Rationale and design of individualized quality improvement based on the Computer Analysing system to improve Stroke management quality Evaluation (CASE): a multicentre historically controlled study

Yi Chen
the second affiliated hospital of Zhejiang university, School of medicine
Wansi Zhong
the second affiliated hospital of Zhejiang university, school of medicine https://orcid.org/0000-0002-4775-7778
Xiaoxian Gong
the second affiliated hospital of Zhejiang university, School of medicine
Haitao Hu
the second affiliated hospital of Zhejiang university, School of medicine
Shenqiang Yan
the second affiliated hospital of Zhejiang university, School of medicine
Xuting Zhang
the second affiliated hospital of Zhejiang university, School of medicine
Zhicai Chen
the second affiliated hospital of Zhejiang university, School of medicine
Ying Zhou
the second affiliated hospital of Zhejiang university, School of medicine
Min Lou (lm99@zju.edu.cn)
https://orcid.org/0000-0002-6627-064X

Study protocol

Keywords: Acute ischemic stroke, Computer-based Analysing system, Key performance indicator, medical quality improvement

Posted Date: December 3rd, 2019

DOI: https://doi.org/10.21203/rs.2.18008/v1

Version of Record: A version of this preprint was published on July 24th, 2020. See the published version at https://doi.org/10.1186/s13063-020-04598-3.

Abstract

Background: Guideline-based medical care has been identified to improve outcomes in stroke. However, data acquisition and medical quality management during hospital stay still need to be improved in China. We have developed a computer-based medical data collecting system, together with automated calculation of Key Performance Indicators (KPIs) and regular individualized education, and thus aim to explore whether it can improve the medical care quality of acute ischemic stroke (AIS) during hospital stay in stroke centers.

Methods: The individualized quality improvement based on the Computer Analysing system to improve Stroke management quality Evaluation (CASE) trial is a prospective, multi-center, historical control study among 30 stroke centers in China. In this trial, the data is directly extracted from the saved original medical record of each AIS patient during hospital stay, regardless of different Electronic Medical Record System (EMRS) in each center. Then the automated calculation of KPIs and the regular education via tele-conference per month allows the clinicians to examine the causes of non-compliance of guideline-based care and develop programs to decrease their frequency.

Discussion: We compare KPIs between pre-intervention stage and post-intervention stage (without or with education) among stroke centers. If proved effective, this approach might be generalized around China and even worldwide, where a unified EMRS is difficult to be applied and in-patient care needs to be improved.

Background

Stroke burden has increased over the past three decades in China, emerging to be the leading cause of mortality[1, 2]. A systematic review indicated that implementing clinical guidelines improved the quality and efficiency of medical care[3]. Moreover, studies such as GOLDEN BRIDGE[4], The Get With The Guidelines (GWTG)[5], BRIDGE STROKE[6] also indicated that increased delivery of in-patient care based on guidelines could contribute to the favorable outcome of stroke patients[7].

To enhance the medical care quality by increasing the compliance with evidence-based performance in stroke patients, China Stroke Center Alliance (CSCA) has been launched in China in 2015. CSCA prompted 13 key performance indicators (KPIs) of acute ischemic stroke (AIS) to monitor the routine in-patient medical care quality, based on the AIS guidelines, involving intravenous thrombosis (IVT), antiplatelet therapy, anticoagulant therapy and so on[8-13]. Then afterwards, CSCA annually collected the required data from about 20,000 in-patients among more than 1500 stroke centers [14], calculated and feedback all of the KPIs to each center.

However, there is a huge diversity in the Electronic Medical Record System (EMRS) in different stroke centers in China currently, which makes it difficult to capture all KPIs from the original medical records by a unified system in each center. Accordingly, clinicians in each stroke center have to report the medical data online manually to achieve the feedback of KPIs from CSCA. Indeed, this is also the way data was collected in the above studies (GOLDEN BRIDGE, GWTG, BRIDGE STROKE).

