Physical Therapy Using Digital Therapeutics in Infants with Congenital Muscular Torticollis: A Prospective Open-label Pilot Study

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Abstract

Background: Congenital muscular torticollis (CMT) is a common musculoskeletal problem associated with unilateral sternocleidomastoid muscle stiffness after birth. Most infants with CMT have a favorable prognosis after early and appropriate physical therapy (PT), including stretching, and the total amount of PT is a key factor in symptom alleviation.

Objective: This study aimed to evaluate the effects of the newly developed digital therapeutics ACESO-APP, a personalized exercise app with real-time feedback using skeleton-based motion analysis and artificial intelligence-driven body reconstruction models, on the clinical outcomes and exercise amount in infants with CMT.

Methods: This was a prospective open-label pilot study. The participants were randomly allocated to a digital therapeutics (DTx) or standard education (SE) group. Participants were encouraged to engage in a 12-week home-based PT program with conventional PT at the hospital. A 12-week home-based personalized PT program was encouraged for both groups through DTx and SE. We measured changes in the torticollis overall assessment (TOA) and amount of PT at 4, 8, and 12 weeks. Usability and satisfaction with digital therapeutics were assessed at 12 weeks.

Results: In all participants, significant changes were observed in TOA at 12 weeks, from a mean of 13.50 points (SD, 2.88) to 16.13(SD, 2.36; P=.010). No statistically significant differences were observed in the changes in TOA score and PT amount between the SE and DTx groups. However, a statistical trend was observed toward an increase in TOA score and amount of PT in the DTx group. The usability, satisfaction, and safety of digital therapeutics were verified.

Conclusions: ACESO-APP is a practical, acceptable, and promising PT program for infants with CMT. These preliminary findings provide a good foundation for further optimization of PT program using DTx and the promotion of large-scale randomized controlled clinical studies for infants with CMT. It may be an additional treatment option and a viable alternative to conventional PT.

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Keywords: congenital muscular torticollis; physical therapy; digital therapeutics; artificial intelligence

Introduction

Congenital muscular torticollis (CMT) is a postural and musculoskeletal deformity that occurs after birth and is the third most common congenital musculoskeletal problem in newborns. Patients with CMT have unilateral stiffness of the sternocleidomastoid (SCM) muscle resulting in lateral flexion of the head to the ipsilateral side and rotation to the contralateral side and commonly exhibit a restricted range of cervical motion [1, 2]. Substantial evidence indicate that early intervention with physical therapy (PT) greatly improve symptoms; however, delayed intervention is associated with a prolonged treatment duration [3, 4]. The primary intervention for CMT involves stretching exercises targeting the affected SCM, with evidence indicating that the total amount of PT is a key factor in symptom alleviation [5]. Because the amount of PT available in hospitals or specialized treatment centers is often limited, structured home-based PT may increase the total amount of PT [6]. Parents

sought medical information about home-based PT programs for CMT on the Internet. A previous study evaluated the usefulness, reliability, and quality of internet video clips on CMT and reported that video clips presented by healthcare professionals were more useful, reliable, and of better quality than video clips with popularity [7]. In this study, we applied the concept of digital therapeutics (DTx) prescribed by a specialized physician for appropriate treatment of CMT.

Digital Therapeutics (DTx) can be defined as "therapeutic interventions through a clinically evaluated, patient-directed-software application intended to improve the process of disease diagnosis, treatment, management, and prevention." The development of therapies incorporating the concept of DTx has increased in recent years, especially targeting chronic and behavior-modifiable condition [8]. It offers the potential for improved cost-effectiveness by facilitating treatment outside healthcare facilities and allowing patients to use computers, smartphones, or tablets for therapy in any setting. Few studies have investigated DTx application in children with behavioral problems, such as autism spectrum disorder and ADHD (which is FDA cleared for prescription in pediatric ADHD) [9, 10]. To the best of our knowledge, no previous study has investigated the development of DTx for CMT treatment. Since most infants with CMT have a favorable prognosis after early, appropriate, and highly intensive PT [11], evidence-based DTx prescribed by physicians may be an appropriate option for improving adherence to PT. Therefore, this study aimed to evaluate whether integrating DTx with conventional PT may improve clinical outcomes in infants with CMT and to assess the adherence to PT and feasibility of DTx.

Our newly developed multiplatform app "ACESO" DTx (ACESO-APP) utilized advanced Artificial Intelligence (AI) such as skeleton-based motion analysis and AI-driven body reconstruction models. A part of DTx has used AI to provide customized and adaptive algorithms and intervention, for example, in a musculoskeletal disease entity, Kaia Health developed an AI-based computer vision technology, which enables smartphones and tablets to analyze the movement patterns of body during exercises and provides corrective feedback for back pain [8, 12, 13]. By implementing AI-based DTx in infants with CMT, we were able to measure and analyze movement data, such as cervical range of motion and provide real-time corrective feedback without wearable devices.

This study aimed to evaluate the effects of a home-based PT program using the ACESO-APP on the clinical improvement of patients with CMT and increase in the amount of PT for the treatment of CMT. We also aimed to assess the usability, satisfaction, and safety of the ACESO-APP to provide a basis for further studies on the broad application of DTx in infants with CMT. We hypothesized that infants treated with the ACESO-APP would report better outcomes and adherence to PT during the follow-up period of 12 weeks than infants who received standard education (SE). It may be a useful addition (an adjunctive option to conventional PT) or even a replacement for center-based PT in infants with CMT.

Methods

Study procedures

This prospective, open-label, randomized controlled trial was performed at a single center.

Participants

Participants were recruited from an outpatient pediatric rehabilitation clinic. The inclusion criteria were as follows: (1) diagnosis of CMT, (2) age <12 months, and (3) compliance of caregivers with the study instructions. The exclusion criteria were as follows: (1) congenital anomalies of the cervical spine, (2) spasmodic torticollis, (3) neurogenic torticollis, and (4) any other therapy for torticollis. An adequate sample size was defined as 14, considering a 20% dropout rate in a pilot study. This study was approved by the Institutional Review Board of our hospital on July 26, 2023 (approval no. 2023-07-007-002), and written informed consent was obtained from all participants.

