Effectiveness of Caregiver Education for Prevention of Shoulder Pain in Acute Stroke Survivors: A Randomised Controlled Trial

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ABSTRACT

Purpose: *This study aimed to determine the effectiveness of caregiver education to prevent or reduce hemiplegic shoulder pain, a complication following stroke that adversely affects functional outcomes and prolongs rehabilitation.*

Method: *The study was a randomised controlled trial involving acute stroke survivors in the hospital and their primary caregivers. The participants were conveniently selected and randomly allocated to the experimental (n = 20) and control groups (n = 20) using block randomisation. The stroke survivors of both the study groups received conventional therapy. In the experimental group, caregivers participated in three individual sessions of the education programme for shoulder care, which comprised provision of information, demonstration and training. The outcome measures at pre-assessment were the Visual Analogue Scale (VAS) for shoulder pain and the Fugyl-Meyer Assessment for Upper Extremity for Motor Recovery. Caregiver feedback scores were obtained following the intervention. The VAS scores were obtained at 30 days following intervention and 30 days following post-assessment (follow-up assessment) through the posted envelopes. Mann-Whitney U test and Chi- square test were used for statistical analysis.*

Results: *There was no significant difference between the groups on VAS at follow-up assessment. The number of stroke survivors reporting "no pain" increased by 29% in the experimental group and decreased by 6% in the control*

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group. Caregiver feedback scores were higher in the experimental group than in the control group (P < 0.001).

Conclusion: *This study indicates that educating caregivers on shoulder care during acute management at the hospital, improves their confidence in handling and positioning the stroke survivor after discharge and could reduce hemiplegic shoulder pain.*

Key words: *stroke, hemiplegic shoulder pain, subluxation, DEDICT, caregiver education*

INTRODUCTION

Stroke is one of the major health problems in India (Banerjee, Mukherjee & Sarkhel, 2001). Post-stroke shoulder pain or hemiplegic shoulder pain (HSP) is a common complication following stroke (Jespersen, Jorgensen, Nakayama & Olsen, 1995). It develops as early as in the second week following stroke (Chantraine, Baribeault, Uebelhart & Gremion, 1999), and has detrimental influences on the rehabilitation process and outcomes (Rizk, Christopher, Pinals, Salazar & Higgins, 1984; Roosink, Geurts & Ijzerman, 2010). Poor handling and improper positioning of the affected upper limb following stroke is reported to be a causative factor for HSP (Jensen, 1980). It is therefore crucial to support and protect the involved shoulder joint (Viana, Pereira, Mehta, Miller & Teasell, 2012), especially during the initial acute, flaccid phase following the stroke event (Andersen, 1985; Gamble et al, 2002). Studies have shown that training the rehabilitation team in proper handling of the affected upper limb reduces HSP (Jones, Carr, Newham & Wilson-Barnett, 1998; Forster, 1999; Jones, Tilling, Wilson-Barnett, Newham & Wolfe, 2005). It is suggested that caregiver education could also be helpful (Zeferino & Aycock, 2010). This would be beneficial in India, where caregivers play a crucial role in the medical care and rehabilitation of stroke survivors.

There are very few stroke units in the country, and these are mostly located in urban areas (Pandian & Sudhan, 2013). Many hospitals do not have an adequate number of trained nurses (Yasmeen, 2014) and rehabilitation professionals to provide comprehensive care. Due to this, caregivers are often involved in the management of the stroke survivors during their hospital stay. Following discharge, as rehabilitation services are often inaccessible and unaffordable (Kamalakannan et al, 2016), caregivers are involved in self-care and therapy of stroke survivors at their homes. Thus, caregiver education could be very helpful to prevent or reduce hemiplegic shoulder pain.

Objective

In India, the prevalence of HSP is reportedly around 47.7% (Joy et al, 2012). This suggests that hemiplegic shoulder pain is a significant concern that needs to be addressed for better rehabilitation outcomes. Currently, there is limited evidence on this aspect of stroke rehabilitation in the Indian context. Innovative education programmes are recommended to meet rehabilitation needs of this population (Kamalakannan et al, 2016). Therefore, the present study aimed to determine the efficacy of a caregiver education programme to prevent or reduce HSP.

