

**EFFECT OF A TAILORED MULTIDIMENSIONAL INTERVENTION ON THE  
CARE BURDEN AND QUALITY OF LIFE AMONG FAMILY CAREGIVERS OF  
STROKE SURVIVORS**

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## SUMMARY

Stroke being one of the most common causes of severe disability <sup>1</sup>, often requires long-term care <sup>2</sup>. Stroke survivors with functional impairment depend on family caregivers, usually family members, to assist them in performing their daily activities <sup>3</sup> and other stroke management and rehabilitation tasks <sup>2,4</sup>. The high level of stress experienced by family caregivers often causes them strain and care burden <sup>5,6</sup>. Literature reveals that family caregivers of stroke survivors often feel insufficiently supported to cope with the care burden <sup>7,8</sup>. This urgent issue indicates the need for evidence-based initiatives that reduce the care burden among family caregivers of stroke survivors <sup>9,10</sup>, and in turn, improving the well-being of stroke survivors as well <sup>11</sup>.

Multiple systematic reviews have investigated interventions designed to support family caregivers of stroke survivors by reducing their care burden and its consequences <sup>12,13</sup>. However, many of these studies have reported mixed results <sup>12-14</sup>. The controversies about the effectiveness of previous interventions have been attributed to several factors, particularly related to the type of the interventions <sup>12,14</sup>. Firstly, most of the interventions assessed were standardised; in other words, they approached the subject with an assumption that all family caregivers have the same needs <sup>15,16</sup>. Whereas, evidence suggests that tailored interventions—customized for the family caregiver’s needs—are the most feasible and have the most positive impact on family caregivers and stroke survivors <sup>17,18</sup>. The need for tailored interventions to mitigate the unmet needs of family caregivers of stroke survivors have been enthusiastically recommended in the literature <sup>19,20</sup>.

Secondly, regarding the components of the interventions, researchers concluded that single-approach interventions, which provide only one component of support, might have limited benefit for the family caregivers of stroke survivors <sup>12,13</sup>. In contrast, interventions that incorporate more than one approach, such as skill-building <sup>4</sup>, psychoeducation <sup>10</sup>, and peer support <sup>5,21</sup>, were likely to have the most significant effects on care burden and other adverse effects <sup>12,14,22</sup>. Therefore, empirical findings endorse conducting future studies that

focus on integrating various approaches. Nonetheless, such interventions have not been tested in various settings, and little is known about their efficacy<sup>5,14</sup>. For instance, in Egypt, the family caregivers of stroke survivors facing tremendous levels of care burden due to several factors as we discussed previously. However, the latest systematic review that aimed to investigate interventions for psychological health of stroke caregivers, didn't find interventions in Egypt<sup>22</sup>. In Egypt, there is still family support system for stroke survivors. However, this support system cannot be maintained for long time of care due to several social determinants. Identifying and implementing strategies that support family caregivers and meet the required care needs have to be considered (Family Caregiving for older people report, 2016).

Reviewing the abovementioned factors, we developed a tailored and multidimensional intervention based on an evidence-based conceptual framework that considers the previous scientific recommendations. The primary objective of this study was to evaluate the effectiveness of the intervention in reducing the care burden of family caregivers. The study findings added to what is known in nursing and medical practices about providing interventions to family caregivers.

### **Aim and hypothesis**

This study aimed to evaluate the effectiveness of a tailored multidimensional intervention in reducing the care burden among family caregivers of stroke survivors. The main hypothesis was that the family caregivers of stroke survivors (IG) who received the tailored multidimensional intervention would experience a reduction in their care burden, relative to those who received an educational booklet (CG).

## **METHODS**

### **Trial design and study participants**

A prospective, open-label, parallel 1:1 RCT, unblinded for outcome evaluation, structured on the basis of the CONSORT<sup>23</sup>, was conducted in Dakahlia Governorate, Egypt<sup>24</sup> from December 2019 to November 2020. The protocol of this study was developed in accordance with the Standard Protocol Items Recommendations for Interventional Trials<sup>25</sup> and registered at ClinicalTrials.gov (NCT04211662). This has been documented in detail elsewhere to ensure reproducibility<sup>26</sup>. In summary, the target group of our study was family caregivers of stroke survivors. The inclusion criteria were: family caregivers who were  $\geq 18$  years of age; agreed to participate in the study; caring for stroke survivors who had a stroke within the previous six months<sup>27,28</sup> and needed assistance with the modified Rankin Scale (mRS) scores of 3–5 at enrolment<sup>29</sup>. Caregivers were excluded if they had cognitive impairment or if their stroke survivors had other physical disabilities or terminal-stage illnesses.

