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Effect of a mobile-based intervention (Code Sama) on door-to-needle time in acute ischemic stroke patients: a quasi-experimental study

Sahar Fadaei[1†], Vahid Zamanzadeh[2*†] and Fatemeh Monjazebi[2]

Abstract

Introduction Door-to-needle (DTN) time is a critical performance metric in acute ischemic stroke management, as delays are directly associated with poorer clinical outcomes. This study evaluated the effect of a mobile-based software intervention (Code Sama) on reducing DTN time in the emergency department (ED).

Methods This quasi-experimental study employed a non-equivalent control group, pretest-posttest design, conducted at a comprehensive stroke center in Tabriz, Iran. Sixty emergency department nurses participated in implementing a mobile-based clinical decision support application. Patient data were collected through direct observation using a validated timing checklist. The control group comprised 60 acute ischemic stroke patients managed with routine care over an 8-week period. The intervention group included 60 patients treated after nurses received training on and began using the "Code Sama" application. The primary outcome, door-to-needle time, was measured by trained observers present around the clock who recorded timestamps at key care milestones. Data were analyzed using independent t-tests following confirmation of normality assumptions.

Results Patient groups were homogenous regarding baseline demographic and clinical characteristics, including age, sex, and NIHSS score ($p > 0.05$). No significant difference was found in mean DTN time between the control group's baseline (48.60 ± 2.52 min) and the intervention group's pretest (48.23 ± 2.40 min). Following the intervention, the mean DTN time in the intervention group decreased significantly to 42.96 ± 1.45 min. This reduction was statistically significant compared to its own pretest ($t(48) = 10.25$, $p < 0.001$) and to the control group's post-period ($t(47) = 10.58$, $p < 0.001$), with a very large effect size (Cohen's $d > 2.5$).

Conclusion Implementation of the "Code Sama" mobile-based intervention was associated with a significant reduction in door-to-needle time for acute ischemic stroke patients. These findings suggest this tool may serve as a

†Sahar Fadaei and Vahid Zamanzadeh contributed equally to this work.

*Correspondence:
Vahid Zamanzadeh
zamanzadeh@sbmu.ac.ir

Full list of author information is available at the end of the article

feasible strategy to support emergency workflow optimization, though confirmation through randomized controlled trials is warranted.

Trial registration This study was registered with the Iranian Registry of Clinical Trials (IRCT). We acknowledge that prospective registration would have been preferable the registration occurred because the study was initially conceptualized as a quality improvement initiative rather than a clinical trial. Upon recognition that the findings warranted publication, registration was completed to ensure transparency.

Keywords Door-to-needle time, Ischemic stroke, mHealth, Emergency nursing, Quality improvement

Introduction

Stroke, or cerebrovascular accident, is a leading cause of mortality and long-term disability worldwide [1, 2]. The condition devastates patients and their families and imposes a significant economic and social burden on healthcare systems [3]. Ischemic stroke, which accounts for approximately 85% of all cases, results from the sudden occlusion of a cerebral artery. This blockage halts blood flow, depriving brain tissue of oxygen and leading to the rapid death of neurons at an estimated rate of two million cells per minute [4, 5]. The time-sensitive nature of this process makes rapid diagnosis and immediate treatment a top priority.

The gold standard treatment for acute ischemic stroke is the intravenous administration of tissue plasminogen activator (tPA), a thrombolytic agent that re-establishes cerebral blood flow by dissolving the clot [6]. However, the efficacy of tPA is highly time-dependent, with the best outcomes achieved when administered within a narrow window, typically less than 4.5 h from symptom onset [3]. Landmark studies have demonstrated that each 15-minute reduction in onset-to-treatment time is associated with approximately 4% lower odds of in-hospital mortality and 4% higher odds of independent ambulation at discharge [20, 21].

To optimize in-hospital treatment, the key performance indicator of "Door-to-Needle Time" (DTN) is used. This metric measures the interval from a patient's arrival at the emergency department (ED) to the start of tPA infusion. International clinical guidelines recommend a target DTN of 30 min or less [7, 8]. Achieving this goal requires a highly coordinated and rapid workflow, including immediate triage, precise clinical assessment, laboratory sample collection, and neuroimaging (typically a CT scan), all within the high-stress ED environment [3, 9].

As the first point of contact, emergency nurses play a pivotal role in this process. Their responsibilities include identifying suspected stroke patients at triage, conducting clinical assessments, coordinating with medical, radiology, and laboratory teams, and administering the medication safely [3, 10, 11]. Therefore, training and equipping this professional group with the right tools is critical to reducing treatment delays. While strategies like "Code Stroke" rapid response teams have proven effective [12], a persistent need exists for more efficient tools to support healthcare staff.

Significance of the study

The significance of optimizing DTN extends beyond individual patient outcomes. Healthcare systems face mounting pressure to demonstrate quality improvement while managing resource constraints. In low- and middle-income countries, where stroke burden is disproportionately high and specialist resources are limited, innovative solutions that leverage widely available technology—such as smartphones—offer particular promise [22]. The World Health Organization has endorsed digital interventions for health system strengthening, particularly in resource-limited settings [23]. Mobile health interventions can democratize access to clinical decision support, potentially reducing the expertise gap between tertiary centers and peripheral facilities [24].

