

## Research Article

## Effect of Transitional Care Model-Based Interventions for Patients with Stroke and Their Caregivers on Increasing Caregiver Competence and Patient Outcomes: A Study Protocol for a Randomized Controlled Trial

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### Abstract

**AIM:** This is a study protocol designed to evaluate the effect of transitional care model based interventions for patients with stroke and their caregivers on the caregivers' perceived competency, their preparedness for caregiving, increasing their electronic health literacy, reducing burnout, the rate of patients' hospital readmissions, and the frequency of pressure injuries.

**METHOD:** The study protocol was planned as a randomized controlled trial with parallel arms. The study will include 70 patients with stroke and their caregivers. Multiple interventions (TEMpEST- Transitional Care Model Stroke Turkey), including at least 3 face-to-face interviews at the hospital, distance education via web, and telephone communications for 3 months, and 1 home visit within 7 days of discharge will be applied to the study group. The control arm will receive routine care.

**RESULTS:** Findings will give after then when completed the study protocol.

**CONCLUSION:** This study will evaluate the feasibility of interventions TEMpEST and its effect on patients with stroke and their caregivers.

**Keywords:** Competence, family caregivers, nursing models, patient discharge, stroke, study protocol

**Trial Registration:** The trial was registered with the ClinicalTrials.gov protocol registration and results system (PRS) (ClinicalTrials.gov reference NCT03708835).

### Introduction

Stroke occurs suddenly and unexpectedly, and therefore, affects the lives of both the patient and caregiver. When evaluated in terms of disease burden, stroke is ranked as the third leading cause of death (Ministry of Health, 2010). Patients who have been treated for stroke are discharged from the hospital after being monitored for at least 1 week in the neurology clinic. After a stroke, patients may experience hemiplegia, paraplegia, and loss of strength. The patient should be closely monitored during treatment for the prevention of a secondary stroke. The most common problems after a stroke are hemiparesis, inability to walk without help, dependence in activities of daily living, depressive symptoms, and aphasia. These patients need home healthcare and family support to prevent a secondary stroke because of the problems they frequently encounter following a

stroke (Durna & Akın, 2014; Güler et al., 2015; Özakgöl & Atabek, 2018). Stroke patients, after discharge from the hospital, have to go to different healthcare facilities for their different needs. They may have to go to the family physician for drug prescriptions, to home care services for medical dressings and catheter insertion if needed, to a neurologist for stroke management control, and to a physiotherapist for physical therapy. In addition, caregivers may need transfer services within the scope of home care services if they are unable to take their patients to the hospital on their own for procedures, such as a blood draw for a follow-up for coagulation times.

The caregivers of patients with stroke play a mandatory caregiver role in many areas, such as in the continuation of the patient's treatment, hospital appointments, transportation, ensuring safety, renewing the patient's health reports, as well as assisting in

\*The study was based on first author's doctoral dissertation under supervision of the second authors.

