Study protocol of the Restore4Stroke self-management study: a multicenter randomized controlled trial in stroke patients and their partners

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Rationale **Many stroke patients and their partners report long-term negative consequences of stroke on their health-related quality of life. Adequate self-management abilities may help manage the consequences of the stroke, but it is unknown what specific intervention might be effective to enhance self-management abilities of stroke patients and their partners.**

Aim **The study aims to investigate the effectiveness of a 10-week group self-management intervention addressing proactive coping strategies compared with a group education intervention in stroke patients and their partners.**

Design **The study is a multicenter randomized controlled trial. A total of 106 stroke patients with, if applicable, their partners are randomly assigned to the self-management intervention or the education intervention within each of the 10 participating hospitals and rehabilitation centers. The main inclusion criteria are a symptomatic stroke at least six-weeks ago, living at home, and reporting at least two participation restrictions on the Utrecht Scale for Evaluation of Rehabilitation-Participation's restriction scale. Measurements are performed at baseline, immediately after intervention, three-months, and nine-months postintervention.**

Study outcomes **Primary outcome measures are stroke patients' and partners' proactive coping competencies (Proactive Competence Inventory) and societal participation (Utrecht Scale for Evaluation of Rehabilitation-Participation's restriction scale).**

Discussion **If effective, the results of this study will enable stroke patients and their partners to deal better with the lasting consequences of stroke. In the context of the growing number of people returning home after stroke, a large number of people may profit from this intervention.**

Key words: clinical trial, health-related quality of life, intervention, proactive coping, stroke

Introduction

Stroke has long-term consequences on the health-related quality of life (HRQoL) of both the patients and their partners (1–3). In the long term, stroke patients living at home become largely responsible for managing their own health, including practical difficulties in daily living function, any medical management of the disease, lifestyle changes, and all the other consequences of stroke (4). Thus, the person requires self-management skills to deal with these tasks effectively (5).

In other chronic diseases, interventions aimed at enhancing self-management skills show positive effects on coping, goal achievement and self-efficacy, HRQoL, and utilization of health-care services (5–8). These interventions, however, may need modification to be useful for stroke patients and their partners, because stroke patients face condition-specific challenges (4,6), such as reducing the impact of cognitive and emotional impairments. A specific self-management intervention for stroke patients and their partners might therefore be helpful (9).

There is some evidence for stroke-specific self-management interventions, at least in the short term (9–13). Many of these interventions aim to enhance cognitions underlying intentions of behavior (e.g. self-efficacy and control cognitions). Another approach is to improve patients' goal-related planning and action strategies. Many stroke patients fail to achieve their goals, as they are restrained by unanticipated consequences of stroke (14). Therefore, it may be effective to teach them 'proactive coping strategies', i.e. to have them learn to anticipate the consequences of their stroke and develop corresponding solutions in advance (15). Aspinwall and Taylor modeled proactive coping as consisting of five interrelated stages: (1) resource accumulation, (2) recognition of potential stressors, (3) initial appraisal, (4) preliminary coping efforts, and (5) elicit and use feedback (15).

In the current Restore4Stroke Self-Management study, we investigate whether a self-management intervention based on the proactive coping model results in an increase in the use of proactive coping strategies and societal participation compared with an education intervention. Additionally, we examine levels of self-efficacy and HRQoL and partner's burden. The present paper describes the study protocol of the Restore4Stroke Self-Management study. This study is part of the Dutch national consortium Restore4Stroke (16–18).

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Methods

Design

In this multicenter randomized controlled trial, stroke patients with, if applicable, their partners, are randomly assigned to either the self-management intervention or an education intervention. Patients are recruited by rehabilitation physicians and nurse practitioners in 10 Dutch hospitals and rehabilitation centers where the self-management and control interventions are offered in addition to standard rehabilitation care. These co-operating centers both recruit a minimum of eight participants, and provide the intervention. Tests are administered at baseline (T0), immediately postintervention (T1), and at three-months (T2) and nine-months (T3) follow-up (Supporting Information Fig. S1). Participants and the researcher sign an informed consent form prior to the T0 measurement.