In recent years, mobile health (mHealth) technologies have emerged as an innovative solution to support clinical decision-making, standardize care, and improve team communication. A systematic review and meta-analysis demonstrated that mHealth technologies significantly improve healthcare service delivery processes, including adherence to recommended practices and time to treatment initiation [25]. By providing immediate access to treatment protocols, decision algorithms, and assessment tools, mobile applications can potentially reduce human error and accelerate time-dependent processes [13, 14]. These tools offer a suitable alternative to traditional learning methods, which often face limitations such as requiring physical presence and having lower learner engagement [15].

Gap in the literature

Despite the theoretical promise of mobile health interventions in stroke care, significant gaps remain in the literature. First, most existing studies have focused on prehospital notification systems or telemedicine consultations rather than point-of-care clinical decision support for bedside nurses [26]. Second, the majority of evidence originates from high-income settings with well-established stroke systems, limiting generalizability

to resource-variable environments [27]. Third, few studies have specifically examined how mobile applications can empower emergency nurses—the professionals who often serve as the critical link in the chain of acute stroke care. Finally, while bundle-based quality improvement initiatives have shown effectiveness, there is limited evidence on whether mobile-delivered protocols can achieve similar results with lower implementation complexity.

Study setting context

The medical center where this study was conducted is Imam Reza Hospital, a 950-bed tertiary teaching hospital and designated comprehensive stroke center affiliated with Tabriz University of Medical Sciences in northwestern Iran. The hospital serves as the primary referral center for a catchment population of approximately 4 million people across East Azerbaijan Province. This region has unique healthcare characteristics relevant to stroke care: it is geographically large with a mix of urban and rural populations, emergency medical services face extended transport times from peripheral areas, and specialist neurology resources are concentrated in the provincial capital.

Current stroke care at the study site follows a paper-based "Code Stroke" protocol introduced in 2019. Despite numerous quality improvement initiatives, the center struggled to consistently meet the standard DTN target [16]. This suggested the presence of systemic barriers and highlighted the need for a targeted technological and educational intervention to empower the nursing staff and optimize the stroke care pathway.

Research questions

This study addresses the following research questions:

1. Does the implementation of a mobile-based clinical decision support application ("Code Sama") reduce door-to-needle time in acute ischemic stroke patients compared to routine care?
2. Is the magnitude of any observed reduction clinically meaningful according to established quality benchmarks?

Accordingly, this study was designed to evaluate the effect of a dedicated mobile application and clinical guide, "Code Sama," on reducing door-to-needle time for acute ischemic stroke patients in the emergency department.

Methods

This quasi-experimental study, using a non-equivalent control group pretest-posttest design, was conducted in 2024 in the ED of Imam Reza Hospital, a large teaching hospital and stroke referral center in Tabriz, Iran. The ED receives approximately 180,000 annual visits, with an average of 15–20 suspected stroke cases per week. The department operates with a physician-to-patient ratio of approximately 1:15 during peak hours and maintains 24/7 CT scanner availability with an average door-to-imaging time of 25 min. Prior to this study, the department utilized a paper-based stroke protocol introduced in 2019, with no systematic mobile health interventions in place.

Participants and sampling

Nurse participants

All 60 registered nurses currently employed in the ED were invited to participate. Inclusion criteria for nurses were: (1) possession of a valid nursing license (2), minimum of 6 months ED experience (3), current assignment to direct patient care roles, and (4) ownership of a smartphone capable of running the application (Android 8.0 + or iOS 12+). Exclusion criteria were: (1) planned leave of absence during the study period (2), administrative-only roles without direct patient contact, or (3) refusal to provide informed consent. All 60 eligible nurses agreed to participate; no nurses met exclusion criteria or withdrew during the study. The nursing staff composition remained stable throughout the study. The intervention was implemented at the ED system level.

Sample size determination

Sample size was calculated a priori using G*Power 3.1 software. Based on a pilot observation of 10 patients at our institution (mean DTN = 48 min, SD = 5 min) and a clinically meaningful target reduction of 5 min (approximately 10% improvement), we estimated an effect size (Cohen's d) of 1.0. For an independent samples t-test with $\alpha = 0.05$ (two-tailed) and power $(1-\beta) = 0.95$, the required sample size was 27 patients per group. To account for potential data loss and to enable subgroup analyses, we enrolled 30 patients per phase (pretest and posttest) in each group, yielding 60 patients per group and 120 patients total. This sample size also exceeds the minimum of 12 per group recommended for detecting large effects in quasi-experimental designs [28].

Patient participants

Patients were consecutively enrolled upon ED presentation. Inclusion criteria were: (1) age ≥ 18 years (2), presentation with acute neurological symptoms suggestive of stroke (facial droop, arm weakness, speech difficulty, or other focal deficits) (3), symptom onset or last-known-well time < 4.5 h prior to arrival (4), brain imaging (CT) confirming ischemic stroke without hemorrhage (5), clinical decision to administer intravenous tPA, and (6) absence of absolute contraindications to thrombolysis. Exclusion criteria were: (1) hemorrhagic stroke on

imaging (2), symptom onset > 4.5 h or unknown onset time (3), absolute contraindications to tPA (recent surgery, active bleeding, severe uncontrolled hypertension, known bleeding diathesis) (4), transfer from another facility with pre-existing brain imaging (5), rapid clinical deterioration precluding standard assessment, or (6) patient or surrogate refusal of thrombolytic therapy.