METHOD

Design

The study design was a randomised controlled trial with an experimental and control group.

Setting

The study was conducted in two tertiary care hospitals in Udupi district of Karnataka State, India.

Sample

The study participants were acute stroke survivors and their primary caregivers. Participants were selected conveniently according to the selection criteria.

Persons admitted for management of first episode of stroke, medically stable, conscious and with National Institute of Health Stroke Scale (NIHSS) scores less than 14, indicating mild to moderate stroke, were included in the study (Kasner, 2006).

Persons who had been more than five days after stroke at the time of referral, with stroke-related language impairments and unilateral neglect, prior history of hemiplegia and shoulder trauma, were excluded. Stroke survivors with NIHSS scores greater than 14, indicating severe stroke requiring long-term care (Brott et al, 1989) were also excluded.

For inclusion, caregivers of the acute-stroke survivors selected for the study were required to have adequate comprehension and communication abilities. Caregivers with any psychiatric comorbidity were excluded.

Informed consent was taken from both the stroke survivors and their caregivers.

Procedure

The sample size was estimated using the formula, $n = 2 (Z_{1-\alpha/2}+Z_{1-\beta})^2\sigma^2 \div d^2$, where $Z_{1-\alpha/2} = 1.96$ at $\alpha = 5\%$ (level of significance), $Z_{1-\beta} = 0.84$ at $\beta = 20\%$ (power), $\sigma = 1.7$ (computed from 10/6, where 10 denotes the range of the value and 6 denotes the standard deviation assuming the data will follow normal distribution of 3 ± SD) and d=2 which was the clinically significant difference on Visual Analogue Scale (VAS) for pain set by the investigators. A sample size of 11 per group was estimated and it was increased by 20% since non-parametric tests were expected by which a sample size of 15 per group was calculated. Since a dropout rate of 20% was expected, the final sample size was determined to be 20 per group.

To ensure equal number of participants in the control and experimental groups, block method of randomisation was used. Considering a block size of four with 10 blocks, a random sequence of codes was generated using computer method. Each code was sealed in an opaque envelope prior to study commencement. Blinding could not be done in this study due to practical constraints. Pre-assessment was done on the fifth day following stroke, using the outcome measures selected for the study. Stroke survivors of both the study groups received conventional therapy. In the experimental group, caregivers participated in the education programme for shoulder care. Following provision of intervention, caregiver feedback was obtained. Post-assessment was done 30 days after intervention and the follow-up assessment was done 30 days following post-assessment. The post- and follow-up assessments were done through telephone and by post.

Outcome Measures

The Visual Analogue Scale (VAS) was used to assess the shoulder pain on a scale ranging from 0 to 10, where 0 indicates “No pain” and 10 indicates “Very severe pain” (Price et al, 1983). Motor recovery of the affected upper limb was assessed with the Fugyl-Meyer Assessment for Upper Extremity (Fugyl-Meyer, Jaasko, Leyman, Olsson & Steglind, 1975). Both these measures were used at pre-assessment (fifth day following stroke). The stroke survivors and caregivers were provided stamped envelopes containing the VAS at discharge. On the scheduled day of post-assessment and follow-up assessment, the investigator instructed the caregivers and stroke survivors, over the phone, to mark the pain scores on the VAS and to post their responses to the investigator.

Caregiver feedback was obtained after intervention using a 5-item ordinal scale. Each item was scored ranging from 1 (lowest score) to 5 (highest score). The items included: 1) satisfaction with information provided about stroke, 2) satisfaction with information about complications following the stroke, especially shoulder pain, 3) satisfaction with instruction and training about handling and positioning, 4) confidence gained in handling and positioning the stroke survivor, and 5) overall satisfaction with the education programme. The average score of the 5 items was computed.