Overall description of ACESO-APP

ACESO is a multiplatform application for iOS and Android. Clinical use is available through Google Play Store and the ACESO App is free to download. The ACESO Web is provided to a specialized physician, who prescribes the details of PT, including direction of exercise (according to the affected side), treatment duration (prescription days), and list of exercise types (tilt and rotation), and then permits participants to use the ACESO-APP. The ACESO-APP includes three categories: (1) daily measurements, (2) PT, and (3) statistical data. The participants daily measured the degree of cervical tilt before the PT. During the PT, the number of repetitions and real-time feedback for corrective movements were provided. The amount of daily PT was recorded and displayed to the participants.

Technology of ACESO-APP

The AI model of ACESO consists of a skeleton-based motion analysis and AI-driven body reconstruction models. The motion data from the camera were transmitted to the AI server during daily measurements and PT, and the data were converted into 3D motion data using an AI model of ACESO. The existing AI models recognize the skeletons and joints of adults; however, for applying AI model in infants, it was additionally trained using 300,000 pieces of physical and behavioral data of infants and toddlers (0–3 years old) in daycare centers, and an algorithm was developed and added to the existing model. To recognize corrective motion during the PT, we trained the AI model using 100,000 image data points that were preprocessed by experts for the relevant PT. In addition, the AI model was trained using images captured with a red blue green (RGB)-Depth (RGBD) camera to determine the accuracy of 3D movement inference. The 2D skeleton data of infants captured by the monocular camera were inferred through the reinforcement learning process on both video sets annotating the infant's motion and pseudo-labeled video sets. The inferred 2D skeletons were sent to the server, and the captured video was deleted to protect user privacy. The 2D skeleton data sent to the server were converted into 3D skeleton data through a temporal–spatial attention-GCNFormer network combining motionBERT [14] and motionAGFormer [15] using an RGBD camera [16]. Furthermore, an advanced technique for extracting data from only a single participant (baby) among the two participants (baby and caregiver) in the video was applied.

Intervention

All participants were randomly allocated to one of two groups for 12 weeks: a standard education (SE) group or a DTx group. Manual stretching was performed by an experienced physiotherapist once a week in both groups. Additional home-based PT programs were provided by standard education in the SE group and the ACESO-APP in the DTx group. Based on the recommendations of the treatment guidelines for CMT, the manual stretching protocol consisted of 10 repetitions and 10 s duration of hold in both groups [1, 17].

SE group

The caregivers of the SE group were educated on how to perform home-based PT by professionals and received a PT instruction brochure. The accuracy of the home PT was checked by the physician on the visit day.

DTx group

The DTx group received a tablet with the ACESO-APP installed, and participated in a PT program

prescribed by a physician for 12 weeks. The physician prescribed the PT program, including the direction of exercise, treatment duration, and list of exercise types, to each participant, and then obtained permission to use the ACESO-APP. The components of the PT program included stretching exercises of head rotation and tilting according to the affected site, as in the brochure of SE group. Before starting the PT program, the participants daily measured the degree of cervical tilt while keeping their gaze focused. The application shows a list prescribed by a physician and provides a PT guide video before starting the PT program. The number of exercise repetitions was counted during the PT, and the application notified the participant of errors in exercise performance using a real-time AI server that converted the camera's 2D movement data into 3D movement data. Statistical data provided the amount of PT to the participants to help them monitor their progress and motivate their participation in the PT program throughout the treatment process (Figure 1).

Outcome Measure

Outcome measures were assessed at baseline and 4, 8, and 12 weeks after the treatment program. The assessments included a clinical assessment and self-completed questionnaires that collected information on the amount of PT. Furthermore, usability and satisfaction with DTx were evaluated using a self-report questionnaire at the final visit in the DTx group.

Clinical assessment

We used the Cheng method [18], which represents the severity of CMT using the torticollis overall assessment (TOA) score. It compromises the following details: deficit of cervical rotation (degrees), deficit of cervical lateral flexion (degrees), craniofacial asymmetry, location of the residual band, and subjective assessment by a parent. Detailed results were scored on a 4-point scale: excellent (3), good (2), fair (1), and poor (0). The overall scores were grouped as excellent (16-18), good (12-15), fair (6-11), or poor (<6), with higher scores indicating better clinical results. Deficits in rotation and lateral flexion were measured using an arthrodial protractor, with the child in the supine position. Limitations in the passive range of cervical and lateral flexion were assessed and compared with those on the normal side.

Amount of PT

The amount of PT was estimated in terms of frequency (number per week) and duration (minutes per day), and the total amount of PT was calculated by multiplying the frequency and duration.

Usability and satisfaction of PT program using ACESO-APP

The Usability of ACESO-APP was evaluated using a standard system usability scale (SUS). The SUS is a widely used self-administered instrument used to assess the usability of a system or product through a series of standardized questions on a five-point Likert-type scale. The SUS scores ranged from 0 to 100, with higher scores indicating better results [19]. Satisfaction with the PT using the ACESO-APP was evaluated using a self-report questionnaire that included eight items as follows: symptom improvement, interest, physical comfort, stability, satisfaction, intention to use, and role expectations for rehabilitation, with a 7-point Likert-type scale, with higher scores indicating better results.

Statistical Analysis

Data were analyzed using SPSS Statistics 25 for Windows (IBM Corp, Armonk, NY, USA). Wilcoxon signed-rank tests were used to detect changes in TOA scores between baseline (T0) and 12 weeks after treatment (T3) for all participants. A mixed-effects model was initially used to examine the interaction between time and group on the outcomes (TOA score and amount of PT) between

baseline and post-intervention. Time and group were considered fixed effects and random intercepts were included to account for variance in the baseline score. In cases where the interaction term was not significant, the Mann-Whitney U test was used to compare the differences between groups. The level of significance was set at *P<.05*.

