

First Year After Stroke

An Integrated Approach Focusing on Participation Goals Aiming to Reduce Depressive Symptoms

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Background and Purpose—Depression is a common issue after stroke. A focus on assisting people to achieve their personal participation goals may reduce levels of depression. The aim of this study was to investigate the effectiveness of a person-centered, integrated approach on facilitating goal achievement in the first year poststroke on depressive symptoms.

Methods—This study was a randomized controlled trial that addressed ways to enhance participation in patient-valued activities and intermittently screen for adverse sequelae postdischarge from rehabilitation. Collaborative goal setting was undertaken in both groups at discharge from inpatient rehabilitation. The control group received standard management as determined by the treating team. In addition, the intervention group received a multimodal approach, including telephone contacts, screening for adverse sequelae, written information, home visits, review of goal achievement, and further referral to relevant health services. The main outcome measure was depressed mood, measured by the 15-item Geriatric Depression Scale.

Results—One hundred ten participants were recruited. No group differences were identified at baseline on any demographic and clinical variables. Using multiple linear regression analysis, there was a significant difference between the 2 groups with respect to the severity of depressive symptoms at 12 months poststroke ($R^2=0.366$; $F(6, 89)=8.57$; $P<0.005$), with the intervention group recording lower depressive scores.

Conclusions—This model of community-based rehabilitation proved effective in reducing poststroke depressive symptoms. An integrated approach using pursuit of patient-identified activities should form part of routine poststroke management.

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Key Words: community participation ■ depression ■ randomized controlled trial ■ rehabilitation ■ stroke

Over time there have been many advancements in acute care management after the event of a stroke. However, stroke episodes continue to have associated complex adverse sequelae that require ongoing attention beyond the initial inpatient acute and rehabilitation phases. Gradual functional decline frequently occurs poststroke and has been associated with inactivity, fatigue, cognitive issues, additional health comorbidities, and enduring low mood status.^{1,2} In particular, poststroke depression (PSD) is a common adverse sequelae of stroke, with a prevalence pooled estimate of 31%.³ There are many risk factors associated with the development of PSD,⁴ and its presence can greatly impact rehabilitation outcomes,⁵ including behavioral consequences, such as diminished motivation and reduced engagement in activities. Rehabilitation interventions that specifically aim to reduce PSD have not been extensively investigated to date. Physical exercise

has been identified as one factor that may potentially influence PSD, especially when conducted at higher intensities.^{6,7} Poststroke programs that aim to target identified needs, with particular attention to engagement in activities considered to be of value to the individual, have also shown to have a positive effect on emotional well-being.⁸

However, many stroke rehabilitation programs continue to focus on the amelioration of basic mobility and self-care deficits, with less emphasis on home and community participation tasks, including social roles and leisure activities. The notion of recovery poststroke is a complex and individual phenomenon, and there is a need for rehabilitation services to assist a person to construct a new sense of self into the chronic phase, while continuing to acknowledge and strive for the prestroke self.^{9,10} There are many theoretical frameworks that exist to try to inform rehabilitation practice, with

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person-centered care and goal setting practices espoused as key components.^{11–13} The goal setting process can be used as a way to engage and motivate patients, and it has been postulated that goal attainment may potentially have implications on mood.¹⁴ However, the effectiveness of facilitating the pursuit of individualized goals on the outcome of PSD has not been investigated.

The aim of this study was to determine the effectiveness of a goal-focused intervention in reducing depressive symptoms 12 months poststroke. The primary hypothesis was that an integrated approach to facilitate goal achievement in the first year after stroke will result in significantly less depressive symptoms, as measured by the Geriatric Depression Scale (15 item; GDS-15), compared with a usual care group.

Methods

Study Design

This study was a prospective randomized controlled trial, with assessment of outcomes at 6 and 12 months poststroke. The participants and outcome data collectors were blinded as to group allocation. The assessments were interviewer-administered during face-to-face contacts. The protocol for this study has been registered (ANZCTR 1260800042347) and previously published in detail.¹⁵

Patient Eligibility and Recruitment Process

All patients with the primary diagnosis of acute cerebrovascular accident (inclusive of cerebral infarction, intracranial hemorrhage, and subarachnoid hemorrhage) were eligible to participate in this study. Patients with communicative and cognitive deficits were included. If a patient was unable to grant informed consent (eg, because of cognitive impairment), then a person responsible was eligible to provide consent on their behalf.

