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One-year follow-up of a randomized controlled trial**

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*Published in:*  
Journal of Rehabilitation Medicine

*DOI:*  
10.2340/16501977-1981

*Publication date:*  
2015

*Document version:*  
Final published version

*Citation for pulished version (APA):*  
Guidetti, S., Ranner, M., Tham, K., Andersson, M., Ytterberg, C., & von Koch, L. (2015). A "client-centred activities of daily living" intervention for persons with stroke: One-year follow-up of a randomized controlled trial. *Journal of Rehabilitation Medicine*, 47(7), 605-611. <https://doi.org/10.2340/16501977-1981>

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ORIGINAL REPORT

A “CLIENT-CENTRED ACTIVITIES OF DAILY LIVING” INTERVENTION FOR PERSONS WITH STROKE: ONE-YEAR FOLLOW-UP OF A RANDOMIZED CONTROLLED TRIAL

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**Objective:** To compare changes regarding perceived participation, independence in activities of daily living (ADL) and life satisfaction between 3, 6 and 12 months after inclusion in a study of a client-centred ADL intervention and usual ADL intervention after stroke.

**Design:** A multicentre randomized controlled trial.

**Methods:** Sixteen rehabilitation units were randomly assigned to provide client-centred ADL intervention or usual ADL intervention. Eligible participants were persons ≤3 months after stroke who had been treated in a stroke unit, were dependent in two ADL domains, had not been diagnosed with dementia, and were able to understand instructions. Data collection was performed by blinded assessors. The primary outcome, perceived participation, was assessed with the Stroke Impact Scale 3.0, domain 8. The secondary outcomes, participation, independence in ADL, and life satisfaction, were assessed with validated instruments. For statistical power, 280 participants were required. Statistical analyses were performed on an intention-to-treat basis.

**Results:** There were no differences between the groups regarding changes in perceived participation, independence in ADL, or life satisfaction during the first 12 months. There was a trend towards a clinically meaningful positive change in perceived participation that favoured client-centred ADL intervention.

**Conclusion:** Further research is required to understand the benefits of client-centred interventions.

Key words: stroke rehabilitation; participation; occupational therapy; multicentre study; lived experience; everyday occupation; activity; longitudinal.

J Rehabil Med 2015; 47: 605–611

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Accepted Mar 27, 2015; Epub ahead of print Jun 16, 2015

INTRODUCTION

This randomized controlled trial (RCT) compared a client-centred activities of daily living (ADL) intervention (CADL)

with usual ADL intervention (UADL) in persons with stroke regarding their perceived participation, independence in ADL, and life satisfaction at 3, 6 and 12 months after inclusion in the study.

A client-centred approach was applied by taking the person's unique lived experiences as the point of departure for collaboration and goal-setting during the rehabilitation process in order to enable the persons with stroke to assume responsibility for their own rehabilitation, ADL, and participation in daily life (1). The client-centred approach involves creating a relationship based on trust, and the therapists and clients sharing experiences and formulating goals together. The objective is to enable the persons to discover their own abilities and learn how to apply problem-solving strategies in daily activities (2) to generate sustainable change in participation over time.

A systematic review of RCTs of person-centred interventions (including the term *client-centred*) reported person-centred care as beneficial to emotional well-being, but there was little evidence for any impact on clinical outcomes (3). Another review including qualitative and quantitative studies indicated that persons who participated in client-centred rehabilitation were better able to recall goals, experienced more involvement in the rehabilitation, and were better able to manage daily activities after the rehabilitation (4). A synthesis of quantitative and qualitative studies concluded that participation in goal setting after stroke can have beneficial effects on psychological outcomes, but further research with robust methodology is required (5). Hence, additional research is needed in order to build evidence for the role of client-centredness regarding participation and other relevant outcomes (5).

Participation is considered a critical outcome for successful rehabilitation and is the goal of rehabilitation for persons with stroke (6). Despite the importance attached to participation, few studies have used participation as a primary outcome (7). Appropriate outcome measures should be applied in order to ascertain the effectiveness of interventions that target participation, but there is no consensus concerning which measures to use, although the Stroke Impact Scale (SIS) and the Frenchay Activities Index (FAI) have frequently been used (8).

A previous study of the effect of the CADL vs UADL at 3-month follow-up showed beneficial effects on self-reported

emotional well-being that favoured the CADL, but there were no other differences between the groups for either the persons with stroke or their significant others. Longer follow-ups were suggested to identify plausible advantages in outcomes of a client-centred rehabilitation approach after stroke (9).