Results

Patient Characteristics

Fourteen participants were enrolled and randomized into DTx (n=7) and SE (n=7) groups. Among the 14 participants, two participants requested to discontinue the program because of difficulty in using the app and the medical condition of the infant, and four participants were lost to follow-up. As a result, a total of 8 participants completed the intervention and assessment. The participants' demographic data are presented in Table 1. At baseline, no significant differences were found in age, sex, affected side, or disease severity (TOA score) between the 2groups. (*P>.05*)

Torticollis Overall Assessment

We observed a significant increase in the TOA score (T3-T0) in all participants after the study intervention, indicating significant improvements in clinical assessment (*P<.010*). The mixed-effects model showed no significant interaction between time and group (*P=.445*) and there was no difference in changes in TOA scores between the DTx and SE groups. However, a statistical trend toward an increase in changes in TOA score in DTx group (T1-T0:2.00 ± 2.83 points; T2-T0:3.00 ± 3.16 points; T3-T0:3.75 ± 3.20 points), with ongoing increase in TOA score at 12 weeks compared to a plateau in the SE group (T1-T0:1.25 ± 2.19 points; T2-T0:2.25 ± 2.38 points; T3-T0:2.63 ± 2.50 points) (Table 2) (Figure 2).

Amount of PT (Adherence)

A mixed-effects model showed no significant interaction (*P=.392*) and no difference was observed in the amount of PT between the groups. However, a statistical trend toward an increase in amount of PT per week in the DTx group (T1:368.75±352.00 min/week; T2:143.75± 185.98 min/week; T3:167.37±164.66 min/week) than the SE group (T1:128.38 ±130.92 min/week; T2:106.25 ±54.37 min/week; T3 60.00±44.91) was observed (Table 3) (Figure 3).

Usability and Satisfaction

Concerning usability, an average SUS score of 73.13 was obtained, implying that it had a grade of "B," corresponding to good (Figure 4). For satisfaction according to a 7-point Likert-type scale, the highest score was observed for "interest" (5.25, SD 1.26), followed by "stability" (5.00, SD 2.16), "satisfaction" (5.00, SD 1.41), "role expectation for rehabilitation" (5.00, SD 1.41), "symptom improvement" (4.75, SD 0.96), "intention to use" (4.75, SD 1.71), and "adequate difficulty" (4.25, SD 2.06), "physical comfort" (3.50, SD 1.29).

Safety Monitoring

No adverse symptoms were reported in either group.

Table 1. Baseline characteristics of participants (n=8)

		DTx group	**SE group**

Age (days)[a]		155(130)	150(64.41)
Sex[b]	Female	2(50)	3(25)
	Male	2(50)	1(25)
Involved side (Left)[b]	Left	3(75)	3(75)
	Right	1(25)	1(25)
TOA score (points)[a]	Total	12.50(3.32)	14.50(2.38)
	Rotation deficits	2.75(0.50)	3.00(0.00)
	Side flexion deficits	2.75(0.50)	2.50(0.58)
	Craniofacial asymmetry	2.25(0.96)	2.00(0.00)
	Residual band	3.00(0.00)	2.50(1.00)
	Head tilt	1.00(0.82)	2.00(0.00)
	Subjective assessment by parents	0.75(1.50)	2.50(1.61)

[a] Mean (standard deviation).
[b] n (%).

Table 2. Baseline and Result of the primary outcome: torticollis overall assessment score

	DTx group (points)			SE group (points)			P-value
	Mean ± SD	Within-individual change		Mean ± SD	Within-individual change		
Baseline (T0)	12.50 ± 3.32			14.50 ± 2.38			
4 Weeks (T1)	14.50 ± 2.08	T1-T0	2.00 ± 2.83	15.00±2.16	T1-T0	1.25 ± 2.19	.486
8 Weeks (T2)	15.50±1.73	T2-T0	3.00 ± 3.16	16.00±1.41	T2-T0	2.25 ± 2.38	.686
12 Weeks (T3)	16.25±2.36	T3-T0	3.75 ± 3.20	16.00±2.71	T3-T0	2.63 ± 2.50	.486

Table 3. Results of the secondary outcome: Amount of PT

	DTx group			SE group			
	Frequency (number/week)	Duration (min/session)	Amount (min/week)	Frequency (number/week)	Duration (min/session)	Amount (min/week)	P value
4 Weeks (T1)	10.25 ± 3.35	38.13 ± 27.64	368.75 ± 352.00	7.50 ± 3.32	14.88 ± 13.54	128.38 ± 130.92	.343
8 Weeks	7.75 ± 4.57	20.00 ± 26.77	143.75 ±	10.25 ±	18.75 ± 13.15	106.25 ±	.686

(T2)			185.98	9.00		54.37	
12 Weeks (T3)	8.63 ± 6.21	19.00 ± 21.15	167.38 ± 164.66	8.00 ± 9.02	12.50 ± 11.90	60.00 ± 44.91	.486