Participants – inclusion and exclusion criteria

Eligible stroke patients are adults aged 18 or over, and living at home who have had a first or a recurrent symptomatic stroke (ischemic or intracerebral hemorrhagic lesion confirmed by a neurologist and recorded in the medical file) at least six-weeks earlier, and have problems on at least two items of the restriction scale of the Utrecht Scale for Evaluation of Rehabilitation-participation, USER-Participation (19). Clinically judged exclusion criteria comprise insufficient mental ability to understand and profit from the intervention, insufficient command of the Dutch language (score <5 on the Shortened version of the Aphasia Scale of the Dutch Aphasia Foundation, SAN (20)), inability to function in a group because of behavioral problems, major depression, and already taking part of a structured, psychological counseling aimed at proactive coping poststroke at the moment of recruitment. Stroke patients can join the study whether or not they have a partner taking part in the study.

Eligible partners have to be at least 18 years of age and have to live together with the stroke survivor taking part in the study. Clinically judged exclusion criteria for partners are inability to function in a group because of behavioral problems and insufficient command of the Dutch language to participate in the intervention or complete the questionnaires. Partners cannot take part without their stroke patient.

Randomization

In blocks of eight, stroke patients are randomized to the two interventions (1:1 ratio), stratified by center. Patients choose one out of eight blank envelopes with their assigned treatment group indicated inside. Partners follow the patient in the appointed intervention.

Interventions

Characteristics of both interventions are summarized in Table 1.

Self-management intervention

This 10-week intervention consists of six two-hour sessions in the first six-weeks and a two-hour booster session in the tenth week. During the first two sessions, participants are introduced to each other and to the self-management intervention, and stroke-related consequences and experiences are discussed. In the third session, the concept of proactive coping is introduced, with the corresponding action plan, which serves as a tool to teach participants how to adopt proactive coping strategies when setting personal goals. Action plans are based on patients' and partners' own goals and consist of the following five steps: (1) getting an idea of what they want to change in their lives; (2) putting a goal into words; (3) mapping restrictions and requirements to achieve the goal, and thinking of possible solutions; (4) formulating the concrete action for the following week; and (5) evaluation of the concrete action (7). The next three sessions involve discussing information, beliefs, emotions, and experiences regarding the

Table 1 Characteristics of both the self-management intervention and education intervention

	Self-management intervention	Education intervention
Duration of the intervention	10 weeks with *7 two-hour* group sessions	10 weeks with *4 one-hour* group sessions
Content	– *Proactive action planning**	
	– Peer support	– Peer support
	– Information provision about the themes	– Information provision about the themes
	(1) general consequences of stroke including the invisible consequences of stroke	(1) general consequences of stroke including the invisible consequences of stroke
	(2) handling negative emotions	*(2) the brain and a stroke*
	(3) social relations and support	*(3) prevention of a recurrent stroke*
	(4) participation in society	
Therapists	*Two* healthcare professionals who have	*One* healthcare professional who has
	– at least a Higher Professional Education degree	– at least a Higher Professional Education degree
	– experience in group counselling	– experience in group counselling
	– *experience in working with brain injury patients*	
	– received *one-day-training* on self-management intervention	– received a *1.5-hour training* on the education intervention
Participants	4–8 participants (4 patients and their partners)	4–8 participants (4 patients and their partners)
Intervention materials	– Guides and presentations for professionals	– Guides and presentations for professionals
	– Workbooks for participants	– Workbooks for participants
Location	Outpatient facilities	Outpatient facilities
Timing of provision	At least six-weeks after stroke	At least six-weeks after stroke

*The italicized items represent the differences between the two interventions.

themes: (1) coping with negative feelings; (2) social support and relations; and (3) participation in society. Resulting insights are integrated with the formulated action plans. At the end of every session, participants are asked to execute the formulated action plan or are asked to further elaborate the action plan if not yet finished. During the booster session, a summary of the provided information is offered and self-management intervention-related improvements are discussed.

The self-management intervention is provided as an outpatient rehabilitation service in the participating hospitals and rehabilitation centers. Further details are provided in Table 1.

Control intervention

The education intervention aims to improve stroke-related knowledge of participants only. This 10-week intervention consists of three one-hour sessions during the first six weeks and a one-hour booster session during the last week. After getting introduced to each other and the education intervention, information is provided about: (1) the brain and a stroke (first session), (2) consequences of stroke (second session), and (3) prevention of a recurrent stroke (third session). During the booster session, a summary of the discussed information and additional information booklets are provided. The education intervention is also provided as an outpatient rehabilitation service in the participating hospitals and rehabilitation centers. Further information is provided in Table 1.