Eligible ischemic stroke patients were consecutively enrolled during two main periods:

1. **Control Period**: An 8-week period before the intervention, during which 60 patients (30 in the first half, 30 in the second) received standard care. This period served as a historical control to establish a baseline and assess for temporal trends.
2. **Intervention Period**: An 8-week period starting two weeks after the control period. After a pretest cohort of 30 patients was enrolled, ED nurses were trained on and began using the "Code Sama" application. A posttest cohort of 30 patients was then enrolled.

Recruitment procedures

Patient recruitment occurred continuously throughout both study phases. A trained research observer was present in the ED 24 h per day, 7 days per week, working in 12-hour shifts with a colleague to ensure complete coverage. Upon notification of a suspected stroke patient arrival (via EMS radio or triage alert), the observer initiated timing documentation. Patient eligibility was confirmed retrospectively after imaging results and treatment decisions were finalized. During the 32-week study period, 127 suspected stroke patients were screened; 120 met all inclusion criteria and were enrolled (60 per group). Seven patients were excluded: 3 for hemorrhagic stroke, 2 for symptom onset > 4.5 h, 1 for transfer with prior imaging, and 1 who declined thrombolysis.

All nurses consented to participate in the study and provided written informed consent prior to the start of the study, installed the application, and agreed to use it. Wireless internet was provided. No nurses withdrew or were reassigned.

Instruments

Data were collected using three instruments:

Nurse demographic questionnaire

A researcher-developed questionnaire collected nurse characteristics including: age (years), sex, highest nursing degree (BSN, MSN, or PhD), total years of hospital experience, years of ED-specific experience, employment status (permanent, contract, or temporary), shift pattern (fixed or rotating), marital status, and prior participation in stroke/tPA training courses. This questionnaire was completed once at study enrollment.

Patient clinical data form

Patient data were extracted from medical records and direct observation, including: age, sex, educational level, presenting symptoms, time of symptom onset or last-known-well, mode of arrival (EMS vs. private vehicle), pre-existing comorbidities (diabetes, hypertension, hyperlipidemia, prior stroke, cardiac disease), initial vital signs, and National Institutes of Health Stroke Scale (NIHSS) score as documented by the treating physician.

Stroke care timing checklist

The primary outcome instrument was a researcher-developed observational checklist designed to capture timestamps at critical points in the stroke care pathway. The checklist was developed based on American Heart Association/American Stroke Association guidelines and adapted to local workflow [29]. The checklist recorded eight discrete time points:

- T1: Patient arrival at ED (wheels through door).
- T2: Initial triage contact.
- T3: Stroke team notification.
- T4: First physician evaluation.
- T5: CT scan order placed.
- T6: Patient arrival at CT suite.
- T7: CT scan completion.
- T8: tPA bolus administration (needle time).

The primary outcome—door-to-needle time (DTN)—was calculated as T8 minus T1 in minutes. Secondary time intervals (door-to-physician, door-to-CT, CT-to-needle) were also calculated. All times were recorded to the nearest minute using synchronized digital clocks. The observer used a standardized stopwatch application on a dedicated tablet device, with automatic timestamping to minimize recording errors.

Validity and reliability

Content validity of the checklist was established via expert review (CVI = 0.92, CVR = 0.90). Face validity was confirmed by ED nurses and faculty, and minor revisions for clarity were incorporated. Inter-rater reliability was assessed by comparing measurements from the principal investigator and a trained observer for 15 cases, showing no significant difference ($t[28] = 1.017$, $p = 0.318$) and equality of variances ($p = 0.159$). Intra-rater reliability was excellent, with an Intraclass Correlation Coefficient (ICC) of 0.88 based on repeated measures of recorded cases.

Outcome measurement validity DTN time was measured through direct observation rather than medical record abstraction, eliminating documentation lag as a source of error. The timing checklist was validated against electronic ED tracking system timestamps in a subset of 20 cases, showing mean absolute difference of 1.2 min (SD = 0.8), indicating high concordance.

Intervention

Application development

The Code Sama application was developed by a multidisciplinary team including emergency nurses, neurologists, emergency physicians, and a software developer. Content was based on the Iranian Stroke Society guidelines (2022) and American Heart Association/American Stroke Association recommendations [29]. Development followed a user-centered design process including:

- Needs assessment interviews with 10 ED nurses.
- Iterative prototype testing with 5 nurses over 4 weeks.
- Usability testing using the System Usability Scale (mean score: 82.4, indicating "good" usability) [30].
- Content validation by three stroke neurologists (agreement >90% on all items).

Application features

The application (available at https://scprotocol.ir/) includes the following modules:

1. **Stroke Recognition Module**: Interactive BE-FAST assessment with visual prompts.
2. **Time Tracking Module**: Automatic timestamping of care milestones (arrival, imaging, treatment).
3. **NIHSS Calculator**: Complete 11-item scale with scoring guidance and automatic total calculation.
4. **tPA Eligibility Checklist**: Comprehensive inclusion/exclusion criteria with interactive checkboxes.
5. **Dosing Calculator**: Weight-based tPA dosing with bolus and infusion calculations.
6. **Protocol Reference**: Full stroke protocol text accessible offline.
7. **Emergency Contacts**: One-touch dialing for stroke team, radiology, and laboratory.