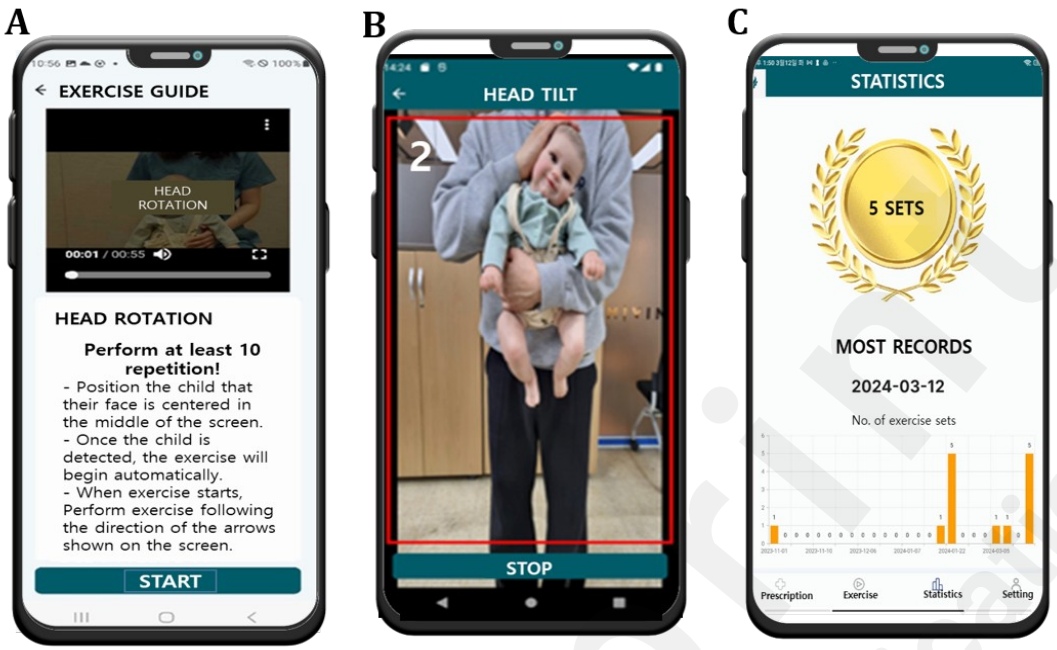


Figure 1. Screenshots of ACESO-APP: (A) PT guide screen, (B) PT screen, (C) Statistic data screen (a record of the amount of PT)

