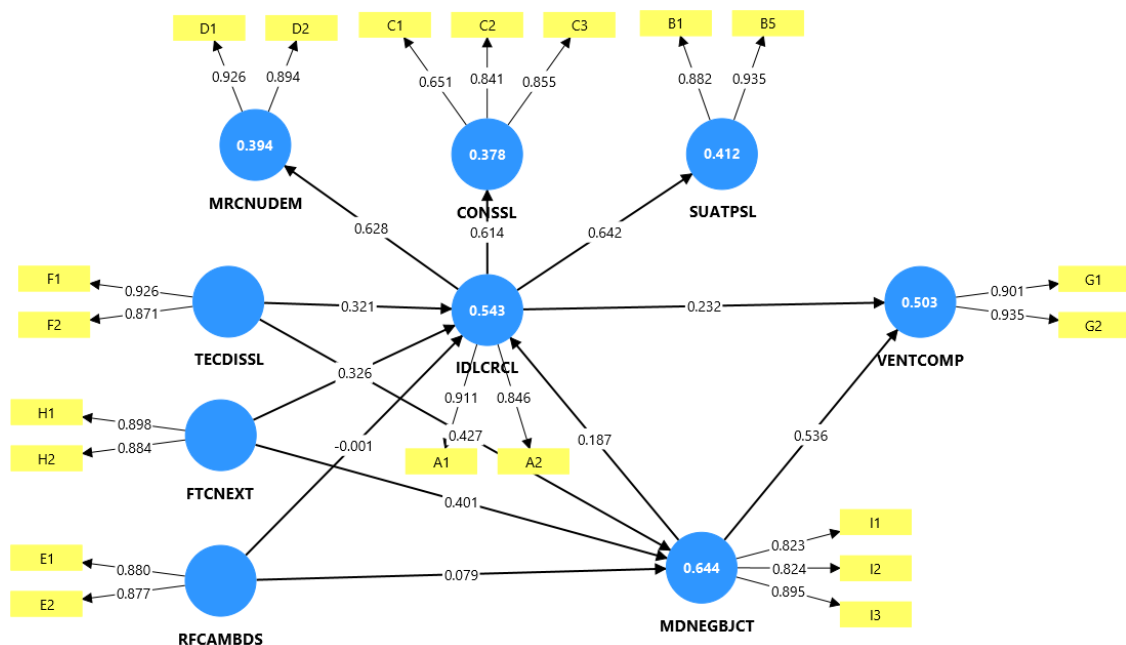


Figure 1.

Path Model Estimation.

Note: Own elaboration (application of the PLS algorithm using SMART PLS Software 4.0).

For the analysis, the following variables are considered: Disruptive Innovation in Low-Cost Retail Clinics (IDLCRCL - A), User Satisfaction in Primary Health Care (SUATPSL - B), Health Consumerism (CONSSL - C), New Demand and Low-End Market (MRCNUDEM - D), Regulation Facilitating Disruptive Change (RFCAMBDS - E), Disruptive Health Technologies (TECDISSL - F), Competitive Advantage (VENTCOMP - G), External Knowledge Sources (FTCNEXT - H), and Low-Cost Business Model (MDNEGBJCT - I).

Next, the evaluation of the measurement instrument and the assessment of the structural model are carried out in two stages [47].

3.1.1. Stage One: Measurement Instrument Evaluation

To evaluate the measurement instrument (Tables 3 and 4) within the initial reflective model, reliability and validity were assessed. First, individual item reliability was examined, confirming that outer loadings exceeded the threshold of 0.70. Next, internal consistency was assessed through composite reliability (CR) and Cronbach's alpha, both surpassing the recommended minimum values, with CR being more appropriate for PLS since it does not assume equal indicator weighting.