Exclusion criteria were as follows: primary cause of disabilities was a diagnosis other than stroke, associated head trauma (such as fractures), epidural or subdural hemorrhage, presence of a cerebral malignancy, discharge destination to a high-level residential care facility, and an inpatient rehabilitation length of stay of <4 days' duration or >6 months' duration.

Participants were recruited from the 2 inpatient rehabilitation sites of St Vincent's Hospital Melbourne, Australia, over a 2-year time frame (from July 2008 to July 2010). This study was conducted in accordance with the protocol approved by the Human Research Ethics Committees of St Vincent's Hospital Melbourne and The University of Melbourne.

Randomization and Blinding

At discharge from inpatient rehabilitation, the participants were allocated to the control or the intervention group by a member of the research team using a computer-generated random allocation sequence (in block sizes of 6) generated by an independent statistician, with further stratification based on admission Functional Independence Measure-Motor score. Participants with an admission Functional Independence Measure-Motor score of ≤ 46 were stratified into a severe group, whereas those with a score of >46 were stratified into a mild group.¹⁶ The participants were assigned in order of completed baseline data set, which was obtained by the assessor (during the week preceding discharge) before group allocation. Sequentially numbered, sealed opaque envelopes were used to conceal the allocation. To assist to maintain blinding of the participants, a level of deception was approved by the presiding Ethics Committees. This stipulated that all participants would receive researcher contact postdischarge from inpatient rehabilitation without indicating that the amount of contact differed between the study groups.¹⁵

Primary Outcomes

The primary outcome was the mean level of severity of depressive symptoms as measured on the summated GDS-15 scores at the 12 months poststroke time point. In addition, proportions of clinically significant depressive symptoms (caseness) were examined using the categorized GDS-15 scores (with depressive symptoms defined as ≥ 6 points).¹⁷ The secondary outcome data (including health-related quality of life, self-care self-efficacy, goal achievement, participation status, and carer outcomes) will be reported in future publications.

Baseline Assessments

General demographic and clinical data were collated before randomization. Information collected included the following: depressive symptoms, GDS-15¹⁸; functional status, 13 motor items of the Functional Independence Measure (FIM-Motor)¹⁹; self-care self-efficacy, Strategies Used by People to Promote Health²⁰; cognition, Mini-Mental State Examination²¹; participant age, sex, type/side of stroke, history of depression (requiring specific management by a healthcare professional), use of antidepressant medications (just before inpatient admission), living arrangements, and availability of an informal carer.

Preceding the initial implementation of the study protocol, the inpatient rehabilitation staff undertook training regarding goal setting principles and the application of Goal Attainment Scaling.²² At discharge from the inpatient rehabilitation admission, all study participants engaged in collaborative goal setting with members of the treating team. This process occurred before randomization into groups. Goals were set across all domains of the International Classification of Functioning, Disability and Health framework; however, emphasis was placed on setting goals that explicitly aimed to enhance home and community participation levels and additionally reflected the participants' valued activities. All the goals were envisaged to be achievable during the first 12 months after the stroke event.

Intervention

Intervention Group

The participants allocated to the intervention group received a multifactorial, integrated approach, which incorporated both standardized and nonstandardized components (see Table 1 and Table I in the [online-only Data Supplement](#)). The intervention protocol was auspiced by the research clinician who was a physiotherapist experienced in stroke rehabilitation. The type and intensity of applied interventions were determined on a needs basis (based on arising flags), with the aim to facilitate goal achievement and community reintegration and to address relevant emerging issues.

Interventions included monitoring, liaising with services, additional referrals, advice and information provision, review of progress, and identification of potential barriers to recovery (see Table 2). There was emphasis on promoting the participants to adopt a self-management approach to arising issues, with strategies such as self-review of current situation and determination of strategies to ameliorate any concerns, accomplishing effective communication with health professionals, and using existing support networks or generating new associations to assist with identified goals and individual recovery processes.

Flags for further intervention included failure to make progress toward personal goals, failure to resume valued activities, evidence of low mood, and falls (see examples in Table II in the [online-only Data Supplement](#)). Intervention group participants continued to receive usual care from health and community resources as deemed appropriate by their treating health practitioners.