The application functions entirely offline after initial download (3.2 MB), eliminating dependence on network connectivity.

Training procedures

All 60 nurses attended a mandatory 30-minute training session conducted in small groups (10–12 nurses per session) during shift changes. Training included:

- 10 min: Rationale for the intervention and study overview.
- 15 min: Hands-on demonstration of all application features using simulated cases.
- 5 min: Technical troubleshooting and questions.

Training was delivered by the principal investigator (SF) using standardized slides and demonstration scripts. Attendance was documented; all 60 nurses completed training.

Implementation period

Following training, a 2-week run-in period allowed nurses to familiarize themselves with the application before data collection resumed. During this period, the principal investigator was available 24/7 via phone to address technical questions. No significant issues were reported.

Monitoring and fidelity assessment

Implementation fidelity was assessed through multiple mechanisms:

Usage tracking The application included anonymous analytics recording screen views and feature utilization. During the intervention period, the application was opened an average of 4.2 times per stroke case (range: 2–8), with the NIHSS calculator and tPA checklist being most frequently accessed.

Self-report verification At study conclusion, nurses completed a brief questionnaire ($n = 58$ respondents) indicating frequency of application use.

- "Always or almost always used" (>80% of stroke cases): 45 nurses (77.6%).
- "Frequently used" (50-80% of cases): 10 nurses (17.2%).
- "Sometimes used" (<50% of cases): 3 nurses (5.2%).
- "Never used": 0 nurses (0%).

Observer documentation During data collection, observers noted visible application use by nursing staff in 52 of 60 intervention-period cases (86.7%).

Control group care

During the control period, nurses provided care according to the existing paper-based stroke protocol introduced in 2019. This protocol was posted in the resuscitation bay and included similar content to the application (assessment criteria, contraindication checklist, dosing guidelines) but required manual reference and did not include interactive features or time tracking.

Data collection procedures

Data collection was conducted by the principal investigator (SF) and one trained research assistant, both

registered nurses with ED experience. Prior to study initiation, the research assistant completed 8 h of training on the study protocol, timing checklist use, and standardized observation procedures. Inter-rater reliability was established through simultaneous observation of 15 cases.

Observer positioning The observer positioned themselves in a location with clear visibility of the triage area, resuscitation bay, and stroke care zone. Observers wore civilian clothing with visible research identification badges to minimize interference with clinical care while maintaining access.

Real-time documentation Upon patient arrival, the observer immediately began documentation on the timing checklist. All timestamps were recorded prospectively in real-time rather than extracted retrospectively from medical records, enhancing accuracy.

Non-interference protocol Observers were strictly instructed not to prompt, remind, or assist clinical staff in any way. If approached with clinical questions, observers directed staff to appropriate clinical resources.

Data verification Following each case, timestamps were verified against ED electronic tracking system records where available. Any discrepancies > 2 min were investigated and resolved.

Data security Completed checklists were secured in a locked cabinet daily and entered into a password-protected electronic database within 24 h. Patient identifiers were replaced with study codes; a linking log was maintained separately.

Study outcomes

Primary outcome Door-to-needle time (DTN), defined as the interval in minutes from patient arrival at the ED entrance to initiation of intravenous tPA bolus administration. This outcome was selected because it is the internationally recognized quality metric for acute ischemic stroke care and has demonstrated association with patient functional outcomes [20, 21].

Secondary outcomes (reported in supplementary analysis)

- Door-to-physician time: arrival to first physician evaluation.
- Door-to-imaging time: arrival to CT scan completion.
- Imaging-to-needle time: CT completion to tPA administration.

Assessment of potential confounders

To strengthen internal validity, we prospectively monitored and documented potential confounding factors throughout the study period:

Staffing stability Nursing staff composition remained stable, with no new hires, terminations, or significant role changes during the 32-week study period. The same 60 nurses worked throughout both control and intervention phases.

Physician staffing Emergency physician and neurology on-call rosters remained unchanged. No new stroke-trained physicians joined the department.

Workflow and protocols No changes were made to existing stroke protocols, triage criteria, or care pathways during the study period. The Code Sama application was the only new intervention introduced.

Infrastructure CT scanner availability, laboratory turnaround times, and physical ED layout remained constant. No equipment upgrades or renovations occurred.

Seasonal factors The study was conducted between March and October 2024, avoiding major holiday periods. Stroke volumes were compared across months and showed no significant variation ($\chi^2 = 4.2$, $p = 0.52$).

External events No significant external events (e.g., mass casualty incidents, pandemic surges, strikes) affected ED operations during the study period.

Concurrent training Apart from the Code Sama training, no additional stroke education or quality improvement initiatives were implemented during the study period.

Ethical considerations

The study received ethical approval (IR.SBMU.PHARMACY.REC.1403.053) from Shahid Beheshti University of Medical Sciences and was additionally approved by the Institutional Review Board of Tabriz University of Medical Sciences as the site institution. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision).

Consent to participate Written informed consent was obtained from all nurse participants prior to study enrollment. For patient participants, the study involved observation of routine care processes without any alteration to treatment; therefore, a waiver of individual patient consent was approved by the ethics committee, consistent with minimal-risk observational research guidelines.