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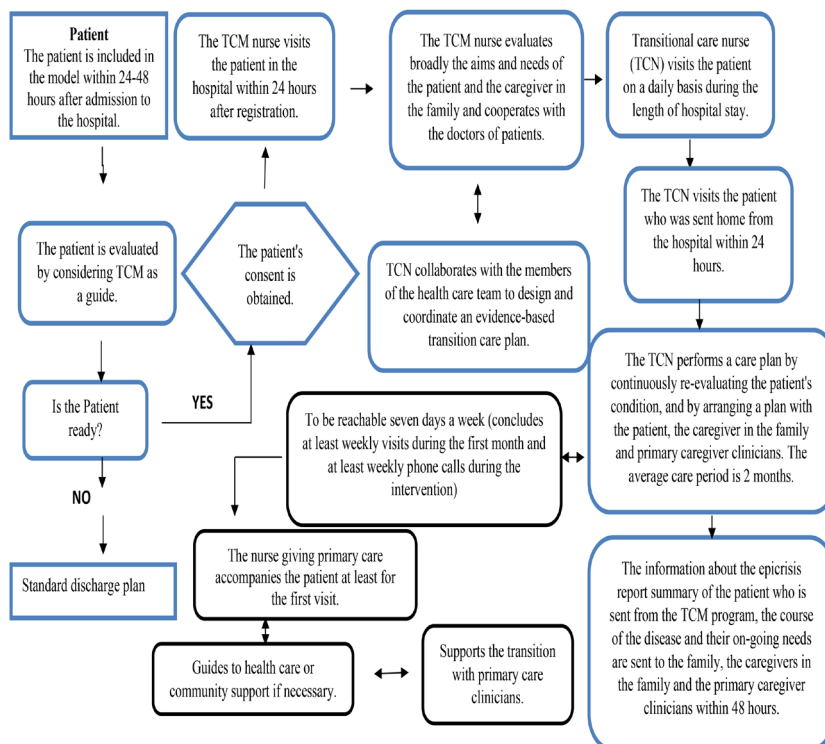
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the daily activities of the patients, including helping with toilet needs, feeding, and hygiene. However, the caregivers have their own personal needs, including shopping, housework, and a job if they are employed while simultaneously taking on their caregiver role (Boyras & Gökçe, 2017). Because of the sudden and unexpected need for caregiving, often these individuals are unable to receive the necessary training on patient care. If caregivers do not receive training during the discharge process, they will most likely have to learn patient care through trial and error. This can lead to caregiver burnout, which may result in a worsening of the patient's outcome (İnci & Temel, 2016a).

As the caregivers' emotional stress increases, the stress of caring for the patient, the likelihood of burnout, and the perception of the duty of care also increase. Studies have described the physical, social, mental, and financial problems of caregivers, but only a limited number of studies have been conducted to improve the caregiving qualifications of caregivers (İnci & Temel, 2016b; Temizer & Gözüm, 2012). Currently, the families of patients with stroke who are about to be discharged from the hospital are usually informed how their patients should take their med-

icines at home and when they should come back to the hospital for a follow-up. Patients and their families need more information and support when they are transferred back home from the hospital. The information needs of caregivers in fact steadily increase in the first months after the transition from hospital to home (İnci & Temel, 2016a).

Home care services can be arranged through a home care services unit and/or from the home care units of the local authorities after application to a coordination center. As each institution acts independently of the other throughout the process, the caregiver has to apply to different institutions for each need. Literature shows that some patients and their relatives use all the healthcare services at the same time, whereas some do not benefit from any of the existing services as they do not know about them, resulting in the caregivers providing home care to their patients by themselves. Therefore, this study will use the transitional care model (TCM) to provide uninterrupted and rapid service to the patients and their families by setting up a network of communication between institutions immediately after patients with stroke are discharged from the hospital (Figure 1).