Obviously, this kind of collection has its inherent shortcomings, including the vast cost of manpower and time from clinicians, and questioning of its authenticity due to the lack of traceability of original medical records and enough quality control of data. To minimize the above limitations, we thus developed a computer-based medical data collecting system, with subsequent automated calculation of KPIs and regular individualized education to improve the adherence to guideline-based care. The main purpose is to decrease the workload of clinicians in stroke centers on reporting data manually. We designed this individualized quality improvement based on the Computer Analysing system to improve Stroke management quality Evaluation (CASE) trial to explore whether this novel approach can improve inpatient medical care quality of AIS in each stroke center.

Method And Design

Design

This is a 18-months prospective, multi-center, historical control study among 30 stroke centers in Zhejiang Province, China. Stroke centers with in-hospital stroke patients voluntarily participate in this trial. All medical documents of consecutive AIS patients admitted in the stroke center according to ICD-10 (I63 and G45) are collected by investigators from Zhejiang Stroke Quality Control Center (ZSQCC). Only the de-identified documents are preserved in a safe information database. The clinical data involved in this study belong to the scope of information collection of routine clinical practice. The local infrastructure and characteristics of each recruited center are also recorded. The study protocol is approved by the institutional review board of the Second Affiliated Hospital of Zhejiang University (SAHZU). Because patient information in the CASE is de-identified and anonymized before being released to the researchers, the informed consent requirement is waived by SAHZU Institutional Review Board. All the protocol item is standardized (see the additional file 1). It was registered at ClinicalTrial. gov (NCT03684629).

There are two stages in this trial: pre-intervention stage (the initial 6 months) and post-intervention stage (the next 12 months). We collect the consecutive data of each center during the pre-intervention stage without feedback of KPIs, and then monthly send its own KPIs to each center during the post-intervention stage. We finally compare the changes of KPIs from pre-intervention stage to the last 6 months of post-intervention stage. **(Figure 1)**

The inclusion criteria for the analysis of medical documents:

1. Patients with 18 years or older;
2. AIS confirmed by computed tomography (CT) or Diffusion weighted imaging (DWI);
3. Admitted within 7 days from symptom onset.

Data monitoring and Confidentiality

After discharge, the original medical document of each patient during hospital stay is saved as images or portable document format (PDF). Specific software recognizes and pre-processes the above material, and send it to multiple Optical Character Recognition (OCR)[15] engines to build documents with recognized text, which are subsequently re-segmented and synthesized in the post-processing. Required data is extracted from the processed text. The error rate is 3.4% compared with the data from manually input method by two separated neurologists. This software also allows the trained study investigators to quickly check the quality of extracted data by pointing out the original extraction site, enabling the authenticity and traceability of original data. The checked data are then imported into the analysing system, and KPIs will be calculated according to the designed formula. **(Figure 2)**

Intervention for medical care improvement

Individualized quality improvement process is divided into 3 steps :

1. Each stroke center receives their own KPIs monthly, as well as the average KPIs level of all 30 stroke centers as contrast, which are automatically calculated by computer analyzing system.
2. Based on the performance of KPI data, stroke experts from ZSQCC identify the items which need to be improved, provide each center with relevant education of guidelines, and help the clinicians to examine the causes of non-compliance of guideline-based care and develop programs to decrease their frequency via regular tele-conference per month and face-to-face lectures quarterly. Meantime, stroke centers with the best KPI performance also share their experiences on medical care improvement.
3. Each stroke center is then required to provide a detailed improvement plan for each KPI and check whether it is implemented one by one during the next tele-conference.