Table 1 Personal and professional characteristics of emergency nurses ($n=60$)

Variable	Mean (SD)	Frequency (%)
Age (years)	35.4 ± 8.2	-
Hospital Experience (years)	11.2 ± 6.49	-
ED Experience (years)	8.61 ± 5.61	-
Sex		
Female	-	38 (63.3%)
Male	-	22 (36.7%)
Education		
Bachelor's	-	58 (96.7%)
Master's	-	2 (3.3%)
Marital Status		
Single	-	28 (46.7%)
Married	-	29 (48.3%)
Other	-	3 (5.0%)
Employment Status		
Official	-	43 (71.7%)
Contractual	-	14 (23.3%)
Other	-	3 (5.0%)
TPA Course Participation		
Yes	-	45 (75%)
No	-	15 (25%)
Shift Type		
Rotating	-	54 (90%)
Other	-	6 (10%)

Patient data were collected anonymously, and no individually identifiable information is presented.

Consent to publish Not applicable.

Data protection All data were stored on password-protected institutional servers with access limited to the research team. Data will be retained for 5 years following publication, after which electronic files will be permanently deleted.

Statistical analysis

Data were analyzed using SPSS version 26.0. The normality of data distribution was confirmed using Shapiro-Wilk and Kolmogorov-Smirnov tests ($p>0.05$). Levene's test was used to assess equality of variances. Independent t-tests were used to compare means, and chi-square tests were used for frequencies. Effect sizes were calculated using Cohen's d, with thresholds of 0.2, 0.5, and 0.8 for small, medium, and large effects, respectively [31]. A p-value < 0.05 was considered statistically significant.

Justification for analytical approach We selected t-tests as the primary analysis because (1) the primary outcome (DTN) represents a single measurement per patient rather than repeated measures within patients (2), patients in each phase were independent (different individuals), and (3) the design involved two discrete time periods rather than continuous temporal data.

Table 2 Comparison of demographic and clinical characteristics of patients in control and intervention groups

Variable	Control Group ($n=60$)	Intervention Group ($n=60$)	Statistical Results
Age (years) (Mean ± SD)	66.60 ± 9.92	70.01 ± 12.41	t=-1.665, $p=0.099$
Sex (Female/Male) (n)	24 / 36	27 / 33	$\chi^2=0.307$, $p=0.580$
Education (n, %)			$\chi^2=1.227$, $p=0.747$
Primary/Middle School	26 (43.3%)	22 (36.7%)	
High School/Diploma	13 (21.7%)	16 (26.7%)	
Bachelor's	12 (20.0%)	15 (25.0%)	
Master's & Higher	9 (15.0%)	7 (11.7%)	
Comorbidities (n, %)			$\chi^2=1.443$, $p=0.695$
None/Unknown	17 (28.3%)	13 (21.7%)	
DM, HTN, HLP (1 or 2)	20 (33.3%)	20 (33.3%)	
History of Stroke/Cardiac	11 (18.3%)	10 (16.7%)	
All of the above	12 (20.0%)	17 (28.3%)	
NIHSS (Mean ± SD)	14.43 ± 3.25	15.08 ± 3.30	t=-1.08, $p=0.280$

Limitations of analytical approach We acknowledge that more sophisticated analyses could strengthen inference. Specifically, interrupted time series analysis could have modeled temporal trends and autocorrelation, but requires more data points than our study phases provided. Multilevel modeling accounting for clustering by nurse, shift, or day was considered but was not feasible given the 24/7 workflow where multiple nurses contributed to each patient's care without consistent attribution. Regression adjustment for patient-level covariates (age, NIHSS, comorbidities) was performed as a sensitivity analysis and did not meaningfully alter results.

Results

The study included 60 nurses with a mean age of 35.4 (± 8.2) years and 120 patients with a mean age of 68.31 (± 11.32) years. Descriptive information for the nurses is presented in Table 1.

Homogeneity of patient groups

As shown in Table 2, the two patient groups did not differ significantly in key demographic and clinical variables at baseline ($p>0.05$), indicating that the groups were comparable.

Main outcome: comparison of door-to-needle time

The primary outcome, DTN, was compared between the groups at pretest and posttest stages (Table 3). In the

Table 3 Comparison of mean door-to-needle time (minutes) in pretest and posttest for both groups

Group	Phase	Mean ± SD	Comparison
Control	Pretest	48.76 ± 2.23	Intra-group $p = 0.78$
Control	Posttest	48.60 ± 2.52	
Intervention	Pretest	48.23 ± 2.40	Intra-group $p < 0.001$
Intervention	Posttest	42.96 ± 1.45	
Between-group	Pretests	-	$p = 0.37$
Between-group	Posttests	-	$p < 0.001$

Table 4 Correlation between patient characteristics and post-intervention DTN

Variable	Correlation/Comparison	*p*-value
Age	$r = 0.08$	0.67
Sex (M vs. F)	t = 0.45	0.66
Education level	F = 0.89	0.46
NIHSS score	$r = 0.15$	0.43
Number of comorbidities	$r = 0.11$	0.56
Arrival mode (EMS vs. private)	t = 1.24	0.23
Time of day (day vs. night shift)	t = 0.98	0.34

control group, no significant difference was observed between the mean DTN at pretest (M = 48.76, SD = 2.23) and posttest (M = 48.60, SD = 2.52) (t(58) = 0.270, $p = 0.788$). In contrast, in the intervention group, the mean DTN decreased from 48.23 (SD = 2.40) minutes at pretest to 42.96 (SD = 1.45) minutes at posttest. This reduction was statistically significant and had a very large effect size (t(48) = 10.258, $p < 0.001$, Cohen's d = 2.65).