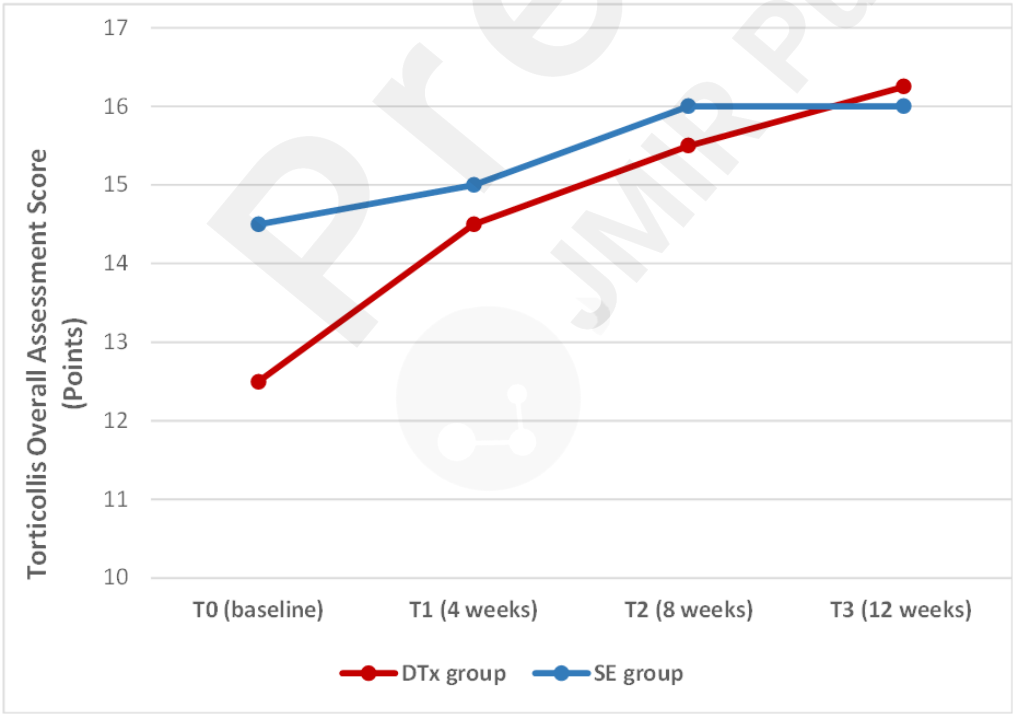


Figure 2. Torticollis overall score in the DTx and SE groups

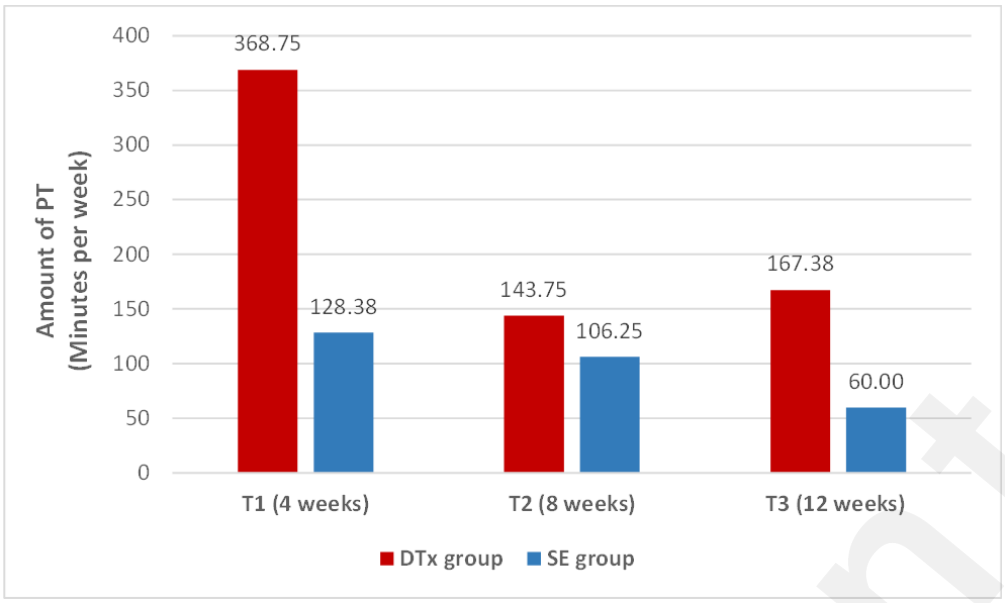


Figure 3. Total amount of PT in the DTx and SE groups

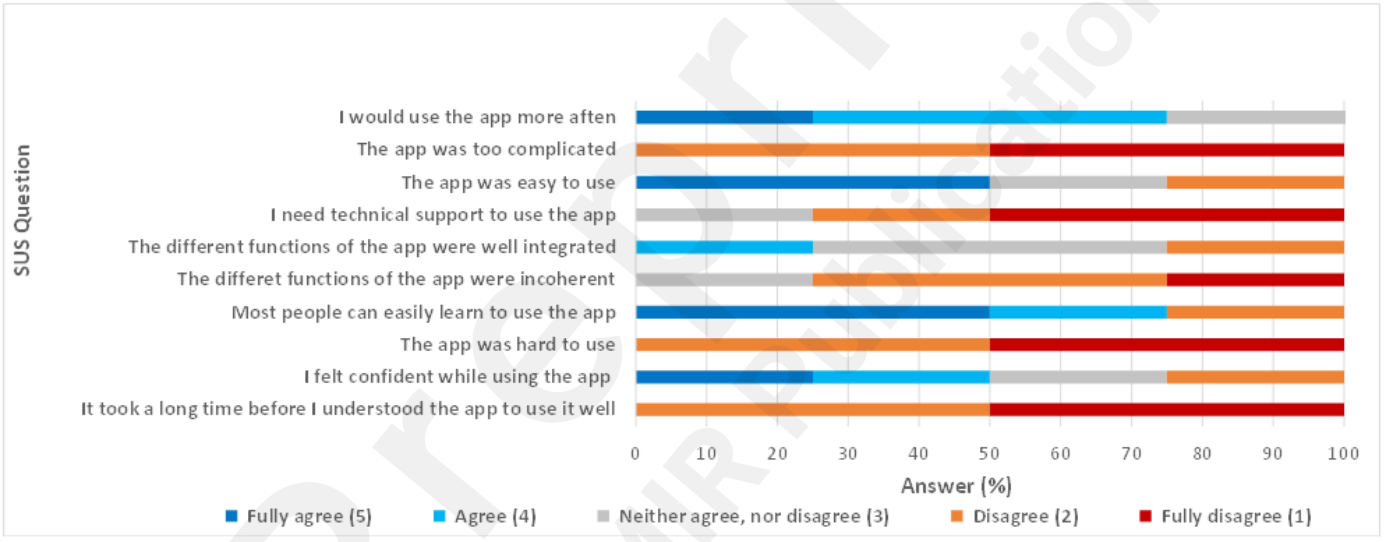


Figure 4. Scores in the SUS of ACESO-APP

Discussion

Principal Results

The purpose of this study was to evaluate the effectiveness, usability, and safety of ACESO-APP, which is the DTx providing home-based, AI-driven, and not-wearable device PT program with real-time feedback for corrective motion in infants with CMT. We observed a significant improvement in clinical assessment (TOA score) in all participants. Although the results of this study indicated no significant difference in changes in clinical improvement and PT amount between the DTx (using the ACESO-APP) and SE (receiving standard education) groups, a statistical trend toward an increase in changes in TOA score and PT amount in the DTx group indicated that a home-based PT program using the ACESO-APP may be a useful addition to conventional physical therapy. Considering that this was a pilot study including a small number of participants, it suggests the possibility of a greater effect of the ACESO-APP through a follow-up study. Moreover, as no major discomfort or good usability was observed with the ACESO-APP, more active research is possible.

Comparison with Prior Work

Research on DTx-utilizing wearable devices has advanced considerably in recent years and numerous sensors have been employed to build wearable systems for human movement monitoring. These sensors recognize human motion data, analyze it, and simulate correct postures. These systems often rely on inertial and electromyography (EMG) sensors to detect body movements [20, 21]. However, in the case of DTx using wearable devices, there are several limitations in terms of wearable comfort and security (e.g., wearable electronic products), especially in infants [20]. This study introduces a noninvasive DTx that uses skeleton-based motion analysis and AI-driven body reconstruction models. To analyze body movements without wearable devices, cameras or vision sensors must be used to track the skeleton. Skeleton-based motion analysis model converted 2D skeleton data to 3D skeleton data [14, 15]. An AI-based body reconstruction model uses AI techniques, such as deep learning, to reconstruct or analyze a user's body [22]. This AI model technique enables continuous AI feedback, assisting users to