Intervention

In both the study groups, the stroke survivors received conventional therapy which included positioning, facilitation of motor recovery and shoulder sling or cuff usage with general instructions. In the experimental group, the caregivers participated in the education programme. The caregiver education programme was developed according to the World Health Organisation guidelines (Gorske, 2011) and a direct skill instructional model called DEDICT (Thomas, 2007). The programme involved three individual or one-to-one sessions over three days. The first session was conducted in the local language, using an illustrated educational handbook with information about stroke and its complications, shoulder pain and subluxation, importance of correct handling and positioning, and proper sling usage. Handouts were provided to the caregivers during the session. The second session included practical demonstrations on proper positioning, handling and transfers of stroke survivors, followed by practice for caregivers. The third session included recall and review for the caregivers, followed by feedback and queries. Each session took 30 to 60 minutes. When possible, stroke survivors were also involved in all the sessions.

Data Analysis

Data analysis was done using SPSS 17.0 Version. The level of significance was $P<0.05$. Comparison of the two groups was done with Mann-Whitney U test and Chi-square, for continuous and categorical variables respectively. Pearson's correlation was done to study the association of Fugyl-Meyer Assessment for Upper Extremity, with VAS at pre-assessment. VAS scores at post- and follow-up assessments were analysed descriptively.

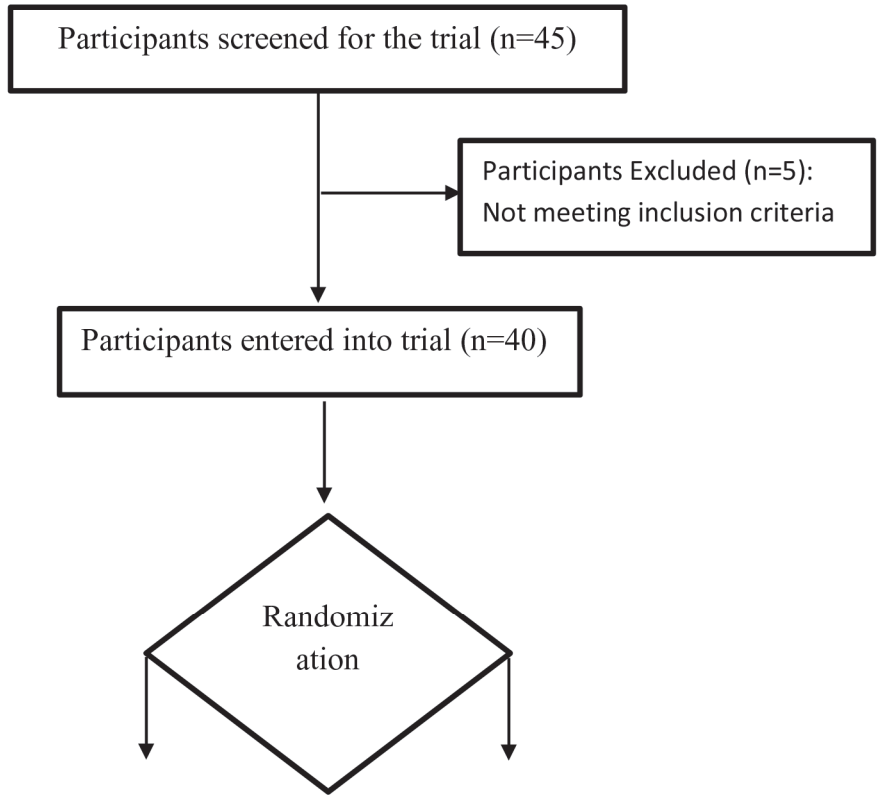
Ethics Approval

Approval of the Institutional Ethical Committee was obtained (IEC 400/2015).

