

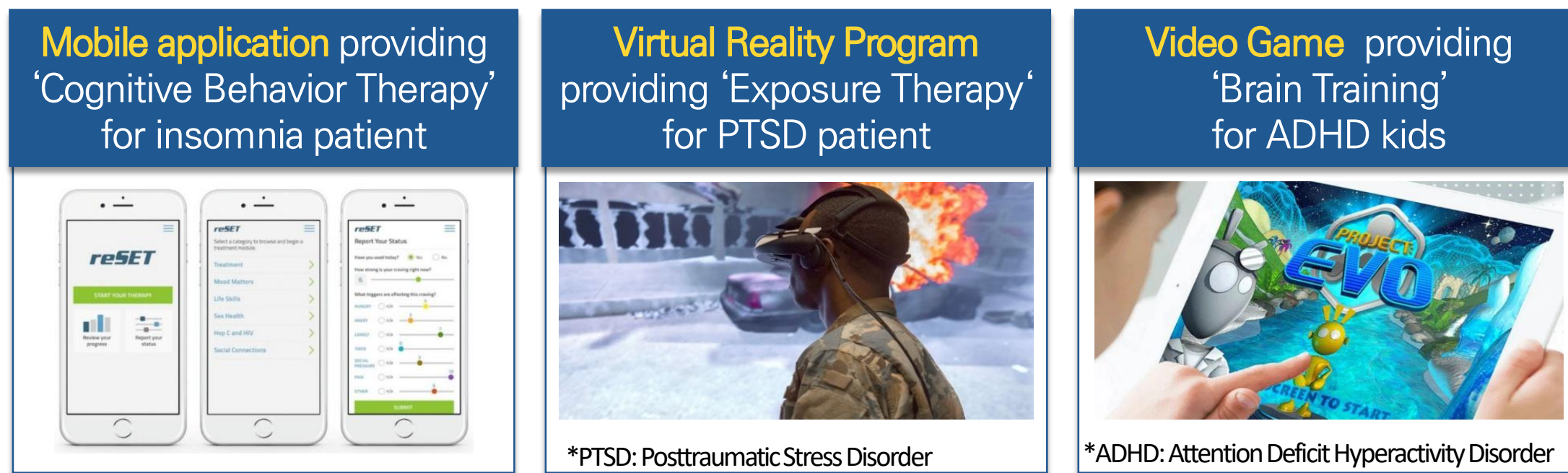
CONTROVERSIAL PERCEPTION ON REIMBURSEMENT FOR DIGITAL THERAPEUTICS IN KOREA

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INTRODUCTION

- Digital therapeutics (DTx) are **therapeutic interventions driven by software** and directly provided to patients, allowing the patients to manage their health with ease in any setting.



[Fig 1] Examples of Digital Therapeutics

- However, they are still **at a premature stage worldwide** and **do not have sufficient evidence on effectiveness, efficiency, and safety**.
- Currently, while DTx companies desire to quickly enter the market, especially by getting their products reimbursed by National Health Insurance (NHI) fund, the NHI is very cautious about DTx due to its uncertainties.
- Thus, **public discussion and social consensus are important building-blocks to reimburse DTx in the NHIS**.
- Nevertheless, previous studies have focused on opinions from the DTx industry, overlooking those from physicians, patients, and consumers who will be users of DTx products.

AIM

- This study aimed to examine diverse stakeholders' awareness and attitudes toward DTx and perceptions of regulatory pathways for adopting DTx.
- To the best of our knowledge, this is the first study to comprehensively analyze the perceptions of various stakeholder groups regarding DTx reimbursement in Korea.

METHOD

Data Collection

- In-depth Interviews (IDI)** were conducted with 11 DTx-related stakeholders in Korea (Industry: 4, Medical professionals: 3, Academia: 2, Consumer 2) using the semi-structured guideline.
- The interviews were conducted either in person or via a video conference from January 25, 2022, to February 15, 2022. The interviews lasted 45–70 minutes, and the entire interview was recorded and transcribed.

Analysis

- This study performed a **qualitative data analysis** called directed content analysis, using interview guidelines as analytical framework [2].
- For accuracy, the principal investigator who facilitated the interview along with one researcher independently reviewed the interview recordings. The reviewers repeatedly read the transcriptions to grasp its meaning and highlighted significant statements.
- Furthermore, they made notes **to identify significant themes** and **categorized them into predefined categories based on guidelines**.