Outcome

Primary Outcome: 7 KPIs including the accomplish of National Institutes of Health Stroke Scale (NIHSS), intravenous thrombosis within 4.5 hours of onset, antiplatelet agents therapy within the first 48 hours,

statin use after hospitalization and at discharge, antithrombotic therapy at discharge, anticoagulant treatment for patients with atrial fibrillation at discharge[8, 9, 11-13]. (see the additional file 2)

Secondary Outcome: 9 KPIs including prevention of deep vein thrombosis, blood vessel evaluation within one week of hospitalization, swallowing function evaluation, blood lipid level assessment, rehabilitation evaluation and implementation, recommendation of life style change, anti-hypertensive therapy, hypoglycemic treatment at discharge, and recurrence rate[10, 11, 16]. (see the additional file 2)

Sample size

Among all the KPI, the adherence to intravenous thrombosis (IVT) was poor in china. Result of investigation before the trial indicated that only approximately 8% of ischemic stroke patients received IVT 4.5h from onset in stroke centers in Zhejiang. To detect 10 % improvement in the adherence to IVT, with α=0.05 and power=90%, at least 16570 patients will be needed in pre-intervention stage and post-intervention stage.

Planned data statistical analysis

Statistical analysis will be performed with SPSS 22.0 (SPSS, Inc, Chicago, USA). Baseline characteristics of each stroke center (see the additional file 3) and the patients enrolled will be analyzed. The achieved rates of all KPIs of 30 hospitals during pre-intervention stage and the last 6 months of post-intervention stage are compared by the paired t test. KPIs are also collected at multiple time points before and after intervention. Interrupted time series (ITS) analysis are performed to assess the efficiency on outcome one year after the intervention is carried out[17, 18] **(Figure 3)** .The multiple time points before the intervention allow the underlying tend to be estimated, the multiple time points after the intervention allow the intervention effect to be estimated accounting for the underlying trend. The schedule of enrolment, interventions, and assessments was included in the Figure 4.

Discussion

It is widely agreed that accuracy and reliability are of importance for data collection, which may interfere with the sample size and data quality for research[19]. Manual report can lead to data errors, and the authenticity of data can not be guaranteed without verification of original medical record. Even the Get With The Guidelines (GWTG)-Stroke program, a national stroke quality improvement for AIS and TIA via the web, also has missing data during the hospital participation in the program, possibly due to the manual input[20]. Importantly, it is difficult for the clinicians to insist on quality improvement based on their manual reporting after busy clinical practice, when faced with a huge numbers of patients. Currently, it is also difficult to deliver automated calculation of KPIs via a unified EMRS around China. In CASE trial, data are directly extracted from the saved original record of each patient based on optimized OCR, having

nothing to do with the work of EMRS itself. Theoretically, this approach can be implemented in all centers and the extraction saves the time of all clinicians.

Based on the reliable feedback, regular individualized education would further improve the adherence to guideline-based care. By providing the participating hospitals with improvement consultation, workshops, and webinars based on guidelines, GWTG-Stroke program achieved significant improvement of composite measure of care from 83.53% to 93.97%[23]. Data analysis from 2010 to 2013 in Germany showed that the mortality was reduced by up to 6.26 (63.7%) deaths per year, if the average hospital boosts its performance to an efficient treatment of stroke patients[24]. In CASE trial, the automated calculation of KPIs identifies the non-compliance of guideline-based care, which allows the clinicians to examine their cause and develop programs to decrease their frequency. The tele-conference per month and the requirement of detailed improvement plan from each center would constitute into an upgraded dynamic feedback and improving system, leading to the enhanced surveillance and monitoring, and decreased medical care errors.

Therefore, it is reasonable to assume that this novel computer-based medical data collecting system, together with subsequent automated calculation of KPIs and regular individualized education could increase the adherence to guideline-based care in each stroke center, finally improving the efficiency and quality of medical care of stroke patients.

This study has some limitations. First, it is a historical control study, thus the quality of care in individual hospital may have changed over time, which can influence the general results of the trial. Second, the 30 hospitals were selected randomly from voluntary hospital rather than all hospital in Zhejiang province, which may lead to selection bias.

Conclusion

In summary, this is a new mode to improve in-patient medical care, which consists of advanced acquisition technique and personalized feedback with persistent education. It can yield real benefits in terms of increased delivery of guideline-based care and reduced manual reporting of clinicians. If proved effective in Zhejiang province, this new quality improvement approach might be generalized around China and even worldwide, where a unified EMRS is difficult to be applied.