Control Group

The control group participants received usual care as arranged by the treating team at discharge from inpatient rehabilitation. A 2- and 6-week postdischarge telephone call was conducted, with a short general inquiry to ensure that postdischarge services had commenced. These phone calls assisted to maintain participant group blinding. There were no interventions offered to the control group participants.

Table 1. Standardized Protocol Components* (Intervention Group)

Time Point	Standardized Component
At discharge from inpatient rehabilitation	Written information about recovery after stroke, booklet and 7 factsheets ²³
	Information about stroke resources, including stroke support groups
	Written copy of the devised goals, given to the participant, general medical practitioner, and community-based rehabilitation service
At 2 and 6 weeks postdischarge	Telephone contacts†
At 3 months postdischarge	Home visit†
At 6 months poststroke	Review of outcomes obtained by the blinded assessor
	Interventions in response to arising needs flags
	Examples: <ul style="list-style-type: none"> • GDS-15 ≥6 would generate correspondence to GP • Failure to resume valued activities or progression toward goals would prompt review of possible barriers to participation and initiation of appropriate strategies (such as liaising with community-based therapists or engaging carers/ social networks)
At 9 months postdischarge	Telephone contact†
At 12 months poststroke	Final outcomes obtained by the blinded assessor

GDS-15 indicates Geriatric Depression Scale (15 item); and GP, general practitioner.

*Refer to protocol publication¹⁵ and the [online-only Data Supplement](#) for more detailed overviews of the standardized interventions.

†The aim of the research clinician’s contacts via telephone and home visits was to gain a general overview of the participants’ progress and to ascertain if any further interventions needed to be initiated. Inquiries were made about how the participant was managing at home; progression with regard to their goals; mood status and presence of concerns; level of informal support available; and episodes of falls or adverse events. Verbal encouragement was given, with specific emphasis on activity level, achievements to date, and efforts toward pursuit of valued goals.

Sample Size and Statistical Analyses

Poststroke data from an intervention study using the GDS-15 provided the basis for the power calculations in this current study.²⁴ With the criterion for significance set at 0.05 (α , 2-sided), and based on a power of 80%, the target sample size was 55 participants for each arm of the study. This computation assumes that the mean difference between groups is -1.4 (corresponding to means of 2.0 versus 3.4), and the common within-group standard deviation is 2.6 (based on SD estimates of 1.8 and 3.2).

Independent samples *t* tests and Pearson χ^2 analyses were used as the statistical methods for baseline comparisons between groups. For the 12-month poststroke data, the primary outcome measure (GDS-15) was analyzed in 2 forms (continuous and categorical). Analysis of the summated GDS-15 scores was conducted with multiple linear regression modeling, controlling for constant independent variables, and the method for reviewing the categorized depression scores was via the use of χ^2 . Exploratory data screening preceded the application of regression analysis, to review whether regression modeling was applicable. Assumption checking was conducted, including examination of the residuals and correlations

between variables. On the basis of conceptual and theoretical groundings from reviewing the literature, the constant variables used in this study were as follows: prior history of depression (Prior Dep); FIM (Motor) at rehabilitation admission (FIM Adm); GDS-15 at rehabilitation discharge (GDS Dch); living arrangements at discharge (Living Arr); total length of stay (Total LOS); and study group allocation (Group). The regression analysis derived the coefficient of multiple determination and included standardized and unstandardized β coefficients.

Intention-to-treat analysis was engaged in this study, with the last observation GDS-15 data being carried forward from the 6-month time point to the 12-month time point for participants with missing data (with the exception of deceased participants). The data were analyzed using IBM SPSS Statistics version 19.²⁵

Results

From the 2 inpatient rehabilitation recruitment sites, 201 patients were admitted with a primary diagnosis of stroke and assessed for eligibility. Of the 138 eligible patients, 110 were randomized into 2 groups (80%), with 54 participants allocated to the intervention group and 56 participants to the control group (see Figure 1).

Baseline demographic and clinical characteristics are outlined in Table 3. Both study groups were comparable on all baseline demographic and clinical parameters. At discharge, all participants were referred for ambulatory or home-based rehabilitation, with 39% of the participants living locally and attending services auspiced by St Vincent’s Hospital and 61% spread across 12 other healthcare regions.