RESULTS

1. Awareness and Attitudes toward DTx

- The industry, academic, and healthcare experts possess a firm understanding of DTx, while the consumers have limited knowledge. Hence, it is highly probable that the **general public remains entirely unfamiliar with DTx** or has a limited understanding of it.
- All participants displayed **favorable and receptive attitudes** toward DTx. They were optimistic about the transition in the healthcare system that DTx will bring but also recognized the high level of uncertainty associated with DTx.

2. Perception about Market Entry & Reimbursement

- Most perceived that **DTx technology deserves market access and agreed to the quick adoption** of this novel technology to prevent it from becoming obsolete.
- However, some participants expressed **doubts about its clinical effectiveness, the appropriate use of the technology by healthcare providers, and patient engagement**.
- Thus, although participants were in favor of reimbursement of DTx in principle, they could **not reach an agreement on pathways for entering the market**.

3. Perception on Adopting Pathways of DTx

- The industry experts sought reimbursement from the NHI fund to ensure a stable market. However, most participants **considered a conservative approach is required along with insufficient clinical evidence**.
- Therefore, for DTx, an interim phase is required to address uncertainties regarding DTx (e.g. therapeutic benefits and user acceptance) before DTx is covered by the NHI**.
- Nevertheless, the participants recognized the potential need for greater flexibility in the determination of reimbursement for DTx once the evidence of its effectiveness is established. This suggests that **traditional criteria assessing clinical and economic value may not adequately capture the value of DTx**.

[Table 1] . Awareness and Perceptions about DTx and its market release and reimbursement

Participants	Categories	Themes	Perceptions	Responses
 Industry (4)	Awareness and Attitude toward DTx	DTx Concept	Industry, Academia, Healthcare: Low High Consumer: Low High	- Software that provides therapeutic interventions - Differences in perceptions regarding physician prescription, target patient groups, environment of use
		Expectations & Concerns regarding DTx	Disagree Agree	- Never heard of DTx - Similar to a wearable device?
	Perception about market entry and reimbursement	Whether DTx deserves to enter the market	Disagree Agree	(+) Considering the expectations of DTx, deserves to be released to the market (-) Uncertain whether it could be utilized effectively (-) Promoting for industrial purposes amid inadequate evidence
		Whether DTx deserve to be reimbursed	Disagree Agree	(+) Helps improve patients' health (+) Government recognizes the efficacy of a novel treatment modality (-) Uncertainties about the effectiveness of DTx and patients' willingness to accept the technology (-) Price is controlled when reimbursed through the NHI
 Medical Professionals (3)	Perception about adoption pathways of DTx	Early Market Entry	Disagree Agree	(+) Fast technology developmental cycle (+) Low risk (+) Easy to collect RWD (real-world data)
		Provisional Reimbursement from the NHI fund	Disagree Agree	(+) Industry: Reduced risk taken for trying a new modality (+) Consumer: Management to adopt DTx properly (+, -) Academia & Healthcare: Support for innovative health technologies is necessary, but selective application to products with high potential for reimbursement in future (-) High uncertainties due to being a novel technology (-) Need to use as a non-covered item to examine the market's response
		Criteria for Reimbursement Decision	Disagree Agree	(+) Need to compare therapeutic benefits with that of standard of care for reimbursement decision (-) Comparison with existing treatments is inappropriate (-) Reimburse only if it is as effective as existing treatments (+) Reimburse based on the unique benefits of DTx even if it is less effective
 Academia(2)				
 Consumer (2)				

Consumer

"This is my first time learning about DTx. So, I searched the news before coming here."
– Consumer, Participant 11

Industry

"To treat patients with insomnia properly, you need to use cognitive behavioral therapy, but it is underutilized in hospitals, right? DTx can fill this gap, providing proper treatment, reducing social costs, and improving the quality of life. It would have these kinds of benefits."
– Industry, Participant 5

Medical Professionals

"There is no reason for not using it that has already been developed, and it can definitely be helpful in managing health."
– Healthcare, Participant 7

Academia(2)

"DTx is much easier to collect RWD (real-world data) from, and due to its digital nature, safety issues are of much less concern. This is why we are trying it on the field to collect data."
– Academia, Participant 2

Industry

"Having our product reimbursed is a very important issue for us because it means that the government acknowledges its effectiveness and officially compensates for it. This will help people distinguish therapeutics that they really need to use from health functional products they can just buy at a market."
– Industry, Participant 4