### **Recruitment procedure and assessment of eligibility**

In this community-based study, the participants were approached by physicians and nurses at seven outpatient clinics located in Mansoura City, the capital of Dakahlia Governorate, and surrounding cities within a 30 km radius. The participants were recruited using the detailed steps provided in the protocol of this study. The researchers contacted family caregivers via telephone to explain the purpose of the study and schedule home visits. Each home visit was conducted by one of the researchers to verify whether the selected participants met the eligibility criteria. All eligibility criteria were verified through interviews with the family caregivers, assessments of the stroke survivors' health conditions, and reviews of the available medical records.

## **Randomisation and allocation**

After confirming the eligibility criteria, the family caregivers were allocated to either the IG or the CG through 1:1 open-label randomisation. The family caregivers were randomised into one of the two groups after stratifying stroke survivors according to dependency level (mRS: 3, 4, or 5) and degree of cognitive impairment (MMSE  $\leq$ 20 or  $>$ 20).<sup>30,31</sup> Randomisation was conducted using a computer-generated series of numbers and performed by a member of the research group—not a part of the intervention, who then informed the researchers which participants had been assigned to which group.

## **Intervention tailoring and delivery**

Each family caregiver in the IG received the tailored multidimensional intervention developed using the evidence-based conceptual framework of this study. An intervention was designed for each caregiver in response to their perceived unmet needs. The interventions were created by an interdisciplinary team of medical and nursing experts.

The intervention was delivered over six months through three 120-minute home visits, six 40-minute telephone calls, and one 90-minute peer support session. The interventions were administered by 10 intervention nurses, each with a bachelor's degree in nursing and experience working in stroke care units. The nurses all underwent a 31-hour training programme before the start of the study. Throughout the six months of intervention, the interdisciplinary team performed monthly checks of the nurses' documentation of the intervention progress and provided constructive feedback.

An instructional booklet with information on stroke and caring for stroke survivors was delivered to the CG participants. The intervention nurses explained this information to each of the CG participants during a special home visit (separate from the visits of baseline and outcome assessments).

## **Data collection and outcomes**

After allocating the study participants to either the IG or CG, the intervention nurses conducted an initial home visit for each group to collect data about the sociodemographic characteristics and health conditions of stroke survivors and their family caregivers. Also, the ZBI, WHOQOL-BREF, FNQ-R, and Brief-COPE were administered to the family caregivers at T0 before the intervention. At T1 (3 months) and T2 (6 months), the nurses again collected the same data through home visits for all IG and CG participants.

## **RESULTS**

Between December 2019 and May 2020, 139 participants were evaluated to determine their eligibility for the study. Of them, 17 participants did not meet the inclusion criteria, eight refused to participate, and four stroke survivors died before randomisation. One hundred and ten family caregivers were allocated to either the IG (n=55) or the CG (n=55). Of the 110 family caregivers (50 in the IG and 47 in the CG), 97 (88.2%) completed the study within six months. The intervention was completed at the end of November 2020, and the data of all 110 family caregivers were analysed.

There were no statistically significant differences between the two groups in terms of the characteristics and the study outcomes ( $p > .05$ ) at baseline (T0). Regarding the care burden, the t-tests showed no statistically significant differences in the care burden between the two groups at T1 and T2 ( $p > .05$ ). In terms of the effect of the intervention over time, no significant differences were observed in the interaction (group  $\times$  time), within groups, or between groups (all  $p > .05$ ).

Concerning QoL, both the physical and environmental domains scores declined over time in the IG and CG. On the contrary, the psychological and social relationship domain scores increased over time in the IG, whereas those in the CG decreased. T-tests revealed no

significant differences between the two groups at T1 and T2 in the four domains of QoL (all  $p > .05$ ). There were no significant differences within groups or between groups for all domains of QoL, while the effects of group and time interaction on the psychological domain ( $p < .001$ ) and social relationship domain ( $p = .036$ ).

Regarding the unmet needs, the unmet needs among were reduced significantly from T0 to T2. There were statistically significant differences among family caregivers in the IG when compared to the control group at T1 and T2 regarding the health information, emotional support, and professional support domains (all  $p < .05$ ). Besides, the comparison of means of scores of family caregivers' unmet needs between evaluation time points (3-month and 6-month) versus baseline within the IG showed significant changes in health information needs, emotional support needs, and professional support needs (all  $p < .05$ ). On the other hand, the intervention does not have a significant effect on the instrumental support, the community support network and the involvement with care domains (all  $p > .05$ ).