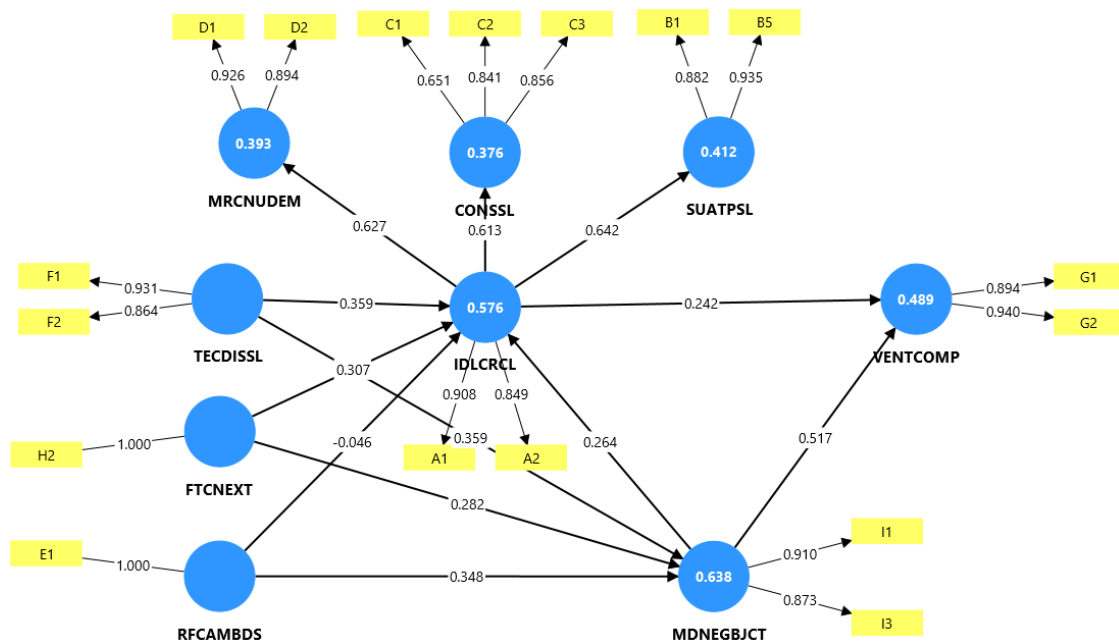
Table 3.
Construct Reliability and Validity.

	Cronbach's alpha	Composite reliability (rho_a)	Composite reliability (rho_c)	Average variance extracted (AVE)
CONSSL	0.713	0.796	0.829	0.621
FTCNEXT	0.741	0.743	0.885	0.794
IDLCRCL	0.710	0.741	0.872	0.773
MDNEGBJCT	0.805	0.809	0.885	0.719
MRCNUDEM	0.794	0.811	0.906	0.828
RFCAMBDS	0.704	0.704	0.871	0.771
SUATPSL	0.793	0.838	0.905	0.826
TECDISSL	0.765	0.802	0.893	0.807
VENTCOMP	0.816	0.840	0.915	0.843

Table 4.
Outer Loadings.

List	Outer loadings	List	Outer loadings
A1 ← IDLCRCL	0.911	E2 ← RFCAMBDS	0.877
A2 ← IDLCRCL	0.846	F1 ← TECDISSL	0.926
B1 ← SUATPSL	0.882	F2 ← TECDISSL	0.871
B2 ← SUATPSL	0.935	G1 ← VENTCOMP	0.901
C1 ← CONSSL	0.651	G2 ← VENTCOMP	0.935
C2 ← CONSSL	0.841	H1 ← FTCNEXT	0.898
C3 ← CONSSL	0.855	H2 ← FTCNEXT	0.884
D1 ← MRCNUDEM	0.926	I1 ← MDNEGBJCT	0.823
D2 ← MRCNUDEM	0.894	I2 ← MDNEGBJCT	0.824
E1 ← RFCAMBDS	0.880	I3 ← MDNEGBJCT	0.895

Convergent validity, which assesses whether indicators adequately represent a single construct, was confirmed via AVE (>0.50), indicating that each construct explains at least 50% of the variance in its indicators (Table 3). Discriminant validity, ensuring differentiation between constructs, was evaluated using the HTMT criterion (<0.90), a robust method for complex models that compares inter- and intra-construct correlations. Constructs exceeding the HTMT threshold were considered for removal or merging. In this study, the latent variables H1, E2, and I2 were removed, while the remaining variables met the criteria, with an average loading of 0.830833 across all retained items. After refining the constructs and indicators, the resulting structural model, shown in Figure 2, was subject to evaluation.

**Figure 2.**

Path Model Estimation.

Note: Own elaboration (based on the application of the PLS algorithm using SMART PLS 4.0 software).

3.1.2. Second Stage: Structural Model Assessment

To evaluate the structural model, collinearity among indicators was first assessed using the Variance Inflation Factor (VIF). Tolerance values below 0.20 or VIF values above 5 indicate critical collinearity issues [48]. As shown in Table 5, the VIF values ranged between 0.2 and 5, confirming an acceptable level of collinearity. Subsequently, the magnitude and significance of the path coefficients and the coefficient of determination (R^2) were evaluated.

Table 5.
Collinearity Analysis (VIF).

Outer model - List	VIF	Outer model - List	VIF
A1	1.434	E1	1.000
A2	1.434	F1	1.624
B1	1.761	F2	1.624
B2	1.761	G1	1.902
C1	1.470	G2	1.902
C2	1.836	H2	1.000
C3	1.355	I1	1.541
D1	1.767	I3	1.541
D2	1.767		

For the path coefficients assessment, the algebraic sign, magnitude, and statistical significance of the standardized regression coefficients were analyzed, as these reflect the hypothesized relationships within the research model. The analysis focused on both the magnitude and the statistical significance of these coefficients.