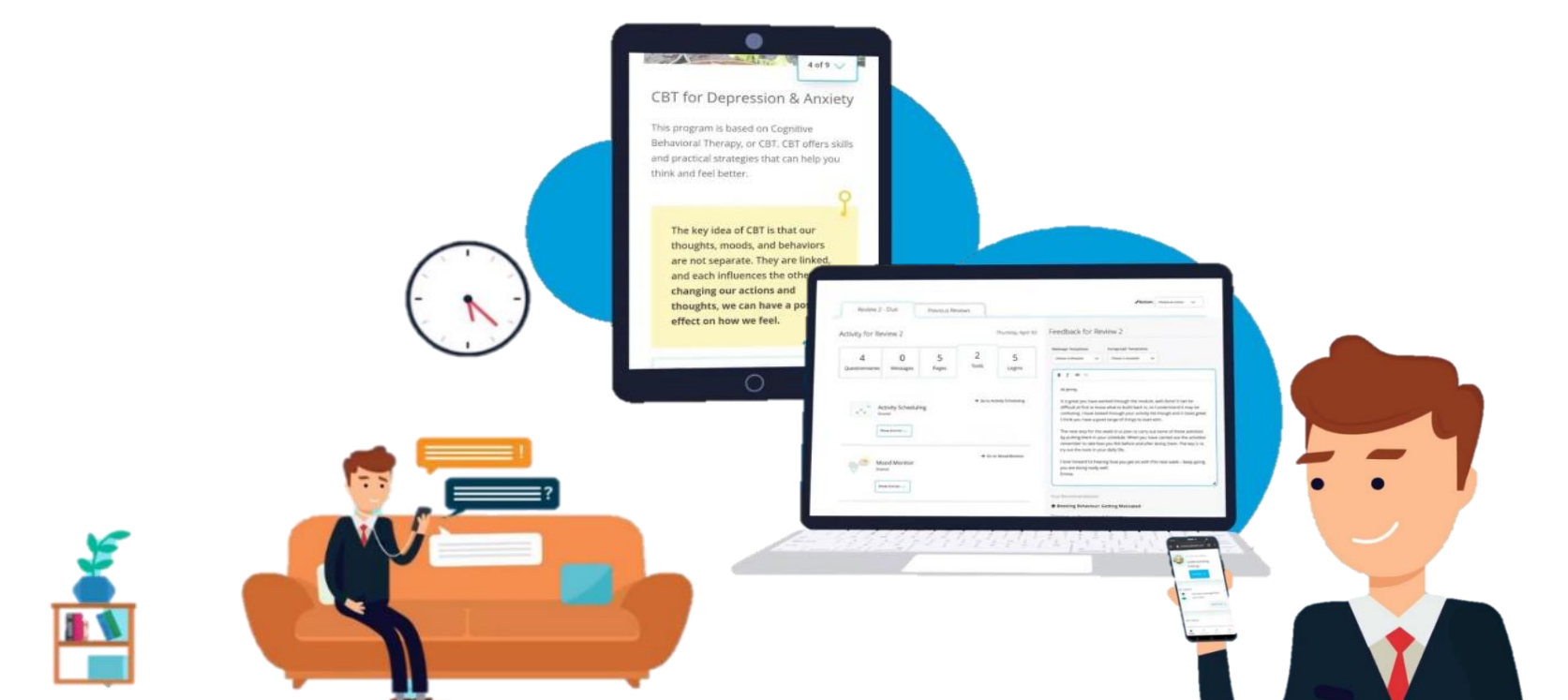
Medical Professionals

"I'm a little cautious about the reimbursement. Reimbursing it as an independent therapeutic should be decided with more deliberation. This is the national budget we are talking about here, and I believe that if there is a better option with more concrete effectiveness, then it is right to give more money to that option."
– Healthcare, Participant 8

CONCLUSIONS

- In this study, we found that stakeholders in Korea had positive attitudes towards DTx, perceived it worth using, and agreed to allow DTx to enter the market.
- The **main issue was not the problem of the technology itself, but the difference in opinion as to reimbursement method** to lower the price.

- Therefore, this study concluded that NHI fund, operated very conservatively, are insufficient to quickly adopt and implement DTx.
- Various reimbursement methods, including tax-based financing, raising innovation fund for new technologies, and pilot studies using NHIS fund, should be employed** to rapidly generate clinical evidence and reduce the uncertainty of DTx so as not to lose their ground in the market.



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