There is a lack of studies examining the long-term effects of client-centred rehabilitation after stroke, and greater attention to theoretical and methodological quality has been recommended (6) because the complexity of interventions in stroke rehabilitation is not taken into consideration in most research designs. The aim of the current study was therefore to compare changes regarding perceived participation, independence in ADL and life satisfaction between 3, 6 and 12 months after inclusion in a study of a CADL and UADL after stroke.

## MATERIAL AND METHODS

A multicentre RCT was conducted in which an intervention group received a CADL and a control group received a UADL. A detailed description of the study has been published elsewhere (9). Sixteen rehabilitation units in Stockholm, Uppsala, and Gävleborg Counties participated in the study. The name of each unit was written on a separate sheet of paper, then units were drawn randomly to supply the CADL or the UADL, stratified by type of rehabilitation: inpatient geriatric rehabilitation for those  $\geq 65$  years old, inpatient medical rehabilitation for those  $< 65$  years old, and home-based rehabilitation. Participants in the study were persons  $\leq 3$  months after stroke onset who: (i) had been treated for acute stroke in a stroke unit; (ii) were dependent in at least 2 ADL domains, according to Katz Extended ADL Index (KE) (10); (iii) had not been diagnosed with dementia; (iv) were able to understand and follow instructions; and (v) had been referred for rehabilitation to 1 of the 16 participating units.

### Interventions

**Content of the CADL.** The CADL intervention was conducted within a client-centred context (1), i.e. the intervention should be adjusted to the individual's ability, motivation, needs, and was conducted in close collaboration between the client and occupational therapist (OT). The CADL intervention offered a structure for how to discover and solve problems encountered in daily activities after stroke. To work in a client-centred way in rehabilitation and in CADL requires viewing the clients as partners in the rehabilitation process and recognizing their experiences, goals and knowledge.

Nine steps were included in the CADL; the focus of the first step was establishing a relationship between the OT and the client with stroke. This was considered essential to understanding the person's lived experiences. Thereafter, the OT observed the client while he or she performed an activity, and then the OT and the client jointly evaluated the performance with the purpose of clarifying the client's ability and perceptions of his/her ability. To enable the client to make his or her own choices and decisions, the OT asked the client to identify 3 goals in different daily activities that he or she needed and wanted to be able to perform, by using the Canadian Occupational Performance Measure (11).

Then the OT introduced the client to the use of a global problem-solving strategy, i.e. a goal-plan-do-check strategy (12) to support the clients in handling their difficulties in ADL. Each client completed the activity that was ranked as the first goal, in order to discover difficulties that he or she experienced reaching that goal. To facilitate the successful performance of the selected activity, the client, in collaboration with the OT, identified specific strategies. Clients were encouraged to use a training log to take responsibility for their goals and for communication with the others involved in the rehabilitation.

At the final meeting, all the strategies used during the intervention were evaluated to facilitate the transfer and use of these strategies to other activities in new situations. The OTs who performed the CADL intervention had been trained to conduct the CADL in a 5-day workshop. All OTs who conducted CADL interventions were contacted monthly by the researchers, who used a checklist in order to monitor fidelity to the intervention.

**Content of the UADL.** The UADL interventions varied in extent and methods according to the knowledge and clinical experience of the individual OT and according to the routines and praxis of the participating rehabilitation units.

The number of OT sessions was not determined in advance for either the CADL or the UADL group. Information concerning the number of occupational therapy contacts during the CADL and the UADL interventions was collected from the OTs' records. The length of rehabilitation, the number of OT contacts, and the focus of the OT sessions are shown in Table I. Participants in both groups received other rehabilitation services as needed (e.g. physiotherapy and speech therapy).

### Data collection

Persons with stroke who met the inclusion criteria and gave their informed consent to participate were assessed at inclusion, and at 3, 6 and 12 months thereafter by an independent research assistant, who was an experienced OT. Data collection was carried out by the same research assistant for each participant on every occasion. The research assistants were unaware of the content of the interventions and were blinded to which type of intervention was carried out at each site. Data were collected by the use of face-to-face interviews. Information regarding the participants' medical history was obtained from medical records and by means of structured interviews. The Mini-Mental State Examination (MMSE) (13) was used to screen for cognitive impairment and items from the Scandinavian Stroke Scale (14) were used to categorize the participants' speech production at inclusion.