Trial Status

The protocol version number is 1 and was finalized in July 2018. The date recruitment began on August 16, 2018. The approximate date when recruitment will be completed is January 2020.

Abbreviations

KPI: Key Performance Indicator

AIS: Acute Ischemic Stroke

CASE: The individualized quality improvement based on the Computer Analysing system to improve Stroke management quality Evaluation

EMRS: Electronic Medical Record System

GWTG: The Get With The Guidelines

CSCA: China Stroke Center Alliance

IVT: Intravenous thrombosis

ZSQCC: Zhejiang Stroke Quality Control Center

SAHZU: the Second Affiliated Hospital of Zhejiang University

CT: Computed tomography

DWI: Diffusion weighted imaging

PDF: Portable document format

OCR: Optical Character Recognition

NIHSS: National Institutes of Health Stroke Scale

ITS: Interrupted time series

Declarations

Ethics approval and consent to participate

Central ethical approval has been confirmed from the Ethics Committee of the Second Affiliated Hospital , School of Medicine, Zhejiang University (Approval Number: (2018)□□□□(095)□) and we will not begin recruiting at other centres in the trial until local ethical approval has been obtained. All participants provided written informed consent before participating in the study.

Consent for publication

Not Applicable.

Availability of data and materials

The dataset is not publicly available due to confidentiality policies.

Competing interests

The authors declare that they have no competing interests.

Funding

This study was supported by the National Natural Science Foundation of China (81622017), the National Key Research and Development Program of China (2016YFC1301503), the Science Technology Department of Zhejiang Province (2018C04011). The funder had no role in the design and interpretation of data; in the writing of the manuscript; and in the decision to submit this manuscript for publication.

Authors contribution

ML led the conception and design of the trial and reviewing the manuscript. YC wrote the manuscript and involved in design of the trial. WZ was closely involved in data collection, data curation and wrote original draft preparation. XG and HH was involved in the project administration and supervision. SY, XZ, ZC and YZ were involved in the design of the study, participated in data interpretation and revised the manuscript critically for important intellectual content. All author read and approved the final manuscript.

Acknowledgements

We thank all participating hospitals, their physicians and nurses.

Additional file

Additional file 1: SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents

Additional file 2: The primary and secondary outcome measures

Additional file 3: The baseline characteristics of primary stroke center (PSC) and comprehensive stroke center (CSC)

References

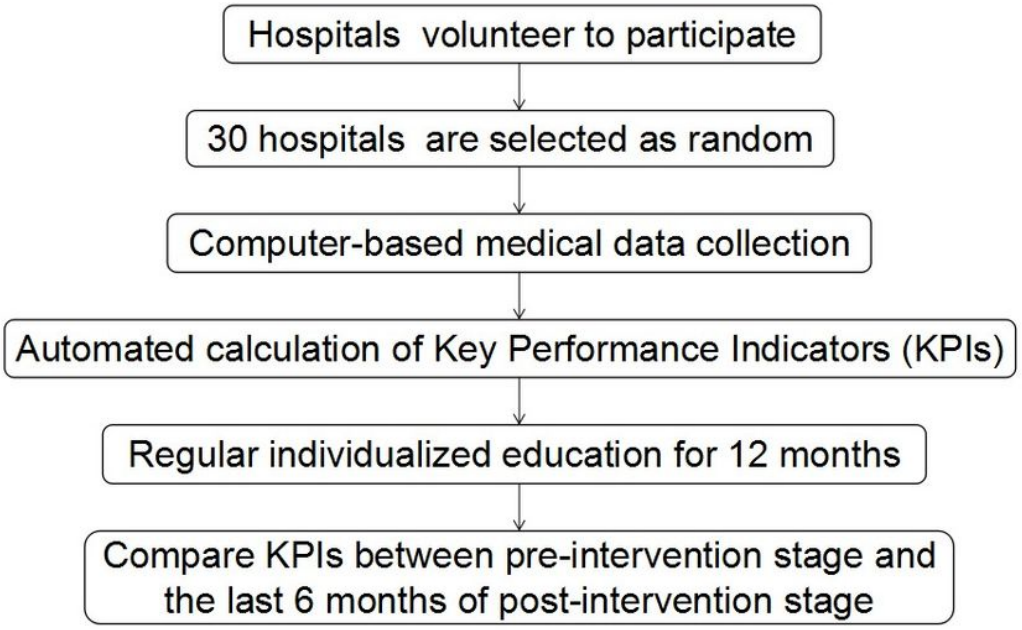
1. Li Z, Wang C, Zhao X, Liu L, et al. Substantial progress yet significant opportunity for improvement in stroke care in china. Stroke. 2016;47:2843-2849