Measurements

An overview of all measures and the time of assessment is presented in Table 2.

Baseline descriptors

The patients are characterized on general clinical, functional, and the cognitive parameters. The Barthel Index is used to assess stroke severity in terms of basic activities of daily living (24), the Shortened version of the Aphasia Scale of the Dutch Aphasia Foundation to assess communicative abilities (20), the Montreal Cognitive Assessment to assess general cognitive functioning (21), the Key Search Task and Zoo Map Test of the Dutch Behavioural Assessment of the Dysexecutive Syndrome to assess executive functioning (22), and the Checklist for Cognitive and Emotional

Table 2 All baseline and outcome measures

		Measurement			
Domain	Instruments	T0	T1	T2	T3
Baseline descriptors					
Demographic factors	Specific questions about age, gender, ethnicity, education level, marital status, and employment	x o			
Stroke characteristics	Specific questions about type, hemisphere, artery, date of stroke and stroke history	x			
Partner participation	Specific question about participating with or without partner in intervention	x			
Cognitive functioning	Montreal Cognitive Assessment (21)	x			
	Dutch Behavioural Assessment of the Dysexecutive Syndrome Key Search Task and Zoo Map Test (22)	x			
	Checklist for Cognitive and Emotional Consequences following stroke (23)	x			
	Shortened version of the Aphasia Scale of the Dutch Aphasia Foundation (20)	x			
Activities of daily living	Barthel Index (24)	x			
Primary outcomes					
Proactive coping	Proactive Competence Inventory (25,26)	x o	x o	x o	x o
Restrictions in societal participation	Restriction subscale of the Utrecht Scale for Evaluation of Rehabilitation-Participation (19)	x o	x o	x o	x o
Secondary outcomes					
Burden	Expanded Caregiver Strain Index (27)	o	o		o
Self-efficacy	General Self Efficacy scale (28)	x o	x o	x o	x o
HRQoL					
General					
Disease specific	Stroke Specific Quality of Life scale-12 (29)	x	x		x
Generic	Six-Dimensional Euro-QoL (30)	x o	x o	x o	x o
Domain specific					
Societal participation	Frequency and satisfaction subscale of the Utrecht Scale for Evaluation of Rehabilitation-Participation (19)	x o	x o		x o
Emotional functioning	Hospital Anxiety and Depression Scale (31)	x o	x o		x o
Subjective well-being	Three life satisfaction questions (32)	x	x		x

x = outcome measure stroke patient; o = outcome measure partner.
HRQoL, health-related quality of life; T0, baseline measurement; T1, posttreatment measurement; T2, first follow-up measurement; T3, second follow-up measurement.

Consequences following stroke to assess subjective cognitive complaints (23). All participants are asked about some demographical characteristics (i.e. age, gender, ethnicity, education level, marital status, employment), and rehabilitation physicians provide data about stroke characteristics in terms of type of stroke, stroke-affected hemisphere and artery, date of stroke, and stroke history. Also, it is registered if the partner of the patient takes part of the intervention.

Primary outcomes

Two primary outcome variables were chosen: the proactive coping competencies measured with the Proactive Competence Inventory (PCI) and participation restrictions measured by the USER-Participation Restrictions scale.

Proactive coping competencies are assessed with the 21-item PCI, a self-report measure with a 4-point response scale ranging from 'not competent at all' to 'competent' (25,26). The PCI has shown good psychometric properties in healthy people and people diagnosed with type 2 diabetes (26). Both the updated English and Dutch versions of the Proactive Competence Inventory are available at http://www.selfregulationlab.nl/questionnaires/.