RESULTS

Forty stroke survivors (20 in the control group and 20 in the experimental group) and their caregivers participated in this study. Figure 1 displays the flow of the participants during the study. The post-assessment had 35 participants (17 in the control group and 18 in the experimental group) and follow-up assessment had 33 participants (16 in the control group and 17 in the experimental group) due to drop-outs. Table 1 shows the sociodemographic and clinical characteristics of stroke survivors and Table 2 shows the sociodemographic characteristics of the caregivers.

Figure 1: CONSORT Diagram showing the Flow of Clients through the Trial



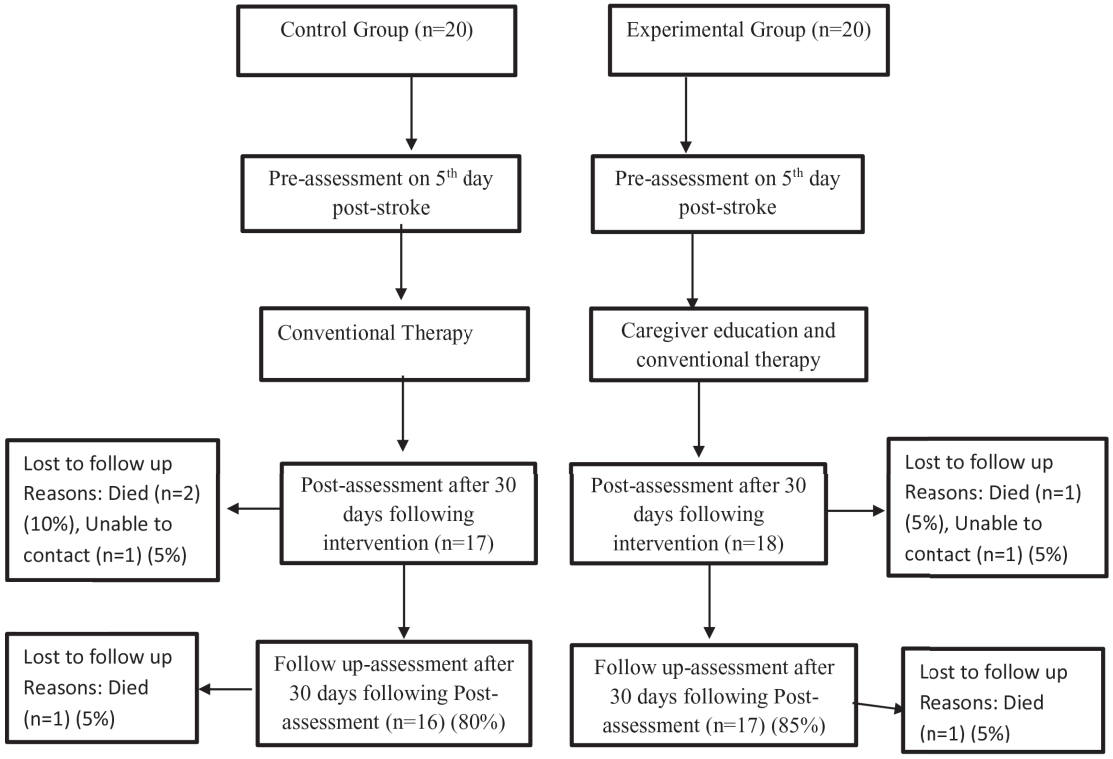


Table 1: Sociodemographic and Clinical Characteristics of Stroke Survivors

Characteristics		Groups	
		Experimental (N=20)	Control (N=20)
Gender	Male	12 (60%)	9 (45%)
	Female	8 (40%)	11 (55%)
Education	None	5 (25%)	5 (25%)
	Up to tenth grade	10 (50%)	13 (65%)
	Diploma/Graduate	5 (25%)	2 (10%)
Occupational status	Working	17 (85%)	20 (100%)
	Retired	3 (15%)	0 (0%)
Side of lesion	Left	10 (50%)	10 (50%)
	Right	10 (50%)	10 (50%)

Chi-square test indicated no statistically significant difference between the stroke survivors of the study groups with respect to gender (P = 0.342), education (P = 0.432) and occupation (P = 0.72). Similarly, Chi-square test suggests no statistically significant difference between the caregivers of the study groups with respect to

gender (P = 1.00), education (P = 0.442), occupation (P = 0.35) and socioeconomic status (P = 0.71). Table 2 shows an important finding that caregivers in both the study groups included more women and parents who were involved in productive work.