### Outcomes

**Perceived participation.** Several instruments were used to assess the outcome participation.

To assess perceived participation and the impact of a stroke on daily life, the Stroke Impact Scale (SIS) 3.0 (15) was used at 3, 6 and 12

Table I. Occupational therapy contacts

|   | CADL<br><i>n</i> = 129 | UADL<br><i>n</i> = 151 |
|---|------------------------|------------------------|
|   | Mean (range)           | Mean (range)           |
| Treatment period, days  | 71 (7–269)             | 59 (1–402)             |
| Occasions/contacts <sup>a</sup>   |                        |                        |
| OT and participant, <i>n</i>  | 21 (1–59)              | 15 (1–166)             |
| OT administration, <i>n</i>   | 4 (0–15)               | 4 (0–20)               |
| Occasions total <sup>a</sup> , <i>n</i>   | 24 (2–74)              | 18 (1–167)             |
| Focus of contacts   |                        |                        |
| Goal setting, planning and evaluation <sup>a</sup> , <i>n</i>   | 3 (0–14)               | 1 (0–5)                |
| ADL <sup>a</sup> leisure and work included, <i>n</i>  | 22 (3–93)              | 15 (0–200)             |
| Training of function <sup>a</sup> , <i>n</i>  | 10 (0–57)              | 7 (0–44)               |
| Environment <sup>a</sup> environmental investigation, technical aids and home modifications, <i>n</i> | 5 (0–24)               | 4 (0–26)               |
| Family <sup>a</sup> contact with significant other, <i>n</i>  | 1.4 (0–17)             | 1.5 (0–15)             |
| Other <sup>a</sup> information about home care and rehabilitation, <i>n</i>                           | 0.2 (0–6)              | 0.2 (0–2)              |

<sup>a</sup>Face-to-face, in group, or by telephone.

CADL: client-centred activities of daily living intervention; UADL: usual activities of daily living intervention; ADL: activities of daily living; OT: occupational therapist.

months. The SIS consists of 8 domains, where domain 8, perceived participation, was the primary outcome. The SIS is made up of 59 items and scores range from 0 to 100; the greater the score, the smaller the impact. For participants who were unable to answer, a proxy version (16) was used when possible. At every data-collection point, perceived recovery was measured on a visual analogue scale, ranging from 0 (no recovery) to 100 (full recovery). The other domains in the SIS and all other measures were secondary outcomes.

To assess participation of performing social activities and everyday activities in the areas of domestic chores, leisure/work, and outdoor activities, the Frenchay Activities Index (FAI) (17) was used at inclusion and at 12 months. The FAI consist of 15 items, the score is based on the frequency with which an activity has been performed during the previous 3 or 6 months, and ranges from 0 (inactive) to 45 (very active).

To assess perceived participation in everyday occupations, the Occupational Gaps Questionnaire (OGQ) (18) was used at 3 and 12 months. The OGQ covers the areas instrumental ADL, work or work-related activities, and leisure and social activities, and comprises a checklist of 28 activities. There are 2 questions pertaining to each activity: (i) whether the person performs the activity (yes/no), and (ii) whether the person wants to perform the same activity (yes/no). An occupational gap is considered to be present when there is a discrepancy between the responses to the 2 questions, and the optimal outcome is a lack of gaps.

To assess perceived participation and autonomy, the Impact of Participation and Autonomy Questionnaire (IPA) (19) was used at 12 months. The IPA assesses perceived participation and autonomy in 32 items pertaining to the domains of autonomy indoors, family role, autonomy outdoors, social relations, and work and education. The score for each item is graded on a 5-point rating scale, ranging from 0 (very good) to 4 (very poor). For each domain the participation score is calculated by summing the item scores. Higher scores denote more restrictions in participation for the specific domain.

**Independence in ADL.** To assess dependence/independence of assistance in ADL the Katz Extended Scale (KE) (10) was used before stroke, at inclusion, and at 3, 6 and 12 months. The KE contains 6 personal ADL (P-ADL) and 4 instrumental ADL (I-ADL) items. The KE was trichotomized into “dependent in both”, “independent in P-ADL or I-ADL”, and “independent in both”.