Regarding coping strategies, there were significant statistical differences between the groups in terms of acceptance ( $p = 0.017$ ), positive reframing ( $p = 0.023$ ), use of emotional support ( $p = 0.037$ ), behavioural disengagement ( $p = 0.034$ ), active coping ( $p = 0.010$ ), and planning ( $p = 0.042$ ). These significant results were also found at 6 months (all  $p < .05$ ) except for active coping and planning ( $p = 0.092$ , and  $0.099$ ) respectively. Concerning the progress of coping strategies over time, it was similarly found there were statistically significant changes in active coping, use of instrumental support, and planning for the IG at T1, but these significances did not continue till T2.

## LIMITATIONS

This study has several limitations that could highlight further interpretations of insignificant results. An important issue that should be emphasised is that the family caregivers' rate of compliance with the intervention was not measured. Thus, the effectiveness of the intervention could not be explored extensively. Additionally, family

caregivers, patients, and the public were not adequately involved in the development of the intervention. Moreover, the feasibility and acceptability of the intervention for the participants were not sufficiently assessed. The amount of intervention throughout the intervention period was also inconsistent. Furthermore, the unblinded outcome assessments and self-reported questionnaires used could also be possible sources of anticipatory bias.

The quantitative assessment might not be sufficient to explore the family caregivers' needs and coping strategies. For example, some coping strategies domains might not be adequately explained to and understood by the family caregivers. The family caregivers think humour is a maladaptive approach. However, it may have two aspects (positive and negative). Also, the use of religion as a coping strategy might not be presented in a comprehensive meaning through only two general questions. The family caregivers may turn to religion for widely varying reasons: religion might serve as a source of emotional support, as a mean for positive reinterpretation and growth, or as a tactic of active coping with a stressor.

One peer support session may not be sufficient for the delivery of the intervention. Unfortunately, we could not hold more than one session because of the participants' limited time. The idea of peer support was not easily accepted by the participants, as family caregivers did not participate actively in the peer support discussion, and other family caregivers did not even attend. This finding could be attributed to two major reasons. First, family caregivers preferred not to share their personal experiences and feelings with strangers. Second, it is difficult to build a strong relationship with peers in only one peer support session.

Finally, the content of our intervention might not be simple for the family caregivers as we anticipated. Caregivers might not have sufficient time to demonstrate the intervention effectively. The intervention itself was likely too burdensome. Moreover, the interventions were delivered by nurses with varying levels of enthusiasm; hence, some sessions may not have been delivered as effectively as desired.



Given the wider context of the setting during the study period, we must consider that the COVID-19 pandemic could have affected the study in the following manner:

- Researchers and intervention nurses applied standard precautions to prevent the spread of the virus. Yet, some family caregivers did not attend the peer support sessions, and other family caregivers were afraid of the intervention nurses during their home visits.
- Two intervention nurses preferred not to be involved in the delivery of the intervention. They were replaced by four nurses who required additional preparation and training.
- The trial extended three months over the anticipated completion date.

## **CONCLUSION**

In conclusion, we performed the first RCT directed at family caregivers of stroke survivors in Egypt at the community level. The study was rigorously designed and conducted following the evidence-based guidelines. In response to the research question of our study, the results showed no significant differences between the IG and CG in terms of reducing the family caregivers' burden or improving their QoL. However, there were significant improvements in some aspects of secondary outcomes (unmet needs and coping strategies). Family caregivers in Egypt may need more than psychoeducation, skill-building, or peer support interventions to reduce their care burden and improve other outcomes. In brief, although our findings are not generalisable, this type of intervention may not be sufficiently effective for family caregivers of stroke survivors in the Egyptian context.

## **RECOMMENDATIONS**

We recommend further testing of various interventions in the Egyptian context. These interventions should be designed in accordance with evidence-based recommendations, as in our intervention, but should also address the limitations of our intervention. Besides, future initiatives should be established through the collaboration of multiple sectors to ensure

adequate support. In other words, we may recommend future interventions considering our findings regarding the unmet needs of the Egyptian family caregivers in general and their needs for instrumental support, community network support, and the involvement with care in specific. We now have left with a question about the efficacy of future interventions which may use such as our conceptual framework combined with the provision of community services.

Moreover, we recommend including process evaluation during the implementation phase to ensure the comprehensiveness of interventions and to obtain an in-depth understanding of the findings. Finally, future studies should also use qualitative approaches to examine the meaning of ‘care burden’ and its determinants among the family caregivers of stroke survivors in the Egyptian context.

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