Table 2: Sociodemographic Characteristics of Caregivers

Characteristics		Groups	
		Experimental (N=20)	Control (N=20)
Gender	Male	7 (35%)	7 (35%)
	Female	13 (65%)	13 (65%)
Relation with stroke survivor	Spouse	6 (30%)	4 (20%)
	Parent	10 (50%)	8 (40%)
	Child	2 (10%)	7 (35%)
	Others	2 (10%)	1 (5%)
Education	Up to tenth grade	4 (20%)	3 (15%)
	Higher secondary	7 (35%)	11 (55%)
	Diploma/Graduate	9 (45%)	6 (30%)
Occupational status	None/ Retired	0 (0%)	4 (20%)
	Working	20 (100%)	16 (80%)
Socioeconomic status	Low	4 (20%)	6 (30%)
	Medium	8 (40%)	8 (40%)
	High	8 (40%)	6 (30%)

Table 3 shows the results of the Mann-Whitney U test. There was no significant difference between the groups for stroke survivors' age, caregivers' age, duration of hospitalisation, NIHSS scores and pain scores. However, the control group had significantly higher Fugyl-Meyer motor function scores than the experimental group. Pearson's correlation coefficient indicated significant association of Fugyl-Meyer motor function scores and pain scores at pre-assessment, Pearson's r = -.41, p = 0.008. As seen in Table 3, the VAS scores of the two groups were similar at post-assessment and follow-up assessment.

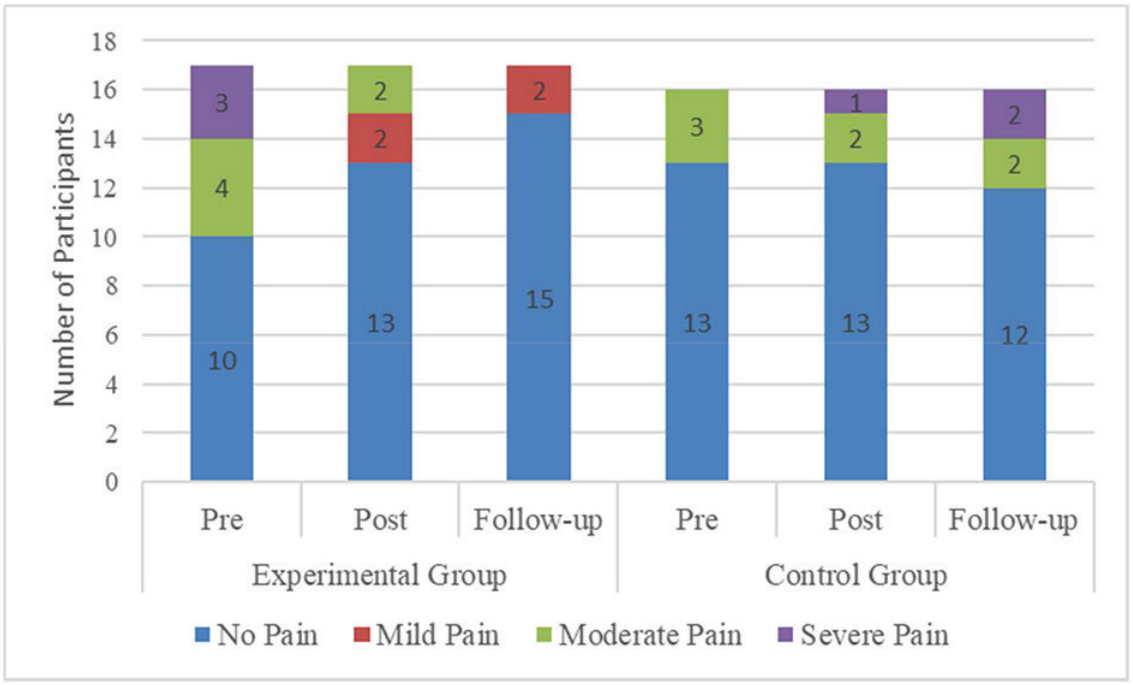
Table 3: Comparison of Participant Characteristics between Study Groups