improve their posture and movement throughout the PT process. For example, previous studies have developed customized programs using AI-based computer vision technology, which analyzes the movement patterns during PT and provides corrective feedback for back pain [12, 13]. Furthermore, to improve the accuracy of inferring 3D movement, the AI model was trained using images captured with an RGBD camera, in this study. Even though quantitative measurement such as marker-based 3D motion analysis is considered the gold standard for motion tracking, it is time-consuming for accurate placement of markers and requires patients' cooperation [23, 24]. These limitations can be overcome using RGBD cameras with integrated 3D body-tracking functionality. These cameras are portable, affordable, and do not require expensive facilities or specialized personnel. The previous studies introduced a deep-learning model converting 2D skeleton data from RGBD cameras to 3D models to monitor patient movement for telerehabilitation with high accuracy [25, 26]. Another study also showed that this system was valid and accurate for various movement tasks in children [16]. The AI model may provide a convenient, safe, personalized, and real-time feedback system for corrective exercises, ultimately enhancing therapeutic effectiveness. It can also be cost-effective and can increase healthcare accessibility for patients who experience difficulties in contacting medical services. We suggest that DTx without wearable devices is a promising management strategy for children, particularly infants.

The primary intervention in infants with CMT involves stretching exercises targeting the affected SCM, and the key factors determining prognosis in CMT treatment are the intensity of the intervention and adherence to the home program [1, 5]. Because the dosage of PT available in hospitals is often limited, structured home-based PT may increase the overall amount of PT [6]. Therefore, ACESO-APP is considered a suitable treatment option for infants with CMT. Infants treated with the ACESO-APP reported a statistical trend of better outcomes and adherence to PT during the follow-up period of 12 weeks. Based on the satisfaction survey, we suggest that the interesting properties of the ACESO-APP contributed to sustained improvement in symptoms and facilitated PT adherence until 12 weeks. This may indicate that a home-based PT program using the ACESO-APP may be a useful addition to the conventional treatment.

