論文内容要旨

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

（脳卒中患者の家族介護者の介護負担とQOLに対する個別化多次元的介入の効果）

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A post-stroke care system has not been established in Egypt, and stroke survivors are cared for by their families at home after discharge from the hospital, even if the degree of disability is severe. Therefore, the care burden on family caregivers is heavy. This study is the first community-based randomised controlled trial (RCT) provided for family caregivers of stroke survivors in Egypt.

INTRODUCTION

Caring for stroke survivors creates a tremendous care burden among family caregivers. Previous initiatives conducted in several countries at alleviating the care burden have been inadequate. This study, therefore, aimed to evaluate the effect of a tailored multidimensional intervention on the care burden and QoL among family caregivers of stroke survivors. Based on the perceived needs of family caregivers, this intervention considered scientific recommendations to combine three evidence-based approaches which were skill-building, psychoeducation, and peer support.

INTERVENTION DESIGNING

An intervention was designed for each caregiver in the intervention group (IG). The intervention nurses assessed the caregiver's needs using the Family Needs Questionnaire-Revised (FNQ-R), which has been used to create individualised interventions and assess their effectiveness. The unmet needs were identified and summarised by an interdisciplinary team of nursing and medical experts who then created tailored plans based on the unmet needs in line with the appropriate skill-building and psychoeducation strategies likely to fulfill the needs identified. A peer support session was included in the intervention plan as an essential strategy.

METHODS

An open-label, prospective randomised (1:1) control trial was conducted in Egypt between December 2019 and November 2020. A total of 110 caregivers aged ≥ 18 years who cared for survivors within six months, stroke survivors of those with modified Rankin Scale scores of 3–5, and without other physical disabilities or terminal illnesses were recruited and enrolled in this study. Participants were assigned to either the IG (n=55) or the control group (CG; n=55). The IG was provided with tailored multidimensional interventions for six months, including three home visits, six home-based telephone calls, and one peer support session. The CG received simple educational instructions at a single visit. The primary outcome was the scores of care burden measured by the Zarit Burden Interview. Score changes in QoL (WHO QoL-BREF), the caregivers' perceived needs (FNQ-R), and coping strategies (Brief-Coping Orientation to Problems Experienced) were the secondary outcomes. Those were evaluated at baseline (T0), 3rd month (T1), and 6th month (T2). Independent t-test or Mann–Whitney U test was performed to investigate the differences between the two groups at the separate time points, and Wilcoxon signed-rank test or two-way repeated measures analysis of variance was conducted to assess changes in the intervention effect between groups over time.

This trial followed CONSORT guidelines. Trial registration number: NCT04211662.

RESULTS

No differences were observed in the baseline data between the groups at T0. Regarding outcomes, the intervention had no significant effects on the care burden and QoL between groups at T1 and T2 or within groups over time. The group and time interaction, however, had significant main effects on QoL psychological domain ($p < 0.001$) and social domain ($p = 0.036$). There were significant differences between groups at both T1 and T2 for the perceived needs in terms of health information, emotional support, and professional support (all, $p < 0.05$). Also, the IG experienced a significant improvement in these needs over time, whereas the control group did not. Regarding coping strategies, there were statistically significant differences between groups at T1; in terms of acceptance ($p = 0.017$), positive reframing ($p = 0.023$), use of emotional support ($p = 0.037$), active coping ($p = 0.010$), and planning ($p = 0.042$). These significant results were also found at T2 (all, $p < 0.05$) except for active coping ($p = 0.092$) and planning ($p = 0.099$). Similarly, there were statistically significant changes on the same strategies within IG at T1 versus T0 (all, $p < 0.05$), whereas these significant changes faded at T2 for both active copings ($p = 0.843$) and planning ($p = 0.166$).

DISCUSSION

The main study results showed that the care burden and QoL among caregivers who received the intervention did not significantly differ from those allocated to the CG. These findings may be attributed to several factors. The lack of a structured healthcare system in Egypt, where there are no direct and professional supports for stroke survivors and their caregivers, is the most relevant factor that may have affected our study results. Furthermore, the care burden of our study participants may have been influenced by the social determinants experienced by caregivers in Egypt, such as poverty, unemployment, and inadequate health services. On the other hands, our provision of relevant information and coping strategies significantly reduced their unmet needs. Considering all results, our intervention may not be adequate to meet the direct and physical support, which was the highest need of caregivers, as they had anticipated.