**Figure 1**  
Transitional Care Model (Transitional Care Model, 2018)

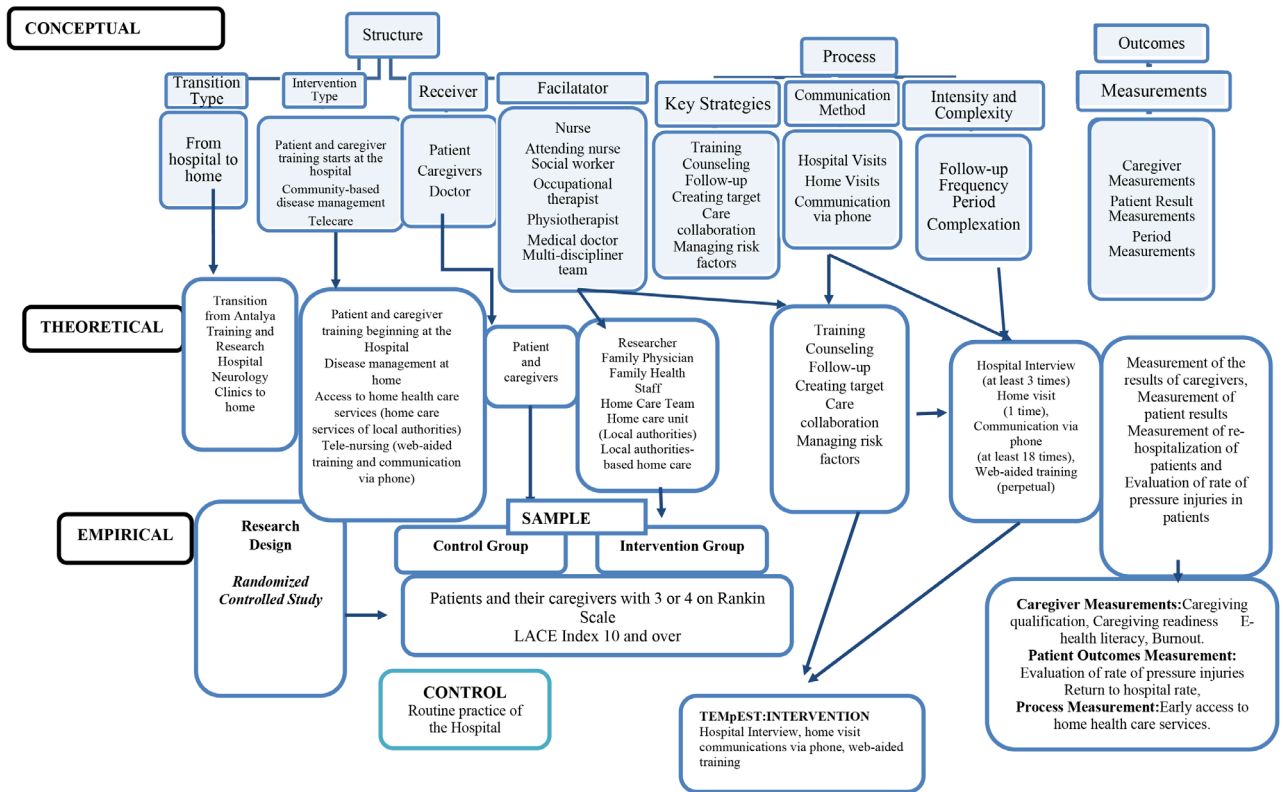


Figure 2  
 CONCEPTUAL-Theoretical-Empirical Structure of the Research (C-T-E: Conceptual-Theoretical-Empirical)