Table 6.
Path Coefficients.

List	Path coefficients	List	Path coefficients
FTCNEXT → IDLCRCL	0.307	MDNEGBJCT → IDLCRCL	0.264
FTCNEXT → MDNEGBJCT	0.282	MDNEGBJCT → VENTCOMP	0.517
IDLCRCL → CONSSL	0.613	RFCAMBDS → IDLCRCL	-0.046
IDLCRCL → MRCNUDEM	0.627	RFCAMBDS → MDNEGBJCT	0.348
IDLCRCL → SUATPSL	0.642	TECDISSL → IDLCRCL	0.359
IDLCRCL → VENTCOMP	0.242	TECDISSL → MDNEGBJCT	0.359

The standardized path coefficients (ranging from -1 to +1) indicate the strength of the predictive relationships between constructs. Higher values suggest stronger relationships, whereas values closer to zero indicate weaker associations (see Table 7). The variable RFCAMBDS exhibits the weakest relationship. To determine the statistical significance of these coefficients, the bootstrapping technique was applied (10,000 resamples with replacement, 95% confidence level). This non-parametric method evaluates the robustness of the relationships among variables [49] and the precision of PLS estimates.

Table 7.
t-values and p-values of Path Coefficients (Bootstrapping).

Variable	Original sample (O)	Sample mean (M)	Standard deviation (STDEV)	T statistics (O/STDEV)	P values
<i>FTCNEXT</i> → <i>IDLCRCL</i>	0.307	0.303	0.099	3.099	0.002
<i>FTCNEXT</i> → <i>MDNEGBJCT</i>	0.282	0.282	0.085	3.304	0.001
<i>IDLCRCL</i> → <i>CONSSL</i>	0.613	0.620	0.063	9.687	0.000
<i>IDLCRCL</i> → <i>MRCNUDEM</i>	0.627	0.632	0.082	7.611	0.000
<i>IDLCRCL</i> → <i>SUATPSL</i>	0.642	0.647	0.055	11.670	0.000
<i>IDLCRCL</i> → <i>VENTCOMP</i>	0.242	0.239	0.120	2.019	0.044
<i>MDNEGBJCT</i> → <i>IDLCRCL</i>	0.264	0.262	0.124	2.131	0.033
<i>MDNEGBJCT</i> → <i>VENTCOMP</i>	0.517	0.521	0.131	3.951	0.000
<i>RFCAMBDS</i> → <i>IDLCRCL</i>	-0.046	-0.035	0.116	0.400	0.689
<i>RFCAMBDS</i> → <i>MDNEGBJCT</i>	0.348	0.338	0.128	2.709	0.007
<i>TECDISSL</i> → <i>IDLCRCL</i>	0.359	0.359	0.092	3.914	0.000
<i>TECDISSL</i> → <i>MDNEGBJCT</i>	0.359	0.374	0.106	3.377	0.001

Except for the non-significant relationship between *RFCAMBDS* and *IDLCRCL* ($p = 0.689$), all variables demonstrated statistical significance ($p < 0.05$), indicating meaningful predictive relationships. To assess the predictive capability of the PLS-SEM model, the coefficients of determination (R^2) were examined, which measure the proportion of variance explained in the dependent variables. The model exhibited substantial (0.627, 0.558) and moderate (0.370, 0.387, 0.406, 0.479) R^2 values, all statistically significant (see Table 9), confirming the model's predictive power.

Table 8.
 R^2 Analysis.

Variable	R-square	R-square adjusted	Variable	R-square	R-square adjusted
CONSSL	0.376	0.370	MRCNUDEM	0.393	0.387
IDLCRCL	0.576	0.558	SUATPSL	0.412	0.406
MDNEGBJCT	0.638	0.627	VENTCOMP	0.489	0.479

Table 9.
 R^2 Significance Analysis (Bootstrapping p-values).

Variable	Original Sample (O)	Sample Mean (M)	Standard Deviation (STDEV)	T Statistics(O/STDEV)	P values
CONSSL	0.376	0.388	0.078	4.849	0.000
IDLCRCL	0.576	0.597	0.061	9.379	0.000
MDNEGBJCT	0.638	0.658	0.066	9.652	0.000
MRCNUDEM	0.393	0.406	0.103	3.815	0.000
SUATPSL	0.412	0.421	0.071	5.837	0.000
VENTCOMP	0.489	0.505	0.076	6.442	0.000

P-values indicate whether the relationships in the model are statistically significant. A p-value less than 0.05 allows for the rejection of the null hypothesis, suggesting that the relationships between variables are indeed significant. Consequently, the model demonstrates predictive validity.