There were no significant differences in the baseline characteristics for those participants who completed the 12 months’ study follow-up (completers, n=94, 85%) compared with the participants for whom 12-month data were unobtainable

Table 2. Examples of Nonstandardized Protocol Components (Intervention Group)

Nonstandardized Components	Examples (in Response to Flags)
Additional telephone contacts with participants (and carers) because of various issues arising or concerns. Frequency: 97 episodes	Episodes of falls
	Evidence of low mood status
	Requests for further information
	Request for additional written information
Additional telephone contacts or correspondence to other services, including general medical practitioners. Frequency: 50 episodes	Medication compliance
	Request for vision review
	Evidence of anxiety
	Equipment inquiries
	Forwarding goals
New referrals or rereferrals to services. Frequency: 20 episodes	Continence clinic
	Memory service
	Orthotist review
	Driving assessment
	Physiotherapy and occupational therapy

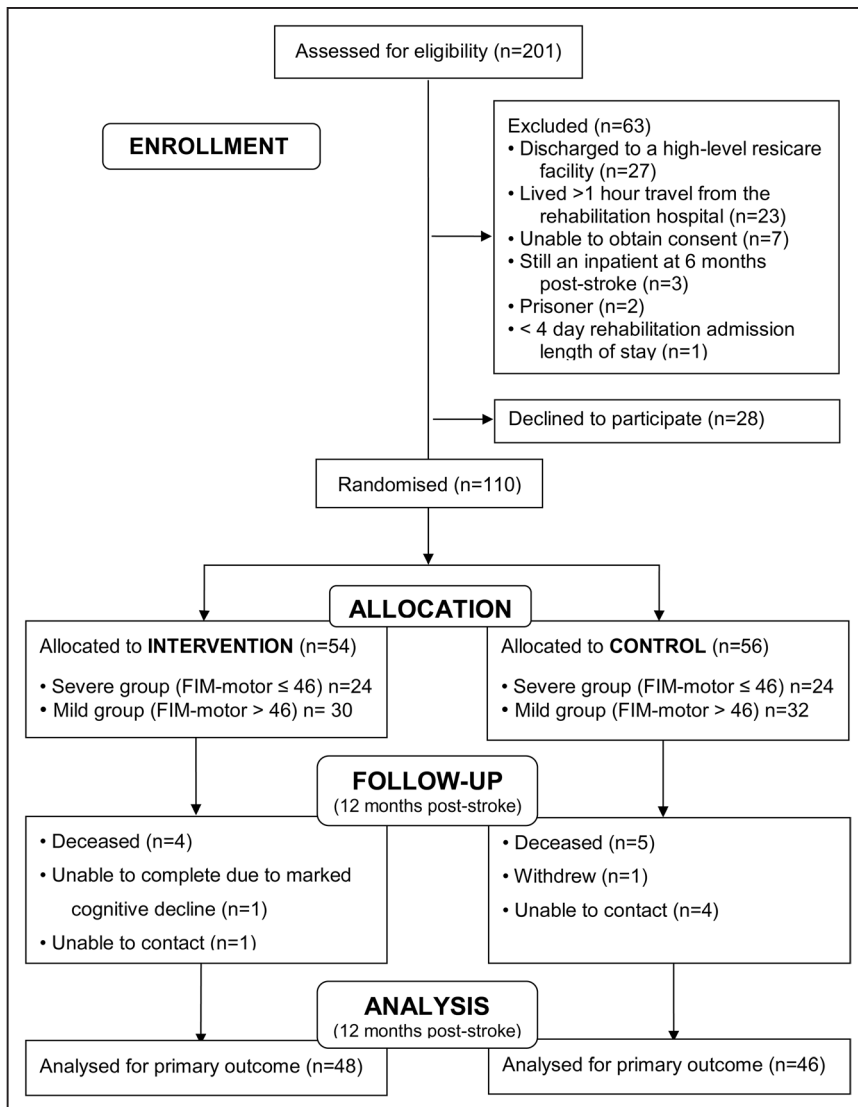


Figure 1. Flowchart of participant recruitment. Person responsible required for consent (n=8). FIM-motor indicates 13 motor items of the Functional Independence Measure.