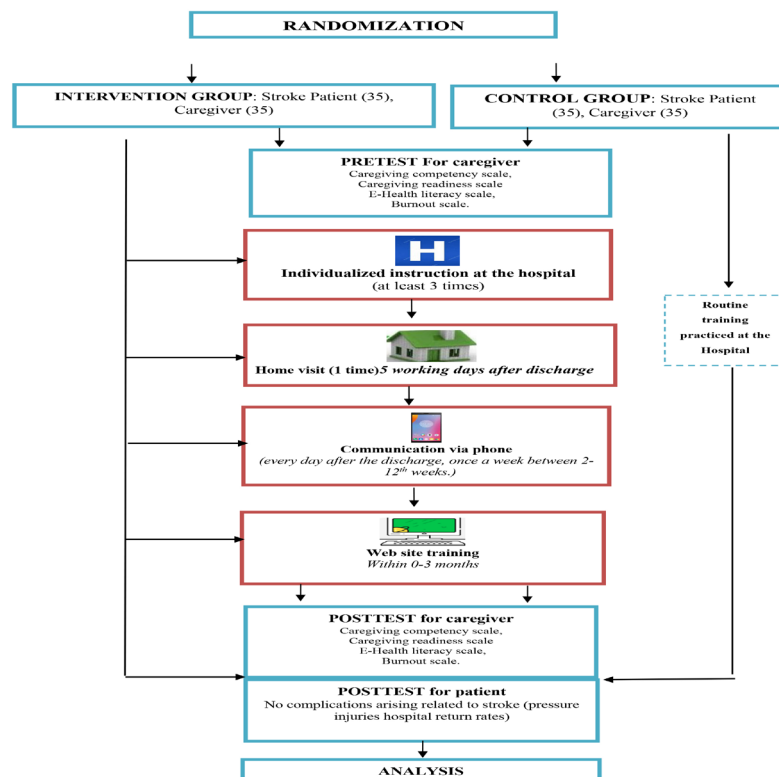


Figure 3  
 Flow Chart of the Trial

The training needed at home to enable the health-care of patients with stroke discharged from hospital should start at the hospital and continue at home with discharge models. TCM can likely reduce complications developing after discharge and improve the caregivers' skills needed for this task (Rennke & Ranji, 2015). This study will confirm the feasibility of TCM and its effect on patients with stroke and their caregivers, starting at the hospital and continuing at home. In addition, this study believe that the caregivers' preparedness, perceived caregiving competencies, and e-health literacy will improve, and burnout will be reduced (Figure 2).

TCM is a discharge transition model that starts during hospitalization under the guidance of a nurse, continues with the planning of discharge, home visits, and telephone communications and lasts for an average of 2 months (Naylor & Cleave, 2010). The aim of this model is to provide caregivers and patients the knowledge and skills needed to achieve the goals of family caregiving and enhance health outcomes and quality of life. The model reduces costs by reducing the rate at which patients need to access healthcare services (Naylor & Keating, 2008).

A study applying TCM found that the psychological status and satisfaction of the participants in the intervention group were at a higher level than in the control group, and their dependence level and depression scores were lower. It was further determined that hospital return, hospitalization, and emergency room admission rates were lower as well (Wong & Yeung, 2015). A systematic review conducted for determining the effectiveness of TCM revealed that discharge support provided by the hospital shortened hospitalization duration for patients with stroke (Prvu Bettger et al., 2012).

TCM, which addresses the entire transition from hospital to home for patients with stroke at the discharge stage, is notably implemented in the United States as well as in Japan and China. The model will be tried for the first time in Turkey. This study will evaluate the effect of TCM-based interventions for patients with stroke and their caregivers on the caregivers' perceived competency, their preparedness for caregiving, their electronic health literacy, and reducing burnout as well as patients' hospital return rates and the frequency of pressure injuries.

The study was designed to evaluate the effect of TCM-based interventions for patients with stroke and their caregivers on the caregivers perceived competency, their preparedness for caregiving, increasing their electronic health literacy, reducing caregiver burnout, as well as on patients' hospital return rates and the frequency of pressure injuries.

## Hypotheses

### **Competency of Caregiver**

H1a: The caregivers' perceived caregiving competency will be at a higher level in the intervention group than in the control group.

H1b: The caregivers' caregiving preparedness will be at a higher level in the intervention group than in the control group.

H1c: The caregivers' electronic health literacy levels will be higher in the intervention group than in the control group.

H1d: The caregivers' burnout levels will be lower in the intervention group than in the control group.

### **Patient Outcomes**

H1e: The hospital return rates of the patients with stroke in the intervention group, except for routine check-ups, will be lower than in the control group.

H1f: The frequency of pressure injuries among the patients with stroke in the intervention group will be lower than in the control group.

### **Process Outcomes**

H1g: Patients with stroke in the intervention group will receive home care services early on.

### **Primary and Secondary Outcomes**

The outcome measures of this study will consist of measurements pertaining to both caregivers and patients. The primary outcomes designated for caregivers are competency, preparedness, e-health literacy, and burnout. Usability of the website is accepted as a secondary outcome. The main outcomes for patients are defined as re-hospitalization and frequency of pressure injuries. The details of the measurement tools are explained under data collection procedures.

## Method

### Study Design

A study protocol for a randomized controlled trial with parallel arms at a single center.