4. Discussion

The quality of the measurement instrument was evaluated, demonstrating that the questionnaire possesses content validity and adequate reliability across all analyzed dimensions. The Partial Least Squares Structural Equation Modeling (PLS-SEM) analysis enabled the examination of the proposed relationships. The assessment of the measurement model confirmed its robustness, with individual reliability tests and internal consistency measures (Cronbach's alpha and composite reliability index) indicating high reliability across all constructs and indicators [49]. Moreover, convergent validity, supported by appropriate factor loadings and AVE values, confirmed that the indicators accurately explain their respective constructs. Discriminant validity, evidenced by HTMT values below 0.90, ruled out multicollinearity issues.

In the structural model evaluation, the analyses revealed that all path coefficients were statistically significant ($p < 0.05$), indicating predictive relationships, except for the relationship between *RFCAMBDS* and *IDLCRCL*, which was not significant ($p = 0.657$).

Several significant relationships emerged: Disruptive Innovation in Low-Cost Retail Clinics (*IDLCRCL*) showed a strong association with Health Consumerism (*CONSSL*) (0.613), as empowered and informed consumers with access to technology find disruptive innovations a suitable response to their needs [22, 23]. Similarly, *IDLCRCL* was linked to the

New Demand and Low-End Market (MRCNUDEM) (0.627), highlighting its role in creating new markets and attracting less demanding customers through affordable offerings [26, 27]. Furthermore, IDLCRCL was positively related to User Dissatisfaction with Primary Health Care (SUATPSL) (0.642), suggesting that disruptive innovations provide fast and affordable solutions to simple health issues, thereby appealing to dissatisfied users [3, 20]. The causal link between Low-Cost Business Models (MDNEGBJCT) and Competitive Advantage (VENTCOMP) (0.517) was also confirmed, as offering affordable prices allows firms to differentiate from competitors, attract price-sensitive market segments, and achieve sustainable competitive advantages [36-38].

Moderate yet statistically significant relationships were also observed, such as that between External Knowledge Sources (FTCNEXT) and IDLCRCL (0.307), indicating that network capacity and cooperation for knowledge acquisition positively influence innovation [9, 34]. FTCNEXT also correlated with MDNEGBJCT (0.282), underscoring that access to and effective use of external sources are vital for the sustainability of low-cost business models and superior performance [44, 45].

A moderate relationship was found between MDNEGBJCT and IDLCRCL (0.264), suggesting that low-cost business models, by simplifying offerings and processes, drive disruptive innovation [13, 35]. A moderate relationship also existed between Disruptive Health Technologies (TECDISSL) and IDLCRCL (0.359), supporting the idea that affordable, accessible disruptive technologies underpin disruptive innovation [8, 29-31, 42].

Regarding IDLCRCL and VENTCOMP (0.242), the positive relationship suggests that disruptive innovation offers a unique and sustainable value proposition [20, 32, 33]. Similarly, Regulation Facilitating Disruptive Change (RFCAMBDS) and MDNEGBJCT (0.348) were linked, indicating that regulation impacts business models by requiring adaptation to regulatory changes [39-41]. Also, TECDISSL and MDNEGBJCT (0.359) showed a positive relationship, reinforcing that technological disruption drives innovation in business models by reducing costs and generating competitive advantages [42, 43].

Although the literature suggests that regulation facilitates disruption [28, 29] our study did not find a significant relationship between Regulation (RFCAMBDS) and Disruptive Innovation in Retail Clinics (IDLCRCL) (−0.046). This apparent contradiction may be explained by the socio-economic context. In developed countries, regulations often support and protect innovations, fostering a favorable ecosystem. However, in emerging economies such as Peru, regulation tends to be slower and more reactive, sometimes exhibiting indifference toward disruptive changes. Consequently, innovation in these contexts may emerge "in spite of regulation" rather than because of it [50].

5. Conclusion

The study successfully achieved its objective by identifying and validating the variables and the questionnaire through satisfactory content validity and reliability tests. The multivariate analysis using Partial Least Squares Structural Equation Modeling (PLS-SEM) led to a well-fitted model following the assessment of the data collection instrument. The model evaluation revealed acceptable collinearity and statistically significant path coefficients ($p < 0.05$), except for the RFCAMBDS–IDLCRCL relationship. Additionally, the model demonstrated significant predictive power, as evidenced by substantial and moderate coefficients of determination (R^2), thereby confirming the validity of the instrument, the reliability and validity of the proposed model, as well as its predictive capacity.

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