(noncompleters, n=16), except for the domain of type of stroke ($\chi^2(2)=7.92, P=0.019$) with noncompleters more likely to have had a stroke pathogenesis of cerebral infarction. Of the 16 non-completers, 9 participants were deceased by the 12-month time point. There were no differences in the dropout rates between the groups.

With regard to intention-to-treat analyses, 2 participants died between the 6-month and 12-month time points; thus, their 6-month data were not carried forward. For various reasons (see Figure 1), 5 additional participants had missing data at the 6-month time point. Six-month data for 2 participants were able to be carried forward. Analysis of completer data (n=94) yielded consistent results with analysis of the carried forward data (n=96, addition of 1 participant per study group), and therefore, the carried forward data have been used in the regression model in this study.

Examination of the severity of depressive symptoms (summed GDS-15 scores at 12 months poststroke) was achieved using multiple linear regression analysis. The mean GDS-15 score at 12 months poststroke was 3.6 (SD=2.7) for the intervention group and 4.8 (SD=3.6) for the control group. In the analysis of multicollinearity, all correlations were <0.2 and

nonsignificant, apart from a moderate negative correlation between the variables FIM Adm and Total LOS ($r=-0.61; P<0.001$). However, variance inflation factors were low, and this expected association was considered of insufficient strength to warrant the removal of either one of these variables during the analysis.

For the 12-month GDS-15 scores, a significant model occurred using the 6 constant variables, with the analysis explaining 36.6% of the variance ($R^2=0.366; F(6, 89)=8.57; P<0.005$). The significant variables were Prior Dep ($\beta=-0.28; P=0.002$), GDS Dch ($\beta=0.44; P<0.005$), and Group ($\beta=-0.20; P=0.023$). Therefore, after controlling for potentially confounding variables, the intervention group had lower depressive scores at 12 months poststroke compared with the control group. Admission FIM score, living arrangements at rehabilitation discharge, and total length of hospital stay did not present as significant contributors to this model (see Table 4).

There was a significant difference identified between the 2 study groups with respect to the proportions of caseness for depression (GDS-15 ≥ 6 points) at the 12-month poststroke time point. The proportion of participants with symptoms of depression in the intervention group (n=7, 14.6%) was

Table 3. Baseline Demographic and Clinical Data

	Total Group (n=110)	Control Group (n=56)	Intervention Group (n=54)	P Value
Demographic data				
Age, mean (SD), y	69.9 (14.2)	70.9 (13.2)	68.9 (15.1)	0.459
Male	57 (52)	31 (55)	26 (48)	0.449
Stroke type				
Infarct	69 (63)	39 (69)	30 (56)	0.154
Hemorrhage	40 (36)	16 (29)	24 (44)	
Mixed	1 (1)	1 (2)	0 (0)	
Stroke side				
Left	51 (46)	26 (46)	25 (46)	0.996
Right	41 (38)	21 (38)	20 (37)	
Bilateral	18 (16)	9 (16)	9 (16)	
Length of stay, mean (SD), d				
Total	49.6 (30.1)	53.1 (37.7)	46.0 (22.5)	0.229
Acute	17.5 (15.2)	18.1 (17.9)	16.9 (12.5)	0.699
Rehabilitation	32.0 (23.2)	35.0 (28.1)	29.0 (18.3)	0.187
Living arrangements				
Home alone	26 (24)	10 (18)	16 (30)	0.146
Home with others	84 (76)	46 (82)	38 (70)	
History of depression				
Answer yes	27 (25)	16 (29)	11 (20)	0.318
Depression scores				
GDS-15 score at discharge, mean (SD)	4.2 (2.9)	3.8 (2.7)	4.6 (3.1)	0.156
GDS-15 ≥ 6 points	32 (29)	14 (25)	18 (33)	0.336
FIM (motor) score at admission, mean (SD)	51.5 (20.9)	50.4 (22.1)	52.6 (19.7)	0.583

Values are n and (%), unless otherwise indicated. FIM (motor) indicates Functional Independence Measure (motor component); and GDS-15, Geriatric Depression Scale (15 item).

significantly lower than the proportion in the control group ([n=16, 34.8%]; $\chi^2(1)=5.19$; $P=0.023$).