### Sample

Patients hospitalized because of stroke and their caregivers in the neurology clinic of the university hospital will be included in the study. The population of the study will include patients hospitalized with a diagnosis of stroke in the neurology clinic of the hospital where the study is planned to be conducted and their caregivers. It is planned to collect the data of the study between March and August 2018. The sample size for the study was calculated using the G power program (Faul et al., 2009). The calculation was based on the "Preparedness for Caregiving Scale," which was used in a similar study (King et al., 2012) and the effect size was found to be .58. The calculation determined 26 cases (pairs of patients and caregivers) for each group at a power of 80% and a margin of error of .05.

Considering the possibility of losses during the intervention and the follow-up period, the plan was to include 35 people in each group (35 patients and 35 caregivers in the intervention group, and 35 patients and 35 caregivers in the control group).

### Eligibility Criteria

The study will be conducted on patients hospitalized in the neurology clinic of the university hospital and their caregivers.

### Inclusion criteria for caregivers

These include taking primary responsibility for helping the patient (performing daily activities of living during the intervention, providing care to the patient suffering a stroke for the first time, having internet access, and having at least one family member who knows how to use the internet).

### Inclusion criteria for patients

These include being hospitalized in the neurology clinic of the university hospital with a diagnosis of stroke, volunteering to participate in the study, living in the city center, suffering a stroke for the first time, being at the 3<sup>rd</sup> or 4<sup>th</sup> levels of the modified Rankin Scale\* (Mrs), being at least semi-dependent as per functional independence measures\*\*, having a score of 10 or more with reference to the LACE Index\*\*\*.

### \*Modified Rankin Scale

This scale includes 6 items and is used to determine the pressure injuries levels of patients. Disability caused by stroke is rated between 0 and 5, with 0 indicating no sign or symptom, 1 no obvious deficit, 2 a light deficit, 3 a medium deficit, 4 a heavy deficit, and 5 a very heavy deficit (Yalın & Sabuncu., 2012).

### \*\* Functional Independence Measurement

This scale, developed to evaluate the functional status of individuals, was adapted into Turkish by Küçükdeveci et al. (2001). It consists of 2 parts: motor skills (13 items) and cognitive skills (5 items). Each item is rated from 1 to 7. The independence of the patient in the context of performing activities is evaluated as follows: 1–2 points, dependence; 3–5 semi-dependence; and 6–7 independence (Küçükdeveci et al., 2001).

### \*\*\*LACE Index (Return to Hospital Index)

This index is used to identify the risk of death within 30 days of discharge from the hospital or of an unplanned return to the hospital. It was developed by van Walraven et al. (2010). The index is calculated automatically after the required information is entered into the system. The result is shown as a percentage. The scoring of the index is as follows: 0–4 points, low readmission risk; 5–9, medium readmission risk; and ≥10 points, high readmission risk (van Walraven et al., 2010).

### Exclusion criteria

These include:

- The patients having a history of dependency not owing to the stroke,
- The caregivers not having internet access and/or use of the internet,
- Providing care for a fee,
- Care will be given by a nonfamily member,
- The patient and caregiver's inability to live in the same house, apartment, or a location nearby.

### Removal criteria

These include a change of caregiver during the course of the intervention and lack of communication in the first week after the discharge.

### Randomization

A simple randomization method was used to randomly select patients with stroke and caregivers and to assign the intervention and control groups

impartially. Randomization was performed using the <https://www.randomizer.org/> website to determine the intervention and control groups according to the list obtained. The patients and their caregivers will be included according to this order.

Patient rooms in the neurology clinics accommodate two people. Randomization indicated that the intervention and control groups may stay in the same room. However, to prevent contamination, patients and caregivers in the same room will not be included in the study. There will be a control or an intervention participant in each room.