CONCLUSION

The main results showed that participants in the IG did not experience an improvement in the primary outcome. Nevertheless, the improvement in the QoL psychological and social domains and other secondary outcomes may have been attributed to our intervention.

エジプトでは脳卒中後のケアシステムが構築されておらず、患者は障害が重くても退院後、自宅で家族により介護される。本研究は、エジプトで初めての、家族介護者の介護負担とQOLに対する個別化多次元介入の効果を測定する，地域ベースの無作為化比較試験（RCT）である。

緒言：脳卒中生存者の介護は、家族に多大な介護負担を強いる。これまでいくつかの国で実施された介護負担軽減のための介入研究の結果は不十分なものであった。本研究では、家族介護者の認識されたニーズに基づき、科学的根拠に基づく3つのアプローチ（技術構築、心理教育、ピアサポート）を組み合わせた介入を構築、家族介護者に対して実施し、その効果を測定した。

介入内容：看護師がFamily Needs Questionnaire-Revised(FNQ-R)を用いて、介護者の未充足ニーズをアセスメントし、多職種医療チームがニーズを満たす技術構築と心理教育を含む、ピアサポートを組み込んだ個別化支援計画を作成し、個々の家族介護者に提供した。

方法：エジプトで非盲検、前向きRCT（1:1)を実施した。参加者は発症後6ヶ月以内の脳卒中生存者（mRS 3-5）を介護する18歳以上の家族介護者110名で、無作為に介入群（n=55）または対照群（n=55）に割り付けた。介入群には6ヶ月間、看護師による3回の家庭訪問、6回の電話訪問、1回のピアサポートセッションが、ケア計画に基づいて行われた。対照群は、1回の家庭訪問での簡単な教育指導を受けた。主要評価項目はZarit介護負担尺度得点の変化で、副次評価指標にはQOL尺度（WHO QoL-BREF)、家族のニーズ質問票尺度得点及びコーピング戦略尺度得点の変化を設定し、ベースライン（T0)、3ヶ月目（T1）及び6ヶ月目（T2）に評価した。統計には、各時点の評価にはt検定またはMann-Whitney U検定を行い、2群間の介入効果及び経時的効果を評価するためにWilcoxon符号順位検定または二元配置反復測定分散分析を行った。

結果：ベースラインデータに群間差はなかった。評価項目については、T1、T2の群間および群内の経時的な介護負担とQOLに、介入は有意な効果を示さなかった。一方で、交互作用では，QoL心理領域（$p < 0.001$）と社会領域（$p = 0.036$）で有意な主効果を示した。また、知覚されたニーズについては、健康情報、情緒的サポート及び専門家サポートについて、T1、T2共に介入群が有意に改善した（すべて、$p < 0.05$)。また、時間経過とともに、介入群ではこれらニーズが改善したが、対照群では観察されなかった。いくつかのコーピング戦略に関しても、各評価ポイントにおいて2群間で統計的有意差が観察された（すべて、$p < 0.05$)。

考察　：本介入では、家族介護者の介護負担の軽減の改善を狙ったが、有意な効果を示すことはできなかった。一方で、介入で実施した心理教育やコーピング戦略に関する情報提供が有意な効果を示した。ニーズ評価の結果からも明らかであったように、家族介護者は訪問した看護師に対して、介護方法等の教育よりも、脳卒中生存者に対する直接ケアの提供を望んでいた。脳卒中後の直接的な専門家による支援体制がないエジプトでは、本研究で構築したプログラムは介護負担の軽減やQoLの改善には寄与できなかったと考えられる。さらに、エジプトにおける貧困、失業、不十分な医療サービス提供体制など、家族介護者の社会的決定要因に影響を受けた可能性がある。

結論：本介入は、家族介護者の介護負担の軽減には効果を示さなかった。その一方で、QOL心理・社会領域やその他の副次的評価項目の改善には、一定の効果を示したと考える。