Overviewing the data, 32 participants (29.1%) of the whole sample (n=110) had a GDS-15 score ≥ 6 at discharge from inpatient rehabilitation. Figure 2 depicts the GDS-15 dichotomized scores and antidepressant medication use. For the intervention group, 18 of 54 participants (33.3%) had a GDS-15 score ≥ 6 at discharge from inpatient rehabilitation. Three of those 18 participants became study noncompleters (ie, they did not have 12-month poststroke GDS-15 data). Of the completers, 7 of the 48 participants (14.6%) had a GDS-15 score ≥ 6 at 12 months poststroke, with 2 participants displaying the emergence of depressed mood during the first year poststroke.

Fourteen of the 56 participants (25.0%) in the control group had a GDS-15 score ≥ 6 at discharge from inpatient rehabilitation. As per the intervention group, 3 of those control group participants became noncompleters of the study. Sixteen of the 46 completers (34.8%) had a GDS-15 score ≥ 6 at 12 months poststroke. Seven participants who rated as depressed at rehabilitation discharge continued to rate as depressed at 12 months poststroke. Nine control group participants, who did not indicate depressive symptoms at inpatient discharge, had

depressed mood by 12 months poststroke. Twenty-six participants (27.7%) were taking antidepressant medications at 12 months poststroke. Seventeen participants (18.1%) belonged to the control group, and the remaining 9 participants (9.6%) were in the intervention group (Figure 2). Nine control group participants and 3 intervention group participants commenced antidepressant medication during the study period.

Discussion

The aim of this study was to investigate the effectiveness on depressive symptoms of a complex rehabilitation intervention that sought to facilitate goal attainment and screen for adverse sequelae during the first 12 months after the event of a stroke. From a review of the published literature, this is one of the first studies to adopt this form of multimodal intervention and to review its effectiveness on the primary outcome of depression. This study demonstrated that the goal-focused intervention resulted in a reduced level of depressive symptoms, as measured by the GDS-15. Of the whole sample in this study, 29.1% showed evidence of depressed mood at discharge from inpatient rehabilitation. By 12 months poststroke, the participants in the control group had a proportion of depression at

Table 4. Summary of the GDS-15 Regression Model

Variables	12-month GDS	B	SE (B)	β	t	Sig (P)
(Constant)		7.15	2.18		3.29	0.001
Prior Dep	-0.38	-2.05	0.63	-0.28	-3.25	0.002*
FIM Adm	-0.04	-0.2	0.02	-0.07	-0.69	0.494
GDS Dch	-0.47	0.52	0.10	0.44	5.09	0.005*
Living Arr	-0.13	-0.54	0.66	-0.07	-0.83	0.411
Total LOS	0.02	0.00	0.01	-0.00	-0.01	0.989
Group	0.18	-1.29	0.56	-0.20	-2.31	0.023*

β indicates standardized beta coefficient; B, unstandardized beta coefficient; FIM Adm, Functional Independence Measure (motor) at rehabilitation admission; GDS Dch, Geriatric Depression Scale (15 item) at rehabilitation discharge; Living Arr, living arrangements at discharge; Prior Dep, prior history of depression; SE, standard error; and Total LOS, total length of stay.

*Significant (variables), $P < 0.05$.

34.8%, consistent with previously reported estimates,³ whereas the proportion of the intervention group was significantly lower (14.6%).

This indicates that participants who had a history of depression, or were depressed at discharge from inpatient rehabilitation, had a greater likelihood of displaying ongoing depressive symptoms during the first year poststroke. These factors have been identified previously in the literature.²⁶ Level of physical disability (as measured on the Functional Independence Measure-Motor and categorized as severe or moderate/mild) was unrelated to depressive symptoms in this study in contrast to several previous studies.²⁶ Clinicians should be mindful that stroke survivors with mild to moderate physical impairments may also be at risk of developing depressive symptoms.

The use of antidepressant medication in the intervention group was low (9.6%) compared with the rate of use in the control group (18.1%, which was slightly higher than the derived figure of 16.0% previously reported in the literature).²⁷ These results indicated that the difference in the proportion of depressive symptoms between the 2 experimental groups was not specifically because of changes in pharmacological management.