Restrictions in societal participation are assessed with the 11-item USER-Participation Restrictions scale. This scale has shown sufficient psychometric properties in rehabilitation outpatients including stroke patients (19,33,34). The final English-language version of the Utrecht Scale for Evaluation of Rehabilitation-Participation is available at http://www.dehoogstraat.nl/images/products/297/USER-Participation%20English.pdf

Secondary outcomes

Partner's burden is assessed with the 18 items of the expanded Caregiver Strain Index, CSI+, which accounts for both positive and negative caregiver experiences (27). General self-efficacy is assessed with the 10 items of Dutch version of the General Self-Efficacy Scale (28). Disease-specific HRQoL is assessed with the 12-item short version of the Stroke-Specific Quality of Life Scale, covering a physical and a psychosocial domain (29). Generic HRQoL is assessed with the six-item Six Dimensional Euro-QoL (30). In addition, the frequency and satisfaction with participation are assessed with the other two scales of the USER-Participation, with 11 and 10 items, respectively (19). Emotional functioning is assessed with the 14-item Hospital Anxiety and Depression Scale, covering symptoms of anxiety and depression (31). Subjective well-being is assessed with three questions covering actual and prestroke life satisfaction, and the difference between them (32).

Data monitoring board

No data monitoring board took part in this study.

Sample size

Sample size calculations are based on both the PCI and restriction subscale of the USER-Participation. For the PCI, a standardized difference of 0.6 was expected, based on previous self-management intervention studies (26). For the Restrictions subscale of the USER-Participation, a standardized difference of 0.5 was expected (34). Based on an alpha ·05 and a power of 80%, a minimum of 2×45 stroke patients is required for sufficient statistical power (35). Assuming a dropout rate of 15%, 106 stroke patients are recruited.

Blinding

Participants are told two interventions are compared without mentioning the specific hypotheses of our study. Baseline measures are conducted before randomization by the researcher and research assistants. Subsequent measures are completed by participants themselves at home. Only when needed, a research assistant who is blinded to group allocation assists participants in filling out the posttreatment questionnaires.

Statistical analyses

By means of independent *t*-tests, Mann–Whitney *U*-tests, and chi-square tests, similarity of the two groups at baseline is checked.

Effectiveness is evaluated using 'intention to treat' and secondarily using 'on treatment' analyses. Differences in effect are determined using repeated measures analysis of variance with measurement (T0, T1, T2 and T3) as within-subject factor, group (self-management intervention, education intervention) as between-subject factor, and the outcome measures as dependent variables. Baseline characteristics which significantly differ between the two groups are included in the analyses as covariates. Both short and long-term effects of the self-management intervention, and the possible transitions between these effects, are of interest. Analyses will be performed using SPSS version PASW Statistics 18.0 (IBM Corporation, Armonk, NY, USA); alpha will be set at 0.05.

Summary and conclusion

In this paper we described the research protocol of the Restore4Stroke self-management study, which examines the clinical effectiveness of a group self-management intervention teaching proactive self-management strategies compared with a group education intervention in stroke patients and partners.

Innovative aspects of the Restore4Stroke research program are clearly present in this study, such as its focus on proactive coping as a psychological variable influencing HRQoL of stroke patients (36), including the generic, disease-specific, and domain-specific perspectives on HRQoL (37), and considering societal participation as a primary outcome of a self-management intervention. Furthermore, a family-centered approach is strongly presented in this study, putting equal focus on patients and partners during the intervention. Moreover, the cost-effectiveness of the intervention is evaluated as well, which is expected to facilitate its implementation if effective (18).

The strengths of this study are its randomized design with blinding for both participants and research assistants, relatively large sample size, and extended follow-up period compared with available studies, and that it is conducted in many institutes, thereby reducing the risk of the result being very dependent upon one person or group. It has an explicit theoretical basis for the intervention and includes a stroke-specific education interven-

tion as control condition instead of referring participants to a care as usual or general self-management programs (9–11). A potential weakness of this study is that the patients are likely to not be representative of all survivors. Furthermore, using an education group control intervention has the risk of insufficient contrast between the experimental and control conditions. The advantage, however, is that this comparison allows to attribute possible between-group differences in outcomes specifically to the self-management component of the trial.

In summary, we have described a study evaluating a novel self-management intervention for stroke patients living at home and their partners. If effective, this study will enable stroke patients and their partners to deal with the lasting consequences of stroke. In the context of the growing number of people returning home after stroke, a large number of people may benefit from this intervention.

Authors' contributions

J. M. A. V-M., C. M. V. H, M. W. M. P, and D. T. W. developed the idea and procured funding for the study. All authors contributed to the design and the protocol of the study. All authors reviewed the manuscript and approved the final version.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Fig. S1 Schematic representation of the procedure of the study.