Limitations

This study had several limitations. The major limitation of this study was its small sample size. Given the nature of the study involving infants, the dropout rate was high and influenced by the infants' medical conditions and caregivers' circumstances. Although we expected that DTx would provide a more effective home-based PT than standard education in CMT treatment, the results showed only a positive trend in the DTx group. We believe that the number of participants was too small to present a significant difference between the two groups. To the best of our knowledge, this is the first clinical study to provide preliminary findings that provide a good foundation for further

optimization of PT programs using DTx in infants with CMT. Second, this study reports the short-term effects of a 12-week PT program in infants with CMT. Our ongoing follow-up study needs to confirm the long-term benefits of DTx in a larger sample size and in a randomized controlled trial based on this pilot study. Finally, technological limitations may have affected the application of home-based PT using DTx. A few errors occurred during the login, which may have interfered with the participation and maintenance of PT. In addition, the ACESO-APP only included key PT (stretching exercise) lists in the pilot study. In the advanced version of the DTx, a more extensive list of exercises should be incorporated, encompassing a wider range of scenarios, such as exercises performed by two caregivers, an infant lying down, and a supplementary list of exercises (strengthening exercise).

Conclusions

In this study, we introduced the development of the digital therapeutic ACESO-APP (home-based, AI-driven, individualized, and real-time feedback) and preliminarily evaluated its potential as an additional or alternative treatment option for infants with CMT. This study addresses the current lack of adherence to home-based PTs in the medical service system. In future, we will continue to optimize the newly developed ACESO-APP and evaluate its efficacy in large-sample randomized controlled studies.

Acknowledgments

This study was supported by NextDoor.

Data Availability

The datasets generated or analyzed in this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

None declared.

Abbreviations

CMT: Congenital muscular torticollis
SCM: Sternocleidomastoid
PT: Physical therapy
AI: Artificial Intelligence
DTx: Digital therapeutics
RGBD: Red Green Blue Depth
TOA: Torticollis overall assessment
SUS: System Usability Scale
EMG: Electromyography

References

1. Kaplan SL, Coulter C, Sargent BJPPT. Physical therapy management of congenital muscular torticollis: a 2018 evidence-based clinical practice guideline from the APTA Academy of Pediatric Physical Therapy. Pediatr Phys Ther; 2018;**30**(4):240-290.
2. Do TTJ. Congenital muscular torticollis: current concepts and review of treatment. Curr Opin Pediatr; 2006;18(1):26-29.

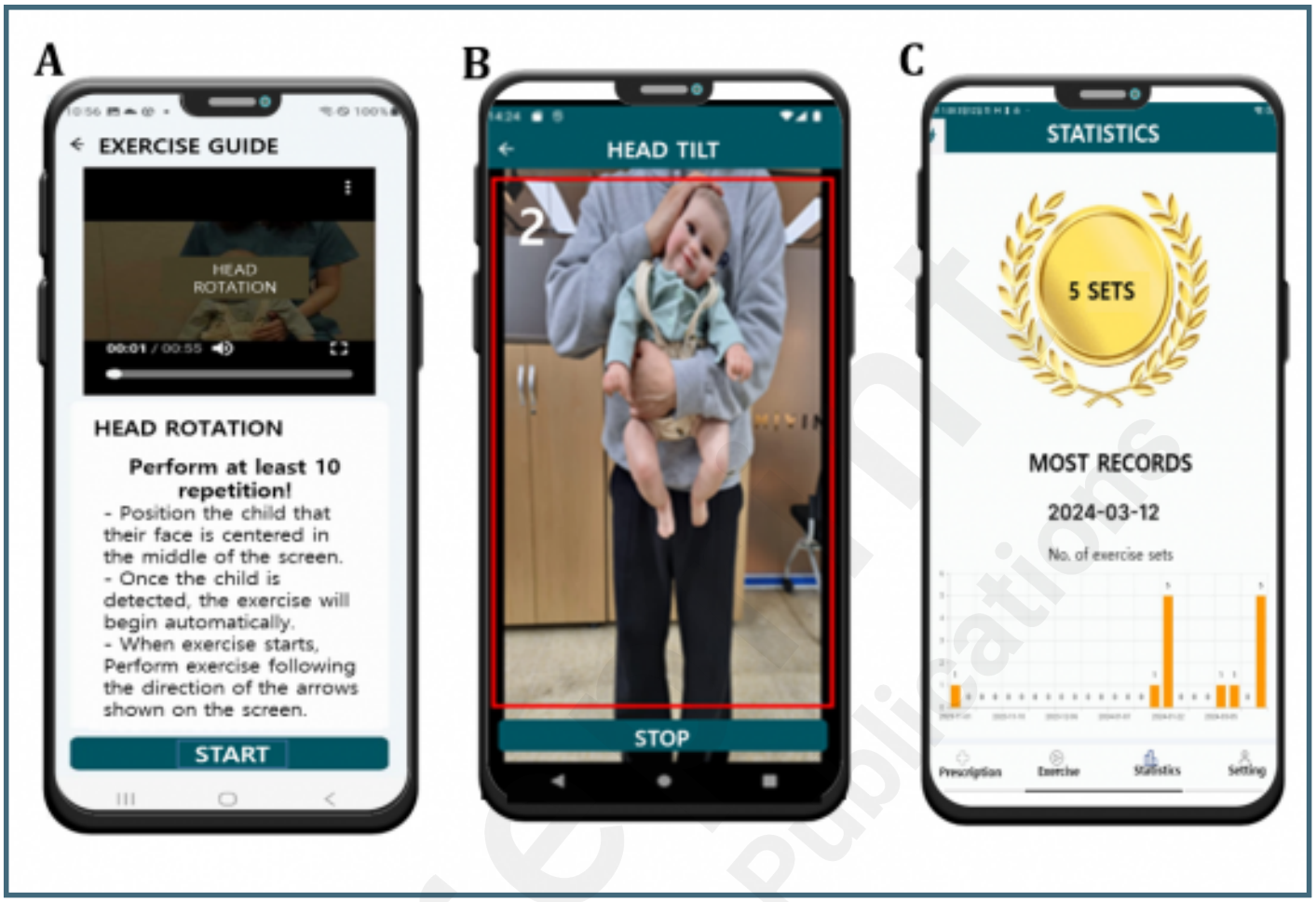
3. Sargent B, et al. Congenital muscular torticollis: bridging the gap between research and clinical practice. Pediatrics;2019;**144**(2).
4. Petronic I, et al. Congenital muscular torticollis in children: distribution, treatment duration and outcome. Pediatr Phys Ther; 2009;**46**(2):153-157.
5. He L, et al. Comparison of 2 dosages of stretching treatment in infants with congenital muscular torticollis: a randomized trial. Pediatrics; 2017;**96**(5):333-340.
6. Oledzka MM, et al. Experiences of parents of infants diagnosed with mild or severe grades of congenital muscular torticollis. Pediatr Phys Ther; 2020;**32**(4):322-329.
7. Jeong K-Y, Lee HJ, Yim S-Y. The usefulness, reliability, and quality of YouTube video clips on congenital muscular torticollis: A STROBE compliant study. Medicine (Baltimore); 2022;**101**(37):e30502.
8. Fürstenau D, et al. Digital therapeutics (DTx). Z Orthop Unfall; 2023;**65**(3):349-360.
9. Davis NO, Bower J, Kollins SH. Proof-of-concept study of an at-home, engaging, digital intervention for pediatric ADHD. PLos One; 2018;**13**(1):e0189749.
10. Kollins SH, et al. A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomised controlled trial. JAMA Netw Open; 2020;**2**(4):e168-e178.
11. Binder H, et al. Congenital muscular torticollis: results of conservative management with long-term follow-up in 85 cases. Pediatr Phys Ther; 1987;**68**(4):222-225.
12. Toelle TR, et al. App-based multidisciplinary back pain treatment versus combined physiotherapy plus online education: a randomized controlled trial. Npj Digit Med; 2019;**2**(1):34.
13. Huber S, et al. Treatment of low back pain with a digital multidisciplinary pain treatment app: short-term results. JMIR Pehabil Assist Technol; 2017;**4**(2):e9032.
14. Zhu W, et al. Motionbert: A unified perspective on learning human motion representations. In proceedings of the IEEE/CVF International Conference on Computer Vision. 2023.
15. Mehraban S, Adeli V, Taati B. Motionagformer: Enhancing 3d human pose estimation with a transformer-gcnformer network. In proceedings of the IEEE/CVF Winter Conference on Applications of Computer Vision. 2024.
16. Hesse N, et al. Concurrent Validity of Motion Parameters Measured With an RGB-D Camera-Based Markerless 3D Motion Tracking Method in Children and Young Adults. Pediatr Phys Ther; 2024.
17. Kaplan SL, Coulter C, Fetters LJ. Physical therapy management of congenital muscular torticollis: an evidence-based clinical practice guideline: from the Section on Pediatrics of the American Physical Therapy Association. Pediatr Phys Ther; 2013;**25**(4):348-394.
18. Cheng J, et al. The clinical presentation and outcome of treatment of congenital muscular torticollis in infants—a study of 1,086 cases. J Pediatr Orthop; 2000;**35**(7):1091-1096.
19. Brooke J. SUS-A quick and dirty usability scale. Usuability Evalutaion in Industry; 1996; **189**(194):4-7.
20. Huang X, et al. Sensor-Based wearable systems for monitoring human motion and posture: A review. Sensors (Basel); 2023;**23**(22):9047.
21. Bailey JF, et al. Digital care for chronic musculoskeletal pain: 10,000 participant longitudinal cohort study. JMIR Form Res; 2020;**22**(5):e18250.
22. Khan G, et al. A Brief Review of Recent Advances in AI-Based 3D Modeling and Reconstruction in Medical, Education, Surveillance and Entertainment. in 2024 29th International Conference on Automation and Computing (ICAC); IEEE; 2024.
23. Eichelberger P, et al. Analysis of accuracy in optical motion capture–A protocol for laboratory setup evaluation. Gait Posture; 2016;**49**(10):2085-2088.
24. Armand S, Decoulon G, Bonnefoy-Mazure A. Gait analysis in children with cerebral palsy.