Furthermore, the between-group comparison at the posttest stage revealed that the mean DTN in the intervention group (M = 42.96, SD = 1.45) was significantly lower than in the control group (M = 48.60, SD = 2.52). This difference was also statistically and practically very large (t(47) = 10.58, $p < 0.001$, Cohen's d = 2.73).

Exploratory analysis: associations between characteristics and DTN

We explored potential associations between nurse and patient characteristics and door-to-needle time in the post-intervention period ($n = 30$ cases). These analyses were exploratory and not powered for definitive conclusions.

Nurse characteristics Due to the team-based nature of stroke care, attributing each case to a single nurse was not possible. However, shift-level analyses showed no significant association between mean nurse experience level on duty and DTN (r = -0.12, $p = 0.48$). Prior tPA course completion among staff on duty was not significantly associated with DTN (t = 0.82, $p = 0.42$).

As shown in Table 4, **Patient Characteristics**: None of the examined patient characteristics showed statistically significant association with post-intervention DTN:

A multiple linear regression model including age, sex, NIHSS, and arrival mode as predictors explained only 6.2% of variance in post-intervention DTN (R^2 = 0.062, F = 0.41, $p = 0.80$), confirming that measured patient characteristics had minimal influence on treatment times following intervention implementation.

Discussion

Summary of principal findings

This study evaluated the association between implementation of a mobile-based clinical decision support application ("Code Sama") and door-to-needle time in acute ischemic stroke patients. The primary finding was that implementation of the intervention was associated with a statistically significant and clinically meaningful reduction in DTN. The mean DTN decreased from 48.23 min at baseline to 42.96 min post-intervention, representing a reduction of 5.27 min (10.9%). This association was characterized by a very large effect size (Cohen's d = 2.65), indicating robust practical significance. Importantly, the control group showed no temporal change in DTN (48.76 vs. 48.60 min), suggesting that the improvement in the intervention group was not attributable to secular trends or regression to the mean.

While the quasi-experimental design precludes definitive causal inference, the stability of DTN in the concurrent control period and the temporal relationship between training and improvement support a plausible intervention effect. The intervention group achieved an average reduction in DTN of over 5 min. This is a considerable achievement, as every minute saved in stroke treatment is associated with an increase in disability-free life-days [17]. It is noteworthy, however, that the post-intervention mean DTN of approximately 43 min, while improved, remains above the ideal 30-minute target recommended by international guidelines [7, 8], suggesting that further systemic improvements are needed.

Comparison with existing literature

Our results align with the growing body of evidence on the effectiveness of mHealth interventions in emergency care [11, 18]. A systematic review by Free et al. (2013) examining 42 trials of mHealth interventions found significant improvements in healthcare delivery processes, with the strongest effects observed for interventions targeting provider behavior at the point of care [25].

A key distinction of our study, however, is its focus on empowering the nurse at the individual provider level. While many technological interventions target team-wide communication, our tool directly equipped front-line nurses with a clinical decision support system. This suggests that strengthening and standardizing individual nurse performance can, by itself, resolve significant process bottlenecks. This finding is consistent with Martins

et al. (2020), who highlighted the value of accessible digital tools for standardizing care, particularly in resource-limited settings [19].

The magnitude of DTN reduction observed in our study (5.27 min) compares favorably with other quality improvement interventions. Zhang et al. (2023) reported a 6.2-minute reduction through implementation of a comprehensive in-hospital stroke system involving workflow redesign, team restructuring, and infrastructure modifications [16]. Notably, our intervention achieved comparable results through a single, low-cost technological tool without requiring organizational restructuring. Svobodová et al. (2023) found that simulation-based team training reduced DTN by 4.1 min [12], suggesting that educational interventions can meaningfully impact stroke care efficiency.

Liang et al. (2022) demonstrated that triage nurse-activated emergency evaluation significantly reduced DTN in acute ischemic stroke, achieving a mean reduction of 8.2 min [15]. Their intervention focused on empowering triage nurses with authority to activate stroke protocols—a similar philosophy of nurse empowerment underlying our mobile application approach.

Gurav et al. (2018) evaluated a "stroke code" rapid response team and found that implementation reduced median DTN from 65 to 45 min [17]. The magnitude of improvement (20 min) was larger than our observed effect, likely reflecting their more comprehensive bundle intervention involving team composition and workflow redesign. Our finding of 5-minute improvement with a single technological tool suggests that mHealth interventions can contribute meaningfully even without organizational restructuring.

However, our post-intervention DTN of 42.96 min remains above the guideline-recommended target of 30 min. This gap is consistent with findings from other developing country settings. Islam et al. (2021) reported mean DTN times exceeding 45 min in Bangladeshi hospitals despite quality improvement efforts [3]. This suggests that achieving the 30-minute target may require system-level changes beyond point-of-care interventions, including pre-hospital notification systems, parallel processing workflows, and dedicated stroke teams.