Variables	Groups		'P' value
	Experimental Median(IQR)	Control Median(IQR)	
Client age (n = 40)	59.5(50-71)	59(46-64)	0.357
Caregiver age (n = 40)	32.5(26-49)	38(31-55)	0.180
Duration of hospitalisation(n = 40)	8(7-10)	7(7-9)	0.350
NIHSS scores (n = 40)	8(0-12)	4(0-15)	0.074
Fugyl-Meyer motor function (n = 40)	0(0-21)	36.5(0-65)	0.042*
Caregiver feedback (n = 40)	4.9(4.45-5)	2.4(1.65-3)	0.000*
Visual Analogue Scale			
Pre-assessment (n = 40)	1.5(0-7)	0(0-3)	0.172
Post-assessment (n = 35)	0(0-4)	0(0-7)	0.929
Follow-up assessment (n = 33)	0(0-2)	0(0-8)	0.581

*level of significance at $P < 0.05$; IQR- Interquartile Range

Figure 2 shows the VAS pain scores of the participants of the two groups who completed the pre-, post- and follow-up assessments. In the experimental group of 17 participants, the number of stroke survivors with 'no pain' increased from 10 (59 %) at pre-assessment to 15 (88 %) at follow-up. In the control group of 16 participants, the number of participants with 'no pain' reduced from 13 (81%) to 12 (75%). Also, the number of stroke survivors reporting "moderate to severe pain" decreased in the experimental group and increased in the control group during the follow-up assessment. Caregiver feedback scores were significantly higher in the experimental group than the control group as seen in Table 3.

Figure 2: VAS Pain Scores in the Study Groups



DISCUSSION

The experimental and control groups in the present study were similar in baseline characteristics, except for Fugyl-Meyer motor function scores that indicated moderate level of impairment in the control group and severe level of impairment in the experimental group (Woytowicz et al, 2017). At follow-up assessment, although the pain scores were similar in both the groups, the number of stroke survivors reporting "no pain" increased in the experimental group. In contrast, although the control group had better motor function scores at baseline, at follow-up the number of people with "no pain" decreased while those with "severe pain" increased. This finding was surprising as hemiplegic shoulder pain has been found to correlate with poor arm motor function and range of motion restriction in the acute and chronic stage of hemiplegia, and also with spasticity in the chronic stage (Pong et al, 2009; Pong et al, 2012) which is also supported by significant association between Fugyl-Meyer motor function scores and VAS pain scores at pre-assessment in the present study. Thus, a possible explanation is that stroke survivors in the control group with moderate level of upper limb impairment may have developed HSP due to abnormal humeral and scapular

kinematics caused by weakness and spasticity of the rotator cuff and scapular muscles, incorrect exercises, especially overstretching or overloading and handling (Lindgren, Jonsson, Norrving & Lindgren, 2007; Pong et al, 2009). The follow-up assessment was done around two months after stroke during which time stroke survivors commonly develop shoulder subluxation (Suethanapornkul et al, 2008), spasticity (Pong et al, 2009) and range of motion restriction (Pong et al, 2012). Rotator cuff injuries, tendinosis of the long head of the biceps tendon and supraspinatus are the common findings associated with HSP in the chronic stages. This could hinder motor and functional recovery of the hemiplegic arm (Rizk et al., 1984; Roosink et al., 2010). In view of these findings, future clinical trials may have to consider using stratified randomisation based on levels of upper limb motor impairment.