Expert Rev Med Devices; 2016;**1**(12)448-460.
25. Zhu J, et al. Transformative skeletal motion analysis: optimization of exercise training and injury prevention through graph neural networks. J Biomech; 2024;**18**:1353257.
26. Maskeliūnas R, et al. Biomac3d: 2d-to-3d human pose analysis model for tele-rehabilitation based on pareto optimized deep-learning architecture. Comput Methods Programs Biomed; 2023;**13**(2):1116.

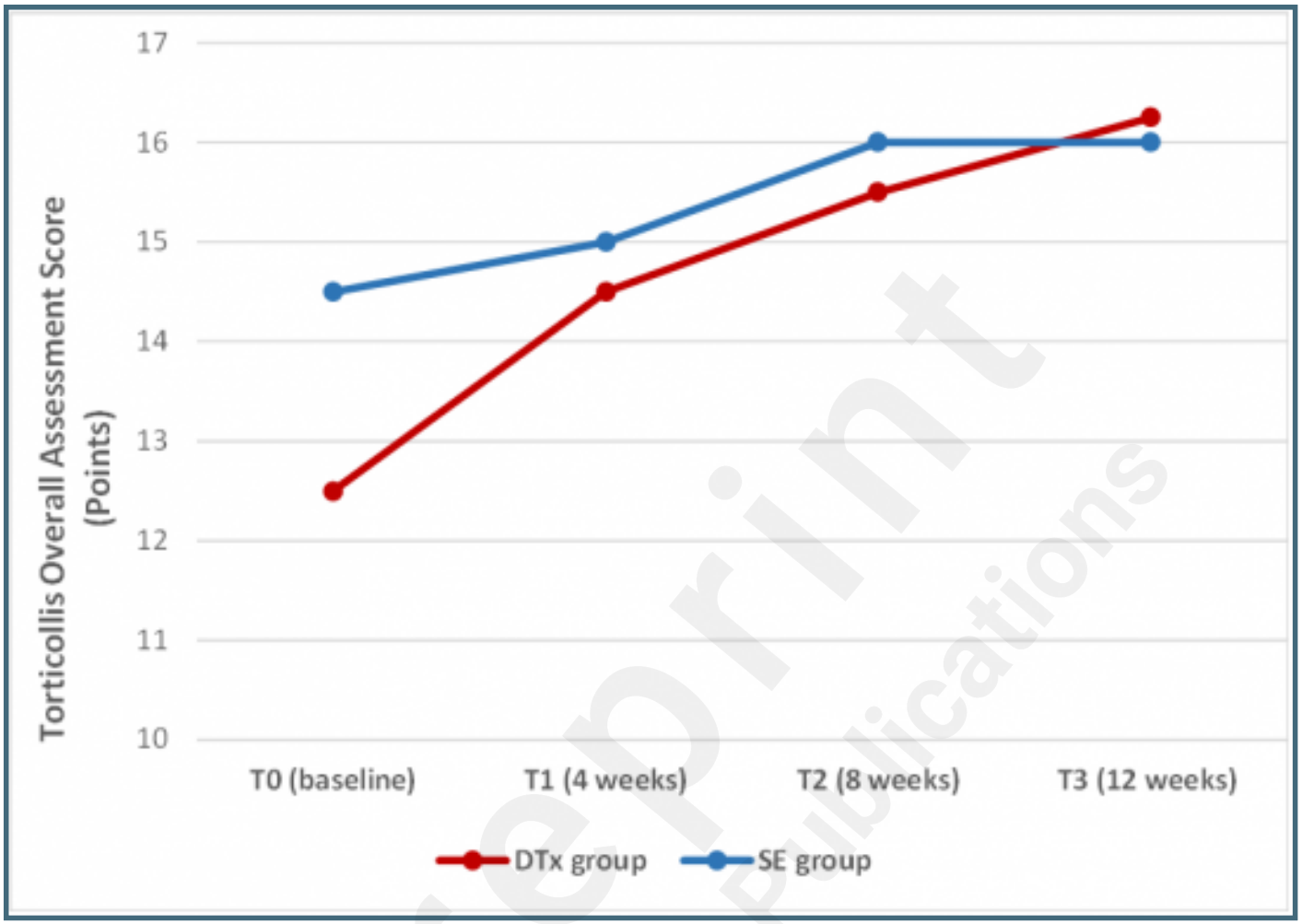
Supplementary Files

Figures

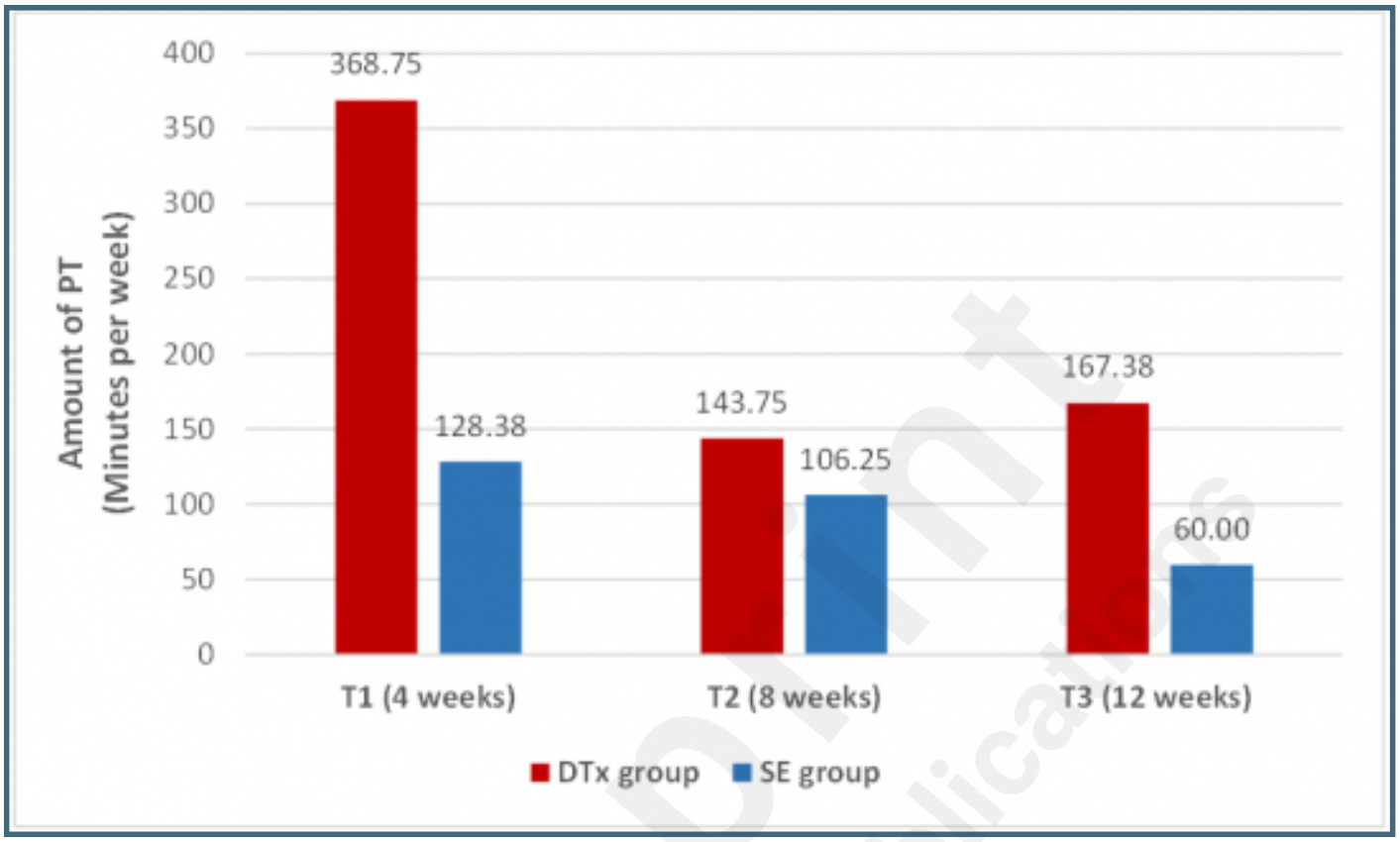
Screenshots of ACESO-APP: (A) PT guide screen, (B) PT screen, (C) Statistic data screen (a record of the amount of PT).



Torticollis overall score in the DTx and SE groups.



Total amount of PT in the DTx and SE groups.



Scores in the SUS of ACESO-APP.