The Barthel Index (BI) (20) was administered at inclusion and was used in the present study to determine stroke severity, where scores of <15 represented a severe stroke, 15–49 a moderate stroke, and 50–100 a mild stroke (21). The BI (20) was also used at inclusion, 3, 6 and 12 months to assess independence and dependence in ADL. The BI comprises 10 self-care and mobility activities. Scores range from 0 to 100, and a lower score indicates greater dependency in ADL.

**Life satisfaction.** To assess life satisfaction the Life Satisfaction Scale (LiSat-11) (22) was used at 3 and 12 months. The LiSat-11 contains 11 items about overall and domain-specific life satisfaction, self-rated on an ordinal scale ranging from 6 (very satisfactory) to 1 (very dissatisfactory). One global question was used to assess the participants’ overall satisfaction with life. When analysing the LiSat-11, the

score was dichotomized into “satisfied=yes” (score 5–6) and “not satisfied=no” (score 1–4).

*Statistical methods*

A power calculation was performed based on the variance in the pilot study (23) and based on a difference of 15 points in SIS domain 8 (participation), as it has been suggested that this may represent a clinically meaningful change for the patient (15). Allowing for a 20% dropout rate, 280 people with stroke had to be included in the study (alpha set at 0.05 and beta at 0.80). Characteristics of the participants at inclusion and outcomes at 3, 6 and 12 months after inclusion are presented using descriptive statistics. Intention-to-treat analysis was used when comparing the outcomes of the CADL and the UADL groups. Statistical analyses of differences in change over 1 year between the CADL and the UADL groups were performed with linear mixed-effects models for continuous outcomes (SIS domains 1–7, OGQ, FAI) and with generalized estimating equations (GEE) for categorical outcomes (LiSat-11, a clinically meaningful change in SIS domain 8).

SIS domain 8 was trichotomized into “a positive clinically meaningful change” when the difference was +15 points or more, “no change” when the difference was between –14 and +14, and “a negative clinically meaningful change” when the difference in score was –15 or more (15). Separate GEE analyses were performed for “a positive clinically meaningful change” and “a negative clinically meaningful change”, i.e.

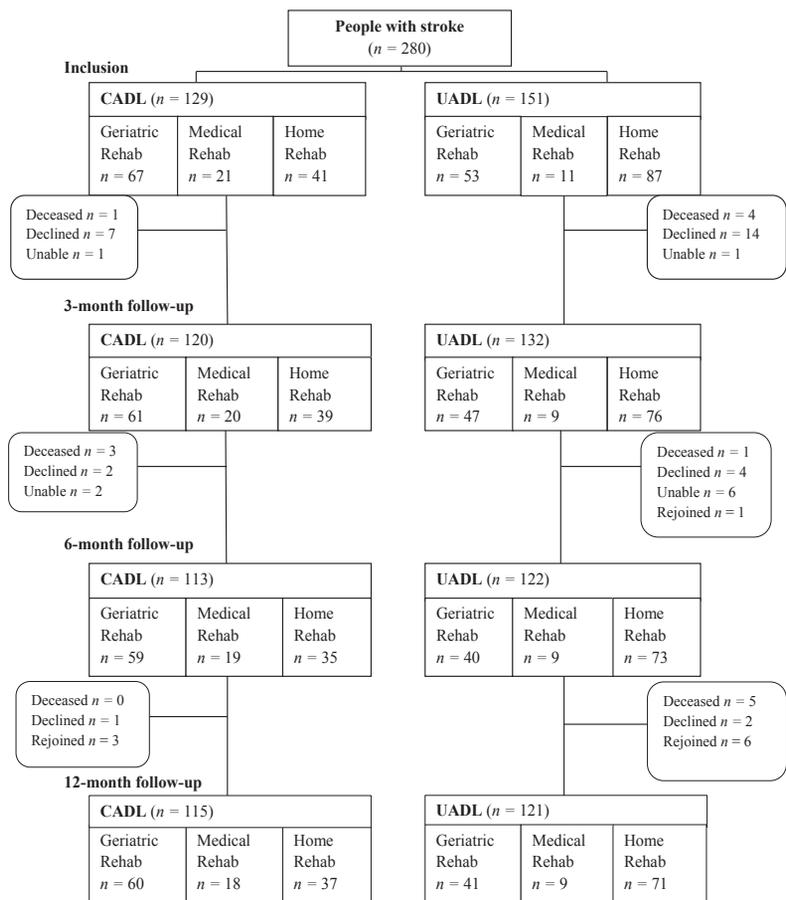


Fig. 1. Participant flow from inclusion to the 12-month follow-up. Unable: unable to participate in the follow-up but did not decline to participate in the study. Rejoined: followed-up, unable in an earlier follow-up; CADL: client-centred activities of daily living intervention; UADL: usual activities of daily living intervention; Rehab: rehabilitation.