### Prevention of Blinding and Bias

Because of the nature of the intervention, the researcher and the patient and their relatives will not be blinded. Randomization was performed to prevent selection bias. During the final measurements, the processes of collecting posttests, coding data, and evaluating statistics will be blinded to avoid bias. The questionnaires that will be used in the study will be added to the website [www.hastayakini.net](http://www.hastayakini.net). The posttest questionnaires for the intervention group caregivers will be filled out on the website. The posttests of the control group will be filled out via WhatsApp. The data input will be carried out by a person other than the researcher. To control detection and statistical bias, the analysis of the data will be performed by a professional statistician at Akdeniz University statistical consultancy application and research center.

### Classification of Events

#### Intervention arm

The Transitional Care Model Stroke Turkey (TEMPEST) program (ClinicalTrials.gov.NCT03708835) comprising a combination of 4 basic interventions will be implemented in this study. The process will begin in the hospital and will then continue at the patients' own homes after discharge within the scope of home healthcare.

The researcher will call the caregivers at least once at a predetermined hour every day in the first week after discharge and then between the 2nd and 12th weeks. For 3 months after discharge, the caregivers of the patients with stroke will have 24/7 access to the website prepared for them (Figure 2). The patients and their relatives will be followed up for a period of 13–20 weeks, including 12 weeks after discharge.

**Hospital Interview:** The initial interview with the patients and caregivers will take place within 24 to 48 hours after hospitalization. The second interview will be conducted on the first day of hospitalization. The third and subsequent interviews will be scheduled daily until the patient is discharged from the hospital, and a consultation with the caregiver is also planned.

**Home Visit:** The researcher, together with the coordinating center (that is, home care services provided by the local authorities), will make a planned home visit within 5 working days of discharge. Topics related to the care of the patient will be discussed with the caregivers during the home visit, and the home environment will be assessed for patient safety. The patient's home care needs will be assessed and followed up.

**Telephone Interview:** In the first week of discharge, the researcher will call the caregivers at a specified time every day. Between the 2nd and 12th weeks, the researcher will call the caregivers at least once. During each call, the caregivers will be asked about the face, arms, speech, and time (FAST) warning signs and symptoms of stroke. In addition, the patient's pain, falls, pressure points, frequency of position change, and activities of daily living will also be assessed.

**Web-based Training:** The caregivers will access the website by logging in with their password. The website will be accessible 24/7 for a 3-month period following discharge. The main headings on the website include the discharge period, stroke disease, a useful care guide, being a patient's relative, emergency situations, Q&A, and contact information. Images, graphics, and video clips made available on the website will be prepared according to the topics. The system will record how many times, how long, and when the caregivers use the website and make a note of the sections they visit.

Summary; the process initiated in the hospital for each patient will continue with home visits or phone calls. A researcher or the provincial health directorate home-based healthcare services coordination unit will make home visits to the discharged patients when called by the researcher or the caregiver. The study will thus be conducted in the hospital during the patient's hospitalization and at the patient's home after discharge. Figure 3 shows the planned study design.

### **Control Arm**

The preparation of the control group for discharge will be handled by the clinical staff according to the routine procedures of the hospital. At the first interview after hospitalization, the intervention and control groups will be administered a pretest and a posttest at the end of 3 months after discharge. After the posttests, the website will be made available for the control group.

### **Data Collection**

The first interview will be conducted face-to-face in the hospital where the researcher will collect the baseline data, and the final measurements will be taken from the online self-report. The measurement tools for caregiver and patient outcomes are explained below:

### **Data Collection Tools**

#### **Caregiver outcome measures**

##### **Caregivers' competence**

The Caregiving Competence Scale will be used to assess competence. This scale developed by Pearlin et al. (1990) and adapted to Turkish by Demir Avcı and Gözümlü (2021) is a Likert-type scale consisting of 4 questions. It is rated as 1 - not at all, 2 - just a little, 3 - fairly, and 4 - very; with the lowest score being 4 and the highest 16. Higher scores signify a higher level of competence in caregiving. The Cronbach alpha for the scale was .83.