Limitations

There are several issues for consideration during the implementation of this study. The trial was underpowered, with 83% of the proposed recruitment obtained. The difference between the groups (of 1.2) fell short of the hypothesized difference of 1.4 as proposed in the protocol.¹⁵ Although statistical significance was achieved, caution is required in interpreting the clinical meaningfulness of the results. The difference is equivalent to one item of the 15-item GDS. In addition, the regression analysis had a low ratio of cases to predictors. The study should ideally be replicated with a larger sample size. A structured interview was not used for the diagnosis of depression (such as the *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition, Text Revision [DSM-IV-TR]).²⁸ For clinical purposes, a valid and easily administered screening tool (GDS-15) was chosen as it could be readily applied in the community setting. Recruitment of the study sample was from only 2 rehabilitation sites; hence, inpatient rehabilitation practice may differ from other rehabilitation centers. However, it should be noted that in this trial, participants received their post-discharge rehabilitation over a range of healthcare services.

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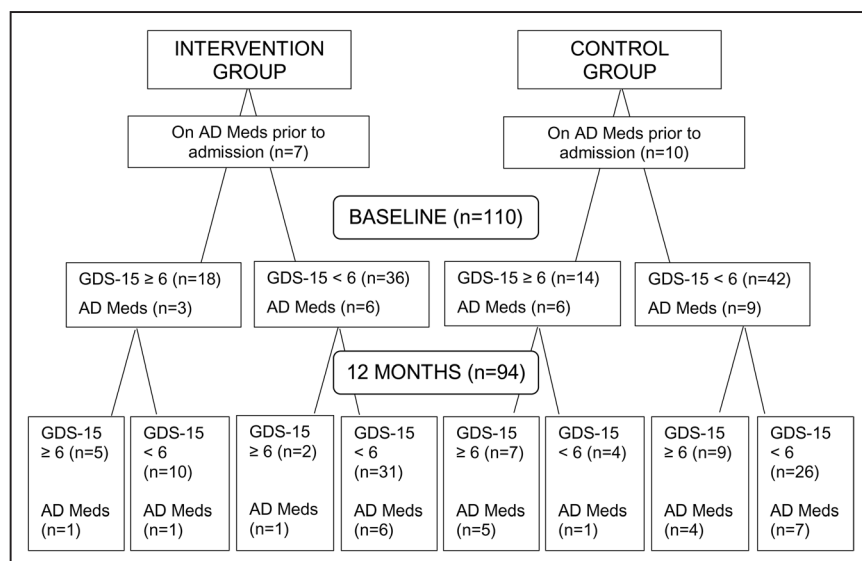


Figure 2. Flowchart of depressive symptoms and antidepressant medication use. AD Meds indicates antidepressant medication; and GDS-15, Geriatric Depression Scale (15 items).

Home visits conducted by the research clinician were only afforded to the intervention participants, with no provision of attention control to both groups. Because of the protocol structure, at times the 3-month postdischarge research clinician home visit and the 6-month poststroke assessor visit were closely aligned because of extended length of inpatient rehabilitation admission. These visits were conducted by separate people at differing times, and the assessor remained blinded to group allocation. This study did not undertake any economic evaluation; therefore, the cost of the intervention has not been determined.

Implications for Clinical Practice

From the results of this study, several key aspects of poststroke management could potentially be incorporated into clinical practice:

1. Collaborative individualized goal setting, with ongoing encouragement to pursue goals and monitoring of barriers to goal achievement
2. Screening at set time points for adverse poststroke sequelae (such as depression, falls, and functional decline), and engagement of appropriate services to address the arising issues
3. Adoption of a self-management approach, aiming to optimize the level of engagement in the ongoing management of one's own health
4. Promotion of ongoing physical exercise and encouragement to optimize activity and participation levels

Greater awareness of the holistic sequelae that can occur poststroke (including elements such as depressed mood, participation restrictions, and reduced social network engagement) may focus the clinicians' interventions to achieve outcomes that align themselves more with the patients' situations, requirements, and their concepts of recovery. The one-size-fits-all approach is not appropriate, and a multimodal approach should be considered. Additional clinical trials of multifaceted interventions poststroke (with a larger sample across multiple centers) would be of benefit to determine whether supplementary clinical recommendations can be advocated.

Conclusions

This current study has added to the evidence base for the positive impact of individualized, goal-centered, comprehensive poststroke management for reducing depressive symptoms during the first year poststroke. Aspects of the intervention protocol can be readily incorporated into existing community rehabilitation services.

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Disclosures

None.

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