change between 3 and 6 months compared with changes between 6 and 12 months. The change over time in each outcome for the CADL and the UADL groups was compared with and without interaction effect between time and group. Ordinal regression was used for analyses of differences between the CADL and the UADL groups with regard to the IPA. The covariates included in all statistical analyses were sex, age, stroke severity (mild or moderate/severe), type of rehabilitation (geriatric, medical, or home rehabilitation), frequency of social/lifestyle activities before the stroke according to the FAI at inclusion, and time (3, 6 and 12 months) after inclusion. In the analysis with the FAI as the dependent variable, independence in ADL before the stroke according to the KE at inclusion was included as a covariate instead of the FAI at inclusion. A  $p$ -value  $<0.05$  was accepted as statistically significant. Pair-wise comparisons were adjusted for multiple comparisons using a Bonferroni correction. Results are presented as odds ratios with 95% confidence intervals (95% CI) and  $p$ -values for differences between CADL and UADL. The analyses were conducted using SAS (Science Analysis System) and SPSS (Statistical Package for the Social Sciences).

## RESULTS

Between 6 October 2009, and 7 September 2011, 280 people with stroke were included in the study. Participant flow is illustrated in Fig. 1, and inclusion characteristics are presented in Table II. The clinically meaningful changes in the primary outcome, SIS domain 8 (participation), are shown in Table III. The odds for a positive clinically meaningful change between 3 and 12 months were 1.53 for the CADL group compared with the UADL group (CI 0.93–2.51,  $p=0.098$ ). The odds for a negative clinically meaningful change between 3 and 12 months were 0.67 for the CADL group compared with the UADL group (CI 0.38–1.19,  $p=0.168$ ). Regardless of whether covariates were included in the models, the results were the same; therefore, the participants' outcomes in raw scores regarding perceived participation, independence in ADL, and life satisfaction at 3, 6 and 12 months are shown in Table IV. No statistically significant differences in change over 12 months were found between the CADL group and the UADL group. Furthermore, no significant differences were found between the groups in perceived participation or in autonomy at 12 months.

The mean duration of rehabilitation for persons admitted to the participating units during 1 year was 40 days (range 7–120 days).

## DISCUSSION

This is the first RCT study to report a 12-month follow-up regarding the effects of a client-centred ADL intervention on participation after a stroke. The results show that there were no statistically significant differences between the CADL and the UADL groups regarding changes in perceived participation, independence in ADL, or life satisfaction during 12 months. However, a possible trend was observed in favour of the CADL group compared with the UADL group regarding a clinically meaningful positive change in perceived participation, as measured by SIS domain 8 (participation), during the 12 months.

Our hypothesis, that a client-centred ADL intervention would have an effect on participation superior to that of the usual ADL interventions during the first year after a stroke, could thus not be