##### **Caregivers' preparedness**

The Preparedness for Caregiving Scale will assess preparedness. The scale, developed by Archbold et al. (1990) and adapted to Turkish by Karaman and Karadakovan (2015) is a Likert-type scale consisting of 9 questions. It is rated as 0 - not at all prepared, 1 - not too well prepared, 2 - somewhat well prepared, 3 - pretty well prepared, and 4 - very well prepared; with the lowest score being 0 and the highest 32. Higher scores signify a higher level of competence in caregiving. The Cronbach alpha for the scale was .92.

##### **Caregivers' e-health literacy**

The e-Health literacy scale will be used to assess e-health literacy. The scale was developed by Norman and Skinner (2006) and adapted to Turkish by Coşkun and Bebiş (2015). The scale includes 8 items and measures internet usage in 2 items and internet attitude in 6 items. The scale items are rated

on a 5-point Likert-type scale with a scores as: 1 - strongly disagree, 2 - disagree, 3 - neutral, 4 - agree, and 5 - strongly agree; with the lowest possible score being 8 and the highest 40. The Cronbach alpha for the scale was .78.

##### **Caregivers' burnout**

The Maslach Burnout Inventory-General Form (MBI-GF) will be used to assess burnout. The inventory, developed by Schaufeli et al. (1996) and adapted to Turkish by Gündüz et al. (2013), a Likert-type scale consisting of 15 items and 3 subscales. The emotional exhaustion subscale includes 5 items (1, 4, 7, 10, and 13), the depersonalization subscale 5 items (2, 5, 8, and 11), and the personal accomplishment subscale 5 items (3, 6, 9, 12, 14, and 15). The views on each item are scored as: 1 - never, 2 - sometimes, 3 - usually, 4 - mostly, and 5 - always. Higher scores in the emotional exhaustion and depersonalization subscales and lower scores in the personal accomplishment (reverse-scored) subscale indicate burnout. A total of 3 separate burnout scores are calculated for each person. The Cronbach alpha was .82 for the emotional exhaustion subscale, .77 for the depersonalization subscale, and .79 for the personal accomplishment subscale.

##### **Caregivers' usability of the website**

The System Usability Scale, developed by Brooke (1996) and adapted to Turkish by Kadirhan et al. (2015), is a Likert-type scale consisting of 10 questions. In the Likert evaluation, scores are rated as: 0 - strongly disagree, 1 - disagree, 2 - undecided, 3 - agree, 4 - strongly agree; and items 2, 4, 6, 8, and 10 are scored in reverse-scored. A score ranging between 0 and 100 is obtained by multiplying the score with 2.5. Higher scores indicate an increased usability level and a score of 65-70 indicates that the webpage is acceptably usable (Kadirhan et al., 2015) The Cronbach alpha for the scale was .78.

##### **Patient outcome measures**

The form prepared by the researchers includes two questions. First question is emergency room visit after discharge and other question is development of pressure injuries in the patient after discharge.

##### **Statistical Analysis (Primary and secondary outcomes)**

The Statistical Package of Social Science (IBM SPSS Corp., Armonk, NY, USA) version 23.0 soft-

ware will be used for the analysis of the data to be obtained from the quantitative research. The normality test will be applied after the data are collected and before the analysis. The mean and standard deviation for the continuous variables of the sociodemographic data of the patients and caregivers in the control and intervention groups and the percentage and numerical values for categorical data will be calculated. For the intervention and control groups, the Cronbach alpha coefficients, mean scores of the scales, and minimum-maximum values of the scales to be applied to the pretest and posttest will be examined. In case of any loss in the sample, an intention-to-treat analysis will be performed.

A *t* test (paired samples *t* test or Wilcoxon signed ranks test) will be carried out to analyze the caregivers' primary outcomes in terms of competency, preparedness, e-healthy literacy, and caregiver burnout. The control and intervention groups will be compared using the independent samples *t* test or the Mann-Whitney U test. The secondary outcome of website usability will be assessed based on mean scores.

Primary outcomes of patients, re-hospitalization, and pressure injuries will be assessed in terms of frequency.