2. Zhou M, Wang H, Zhu J, et al. Cause-specific mortality for 240 causes in china during 1990-2013: A systematic subnational analysis for the global burden of disease study 2013. Lancet. 2016;387:251-272
3. Grimshaw J, Eccles M, Thomas R, et al. Toward evidence-based quality improvement. Evidence (and its limitations) of the effectiveness of guideline dissemination and implementation strategies 1966-1998. Journal of general internal medicine. 2006;21 Suppl 2:S14-20
4. Wang Y, Li Z, Xian Y, et al. Rationale and design of a cluster-randomized multifaceted intervention trial to improve stroke care quality in china: The golden bridge-acute ischemic stroke. American heart journal. 2015;169:767-774 e762
5. Hassan AE, Ossowski SE, Malik AA, et al. Does hospitalist directed care for acute ischemic stroke patients improve adherence to "get with the guidelines"? Journal of vascular and interventional neurology. 2016;9:30-33
6. Machline-Carrion MJ, Santucci EV, Damiani LP, et al. An international cluster-randomized quality improvement trial to increase the adherence to evidence-based therapies for acute ischemic stroke and transient ischemic attack patients: Rationale and design of the bridge stroke trial. American heart journal. 2019;207:49-57
7. Grau AJ, Eicke M, Biegler MK, et al. Quality monitoring of acute stroke care in rhineland-palatinate, germany, 2001-2006. Stroke. 2010;41:1495-1500
8. Schade CP, Cochran BF, Stephens MK. Using statewide audit and feedback to improve hospital care in west virginia. Joint Commission journal on quality and safety. 2004;30:143-151
9. Alyousif SM, Alsaileek AA. Quality of anticoagulation control among patients with atrial fibrillation: An experience of a tertiary care center in saudi arabia. Journal of the Saudi Heart Association. 2016;28:239-243
10. Drury P, Levi C, D'Este C, et al. Quality in acute stroke care (qasc): Process evaluation of an intervention to improve the management of fever, hyperglycemia, and swallowing dysfunction following acute stroke. International journal of stroke : official journal of the International Stroke Society. 2014;9:766-776
11. Sherman DG, Albers GW, Bladin C, et al. The efficacy and safety of enoxaparin versus unfractionated heparin for the prevention of venous thromboembolism after acute ischaemic stroke (prevail study): An open-label randomised comparison. Lancet. 2007;369:1347-1355
12. Lees KR, Bluhmki E, von Kummer R, et al. Time to treatment with intravenous alteplase and outcome in stroke: An updated pooled analysis of ecass, atlantis, ninds, and epithet trials. Lancet. 2010;375:1695-1703
13. Amarenco P, Bogousslavsky J, Callahan A, et al. High-dose atorvastatin after stroke or transient ischemic attack. The New England journal of medicine. 2006;355:549-559
14. Wang Y, Li Z, Wang Y, et al. Chinese stroke center alliance: A national effort to improve healthcare quality for acute stroke and transient ischaemic attack: Rationale, design and preliminary findings. Stroke and vascular neurology. 2018;3:256-262