Table II. Inclusion characteristics

|  | CADL<br><i>n</i> =129 | UADL<br><i>n</i> =151 |
|--|-----------------------|-----------------------|
| Age, year, mean (SD)                           | 74 (10)               | 71 (11)               |
| Men/women, <i>n</i> (%)                        | 73/56 (57/43)         | 95/56 (63/37)         |
| Cohabiting, <i>n</i> (%)                       | 68 (53)               | 91 (60)               |
| Level of education, <i>n</i> (%)               |                       |                       |
| Elementary school/high school                  | 94 (73)               | 113 (75)              |
| University                                     | 35 (27)               | 37 (24)               |
| No formal education                            | 0 (0)                 | 1 (1)                 |
| Before stroke, <i>n</i> (%)                    |                       |                       |
| TIA  | 15 (12)               | 11 (7)                |
| Stroke   | 34 (26)               | 38 (25)               |
| Diabetes                                       | 29 (22)               | 40 (26)               |
| Frenchay Activities Index (FAI),<br>0–45, mean | 29                    | 31                    |
| Katz Extended ADL index (KE), <i>n</i> (%)     |                       |                       |
| Dependent in P-ADL and I-ADL                   | 16 (12)               | 6 (4)                 |
| Independent in P-ADL or I-ADL                  | 34 (27)               | 42 (28)               |
| Independent in P-ADL and I-ADL                 | 79 (61)               | 103 (68)              |
| After stroke                                   |                       |                       |
| Hemisphere, <i>n</i>                           |                       |                       |
| Left/right/unspecified                         | 61/67/1               | 74/74/3               |
| Haemorrhage/infarct/unspecified stroke         | 13/96/20              | 19/110/22             |
| Stroke unit, days mean (range)                 | 11 (3–34)             | 16 (1–60)             |
| Included after stroke, days, mean (range)      | 25 (6–96)             | 28 (3–115)            |
| At inclusion                                   |                       |                       |
| Stroke severity, <i>n</i> (%)                  |                       |                       |
| Mild (BI=50–100)                               | 94 (73)               | 129 (86)              |
| Moderate (BI=15–49)                            | 31 (24)               | 20 (13)               |
| Severe (BI=<15)                                | 4 (3)                 | 2 (1)                 |
| Speech productions, <i>n</i> (%)               |                       |                       |
| No aphasia                                     | 96 (74)               | 116 (77)              |
| Limited vocabulary                             | 25 (19)               | 28 (18)               |
| More than yes/no                               | 6 (5)                 | 3 (2)                 |
| Only yes/no or less                            | 2 (2)                 | 4 (3)                 |
| MMSE (0–30), median (interquartile<br>range)   | 26 (23–29)            | 27 (24–29)            |
| SIS (Recovery 0–100), mean (SD)                | 32 (21)               | 42 (24)               |
| BI (0–100), median (range)                     | 65 (5–100)            | 80 (10–100)           |

FAI ranges from 0 (inactive) to 45 (very active); SIS ranges from 0 to 100; the greater the score, the smaller the impact; BI ranges from 0 to 100; a lower score indicates greater dependency.

CADL: client-centred activities of daily living intervention; UADL: usual activities of daily living intervention; SD: standard deviation; ADL: activities of daily living; P-ADL: personal ADL; I-ADL: instrumental ADL; BI: Barthel Index; TIA: transient ischaemic attack; MMSE: Mini Mental State Examination; SIS: Stroke Impact Scale.

Table III. Clinically significant changes in the participation domain of the Stroke Impact Scale for the client-centred activities of daily living intervention (CADL) and the usual activities of daily living intervention (UADL) groups at 6 months (3–6) and 12 months (6–12)

|                               | 3–6 months            |                       | 6–12 months           |                       |
|-------------------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                               | CADL<br><i>n</i> =110 | UADL<br><i>n</i> =122 | CADL<br><i>n</i> =110 | UADL<br><i>n</i> =114 |
| Positive change, <i>n</i> (%) | 26 (24)               | 25 (21)               | 24 (22)               | 14 (12)               |
| No change, <i>n</i> (%)       | 76 (69)               | 82 (67)               | 66 (60)               | 83 (73)               |
| Negative change, <i>n</i> (%) | 8 (7)                 | 15 (12)               | 20 (18)               | 17 (15)               |

Positive clinically meaningful change=+15 points or more,

No change=difference between –14 and +14 points,

Negative clinically meaningful change=–15 or more.