### Follow-up/Monitoring

Participants in both arms of the study will be followed up for 3 months after the initial 12-week intervention. During the follow-up period, the patients will also be routinely followed up as part of the neurology clinic procedures. The interventions, data management, and audit of this study will be monitored by the researcher's thesis monitoring committee every 6 months and each year by TÜBİTAK. As no potential risk is foreseen for the patients and their caregivers, no harm monitoring will be performed.

### Ethical Considerations

Approval from the ethics committee of the Republic of Turkey Ministry of Health Antalya Provincial Health Directorate Antalya Training and Research Hospital (01/06/2017:10707) and legal permissions from the city health administration were obtained for the conduct of the study. In addition, written consent of the caregivers participating in the study will be obtained.

## Discussion

Observations of the lack of unity between the health institutions in the field, the difficulties experienced by the caregivers of patients, and the negative effect of these factors on patient outcomes were the driving force behind this study. The effect of the TCM-based TEMpEST program, developed for adaptation to the healthcare system, will be evaluated to improve caregiving capabilities of families of patients with stroke, to enhance patient care outcomes, and to improve processes to ensure continuity of care.

According to the study conducted by Henriksen and Stuckey (2018) to evaluate the effectiveness of the TCM, 75 hospitals using TCM in the United States have reduced hospital readmissions of patients benefiting from the Medicare system by 50% and have diminished reimbursement costs of health insurance by 50%. In a similar study, Araújo et al. (2018) evaluated stroke-related skills, stroke-related care burden, and the quality of life of informal caregivers of patients with stroke during the care process. They revealed that the mental and general health of the caregivers in the intervention group was better than in the control group, their level of care burden was lower, and the caregivers were able to develop their disease management skills to a greater extent.

Following the intervention, it is expected that caregivers of patients with stroke will have received the information they need during and after treatment, experience reduced burnout, and their caregiving competency and electronic health literacy will improve. In addition, it is expected that reducing the re-hospitalization of patients with stroke will contribute to cost-effectiveness.

### Study Limitations

This study will focus on a small sample of patients with stroke and their voluntary caregivers in a single center. Therefore, the generalizability of the results will be specific only to the participants in the study.

## Conclusion and Recommendations

TCM provided to the caregivers of patients with stroke, beginning in the hospital and continuing at home, will ensure continuity of care. This study believe that this study may provide a sample homecare model for the country as a whole. The multiple interventions will start from admission to the hospital in



the form of training, introduction to an informative website, telephone communications, home visits, and ensured access to home health services. As the caregivers of patients with stroke begin to receive training regarding every issue they may face during and after the treatment of their patients, the effect of this support will be seen as their caregiving competencies increase, burnout reduces, and e-health literacy improves. In addition, repeated hospitalizations of stroke patients will reduce. This study also believe that the study will be a cost-effective application in the long run. Once the website, [www.hastayakini.net](http://www.hastayakini.net), for the caregivers of patients with stroke is established, the data acquisition process of the treatment group will be completed, and the website will be used in the neurology clinics. If successful results are achieved, the use of TCM in the clinics will be recommended.

**Ethics Committee Approval:** Ethics committee approval was received for this study from the ethics committee of Republic of Turkey Ministry of Health Antalya Provincial Health Directorate Antalya Training and Research Hospital (01/06/2017:10707).

**Informed Consent:** Written consent will be obtained before delivering the questionnaires.

**Peer-review:** Externally peer-reviewed.

**Author Contributions:** Concept – Y.D.A., S.G.; Design – Y.D.A., S.G.; Supervision – Y.D.A., S.G.; Resources Y.D.A., S.G.; Materials – Y.D.A., S.G.; Data Collection and/or Processing – Y.D.A., S.G.; Analysis and/or Interpretation – Y.D.A., S.G.; Literature Search – Y.D.A.; Writing Manuscript – Y.D.A., S.G.; Critical Review – Y.D.A., S.G.; Other – Y.D.A., S.G.

**Conflict of Interest:** The authors have no conflicts of interest to declare.

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