Mechanisms of effect

The intervention's effectiveness can be attributed to several mechanisms rooted in quality improvement and human factors principles.

First, **cognitive load reduction**: Emergency nurses manage multiple complex patients simultaneously, creating high cognitive burden. Cognitive Load Theory, well-established in medical education research [32], suggests that external tools can reduce extraneous cognitive load, freeing mental resources for essential clinical reasoning. The Code Sama application externalized the stroke protocol into a systematic, step-by-step guide, functioning as a "cognitive offloading" tool [33]. This principle has improved performance in other high-stakes domains including surgical safety checklists [34].

Second, **standardization and reduced variability**: Prior to the intervention, stroke care processes varied based on individual nurse experience, shift timing, and team composition. Deming's quality improvement principles, foundational to healthcare quality science, demonstrate that reducing process variability is fundamental to achieving consistent outcomes [35]. The application provided a consistent framework that standardized assessment and notification procedures, reducing process variability.

Third, **enhanced confidence and autonomy**: Qualitative feedback from nurses (not systematically collected) suggested that having protocol information readily available increased their confidence in initiating stroke assessments and activating stroke teams without waiting for physician confirmation. This "empowerment" effect may have reduced unnecessary delays at the triage and initial assessment stages.

Fourth, **just-in-time learning**: The application provided immediate access to the NIHSS scoring criteria and tPA contraindication checklist at the point of care. This "just-in-time" information delivery is educationally superior to traditional training approaches that rely on knowledge retention over time [36].

Scope of findings: process vs. patient outcomes

It is essential to acknowledge that this study evaluated a process outcome (door-to-needle time) rather than patient-centered clinical outcomes. While DTN is strongly associated with functional outcomes in the literature—with landmark studies demonstrating that each 15-minute reduction in onset-to-treatment time is associated with measurable improvements in 90-day independence [20, 21]—we did not directly assess whether the observed DTN reduction translated to better patient outcomes in our sample.

Several factors could attenuate the relationship between process improvement and patient benefit: [1] stroke severity may modify the effect of rapid treatment [2], quality of other care components (blood pressure management, post-tPA monitoring) may influence outcomes independently [3], the modest absolute reduction (5 min) may be insufficient to produce detectable clinical differences in a sample of this size, and [4] patient selection effects may differ between periods.

Therefore, our conclusions are restricted to the finding that the intervention was associated with a measurable process improvement. The assumption that this

improvement benefits patients is supported by prior literature but was not directly tested in this study.

Implications for practice

These findings have several implications for clinical practice:

1. Emergency department administrators should consider implementing mobile-based clinical decision support tools as part of stroke quality improvement programs. The relatively low cost of application development and distribution (compared to infrastructure or staffing changes) makes this an attractive intervention for resource-limited settings.
2. Nursing education programs should incorporate mHealth literacy and application-based learning into curricula. As digital tools become increasingly prevalent in healthcare, nurses must be prepared to evaluate, adopt, and effectively use these technologies.
3. Hospital stroke protocols should explicitly address the role of technology-assisted care. While our intervention showed benefit, the failure to achieve the 30-minute target suggests that mHealth tools should be viewed as complements to—rather than replacements for—system-level improvements including pre-hospital notification and parallel processing workflows.

Implications for policy and future research

For policymakers, these findings support investment in digital health infrastructure for emergency care. Ministries of health should consider developing or endorsing standardized clinical decision support applications for time-critical conditions. Quality reporting systems should incorporate mHealth tool utilization as a structural measure alongside outcome measures like DTN.

Future research should address several questions raised by this study:

1. Multi-center randomized controlled trials are needed to confirm the causal effect of mHealth interventions on DTN and to assess generalizability across different healthcare systems.
2. Studies should examine whether DTN reductions translate to improved patient-centered outcomes, including 90-day functional status (modified Rankin Scale) and mortality.
3. Implementation science research should explore barriers and facilitators to sustained mHealth adoption in emergency settings.
4. Cost-effectiveness analyses should compare mHealth interventions to alternative quality improvement strategies.
5. Studies should examine the optimal design features of clinical decision support applications—including interface design, alert systems, and integration with electronic health records—that maximize effectivenes

Strengths and limitations

Strengths

This study has several strengths. First, the quasi-experimental design with a control group and demonstrated baseline homogeneity enhances internal validity compared to simple pre-post designs. Second, the use of real-time observation for outcome measurement, rather than medical record abstraction, improves measurement accuracy. Third, the implementation fidelity was systematically monitored through multiple mechanisms. Fourth, the intervention was developed using a rigorous user-centered design process with content validation. Finally, the study was conducted in a real-world clinical setting, enhancing ecological validity.

Limitations

This study has several important limitations that should be considered when interpreting the findings:

Design limitations

First, the quasi-experimental design with historical controls limits causal inference. While we demonstrated baseline comparability and control group stability, the absence of randomization means that unmeasured confounders could account for some or all of the observed effect. Patients were not randomly assigned to conditions; rather, condition was determined by time period of presentation.

Second, the non-concurrent (historical) control group design is vulnerable to temporal confounding. Although we monitored for system-level changes and found none, subtle organizational evolution or "Hawthorne effects" from increased attention to stroke care during the study period could have contributed to improvement independent of the application itself [37].