Table IV. Outcomes in raw scores at 3, 6 and 12 months after inclusion

|  | 3 months              |                       | 6 months              |                       | 12 months             |                       |
|--|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|  | CADL<br><i>n</i> =120 | UADL<br><i>n</i> =132 | CADL<br><i>n</i> =113 | UADL<br><i>n</i> =122 | CADL<br><i>n</i> =115 | UADL<br><i>n</i> =121 |
| Stroke Impact Scale (0–100), mean                    |                       |                       |                       |                       |                       |                       |
| Strength   | 55                    | 60                    | 57                    | 64                    | 54                    | 61                    |
| Memory thinking                                      | 82                    | 84                    | 83                    | 86                    | 80                    | 85                    |
| Emotion  | 74                    | 73                    | 75                    | 76                    | 72                    | 75                    |
| Communication  | 84                    | 88                    | 83                    | 89                    | 83                    | 87                    |
| Activities of daily living                           | 69                    | 75                    | 71                    | 77                    | 69                    | 77                    |
| Mobility   | 69                    | 74                    | 70                    | 77                    | 69                    | 75                    |
| Hand function  | 48                    | 58                    | 49                    | 63                    | 49                    | 63                    |
| Participation  | 59                    | 63                    | 64                    | 67                    | 65                    | 67                    |
| Recovery   | 52                    | 58                    | 56                    | 62                    | 55                    | 64                    |
| Frenchay Activities Index (FAI) (0–45), mean         |                       |                       |                       |                       | 18                    | 22                    |
| Occupational Gaps (OGQ), 0–28, mean                  | 8                     | 7                     |                       |                       | 6                     | 4                     |
| Impact on Participation & Autonomy (IPA) (0–4), mean |                       |                       |                       |                       |                       |                       |
| Autonomy indoors                                     |                       |                       |                       |                       | 1.0                   | 0.7                   |
| Family role  |                       |                       |                       |                       | 1.6                   | 1.4                   |
| Autonomy outdoors                                    |                       |                       |                       |                       | 2.0                   | 1.6                   |
| Social life and relationship                         |                       |                       |                       |                       | 1.2                   | 1.1                   |
| Personal & Instrumental-ADL (KE), <i>n</i>           |                       |                       |                       |                       |                       |                       |
| Dependent in both                                    | 64                    | 54                    | 55                    | 43                    | 61                    | 42                    |
| Independent in P-ADL or I-ADL                        | 37                    | 49                    | 43                    | 46                    | 31                    | 46                    |
| Independent in both                                  | 19                    | 29                    | 15                    | 33                    | 23                    | 33                    |
| Barthel Index (BI) (0–100), mean                     | 81                    | 86                    | 83                    | 88                    | 82                    | 88                    |
| Satisfied with life (LiSat-11), yes, <i>n</i>        | 47                    | 56                    |                       |                       | 42                    | 48                    |
| Falls, yes, <i>n</i>                                 | 50                    | 54                    | 39                    | 37                    | 38                    | 37                    |

SIS ranges from 0 to 100; the greater the score, the smaller the impact; FAI ranges from 0 (inactive) to 45 (very active); OGQ ranges from 0 to 28 gaps, where the optimal outcome is a lack of gaps; IPA ranges from 0 (very good) to 4 (very poor); BI ranges from 0 to 100; a lower score indicates greater dependency.

CADL: client-centred activities of daily living intervention; UADL: usual activities of daily living intervention; ADL: activities of daily living; P-ADL: personal ADL; I-ADL: instrumental ADL; KE: Katz Extended ADL Index.

confirmed in the present study. However, the lack of differences in outcomes aligns with the conclusions of a recent systematic review of RCTs examining patient-centred interventions, which has shown that the beneficial effects in favour of patient-centred care or rehabilitation were reported mainly in the areas of patient satisfaction and perceived quality of care (3).

The CADL group nevertheless demonstrated a trend towards a positive clinically meaningful change in participation that was more pronounced than that observed in the UADL group. One interpretation is that the participants in the CADL group had developed generic skills for solving problems in daily activities, even long after a stroke onset that might have influenced their perceived participation. Even though there were no differences on a group level a small change might be of importance for the individual. Furthermore, the measures used in the present study did not include the value the individual attached to the different outcomes or to the magnitude of the changes. Hence, further research including qualitative studies regarding the meaning for the individual of such a change and longer follow-ups is recommended, as it has been reported that participation after stroke within a client-centred approach should also consider the meaning of the concept (24).

The notions of patient-, person- and client-centred care or rehabilitation and similar terms are frequently used interchangeably, and this is also the approach acknowledged in Swedish

healthcare legislation (25). There is, however, no consensus regarding how the concept should be operationalized in clinical trials (3) or what the expected outcomes are from the perspectives of, for instance, healthcare legislators. Furthermore, as has been pointed out (26), client-centred practice does not necessarily produce healthcare that meets the specific needs, values, and beliefs of the person in need of care and rehabilitation. In this study we applied and evaluated a client-centred intervention that was developed specifically to take the point of departure from the lived experience of the person in need of rehabilitation, taking into account the individual's specific needs, values and beliefs. We nevertheless might have failed to identify the specific principles of the CADL and the ways the intervention relates to outcome.