15. Li X, Hu G, Teng X, Xie G. Building structured personal health records from photographs of printed medical records. AMIA ... Annual Symposium proceedings. AMIA Symposium. 2015;2015:833-842
16. Nimptsch U, Mansky T. Quality measurement combined with peer review improved german in-hospital mortality rates for four diseases. Health affairs. 2013;32:1616-1623
17. Weatherburn CJ. Benzodiazepines and non-benzodiazepine hypnotics - impact of a cluster adopted protocol on primary care prescribing. Scottish medical journal. 2019:36933019849369
18. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. Journal of clinical pharmacy and therapeutics. 2002;27:299-309
19. Dippel DW, Simoons ML. Improving adherence to guidelines for acute stroke management. Circulation. 2009;119:16-18
20. Reeves MJ, Grau-Sepulveda MV, Fonarow GC, Olson DM, Smith EE, Schwamm LH. Are quality improvements in the get with the guidelines: Stroke program related to better care or better data documentation? Circulation. Cardiovascular quality and outcomes. 2011;4:503-511
21. Purvis T, Moss K, Francis L, et al. Benefits of clinical facilitators on improving stroke care in acute hospitals: A new programme for australia. Internal medicine journal. 2017;47:775-784
22. Middleton S, Bruch D, Martinez-Garduno C, Dale S, McNamara M. International uptake of a proven intervention to reduce death and dependency in acute stroke: A cross-sectional survey following the qasc trial. Worldviews on evidence-based nursing. 2017;14:447-454
23. Fonarow GC, Reeves MJ, Smith EE, et al. Characteristics, performance measures, and in-hospital outcomes of the first one million stroke and transient ischemic attack admissions in get with the guidelines-stroke. Circulation. Cardiovascular quality and outcomes. 2010;3:291-302
24. Pross C, Strumann C, Geissler A, Herwartz H, Klein N. Quality and resource efficiency in hospital service provision: A geoadditive stochastic frontier analysis of stroke quality of care in germany. PloS one. 2018;13:e0203017