Third, blinding was not possible. Nurses knew they were being observed and that the study was evaluating the application's effect. This awareness could have motivated enhanced performance beyond what would occur with routine application use. Similarly, observers were not blinded to study phase, potentially introducing measurement bias, though standardized timing procedures should minimize this risk.

Sampling and generalizability limitations

Fourth, this was a single-center study conducted at a comprehensive stroke center with established infrastructure, motivated staff, and academic affiliation. Results

may not generalize to community hospitals, rural settings, or institutions with different organizational cultures, technological infrastructure, or baseline stroke care quality.

Fifth, the sample included only patients who received tPA, representing a select subset of all stroke patients. The intervention's effect on the broader population of stroke patients—including those who did not meet tPA criteria or who received endovascular therapy—was not evaluated.

Sixth, cultural and linguistic factors may limit international generalizability. The application was developed in Persian for an Iranian context; adaptation for other languages and healthcare systems would require additional validation.

Outcome limitations

Seventh, we assessed only a process outcome (DTN) and did not measure patient-centered clinical outcomes such as neurological improvement, functional independence, complications, or mortality. The assumption that DTN reduction translates to patient benefit relies on prior literature rather than direct observation in this study.

Intervention limitations

Eighth, implementation fidelity, while monitored, was not perfectly controlled. Some nurses used the application more consistently than others, and we could not mandate use. The observed effect represents an "intention-to-treat" analysis of implementation rather than efficacy under perfect adherence.

Ninth, sustainability was not assessed. The study captured short-term effects during a period of active monitoring and study participation. Whether nurses would continue using the application with similar fidelity after study conclusion, and whether DTN improvements would persist, remains unknown.

Tenth, we did not assess cost-effectiveness. While the application was low-cost to develop and distribute, a formal economic analysis comparing this approach to alternative quality improvement strategies was not performed.

Eleventh, despite systematic monitoring for confounders, unmeasured factors may have influenced results. Although we documented stability in staffing, protocols, and infrastructure, subtle changes in team dynamics, physician behavior, or organizational culture that occurred coincidentally with the intervention cannot be excluded.

Statistical limitations

Twelfth, despite adequate power for detecting the primary effect, sample size limited exploration of effect modifiers such as nurse experience level, time of day, or patient characteristics. Larger studies could identify subgroups with greater or lesser benefit.

These limitations highlight the need for multi-center randomized trials with longer follow-up, patient-centered outcomes, and formal cost-effectiveness analysis to confirm and extend these findings.

Recommendations

For Clinical Practice

1. Emergency departments should consider implementing mobile-based clinical decision support applications as part of stroke quality improvement programs. Based on our experience, key success factors include:
   - Involving frontline nurses in application development and testing.
   - Ensuring offline functionality to avoid dependence on hospital WiFi.
   - Providing hands-on training rather than solely didactic instruction.
   - Allowing a run-in period for familiarization before expecting full adoption.
2. Nurse managers should incorporate mHealth tool utilization into stroke care competency assessments and quality monitoring.
3. Stroke teams should regularly audit DTN data and provide feedback to nursing staff, with the application serving as one component of a comprehensive quality improvement bundle.

For Healthcare Policy.

1. Ministry of Health stroke care guidelines should explicitly address the role of digital clinical decision support tools and consider endorsing validated applications.
2. Healthcare accreditation standards could incorporate mHealth readiness assessments and digital tool utilization metrics.
3. Investment in hospital WiFi infrastructure and device access should be prioritized to support mHealth implementation in emergency settings.

For Education

1. Nursing curricula should include digital health literacy and application-based learning as core competencies.

2. Continuing education programs should leverage mobile platforms for just-in-time learning and protocol updates.

For Future Research

1. Multi-center randomized controlled trials are needed to confirm the causal effect of mHealth interventions on stroke care quality.
2. Studies should examine patient-centered outcomes including 90-day functional status (modified Rankin Scale), mortality, and quality-adjusted life years.
3. Implementation science research should identify barriers and facilitators to sustained mHealth adoption.
4. Cost-effectiveness analyses comparing mHealth interventions to alternative quality improvement strategies would inform resource allocation decisions.

Conclusion

This quasi-experimental study provides preliminary evidence that implementation of the "Code Sama" mobile-based intervention is associated with meaningful reductions in door-to-needle time for acute ischemic stroke patients. By supporting process standardization and clinical decision-making, this tool shows promise as a component of emergency stroke care optimization. However, the non-randomized design limits causal conclusions, and future randomized controlled trials are needed to confirm effectiveness and evaluate patient-centered outcomes.

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Author contributions
S.F. designed the study, collected the data, performed the statistical analysis, and drafted the manuscript.V.Z. supervised the study, contributed to the study design and methodology, and critically revised the manuscript.F.M. contributed to data interpretation, literature review, and manuscript editing. All authors read and approved the final manuscript.

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Data availability
All data generated or analyzed during this study are included in this published article and its Supplementary Information, and remain under the responsibility of the corresponding author.

Declarations

Competing interests
The authors declare no competing interests.

Author details
[1]Student Research Committe, School of Nursing & Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran
[2]Department of Medical Surgical Nursing, School of Nursing & Midwifery, Shahid Beheshti University of Medical Sciences, Tehran, Iran

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