Thus, as recommended by earlier studies, prevention of shoulder pain should be an essential component of acute stroke care, especially for those with low general health status and poor arm function at baseline (Turner-Stokes & Jackson, 2002; Pong et al, 2012). In addition, stroke survivors with better arm motor control at baseline would also benefit from education programmes during acute care to prevent shoulder pain and support further motor recovery.

The caregiver feedback scores were higher in the experimental group than in the control group. Thus, caregivers were satisfied with the programme as it improved their confidence about shoulder care. This finding further supports the usefulness of the caregiver education programme.

The caregiver education programme in the present study was adapted from the DEDICT model (Thomas, 2007), that involves demonstration, explanation, second demonstration, imitation, correction/coaching and trials. Though this model was originally developed for physical education, it was used in this programme for educating and training caregivers. Compared to home programmes through handouts or verbal instructions at discharge, the present study suggests that a discharge programme involving education and training probably facilitates better generalisation or application of home programmes following discharge to effectively reduce shoulder pain. This could be due to better understanding about the shoulder joint, mechanism of the injury, complications such as shoulder hand syndrome and its prevention. Instead of merely explaining dos and don'ts, the caregiver education programme helped the caregivers in understanding the rationale of treatment and gave them a sense of control. The practice session, recall

and review, followed by caregiver feedback and queries, facilitated confidence in the caregivers about shoulder care of stroke survivors.

Limitations and Recommendations

The present study intended to have follow-up assessments for the stroke survivors' motor recovery and functional independence, at one month and two months following discharge. The study was carried out at a super-specialty hospital that caters to clients from neighboring districts and states. The duration of hospital stay is usually short (around 7 - 10 days) and stroke survivors are discharged once they are medically stable. Following discharge, most of the stroke survivors tend to follow-up at hospitals or clinics near their homes. Thus, follow-up at this tertiary hospital is usually challenging. Cognizant of this, in the present study the follow-up assessments for VAS scores were obtained through post but Fugyl-Meyer motor function assessment could not be done. Due to the short hospital stay and poor follow-up, detailed assessments could not be done including clinical assessments for stroke survivors' motor and functional recovery, factors associated with HSP such as subluxation, spasticity, other conditions such as thalamic pain, and objective assessments such as radiography, sonography, etc. The impact of these on study findings cannot be ruled out. Due to practical constraints and challenges in participant recruitment, stratification and blinding could not be done. During sample size estimation, in the absence of any literature based on experience, the researchers considered a modest change of 2 points in the VAS scores as the value for clinical significant difference (d) in the formula. This may explain the sample size computed for the study. The use of other interventions such as medications to reduce pain or spasticity following discharge could not be ascertained. In view of these limitations, the study findings need to be generalised with caution.

Thus, the present study could be considered a preliminary study that demonstrates the potential and feasibility of a caregiver education programme in acute care set-ups, to reduce HSP in resource-constrained settings. Considering the implications of shoulder pain to outcomes of stroke rehabilitation, further research on this is warranted. Multi-centric randomised controlled trials with blinding, stratification based on upper extremity motor function scores, larger samples and longer follow-ups with direct, standardised, objective clinical and functional outcome measures are thus recommended.

CONCLUSION

The study demonstrates that educating caregivers about shoulder care during acute management of stroke survivors could reduce hemiplegic shoulder pain.

Implications

The study findings suggest that caregiver education in the acute phase, during hospital stay, of the stroke survivors could reduce HSP. The caregiver education programme developed in this study is practical, feasible and cost-effective. It can be easily integrated with conventional therapy for stroke, even during the short duration of hospitalisation. It can be conducted in groups and can be provided by any healthcare professional. As in the present study, caregivers of stroke survivors are often working people, women and parents. With limited access to and affordability of rehabilitation services in India, innovative and person-centric education programmes (Kamalakannan et al, 2016), as of the present study, are essential to reduce caregiver burden. It will also help increase stroke survivors' participation in daily activities, adherence to long-term rehabilitation and improve treatment outcomes.

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