Figures

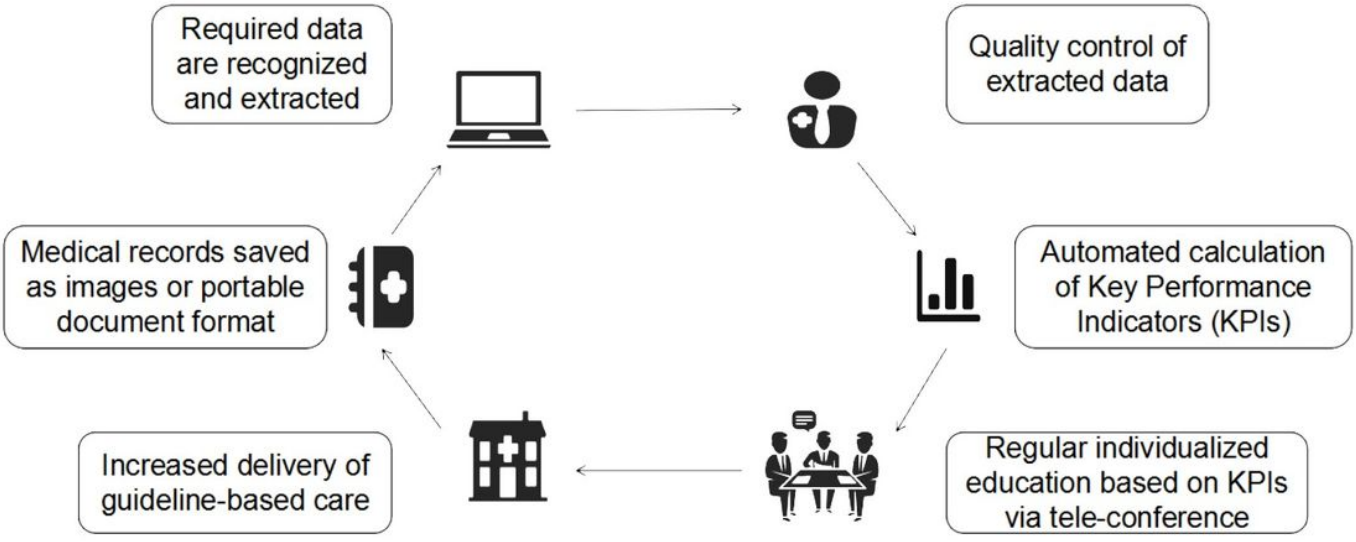
Figures 1



Flow diagram of the process throughout the trial

Figure 1

Flow diagram of the process throughout the trial

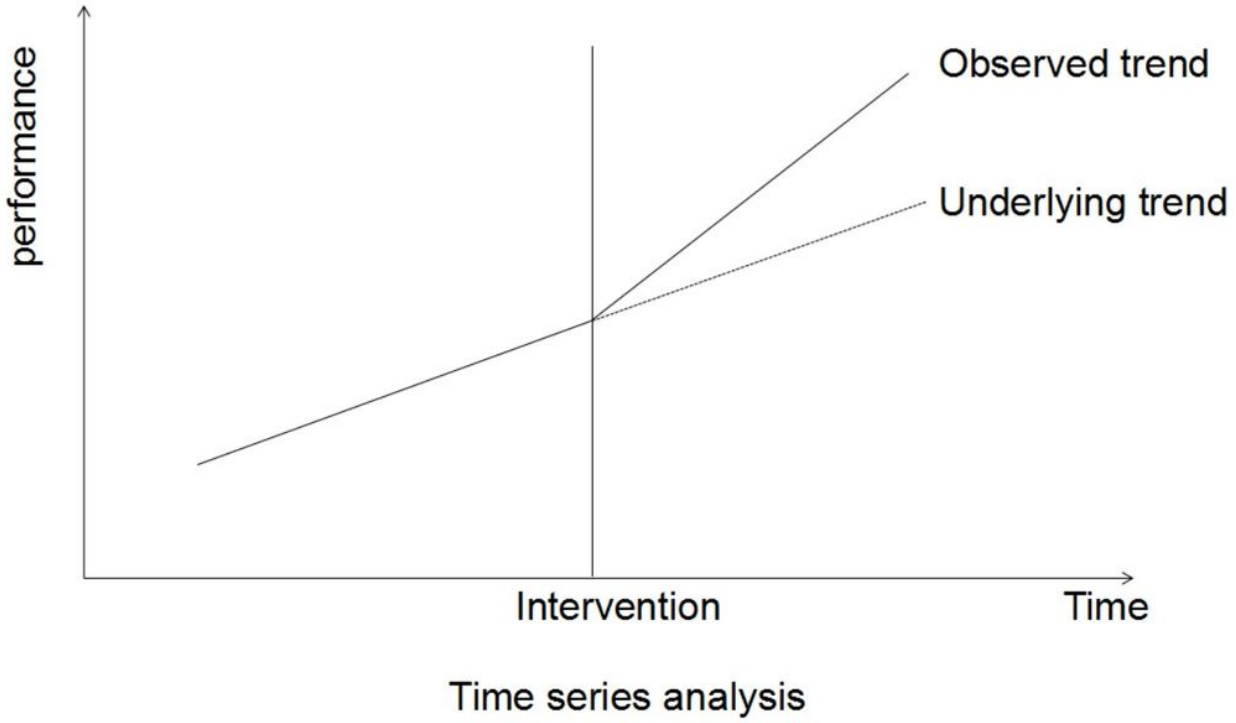


The procedure to improve the quality of medical care in stroke patients.

Figure 2

The procedure to improve the quality of the medical care in stroke patients

Figure 3



Time series analysis

Figure 3

Time series analysis

Figure 4. The schedule of enrolment, interventions, and assessments.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT**	0	0	*6 months*	*12 months*	*18 months*	*19 months*
ENROLMENT:						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
pre-intervention stage						
post-intervention stage				←	→	
ASSESSMENTS:						
Primary Outcome	X		X	X	X	X
Secondary Outcome	X		X	X	X	X

The schedule of enrollment, interventions and assessments demonstrated in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Figure

Figure 4

The schedule of enrolment, interventions, and assessments.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Additionalfile3.docx
- Additionalfile2.docx
- Additionalfile1.doc