We chose to perform an RCT in order to conduct a scientifically rigorous evaluation of this new client-centred ADL intervention. One strength of the RCT design of this study is that the participating rehabilitation units, rather than individual participants, were randomized; this is important because a risk of contamination between the intervention and the control conditions was identified in a pilot study (27). Furthermore, the rehabilitation units in the 3 participating counties represented both urban and rural areas, as well as inpatient and home rehabilitation; variety is relevant because the context in which rehabilitation is performed may affect the outcome (28).

Moreover, and in line with the CONSORT (29), both the independent data collectors and the statistician were blinded, and intention-to-treat analyses both with and without covariates were performed.

The use of RCT designs for the evaluation of complex interventions has been questioned; Redfern et al. (30) advocate instead the use of observational or quasi-experimental studies. It has been highlighted, in addition, that the evaluation of a complex intervention is complicated, since there are several variable components within the intervention, possibly targeting multiple outcomes, making it difficult to use an RCT with a single primary outcome (31). Instead, it is plausible that a complex intervention affects several outcomes of small magnitude. Non-pharmacological interventions should include qualitative studies along with the clinical trial, according to the CONSORT (32) and "Guidance for the Development and Evaluation of Complex Interventions" (33), in order to further understand the processes involved and the experiences of the interventions from different perspectives. Thus, studies on the experiences of the CADL from the perspectives of persons with stroke, their family members, and the OTs involved in their rehabilitation have been performed and will be reported separately.

The possibility that the differences between the 2 interventions might have been too small to render significantly different effects on the outcomes cannot be ignored. The possibility that the UADL intervention included client-centred approaches cannot be ruled out because the client-centred perspective is a prevalent approach favoured by many OTs (26). All OTs in the study, both in the CADL group and in the UADL group, were contacted on a regular basis by the researchers; for the CADL group in order to monitor fidelity to the intervention. However, we cannot be sure that all OTs in the CADL group fully implemented the CADL intervention all the time throughout the study. It has been reported that OTs delivering interventions in a research context might find it challenging and report lack of time and experience to apply the research as intended (34).

Furthermore, post-stroke rehabilitation programmes are usually conducted by interprofessional teams, and there is a lack of information regarding interventions delivered by other professions parallel to the CADL or the UADL. In addition, it is not known to what extent the other team members worked with a client-centred approach or how the absence or presence of client-centredness in the whole team influenced the outcome. An assumption in an RCT is that such variations are random and similar in both groups, but there is no information available to support this assumption. One implication might be that future studies should implement a client-centred approach conducted by an interprofessional rehabilitation team.

It is imperative to identify outcomes and corresponding measures of relevance and meaning, both for the person and from a scientific point of view, in order to assess and compare outcomes of different complex interventions in individuals after stroke when a client-centred perspective is to be assumed. Another strength of this study is that several different instruments were used to assess the primary outcome, participation, and they were all self-reported. We chose the participation

domain of the SIS as the primary outcome, because this measure has been shown to be sensitive to change in persons with minor and with moderate stroke. Moreover, it does not demonstrate the ceiling effects observed with, for example, the Barthel Index (35). The same recommendations apply for the Frenchay Activities Index, one of our secondary outcomes regarding participation (35). In addition, we have analysed the data adjusting for age, gender, and stroke severity, as recommended for the FAI (35).

The participants in this study had different characteristics both before and after they had a stroke. We have, however, adjusted for plausible imbalances by including the covariates sex, age, stroke severity (mild or moderate/severe), type of rehabilitation (geriatric, medical, or home rehabilitation), frequency of social/lifestyle activities before the stroke according to the FAI at inclusion, and time (3, 6 and 12 months).

In conclusion, the results of this study showed no differences in changes in perceived participation, but there was a trend towards a positive clinically meaningful change for the CADL in perceived participation during the first year after stroke. The client-centred rehabilitation approach is challenging to implement and evaluate. Further studies are needed exploring what characterizes persons who show clinically meaningful changes in participation.

*Other information.* This study was approved by the Regional ethical Review Board in Stockholm. Registration Clinical Trials gov. identifier: NCT01417585.

#### ACKNOWLEDGEMENTS

Financial support was provided by the Swedish Research Council, the Health Care Sciences Postgraduate School at Karolinska Institutet, Strategic Research Area in Care Science, KID-funding, the regional agreement on medical training and clinical research (ALF) between Stockholm County Council and Karolinska Institutet, Uppsala County Council, Gävleborgs County Council, Uppsala-Örebro Regional Research Council, and the Swedish stroke association.

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